From: Sent:	Suzanne Harris Wednesday, July 08, 2015 :	10:19 AM	
10.	'a.boobis	's.chang@griffith.edu.au'; 'scohen@unmc.edu'; 'mdovle@uga.edu';	
	'adamdrew@u.washington Field';	.edu'; 'marion@vt.edu';	'Catherine
	Lupton;	; 'john.c.peters@	Joanne Pucdenver.edu';
	'kwallace@d.umn.edu'; 'we	avercm@purdue.edu';	
Cc:	libradfard@upma.adu!u	carmel.james@griffith.	edu.au';
	jbradford@unmc.edu ;	'Usui-Etsuko(?? ??)'; Chels	; sea L. Bishop;
		aan@purdue.edu';	,
Subject:	Reminder for the mid-year ILSI Board of Trustees conference call Thursday, July 9, 2015		
Attachments:	2015 Dial-in information.de DRAFT+AB.docx	oc; ILSI BOT 2015-07-09 agd.doc;	ILSI-BOARD-20150117

Just a reminder that the mid-year ILSI Board of Trustees conference call is tomorrow – July 9, 2015 – beginning at 9:00 a.m. Eastern Daylight Time. All briefing documents are available on the ILSI Board of Trustees portal – <u>https://www.ilsiextra.org/ilsi/bot/SitePages/Upcoming%20Meetings.aspx</u>

See instructions on user name and password at the end of the message below.

TO: ILSI Board of Trustees

FROM: Suzie Harris

The ILSI Board of Trustees mid-year conference call is scheduled for **Thursday, July 9, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than 2 hours. The dial-in instructions are attached here:

The proposed agenda for the conference call is attached here:

Agenda Item II. Draft minutes from the January 17, 2015 ILSI Board of Trustees meeting

All other documents for the ILSI Board of Trustees mid-year conference call will be posted on the ILSI Board portal not later than Wednesday, July 1. You may reach the ILSI Board portal through this link: <u>https://www.ilsiextra.org/ilsi/bot/SitePages/Home.aspx</u>

Your username is the information in your email address before the "@". Password: Password1 To reset your password, go to: <u>https://www.ilsiextra.org/Pages/Change%20Password.aspx</u>

I will send a reminder message on or about July 1. Please let me know if you have questions or need help accessing the documents on the Board portal.

**ILSI Board of Trustees** 

4-3-2015 Draft

## Annual Meeting Saturday, January 17, 2015 Chandler, Arizona

## DRAFT MINUTES

## I. Call to Order

Dr. Samuel Cohen, Chair, ILSI Board of Trustees, called the meeting to order at 8:00 a.m. Mountain Standard Time. He welcomed the trustees, nominees for the Board, staff and guests. Dr. Cohen reviewed the operational rules for the ILSI Board of Trustees meeting. Observers were welcome but were asked to remain silent unless called upon by the chair. The ILSI Board may hold an executive session during which all non-trustees would be asked to leave. All motions, except motions attached to specific agenda items, must be submitted in writing at the time they are offered. Motion forms were included in each trustee's briefing book. Nominees for the ILSI Board of Trustees are welcome to participate in the Board discussions, but may not offer motions or vote. All trustees were asked to complete, sign and turn-in the Conflict of Interest form, which was included in the front pocket of the trustee briefing books.

The meeting agenda and list of participants and observers are attached.

## II. Approval of Minutes from the July 14, 2014 ILSI Board of Trustees Conference Call

These draft minutes were distributed to the ILSI Board of Trustees electronically prior to the meeting and were included in the briefing book given to each trustee. Dr. Alan Boobis requested that the term "worthy" be removed from the last line of the "action" paragraph under Agenda Item VII, and be replaced with less value-laden language. With this change the minutes were unanimously approved.

## III. President's Report

Dr. Jerry Hjelle, ILSI President, began his remarks by thanking the ILSI professional staff based in Washington as well as those based in the branches and Research Foundation for all of their support and efforts to implement the One ILSI strategy over the past two years. The One ILSI strategy was developed by the ILSI Board and professional staff during 2012-2013 and was formally launched at the beginning of his two-year term as ILSI President. Referring to the One ILSI Implementation Plan, which was included in the trustee briefing book, Dr. Hjelle described the components of the plan and its focus on foresight to increase ILSI's credibility and vision.

Four thematic areas were identified that together cover most of the scientific areas addressed by the organization. Dr. Hjelle specifically thanked the professional staff from the branches who had volunteered to lead these four thematic areas over the past two years. Professional development for key staff in the branches and the Research Foundation is a fundamental part of the implementation plan as well.

Dr. Hjelle said that he enjoyed visiting the various branches during his term as ILSI President. This experience allowed him to understand more clearly what a truly remarkable organization ILSI is. He

found his term as ILSI President to be personally gratifying and he thanked the trustees for their support.

#### IV. Progress with Implementation of the One ILSI Strategy

a. ILSI Board Science Advisory Group – Dr. Boobis reviewed the accomplishments of the Science Advisory Groups, whose members are himself and Dr. Peter van Bladeren, serving as Co-Chairs, Dr. Michael Doyle, Dr. Catherine Field, Dr. Lewis Smith, Dra. Sara Valdés, Dr. Connie Weaver and Dr. Flávio Zambrone. The group interacted with the leaders of the four thematic areas and oversaw the development of the key activities chart which is organized by the four thematic area topics. The advisory group also reviewed the Best Practice Guide for Identification of Emerging Issues and surveyed the branches to assess how they went about identifying emerging issues.

The survey results showed that a range of stakeholders were being consulted in the emerging issues identification process, though who is involved varies from branch to branch. The process of prioritization was even more variable with fewer branches involving external stakeholders. The survey results and the issues identified were included in the trustee briefing books. There is substantial overlap among the emerging issues identified by different branches, thus offering opportunities for collaboration.

Dr. Sushila Chang noted that branches operate in culturally different environments, making it unlikely that one specific process would work for all. The best practice approach which provides guidelines and concrete examples would be more helpful. Other trustees noted that some branches list activities rather than emerging issues. Dr. Lewis Smith commented that governance of the One ILSI strategy was needed to increase visibility. There was general agreement that the branches were communicating more effectively with each other, but cooperative and collaborative activities were still rare. More time during the annual meeting should be devoted to identifying areas of synergy and mechanisms to allow collaboration. Dr. Rhona Applebaum noted that doing so requires the branch staff to build the necessary skill set.

Dr. van Bladeren invited all interested trustees to participate in the Science Advisory Group's meeting with the thematic area leaders on Monday afternoon, January 19 at 5:30 pm. The advisory group relies on Board members to volunteer.

b. ILSI Board Value/Stakeholder Group – This advisory group is led by Dr. Todd Abraham, Dr. Cohen and Mr. Geoff Smith. Dr. Applebaum is also an active member of the group. The group worked with Mr. Michael Shirreffs, ILSI Director of Communications to draft a series of value statements for industry members and public advisors based on an online survey of trustees and academic advisors, interviews with key leaders and branch input.

Dr. Abraham noted that a series of materials (handed out at the meeting) were developed to reflect these value statements. Dr. Cohen commented that ILSI was being more proactive, less reactive in its messaging.

Mr. Shirreffs briefly reviewed the materials that were distributed. All are intended to be used as development materials and use a modular approach. There are three versions

of the fold-out document to demonstrate how it can be tailored to different audiences. One of the examples is in Korean, showing that languages other than English may be used. Such materials allow ILSI to centrally control the message, i.e., ensure that everyone speaks with one voice, as long as the translations are accurate. The set of program guides – linked to the four thematic areas – are still in draft so that the branches can comment on them. The objective of these documents is to present what ILSI is doing in a specific area, e.g., healthy aging, in an easy-to-read format. The final document is a case study on caffeine, which provides more detail on what ILSI accomplished with a body of work on a single topic. Additional case studies will be developed. Mr. Shirreffs is still developing the best practices guide for development that will go along with these communications tools.

Dr. Doyle suggested that more detail was needed in the program guide for food and water safety as the current text does not include all that ILSI is doing. Dr. Abraham acknowledged that the guides were still in draft and that he wanted to see the thematic area leaders take ownership of what goes in each guide.

In response to a question about how these materials will be used, Dr. Abraham said that this would be part of the advisory group's work for 2015. He acknowledged that it is hard to know all the ways the materials could be used at the local level and that some customization will be needed. This is why the modular approach was selected. Dr. Hjelle suggested that a master list of contacts made each year be compiled and metrics be developed to track the effectiveness of the materials for each of these contacts.

In 2015, the advisory group's priorities will be to validate the value statements, update the program guides based on branch feedback, identify specific topics for additional case studies highlighting ILSI science, prioritizing additional stakeholders for targeted outreach, and setting outreach goals with measures of success. Dr. Abraham ended his report by asking for volunteers.

**c.** Thematic area collaborations – Dr. Suzie Harris briefly reviewed the outcome of the thematic area discussions during the ILSI Branch Staff Meeting on the previous day. All four groups experienced good cross-branch participation.

**Food and Water Safety** – This group is led by Dr. Eric Hentges, ILSI North America, and Mr. Keng Ngee Teoh, ILSI Southeast Asia Region. In 2015, the branches involved in this thematic area will continue to focus on capacity building on food safety risk assessment in Asia and Africa. Several ILSI branches are involved with the World Bank Global Food Safety Partnership (GSFP) and will undertake pilot testing of a new training module being developed by GSFP. This work links with the Toxicology/Risk Science thematic area as well. The two thematic areas are communicating with each other to leverage each's activity to the greatest extent possible. ILSI Europe volunteered to take on the leadership of the iFoodExposure project and proposed that interested branches join with them to support the expansion of the GUIDEA database of dietary intake/exposure methods beyond Europe. ILSI Japan Center for Health Promotion made a presentation to the group on Project SWAN, a community-based clean water activity.

**Sustainable Agriculture and Nutrition Security** – This group is led by Dra. Mariela Berezovsky, ILSI Brasil, and Dr. Morven McLean, ILSI Research Foundation. The group discussed further the plan to help the ILSI Research Foundation Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security (CIMSANS) in identifying data in countries around the world that could be used to assess sustainable nutrition security for the very first time.

**Nutrition, Health and Well-being** – This group is led by Dr. Diána Bánáti, ILSI Europe, and Mrs. Yeong Boon Yee, ILSI Southeast Asia Region. The group discussed their ongoing effort to collect information on successful healthy aging interventions and to compile these into a public database for others to use in deciding how to support healthy aging. They are planning to organize a session during the 2015 SLAN (Latin American Nutrition Society) meeting and the 2017 International Union of Nutritional Scientists (IUNS) meeting. In addition to this work, the group agreed to explore two other important nutrition topics – nutrition for the first 1000 days of life and nutritional impact on the microbiome. This group also plans to update the matrix of branch activities for this thematic area.

**Toxicology and Risk Science** – This group is led by Ms. Syril Pettit and Dr. Michelle Embry, ILSI Health and Environmental Sciences Institute (HESI). The Risk Science Forum, a branch staff group, is up and running with an online portal. The forum is designed as a way to enhance the understanding of state-of-the-art risk science by the branch staff. The branches involved in the thematic area are also contributing information about risk assessment training courses being offered in their regions. This information will be added to the WHO Risk Assessment Network database, which is managed by HESI. As a new activity the branches involved in this thematic area decided to try to identify groups for which such training is needed and to contribute to planning a workshop to identify best practices for such training.

Dr. Hjelle commented that there was a very high level of participation by the branches and, especially the thematic area leaders, during the discussions on the previous day. He urged trustees to volunteer as "champions" to help the thematic area groups identify potential funding sources. Shortening the period to raise funds will greatly impact the success of these programs.

**d. One ILSI accountability** – Having annual performance evaluation goals linked to One ILSI for branch executive directors is part of the One ILSI Strategic Plan. Dr. Harris noted that this topic was addressed during the ILSI Branch Staff Meeting and all branches were encouraged to develop performance goals for the executive directors and for other staff, if feasible. At present not all branches use an annual performance evaluation system. The branch board should be responsible for ensuring that the branch executive director has a performance goal related to implementation of One ILSI.

Dr. Abraham asked that a common goal be developed, especially for the One ILSI thematic leaders, so that performance can be evaluated across the branch network.

#### V. Communications

Mr. Shirreffs began his report by acknowledging the help he receives from the Value/Stakeholder Advisory Group. He urged other trustees to volunteer to join this group, noting that he would like to have Latin America represented in the group. The primary components of the communications program are: developing messages, crafting strategies to deliver these messages, creating online and print materials, enhancing and maintaining the website, conducting outreach via social media, responding to the media, and improving search engine optimization (SEO) for ILSI. There are three communications tracks – traditional, internal or corporate, and development (the ask).

In 2014, a development kit was initiated. The process of developing the ILSI promotional materials pointed to the need to develop a case study on how to go about developing such materials, a project which he plans to take on this year. In addition, ILSI's social media program, which includes Facebook, Twitter, YouTube and LinkedIn, was enhanced. ILSI's presence on various social media platforms is steadily increasing. Videos of ILSI scientific programs posted on YouTube are popular, with over 69,000 viewing minutes recorded in 2014. In terms of ILSI's media presence, the organization is still not pursuing a proactive media program.

In 2015, Mr. Shirreffs will accelerate ILSI's social media program by adding more scientific content, exploring the feasibility of blogging and developing best practices. Dr. Applebaum endorsed blogging as a tool ILSI should use more. Mr. Shirreffs suggested that a guest editorial approach may be the way to begin. The focus of such blogs would be on science communication. In response to a question from Dr. Boobis about benchmarks for social media, Mr. Shirreffs said that he planned to track the return on investment of the social media tools to determine what is working and what is not. The communications budget includes funding for Mr. Shirreffs to attend several large scientific meetings in 2015, where he will tweet to enhance ILSI's presence on this platform. The Research Foundation and several branches have individuals who do the same for meetings they attend.

Mr. Shirreffs will focus on reenergizing ILSI EXTRA and refreshing the ILSI website, using information collected through surveys of users. ILSI has contracted with a professional web design group to oversee the refresh and a technology group to take care of the technical needs. The transition from the current site to the new one will be managed by him and Mr. Steve Parker, ILSI Information Technology Manager. The transition should be seamless over the course of 2015. The branch staff has been invited to participate in a meeting on Monday afternoon, January 19, with the professional design group to discuss what the branches need and want. The return on investment will be tracked for these communications tools, too. Further into the future, Mr. Shirreffs plans to work closely with ILSI's Information Technology department to determine the feasibility of a customer relations management database more suited to ILSI's communications needs than the current one.

Dr. Adam Drewnowski suggested that the re-fresh process should also include the needs of various international groups with whom ILSI works or wants to work. Mr. Shirreffs acknowledged this potential audience and noted that many were currently "following" ILSI through social media. Personal contact was suggested by Dr. Cohen as another way to reach the broader stakeholder audience.

Dr. John O'Brien complemented Mr. Shirreffs for developing such a clear path to enhancing ILSI's impact, but he also asked for more.

## VI. **Report from the Publications Committee**

Dr. Connie Weaver, Chair of the Publications Committee, thanked the other members of the committee, Dr. Chang, Dr. Field, Dr. Michael Knowles, Dr. M.T. Kuwata, Mr. Felipe Rodriguez, Dra. Valdés, and Dr. Zambrone, for their help throughout the past year. The committee will meet on Monday, January 19, and other trustees are welcome to attend. Dr. Weaver also thanked Ms. Allison Worden, ILSI Publications Manager, for all of her work over the past year.

In 2014, the committee oversaw the search and selection process for a new publishing partner for *Nutrition Reviews*. One of the primary reasons was to improve financial returns from the journal. The committee also began exploring the potential benefits and risks of open data and open access initiatives with the goal of developing best practices guidelines. The committee also provided input toward the development of a new textbook, *Present Knowledge in Food Safety*.

Dr. Naomi Fukagawa is the current editor-in-chief of *Nutrition Reviews* and has been in this position since 2009. Beginning in January 2015, the journal will be published in partnership with Oxford University Press. The new publishing agreement included a signing bonus (\$100,000), increased royalty payments, and increased annual stipend for ILSI's costs associated with preparing manuscripts for publication. Dr. Weaver noted that *Nutrition Reviews* is the most highly cited monthly review journal in nutrition (Impact Factor = 5.541). ISI ranks *Nutrition Reviews* as fifth out of 78 journals in nutrition and dietetics. The journal is being translated into Japanese, Chinese, and Spanish by ILSI branches. Furthermore, as shown in Appendix A of the committee's report, *Nutrition Reviews* makes a profit for ILSI (\$87,386 projected in 2014). Dr. Abraham asked for information about how ILSI's revenue from *Nutrition Reviews* compares to that of other journals.

ILSI's other publication, *Present Knowledge in Nutrition (PKN), Tenth Edition,* was published in print and electronic formats in 2012. It is an essential reference text for researchers, health professionals, policy experts, educators and students. Dr. Weaver said that work on the eleventh edition is expected to begin in 2015. This work will include evaluating potential publishers, beginning a search and selection process for the new edition's editors, and conducting a market analysis to optimize the new edition for current research and teaching methods.

Dr. Knowles was given credit by Dr. Weaver for developing an exciting proposal for a new textbook, *Present Knowledge in Food Safety.* He serves as the lead editor for this proposed publication, which is intended to serve as a reference and teaching tool in the model of PKN. A publishing proposal will be sent to potential publishers in 2015.

Ms. Worden also led the initiative to find new metrics with which to measure the impact of ILSI scientific publications. She gave a well-received presentation on a new tool, Altmetric, during the ILSI Branch Staff meeting on Friday, January 16. Some of the Oxford University Press signing bonus will be used to subscribe to Altmetric and track the coverage of ILSI publications in social media, traditional media and government policy documents. These data will be used by each of ILSI's entities to set their own goals.

The committee recently began looking at issues related to open access and open data in an effort to understand the trends and potential implications for ILSI's publications. In line with most journals, *Nutrition Reviews* provides an opportunity for authors to purchase instant open access for their articles as well as gratis online space for sharing supplementary data sets related to their articles. To convert the journal to an entirely open access model in the current pricing environment would not be financially sustainable. Since the issues of open access and open data affect much of ILSI's work beyond

publications ILSI owns, the committee will draft best practice guidelines for open data and open access projects and share them with the ILSI Board for review.

Thus, the future work of the committee includes overseeing *Nutrition Reviews'* progress under its new publisher, overseeing development of *Present Knowledge in Food Safety* and the eleventh edition of PKN, monitoring evolving trends in scholarly publishing, proposing best practice guidelines for open data and open access endeavors, overseeing selection of metric tools to measure the impact of ILSI's scientific outputs, and exploring other publishing opportunities.

#### VII. Report of the Financial Oversight Committee

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began her report by thanking the members of the committee – Dr. Abraham, Dr. Chang, Dr. Gerhard Eisenbrand, Dr. Joanne Lupton, Mr. Rodriguez, and Dr. Lewis Smith. She also thanked Ms. Beth-Ellen Berry, ILSI Chief Financial Officer, for her excellent work throughout the year. The committee's report and ILSI financial statements were distributed to the trustees electronically prior to the meeting and were included in the trustee briefing book. The financial statements were the balance sheet as of November 30, 2014 and the functional activity statement with 2014 year-end projections and 2015 proposed budget. Also included in the briefing books was a document titled, "How to Read Your ILSI Financial Statements."

Beginning with the balance sheet, which shows assets, liabilities and net assets on November 30, 2014, Dr. Westring noted that the final balances for the year were not provided. However, the November 30, 2014 balances provide a reasonable indication of ILSI's financial health. The year-end balances will be prepared and will be audited in early 2015. The November 30, 2014 balances show that ILSI is maintaining sufficient liquidity and has healthy assets in both the ILSI unrestricted and restricted activities.

ILSI has a Board-designated reserve fund which was officially established in 2013, with a target balance of 50 percent of the annual unrestricted budget (~\$600,000). The investment policy for this reserve fund was revised by the Financial Oversight Committee in the fourth quarter of 2014. Going forward the asset allocation will change from being 100 percent invested in fixed income instruments to 40 percent equity and 60 percent fixed income. While this change to a more diversified portfolio will increase opportunities for long-term growth, it will also mean that month-to-month volatility is more likely. The Board-designated reserve fund is invested in broad market index funds with low fees. On December 31, 2014, the balance was \$576,229 with earnings of 1.7 percent for the year.

Moving to the revenue and expenses (income statement) by functional area, Dr. Westring first focused on the unrestricted activities of ILSI Governance and Coordination (GC), Communications and Press. ILSI GC covers the international network of branches, the ILSI Board of Trustees, and ILSI's portion of the annual meeting. Communications covers proactive outreach, the ILSI website and the branch extranet. ILSI Press covers *Nutrition Reviews*, ILSI's monthly scientific journal, and *Present Knowledge in Nutrition*, 10<sup>th</sup> edition. Looking at the subtotal for the ILSI unrestricted functions, Dr. Westring noted that revenue in 2014 exceeded budget by 9 percent, primarily due to the \$100,000 signing bonus from Oxford University Press, the new publisher for *Nutrition Reviews*, beginning in 2015. In response to a question about advertising revenue, Ms. Berry said that banner ads are being run in the online journal. Such revenue is included in the publishing agreement with Oxford University Press.

Expenses exceeded budget by 7 percent due to two unbudgeted grants for One ILSI projects, one to ILSI Health and Environmental Sciences Institute (HESI) and the other to ILSI Southeast Asia Region. Funds were raised in 2013 to provide support for the One ILSI projects in the thematic areas, although the particular projects and necessary funding were not mapped out at the time the 2014 budget was developed. ILSI is projected to end 2014 with net assets of \$1,078,256, which will be a decline in net assets of \$2,901 from the beginning of 2014.

In comparing 2014 projections to the 2015 proposed budget, Dr. Westring noted that ILSI had been sharing an executive director with the ILSI Research Foundation and received reimbursement for the foundation's share of salary/benefit expenses. This is shown in the "fee for service" line under revenue. In 2015, Dr. Harris will move to 60 percent effort for ILSI only and the foundation will employ its own full-time executive director. Thus, both salary/benefit expenses and "fee for service" revenue will be reduced in 2015 by approximately \$95,000. Small increases for operating costs have been included in the 2015 budget and the annual meeting expenses have been increased to account for a more expensive venue, compared to 2014. The proposed 2015 budget shows year end net assets of \$1,103,893 compared to \$1,078,256 at the projected 2014 year-end net assets.

Turning to the restricted functions, which include functions mandated by branch leadership, steering committees, or outside donors, Dr. Westring reminded the ILSI Board of Trustees that these funds are not available to fund unrestricted activities and these accounts must maintain positive net assets. The current restricted functions are:

- Platform for International Partnerships (PIP) -- manages ILSI's interactions with WHO and FAO
- Global Travel Fund supports branch staff travel to other branches
- Developing Food and Water Safety Capacity in Sub-Saharan Africa and Asia supports training and internship programs in developing countries
- Malaspina Travel Award supports outreach to young scientists
- International Branch Activity supports local activities for ILSI Focal Point in China and Latin American branches coordination
- Shared Services support human resources, accounting, legal, and information technology for the ILSI corporations based in Washington, DC, USA.

The revenue from contributions in 2014 exceeded the budget by 25 percent. In addition to annual contributions from ILSI member companies, PIP received a one-time contribution from the Industry Council for Development (ICD). The Coca-Cola Company contributed \$325,000 for 2014 and \$350,000 for 2015 to fund PIP activities, food and water safety programs, the Malaspina International Scholar Travel Award, and a coordination position to strengthen the ILSI branch network in Latin America. Plans for the restricted programs were not developed at the time that the 2014 budget was prepared, thus expenses exceed what was included in the budget by 13 percent. The projected 2014 year-end net assets for the restricted functions are \$857,355 compared to the budget value of \$539,225.

Comparing the projected 2014 year-end restricted functions to the proposed 2015 budget, Dr. Westring noted that revenue from contributions is down by 22 percent, though substantial contributions made in 2014 were for 2015 activities. Annual contributions from ILSI member companies for PIP and the Sub-Saharan Africa program are expected to continue. Expenses are budgeted to be down by four percent, as program plans are still being developed for some of the 2015 restricted activities. The proposed 2015

budget shows net assets at the end of the year of \$769,003, compared to the projected 2014 year-end net assets of \$857,355.

Summarizing the total ILSI functional activity statement, the 2014 projected year-end net assets are \$1,935,610, compared to the year-end net assets for the 2014 budget, which were \$1,585,236. The proposed 2015 budget shows total year-end net assets of \$1,872,897.

## VIII. Adoption of the ILSI Budget

**Action:** Dr. Westring moved that the 2015 ILSI budget be approved as presented to the board. The motion was seconded and passed unanimously.

## IX. Report from the ILSI Research Foundation

Dr. Adam Drewnowski, Chair, ILSI Research Foundation Board of Trustees, began his report by thanking the members of the ILSI Research Foundation Executive Director Search Committee, several of whom are ILSI Trustees. He also congratulated Dr. Morven McLean, who accepted the offer to become the first full-time executive director for the foundation.

A written report of the foundation's accomplishments in 2014 was included in the trustees' briefing book. Dr. Drewnowski described the ILSI Research Foundation as an international entity that works both independently and in concert with other ILSI entities, to advance the mission of ILSI. In 2014, the foundation had four centers of excellence – Center for Environmental Risk Assessment (CERA), Center for Risk Science Innovation and Application (RSIA), Center for Safety Assessment of Food and Feed (CSAFF), and the Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security CIMSANS). There was also a program on nutrition and health.

To date, CERA has focused largely on applied research, related to improving how genetically-modified crops are evaluated for potential adverse environmental impacts. Developing environmental risk assessment tools for low exposure scenarios continues to be an important topic for CERA as the disproportionate focus on hazard assessment has led to trade disruptions as well as limitations on research and development. The so-called "low-level presence" occurs when small amounts of genetically-modified grain that has been commercially approved in the country of export is subsequently discovered in shipments to countries of import where approval for the specific grain is absent or pending.

CERA also works collaboratively with multiple public and private sector organizations to improve and standardize the risk assessment methods applied to evaluating the potential environmental impacts that a transgenic protein may have on non-target organisms. This work has been translated into hands-on field and lab training programs, with attendees from many of the developing countries where CERA is active. CERA developed a conceptual framework that provides a scientifically defensible process for evaluating if existing data from experimental field trials are relevant and/or sufficient for environmental risk assessments conducted in other countries. Additionally, it promotes a strategic approach to identifying field trial site locations, so that field data will be transportable from one regulatory jurisdiction to another.

Capacity building is a key function for CERA, making sure that the good science being done at ILSI and elsewhere is accessible to the people who need it to support their work. The Partnership Project in

Biosafety Risk Assessment & Regulation, which ended in 2014, was active in eight countries (Bangladesh, Colombia, Kenya, Paraguay, Tanzania, Uruguay, Uganda, and Vietnam). Having met all of its milestones, the project is now undergoing an external assessment as part of the funding agreement with the World Bank.

CSAFF promotes science-based approaches to the safety assessment of food and feed, with a strong emphasis on improved knowledge dissemination and capacity building. A tripartite scientific advisory council is being established to provide scientific guidance to the center, in line with the councils that have been put together for CERA and CIMSANS.

CSAFF also maintains the ILSI Crop Composition Database, a valuable tool for comparative food safety assessment. The most recent update (Version 5.0) contains over 800,000 data points for comparative assessment, covering 3150 compositional components for six crops, including newly added canola, sweet corn and rice.

In 2014, CSAFF organized a tripartite, multi-stage capacity building program on toxicity testing relevant to safety assessment of genetically modified foods. This work was supported by a grant from the U. S. Agency for International Development and with materials donated by DuPont Pioneer. The first phase of the training, in New Delhi, India, included classroom lectures and practical exercises for food safety training. The second phase, which took place at the Stine Haskell Research Facility in Newark, Delaware, USA, involved actual laboratory experience related to toxicity testing.

The primary mission of CIMSANS is to foster new public-private partnerships on integrated modeling that improve both scientific understanding and public policy around the growing impacts of climate change and resource scarcity – especially water – on sustainable nutrition security (SNS). Through a series of peer-reviewed publications, the center has already helped release private-sector maize breeding trial data as Open Data and has produced improved assessment methodologies for maize and other major row crops. As with other ILSI entities, CIMSANS has quickly become an important global partner, engaging hundreds of influential scientists among dozens of key organizations within academia, governments, and the private sector. CIMSANS has co-hosted a series of conferences with increasing levels of global impact. CIMSANS is now gathering the partners and resources needed to produce the first credible, comprehensive, global SNS assessment that includes all of the world's most important staple and non-staple foods.

Active partnerships include GEOSHARE and SUSFANS, which also includes ILSI Europe. CIMSANS is partnering with several public and private sector organizations to finalize the metrics that will be included in the sustainable nutrition security assessment. A workshop is scheduled for February 17, Washington to "co-create" with a broad set of stakeholders, including the International Food Policy Research Institute (IFPRI), mathematical expressions for the nutrition metrics. These expressions will then be added to the available integrated models. A paper describing the finalized SNS metrics will be published in the peer-reviewed scientific literature.

RSIA was active with two major topics in 2014. The center provided a grant to the Harvard Center for Risk Analysis to support a conference and development of a series of case studies on risk of risk perception. After publishing a series of papers on how to go about measuring the release of nanomaterial in various products, RSIA handed off the standard methods development to the U.S. National Institute for Occupational Safety and Health and the National Institute of Standards and Technology. RSIA ceased operation at the end of 2014.

Dr. Drewnowski reported that 59 percent of the foundation's funding came from the public sector in 2014, with 36 percent from the private sector, 2 percent from foundations, 2 percent from other ILSI entities and 1 percent from nongovernmental organizations. The foundation actively collaborated with nine ILSI branches in 2014 – Argentina, Brasil, Europe, India, Korea, North America, North Andean, South Andean, and Southeast Asia Region. He also called attention to the foundation's output during the past year – 35 conferences, meetings and workshops and 18 peer-reviewed publications.

Going forward, Dr. Drewnowski described the focus of the Research Foundation as agriculture, food safety, sustainability and nutrition security. In his view, health and non-communicable disease prevention easily fit within these topics. In the future, he suggested that there would be more emphasis on understanding dietary intake, both from the risk assessment and the nutrition perspectives.

Dr. Knowles pointed out that the Horizon 2020 program in Europe is actively seeking to increase international partnerships, particularly with the United States, BRIC countries, Africa and Latin America. He encouraged the foundation to utilize this interest to their advantage.

In response to trustee questions about why RSIA activities were terminated and what would be done with the remaining funds, Dr. Harris said that she made the decision to close RSIA because the center was not able to fund its programs. The ILSI Research Foundation Board of Trustees set a policy of maintaining positive net assets for all centers. RSIA had not been able to meet this criterion for several years and plans for 2015 did not show that meeting the criterion would be feasible. Any remaining funding commitments made by RSIA will be honored.

## X. Report from the ILSI Platform for International Partnerships

A written report on the 2014 activities of the ILSI Platform for International Partnerships (PIP) was included in the trustee briefing book.

Dr. Harris asked the ILSI Board of Trustees to consider an amendment to the membership section of the ILSI bylaws as a way of addressing a concern recently raised by the World Health Organization (WHO). ILSI's status as a recognized nongovernmental organization is up for renewal as part of an ongoing three-year cycle used by WHO. ILSI provided the requested information about its performance under the 2012-2014 WHO/ILSI Plan of Work and developed a new three-year plan of work with various parts of WHO. These materials were all submitted on time. In late December, Dr. Harris received an email request to update an informational database which included a question about whether ILSI had members that were involved with tobacco. ILSI answered the question accurately, saying that one member – ITC Food Businesses – was part of a conglomerate that included a tobacco company. ITC actually stands for Indian Tobacco Company. This company has been a member of ILSI-India for many years and ILSI has repeatedly acknowledge them as a member and told WHO that ILSI-India and ILSI were not in any way involved with tobacco.

About one week prior to the ILSI Annual Meeting, Dr. Harris learned that the WHO Secretariat's report on the "Review of nongovernmental organizations in official relations with WHO" (EB136/NGO/WP/1) specifically called attention to the fact that "a member company of one of its branches is owned by a company that manufactures and sells tobacco products." The secretariat report goes on to recommend that ILSI's status be renewed. In talking with the ILSI assigned technical officer at WHO, Dr. Harris was encouraged to take action to resolve the problem – membership by a tobacco-associated company. Hence, with help from Mr. Shawn Sullivan, ILSI Legal Counsel, and others, an amendment to the bylaws (attached) was drafted and was distributed to the ILSI Board of Trustees for consideration.

During the discussion that followed several trustees expressed frustration that this member was being singled-out unfairly as the member was not involved in tobacco production, manufacturing, marketing or sales. Others noted that this is a serious issue. Dr. Boobis said that as an academic working at a United Kingdom university, he is required to annually certify that he is not involved with any organization associated with tobacco. Failure to do so would limit his ability to receive government funding. Dr. Peter van Bladeren said that if ILSI were to be publicly linked with tobacco, his company, Nestlé, would seriously consider dropping out of the organization. Others suggested that ILSI should carefully monitor its relations with WHO.

**Action:** A motion was made to amend Article II: Membership of the ILSI bylaws to add the proposed two final sentences. The motion was seconded and passed by a hand vote of 28 in favor and one abstention.

Dr. Harris thanked the Board for their swift and decisive action and said that she would report this action to WHO immediately. She then turned to a second, and perhaps more difficult issue, of how ILSI may be categorized by WHO in the draft non-State actors framework. The draft being considered by the WHO Executive Board has four categories – nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions. ILSI categorized itself as a scientific/academic entity in an online questionnaire distributed by WHO. The WHO Secretariat states in their "Review of nongovernmental organizations in official relations with WHO" (EB136/NGO/WP/1; para 7) that ILSI should be listed as a private sector entity. Such a categorization by WHO is unacceptable to ILSI, because ILSI is incorporated as a public charity. Should WHO insist on calling ILSI a private sector entity, ILSI may have to end all activities with WHO to avoid such a classification. ILSI is preparing a letter to WHO explaining its concerns and asking for a meeting at which to discuss them.

Before moving on to the next agenda item, Dr. Cohen called attention to the new Malaspina International Scholar Travel Award. Ten such awards were given this first year and nine of the ten awardees have come to the 2015 ILSI Annual Meeting. These scholars were nominated by the branches in the region where the scholar lives and the final list of awardees was chosen by a selection committee composed of mostly ILSI trustees. The scholars are at a mid-level point in their careers and will hopefully gain a good appreciation of ILSI from the annual meeting experience. Dr. Cohen acknowledged The Coca-Cola Company for supporting this award. He also encouraged all trustees to meet the awardees. They will be recognized during the ILSI Assembly of Members meeting on Sunday, January 18, 2015.

## XI. Report of the ILSI Nomination Review Committee

Dr. Takeshi Kimura, Chair, ILSI Nomination Review Committee, began his report by thanking the members of the committee – Dr. Cohen, Dr. Knowles, Dr. Weaver, and Dr. Flávio Zambrone – for their assistance with the committee's tasks. The committee's report was included in the trustees briefing book.

The first of the three tasks given to the ILSI Nomination Review Committee was to review the nominees for seats on the ILSI Board of Trustees. Three trustees will retire from the board – Mr. Felipe Rodriguez, Dr. P.K. Seth, and Dr. Geoff Thompson (resigned mid-year). Dr. Kimura asked the board members to acknowledge the service of these three trustees with a round of applause.

The following individuals were re-nominated by the branches in the respective regions for additional three-year terms on the ILSI Board of Trustees:

Asia-Pacific North	Dr. Takeshi Kimura (I)
Europe/Africa	Dr. John O'Brien (I)
	Dr. Peter van Bladeren (I)
HESI	Dr. Alan Boobis (P)
	Dr. Lewis Smith (P)
Latin America	Dr. Flávio Zambrone (P)
North America	Dr. Todd Abraham (I)
	Dr. Michael Doyle (P)
	Dr. Catherine Field (P)
	Dr. Joanne Lupton (P)
Research Foundation	Dr. Adam Drewnowski (P)

New Nominees offered by the branches are:

Asia Pacific South	Dr. B. Sesikeran (P)
Europe/Africa	Dr. Peter Weber (I)
Latin America	Mr. Ary Bucione (I)

Bios for the new nominees were included in the trustee briefing book. Dr. Kimura reminded the trustees that in January 2013, the ILSI Board of Trustees elected Dr. Applebaum as the ILSI Vice-President. She was added to the ILSI Board of Trustees in a special 32<sup>nd</sup> seat as allowed under the bylaws (Article IV, Section 1). But this special seat is only valid for a year at a time, so it is necessary to re-elect her for this year.

The ILSI Nomination Review Committee approved all of these nominations and Dr. Kimura will present these names to the ILSI Assembly of members meeting on Sunday, January 18, 2015, for election.

To allow Dr. Applebaum to remain on the ILSI Board, Dr. Kimura asked that the ILSI Board approve the expansion of the Board by one seat, as allowed by the bylaws. The number of public sector trustees will still exceed the number of private sector trustees with Dr. Applebaum's election to this additional seat.

**Action:** Dr. Kimura moved that the ILSI Board of Trustees be expanded by one seat to 32 seats to allow Dr. Rhona Applebaum to remain a member of the ILSI Board of Trustees. The motion was seconded and passed unanimously.

The second task for the ILSI Nomination Review Committee was to nominate officers of the board and at-large members of the ILSI Executive Committee. Officers serve two-year terms; at-large members are elected annually. The succession plan adopted several years ago calls for the Vice President and Vice Chair to move up to the positions of President and Chair, if acceptable. The Nomination Review Committee agreed that the current Vice President, Rhona Applebaum, should become the ILSI President. The committee also agreed to nominate Dr. Peter van Bladeren as the new Vice President. If elected both are willing to serve.

In January 2014, Dr. Alan Boobis agreed to move into the Chair role in January 2015, assuming the next Nomination Review Committee agreed. Dr. Kimura reported that the committee did agree. The committee also agreed to nominate Dr. Connie Weaver as the ILSI Vice Chair for one year. Both Dr. Boobis and Dr. Weaver are being proposed for one-year terms to return to the regular rotation cycle in January 2016. Both may be re-elected at that time for full two-year terms as Chair and Vice Chair, respectively. Both were willing to serve.

The committee nominated Dr. Flavio Zambrone for a two-year term as Secretary. Dr. Zambrone was willing to serve, if elected. The committee nominated Dr. Marion Ehrich, Dr. Tamotsu Kuwata, Mr. Geoff Smith and Dr. Peter Weber for one-year terms as At-Large Members of the ILSI Executive Committee. All agreed to serve, if elected.

Action: Dr. Kimura moved the election of Dr. Applebaum as President, Dr. van Bladeren as Vice President, Dr. Boobis as Chair for one year, Dr. Weaver for Vice Chair for one year, Dr. Zambrone for Secretary, and Drs. Ehrich, Weber, and Kuwata and Mr. Geoff Smith as At-Large Members, with the understanding that Dr. Applebaum and Dr. Weber would be elected to the Board by the Assembly of Members on Sunday, January 18, 2015. The motion was seconded and carried unanimously.

The third and final task of the ILSI Nomination Review Committee was to nominate candidates for threeyear terms on the ILSI Research Foundation Board of Trustees. Nominees submitted by the ILSI Research Foundation Nominating Committee were reviewed by the ILSI Nomination Review Committee and approved. The nominees were Dr. Jerry Hjelle (renomination), Dr. Ronald Kleinman, and Dr. Ivonne Rietjens. Bios for Drs. Kleinman and Rietjens were included in the trustee briefing book. Dr. Applebaum, as ILSI President, has an assigned seat on the ILSI Research Foundation Board of Trustees.

**Action:** Dr. Kimura moved the election of Drs. Hjelle, Kleinman and Rietjens each for a three-year term on the ILSI Research Foundation Board of Trustees. The motion was seconded and passed unanimously.

Dr. Kimura also recognized the ILSI Research Foundation trustees whose terms expired at the end of the 2015 ILSI Annual Meeting -- Dr. Dennis Bier, Dr. Jim Bus, and Dr. John Peters.

## XII. Comments from the ILSI President and ILSI Board Chair

Dr. Applebaum thanked the ILSI Board of Trustees for their support, saying that she was honored to serve as president for ILSI, an organization about which she was passionate. She said that she would operate with an "open-door" policy and encouraged trustees to contact her with questions, comments or concerns at any time. She described her belief in the strength of "threes", such as ILSI's tripartite nature. She likes to use scorecards to follow complex and competitive tasks. Though she admitted that she would not be able to fill Dr. Hjelle's shoes, she will focus on collaboration, value and communication as the three areas she will strengthen during her two-year tenure as the ILSI President.

Dr. Boobis also thanked the ILSI Board of Trustees for their support. He noted that leading ILSI presents a substantial challenge. The organization is dynamic and not afraid to ask itself tough questions. ILSI carries out substantial work with very small resources. He noted that ILSI needs to think carefully about the challenges it faces, as the organization is still under attack. Dr. Boobis also complimented Dr. Cohen on his outstanding service to ILSI as the chair for the past three years. He described Dr. Cohen as a leader who makes ILSI an organization worth being involved with. Dr. Cohen is also a strong leader who executes with kindness and tact. He presented Dr. Cohen with a gift.

In turning over the chairmanship of the ILSI Board of Trustees to Dr. Boobis, Dr. Cohen stated that he greatly enjoyed serving as the board chair and noted that working with ILSI has given him the opportunity to work with the "most phenomenal people in the world."

## XIII. Other Business

a. New Branch Proposals – Dr. Knowles, Chair of the ILSI Branch Development Committee, briefly described the application for branch status from the study group in the Middle East. The ILSI Branch Development Committee reviewed the application in detail during their meeting on Friday evening, January 16. The committee members present (Mike Knowles, P.K. Seth, and Geoff Smith) agreed that the study group had satisfied the eight criteria for forming a new branch. While the proposed branch constitution still needs some editorial revisions, the committee recommended that the new branch, ILSI Middle East, as described in the written motion distributed at the meeting (attached), be approved.

Action: Dr. Knowles moved adoption of the motion. There was a second and the motion carried unanimously.

Dr. Knowles also reminded the board that the former branch, ILSI North Africa and Gulf Region, had been closed. There is some interest in North African countries like Morocco, especially among academics to develop ILSI-led collaborations. He will monitor this situation and report back to the ILSI Board of Trustees.

ILSI South Africa is still interested in expanding to cover more of Sub-Saharan Africa and they may establish a study group to explore which countries and the timetable for such expansion. Dr. Knowles said there was substantial external interest in such an expansion.

b. Proposal from ILSI Japan Center for Health Promotion – Mr. Takashi Togami, Director, ILSI Japan Center for Health Promotion (CHP), was invited by the chair to make a presentation about the center's work to the ILSI Board of Trustees. Mr. Togami's presentation was distributed to the trustees prior to the meeting.

Mr. Togami reviewed the significant outcomes from three programs managed by his center – Project IDEA, Project SWAN and Project PAN, all of which are contributing to improving public health in one or more Asian countries. To date ILSI Japan CHP has been supported by strong links with respected academic and administrative networks in these countries. ILSI Southeast Asia has been an important collaborator for ILSI Japan CHP. Other opportunities have been suggested especially in Africa. However, ILSI Japan CHP is facing a critical shortage of resources – funds and professional manpower. The annual budget of ILSI Japan CHP has been in the range of \$300,000 – 500,000 in recent years. This funding has come from members of ILSI Japan and public funds from the government of Japan. Mr. Togami said that the programs now need a broader funding base.

Over the past 15 years, ILSI Japan CHP showed that ILSI could contribute to and improve the public health and directly benefit at-risk populations. Especially, ILSI Japan CHP has

shown that ILSI's tripartite partnership can effectively work to solve public health problems based on scientific evidence. Mr. Togami asked the ILSI Board of Trustees to study whether ILSI organizations can initiate and participate in social programs and how ILSI fundraising, financial operation, and collaboration with international organizations could contribute.

Several trustees suggested possible partners for ILSI Japan CHP, including the International Water Association (IWA) for Project SWAN and the International Finance Corporation (IFC) at the World Bank.

Dr. Boobis suggested that Dr. van Bladeren lead a study group with the following members – Dr. Hjelle, Mr. Geoff Smith and Mr. Togami – to review the information provided by Mr. Togami and report back to the ILSI Board of Trustees.

## c. Plans for 2016, 2017, and 2018 ILSI Annual Meetings

Dr. Harris referred the trustees to the flyer at the back of the trustees briefing book for the dates and venues for these three meetings:

22-26 January 2016 – Renaissance Vinoy Resort & Golf Club, St. Petersburg , FL, USA 20-25 January 2017 – Hilton La Jolla Torrey Pines, LaJolla, CA, USA 19-24 January 2018 – Fairmont Southampton, Southampton, Bermuda

Mr. Geoff Smith suggested that staff investigate having the ILSI Annual Meeting outside of the United States.

## XIV. Adjournment

As there was not further business, Dr. Boobis thanked the trustees for their active participation and adjourned the meeting at noon.

Signed:	Date:
- 0	

## ILSI Board of Trustees Meeting

## Saturday, 17 January 2015 8:00 am –Noon Chandler, Arizona

#### AGENDA

	Ι.	Call to Order	Dr. Sam Cohen
	II.	Approval of Minutes from the July 14, 2014 ILSI Board of Trustees Conference Call	Dr. Sam Cohen
	III.	President's Report	Dr. Jerry Hjelle
	IV.	<ul> <li>Progress with Implementation of the One ILSI Strategy</li> <li>a. ILSI Board Science Advisory Group Dr. Peter van Bladeren/Dr. Alan Boobis</li> <li>b. ILSI Board Value/Stakeholder Group - Dr. Todd Abraham/Dr. Sam Cohen/Mr. Geoff Smi</li> <li>c. Thematic area collaborations</li> <li>d. One ILSI accountability</li> </ul>	
	V.	Impact of Communications	Mr. Michael Shirreffs
	VI.	Report from the Publications Committee	Dr. Connie Weaver
	VII.	Report of the Financial Oversight Committee	Dr. Liz Westring
		a. 2014 Year-end Projections and 2015 Budget	
	VIII.	Adoption of the ILSI Budget for 2015	Dr. Sam Cohen
BRE	AK – PH	OTO (30 minutes)	
	IX.	Report from the ILSI Research Foundation	Dr. Adam Drewnowski
	Х.	Report from the ILSI Platform for International Partnerships	Dr. Suzie Harris
	XI.	<ul><li>Report of the Nomination Review Committee</li><li>a. Introduction of Nominees to the ILSI Board of Trustees</li><li>b. Election of Officers and Executive Committee Members</li><li>c. Election of Trustees to the ILSI Research Foundation Board</li></ul>	Dr. Takeshi Kimura
	XII.	Comments from the ILSI Board Chair and Comments from the ILSI President	Dr. Alan Boobis Dr. Rhona Applebaum

- a. New Branch Proposal
- b. Proposal from ILSI Japan
- c. Plans for 2016 and 2017 Annual Meetings

Dr. Michael Knowles Mr. Takashi Togami Dr. Suzie Harris

IX. Adjournment



# ILSI Board of Trustees Meeting

# Saturday, 17 January 2015 Chandler, Arizona, USA

## ATTENDEES

Dr. Todd Abraham Mondelēz International HQ

Dr. Rhona Applebaum The Coca-Cola Company

Dr. Scott Belanger The Procter & Gamble Company

Ms. Beth-Ellen Berry ILSI

Dr. Alan Boobis Imperial College London

Mr. Ary Bucione Dupont do Brasil

Dr. Sushila Chang Griffith University

Dr. Samuel Cohen University of Nebraska Medical Center

Frederick H. Degnan, Esq. King & Spalding

Dr. Dennis Devlin Exxon Mobil Corporation

Dr. Michael Doyle University of Georgia

Dr. Adam Drewnowski University of Washington Dr. Marion Ehrich VA-MD Regional College of Veterinary Medicine

Prof. Gerhard Eisenbrand University of Kaiserslautern

Dr. Catherine Field University of Alberta

Dr. Jerry Hjelle Monsanto Company

Dr. Suzanne Harris ILSI

Dr. Takeshi Kimura Ajinomoto Co., Inc.

Dr. Michael E. Knowles (retired) The Coca-Cola Company

Dr. Tamotsu Kuwata University of Human Arts and Sciences

Dr. Joanne Lupton Texas A&M University

Prof . John O'Brien Nestlé Research Center

Prof. Gerhard Rechkemmer Max Rubner-Institute (Federal Research Institute of Nutrition and Food) Mr. John Ruff ILSI Past President

Dr. Prahlad K. Seth Lucknow Biotechology Park

Mr. Michael Shirreffs

Mr. Geoff Smith Nutrition Strategies International

Dr. Lewis Smith (retired) University of Leicester

Mr. Shawn N. Sullivan ILSI

Dr. Sara Valdés Martínez Universidad National Autonoma de Mexico

Dr. Peter van Bladeren Nestec S.A

Prof Kendall Wallace University of Minnesota Med School

Dr. Connie Weaver Purdue University

Prof. Peter Weber DSM Nutritionals

Dr. Elizabeth Westring General Mills

Dr. Flávio A.D. Zambrone Planitox

#### OBSERVERS

Prof. Lucia Anelich ILSI South Africa

Ms. Vivian Aranda ILSI South Andean

Prof. Dianá Bánáti ILSI Europe

Ms. Mariela Berezovsky ILSI Brazil

Mr. Javier Castellanos ILSI Latin America Coordinator

Dr. Morven McLean ILSI Research Foundation Mrs. Olga Mora ILSI North Andean

Ms. Syril Pettit HESI

Dr. Andrew Roberts ILSI Research Foundation/CERA

Ms. Rekha Sinha ILSI-India

Mr. Takashi Togami ILSI Japan

Ms. Allison Worden ILSI Dr. Ryuji Yamaguchi ILSI Japan

Mrs. Boon Yee Yeong ILSI Southeast Asia Region

Dr. Myeong-Ae Yu ILSI Korea

## ILSI Board of Trustees Mid-year Conference Call

## Thursday, July 9, 2015 9:00 – 11:00 a.m. Eastern Daylight Time

# AGENDA

I.	Call to Order	Dr. Alan Boobis
II.	Approval of Minutes from the 17 January ILSI Board of Trustees Meeting	Dr. Alan Boobis
III.	President's Report	Dr. Rhona Applebaum
IV.	Progress with Implementing the One ILSI Strategy	
	<ul> <li>a. Science Advisory Group</li> <li>b. Value/Stakeholder Group</li> <li>c. Thematic area activities</li> <li>d. Governance policies and best practices</li> </ul>	Dr. Peter van Bladeren Dr. Sam Cohen Dr. Suzie Harris Mr. Shawn Sullivan
V.	Impact of Communications	Mr. Michael Shirreffs
VI.	Report from the Publications Committee	Dr. Connie Weaver
VII.	Report of the Financial Oversight Committee	Dr. Liz Westring
VIII.	Update on Branch Development	Dr. Michael Knowles
IX.	Report from the ILSI Research Foundation	Dr. Adam Drewnowski
X.	Report from the ILSI Platform for International Partnerships	Dr. Suzie Harris
XI.	Other Business	
	<ul><li>a. Follow-up on Center for Health Promotion proposal</li><li>b. Malaspina International Scholars Travel Award</li><li>c. Plans for 2016 Annual Meeting</li></ul>	Dr. Peter van Bladeren Dr. Suzie Harris Dr. Suzie Harris
VII	A 11	

XII. Adjournment

# ILSI<sup>®</sup> INTERNATIONAL LIFE SCIENCES INSTITUTE

# ILSI Board of Trustees 2015 Mid-year Conference Call Information

# The conference room number for all calls is 476-399-389 #

Country	Toll Free Dial-In	Note
Australia	1 800 064 762	NOLE
Australia	1-800-004-782	
Brazil	0800-047-4905	
Canada	1-888-299-2873	
Germany	0-800-723-5123	
Greece	00-800-4414-2827	
India	000-800-852-1446	
Japan	0-120-615-800	
Korea	0806140880	
Mexico	01-800-083-5534	
Singapore	800-852-3903	
Switzerland	0-800-002-347	41-(0)-225-3311-19 – long distance
United		
Kingdom	0-800-169-0430	
United States	1-888-585-9008	

If you are calling from a country not listed, please contact Beth Brueggemeyer

From:Joanne LuptonSent:Wednesday, June 24, 2015 1:42 PMTo:'nutritionreviews@ilsi.org'Cc:'sdonovan@illinois.edu'Subject:RE: Reminder: Review Overdue

Yes, I'm sorry. When I get back to my home early this evening I will go back over this. Joanne

Joanne R. Lupton, Ph.D.

-----Original Message-----From: <u>onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com</u> [<u>mailto:onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com</u>] On Behalf Of <u>nutritionreviews@ilsi.org</u> Sent: Wednesday, June 24, 2015 2:36 AM To: Joanne Lupton Cc: <u>sdonovan@illinois.edu</u> Subject: Reminder: Review Overdue

24-Jun-2015

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you agreed to review Manuscript ID NUTR-REV-088-LA-04-2015, entitled "Consumption of whole grains and cereal fiber in relation to cancer risk: a systematic review of longitudinal studies." A previous e-mail was sent to you one week ago as a reminder that your review was due, but we have yet to receive your review of this manuscript.

Please complete and then submit your review via the ScholarOne Manuscripts reviewing site at <u>https://mc.manuscriptcentral.com/nutr-rev</u>.

To access just the manuscript for review, with no need to enter log in details, please click the link below:

https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=706d79fcc1ca48d4bbbd65e352dc8de6

To log in to your account, please go to <u>https://mc.manuscriptcentral.com/nutr-rev</u>. Your case-sensitive USER ID is <u>jlupton@tamu.edu</u>. For security purposes your password is not listed in this email. If you are unsure of your password, you may click the link below to set a new password.

https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=453d8ed53a5f4e9495e42ce812c9071f

Your participation in our review process is most sincerely appreciated. If you are having any difficulties completing your review or accessing the reviewing site, please contact me directly.

Sincerely,

Allison Worden Publications Manager Nutrition Reviews E-mail: <u>nutritionreviews@ilsi.org</u>

Present Knowledge in Nutrition E-mai

cc. Dr. Sharon Donovan Editor

[email ref: ENR-SW-6-c]

From: Sent: To:

Delia Murphy Thursday, June 18, 2015 8:52 AM DAllison@uab.edu; fergc@foodsci.umass.edu; mdoyle@uga.edu; dwyerj1 @od.nih.gov; jwerdman@illinois.edu; Eric Hentges; james.hill@ucdenver.edu; dblund@wisc.edu; Joanne Lupton;

weavercm@purdue.edu;

Cc:Alison KretserSubject:ILSI North America Scientific Integrity Working GroupAttachments:Final Plan of Work for Scientific Integrity\_6\_17\_15.docx

To: ILSI North America Scientific Integrity Working Group Re: Final Plan of Work

Ρ

Thank you to Working Group members for providing feedback to the draft plan of work. Alison and I have combined the edits into the finalized Plan of Work for the Scientific Integrity Working Group, attached. This Plan of Work will be presented to the Board of Trustees at ILSI North America's Mid-Year Meeting on 1 July for the Board's approval.

Thank you again for the hard work put into developing this plan for the Working Group. We have an exciting few years ahead of us!

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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# Scientific Integrity Working Group

## Background/Recommendations from the Scientific Integrity Working Group from 30 April Meeting

- 1. Given the extensive work being done by federal agencies and other organizations on scientific integrity (see Compilation of Scientific Integrity Work by Various Organizations document completed by ILSI North America), why is there still an ongoing need to address the issue? What are the reasons for an apparent increase in scientific fraud and misuse of scientific data? What are the pressures that cause these actions? What can be done to instill scientific integrity in all researchers?
- 2. ILSI North America should synthesize the Compilation document into a three-point framework (science, research, and people) and publish it to emphasize the work that has already been done by the federal agencies and other organizations. Based on this, ILSI North America should then develop a set of principles/best practices on scientific integrity that can be easily used by all scientists and researchers.
- 3. The Working Group feels that ILSI North America should seek a broader group of collaborators than we have previously worked with in order to have a greater impact; ones that have impeccable reputations and are not focused on only one area of science. Possible candidates are:
  - a. American Association for the Advancement of Science (AAAS)
  - b. Association of Public and Land-grant Universities (APLU)
  - c. Association of American Universities (AAU)
  - d. The National Academies (NAS)
- 4. ILSI North America's focus should be on implementation of these principles/best practices. To accomplish this goal, ILSI North America will bring visibility to the published principles/best practices by hosting a "tournament" on an annual basis to identify outstanding papers within specific categories that can be held up as examples and model publications. The following categories are under consideration because they were identified in the ILSI North America membership survey on scientific integrity: study design, statistical analysis, reporting fidelity, open source data sets, best reviewer, and best in class. This "tournament" would show the principles/best practices in action by focusing on the strengths and weaknesses in each category.
- 5. The COI Summit Consortium, a group of federal agencies and nutrition, food science, and food safety professional societies who originally met in December 2014 to agree on and endorse a set of principles to provide a framework for research public-private partnerships (PPPs), has agreed to reconvene in two years to reassess the PPP principles. At this future meeting, ILSI North America could introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

## Proposed Plan of Work for the Scientific Integrity Working Group

1. A Compilation of Scientific Integrity Work by Federal Agencies and Other Organizations was completed in April 2015. This information will be placed into a framework using three categories that encompass scientific integrity (science, research, and people.)

- a. This work will be submitted to a peer reviewed journal as a manuscript in order to have it published in a timely manner. Dr. Fergus Clydesdale has offered to publish this manuscript in *Critical Reviews in Food Science and Nutrition*.
- b. This compilation should remain a living document. With the journal, explore the possibility of an online version of the publication, capturing activities on scientific integrity on a regular basis.
- 2. Develop and publish a second paper in collaboration with AAAS, APLU, and AAU that builds on the first manuscript. The paper will synthesize a set of principles/best practices for scientific integrity using the framework (science, research, and people) to establish the first "rulebook" on scientific integrity and will describe how to implement them. In developing this monograph, it will be helpful to incorporate sports analogies (i.e. rules of the game, batters, umpires/referees) to better illustrate this issue. A secondary goal of the publication will be to raise awareness of the real consequences of scientific misconduct, i.e. the penalty phase. This can be done by examining case studies of scientific misconduct (worst practices) to incorporate into the manuscript (for example, the NSF and HHS Office of Research Integrity jointly issue a list of case summaries of scientific misconduct each year https://ori.hhs.gov/case\_summary). The publication will highlight the punishments that are currently being dispensed for scientific misconduct. Little attention has been given to this area within the scientific community.
  - a. The ILSI North America body of work on conflict of interest to date can be highlighted in the "people" section of the framework as it focuses on personal scientific integrity. For example, an individual researcher should be aware that he/she has certain conflicts of interest which can affect his/her personal integrity, and also must adhere to other ethical and moral aspects of science.
- 3. In collaboration with AAAS, APLU, and AAU, begin development of an annual "tournament" to identify outstanding papers within specific categories across all scientific disciplines. Begin development of criteria/rubric for grading papers at the "tournament" with collaborators (review current grading scales, i.e. HHS NIH National Cancer Institute, USDA National Institute of Food and Agriculture, etc.) Dr. David Allison has begun to outline the procedure for evaluating papers.) The first "tournament" will be held in late 2017-early 2018.
  - a. Nutrition, food science, and food safety professional societies may be interested in sponsoring specific categories within the "tournament" (i.e. award prize money for winners of "tournament".)
- 4. Present the new framework and principles/best practices at major professional society meetings beginning in 2016-2017, educating attendees (with a focus on young researchers/post docs) on the components of scientific integrity (i.e. learning to throw the baseball before you play the game.) The session would outline current efforts in scientific integrity, what it means for institutions and researchers, and where it is going and will bring to light how it applies to your professional organization. (If an individual researcher does not implement the principles/best practices, it can ruin one's career.) The case studies used would be specific to the professional meeting. The session will also include a description of the "tournament" and the proposed criteria/rubric developed for grading the papers for additional feedback from attendees.
  - a. Potential Meetings to Present the Framework and Principles/Best Practices:
    - i. American Association for Advancement of Science (AAAS)
    - ii. Association of Public and Land-grant Universities (APLU)
    - iii. Association of American Universities (AAU)
    - iv. World Conference on Research Integrity
    - v. American Society of Nutrition- Experimental Biology (EB)
    - vi. International Association for Food Protection (IAFP)
    - vii. Academy of Nutrition and Dietetics FNCE
    - viii. Canadian Nutrition Society (CNS)

- ix. Canadian Child Health Clinician Scientist Program (CCHCSP)
- x. Canadian Institute of Food Science and Technology (CIFST)
- xi. Society of Toxicology (SOT)
- xii. Society for Risk Analysis (SRA)
- xiii. Institute of Food Technologists (IFT)
- xiv. International Union of Food Science and Technology (IUFoST)
- xv. International Society for Behavioral Nutrition and Physical Activity (ISBNPA)
- 5. Finalize the criteria/rubric for grading papers and train the "referees" for the "tournament," recognizing that over time, the principles/best practices may evolve, as demonstrated in sports.
- 6. Hold "tournament" in Washington, DC.
- 7. Post winning papers in the different "tournament" categories to NIH PubMed Commons for recognition.
- 8. When the COI Summit Consortium reconvenes in two years, ILSI North America will introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

## **Proposed Timeline for Plan of Work:**

- 1. Presentation of plan of work to the ILSI North America Board of Trustees: July 2015
- 2. Meet with AAAS and APLU to share Plan of Work: Summer 2015
- 3. First manuscript on Compilation of Scientific Integrity Work: Submission September 2015
- 4. Second manuscript on principles/best practices, developed in collaboration with AAAS and/or APLU: mid-2016
- 5. Roadshow at Major Professional Society Meetings: 2016-2017
- 6. Second COI Summit Consortium Meeting: December 2016- early 2017
- 7. First Annual "Tournament": late 2017-early 2018

From: Sent: To:	Suzanne Harris Wednesdav. June 17. 2015 3:47 PM			
		s.chang@griffith.edu.au'; 'scohen@unmc.edu';		
	'adamdrew@u.washingtor Field';	.edu'; 'marion@vt.edu';	, madyle@	'; 'Catherine
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	'jbradford@unmc.edu'; ' 'Usui-Etsi	'Usui-Etsuko(?? ??)	; Chelsea L. Bishop;	
		RSA'; 'haan@purdue.edu';		
	Shirroffe: Shawn Sullivan	Beth Brueggeme	yer; Beth-Ellen Berry	; Michael
Subject: Attachments:	Date for the mid-year ILSI Board of Trustees conference call Thursday, July 9, 2015 2015 Dial-in information.doc; ILSI BOT 2015-07-09 agd.doc; ILSI-BOARD-20150117 DRAFT+AB.docx			

TO: ILSI Board of Trustees

FROM: Suzie Harris

The ILSI Board of Trustees mid-year conference call is scheduled for **Thursday, July 9, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than 2 hours. The dial-in instructions are attached here:

The proposed agenda for the conference call is attached here:

Agenda Item II. Draft minutes from the January 17, 2015 ILSI Board of Trustees meeting

All other documents for the ILSI Board of Trustees mid-year conference call will be posted on the ILSI Board portal not later than Wednesday, July 1. You may reach the ILSI Board portal through this link: <u>https://www.ilsiextra.org/ilsi/bot/SitePages/Home.aspx</u>

Your username is the information in your email address before the "@". Password: Password1 To reset your password, go to: <u>https://www.ilsiextra.org/Pages/Change%20Password.aspx</u>

I will send a reminder message on or about July 1. Please let me know if you have questions or need help accessing the documents on the Board portal.

**ILSI Board of Trustees** 

4-3-2015 Draft

## Annual Meeting Saturday, January 17, 2015 Chandler, Arizona

## DRAFT MINUTES

## I. Call to Order

Dr. Samuel Cohen, Chair, ILSI Board of Trustees, called the meeting to order at 8:00 a.m. Mountain Standard Time. He welcomed the trustees, nominees for the Board, staff and guests. Dr. Cohen reviewed the operational rules for the ILSI Board of Trustees meeting. Observers were welcome but were asked to remain silent unless called upon by the chair. The ILSI Board may hold an executive session during which all non-trustees would be asked to leave. All motions, except motions attached to specific agenda items, must be submitted in writing at the time they are offered. Motion forms were included in each trustee's briefing book. Nominees for the ILSI Board of Trustees are welcome to participate in the Board discussions, but may not offer motions or vote. All trustees were asked to complete, sign and turn-in the Conflict of Interest form, which was included in the front pocket of the trustee briefing books.

The meeting agenda and list of participants and observers are attached.

## II. Approval of Minutes from the July 14, 2014 ILSI Board of Trustees Conference Call

These draft minutes were distributed to the ILSI Board of Trustees electronically prior to the meeting and were included in the briefing book given to each trustee. Dr. Alan Boobis requested that the term "worthy" be removed from the last line of the "action" paragraph under Agenda Item VII, and be replaced with less value-laden language. With this change the minutes were unanimously approved.

## III. President's Report

Dr. Jerry Hjelle, ILSI President, began his remarks by thanking the ILSI professional staff based in Washington as well as those based in the branches and Research Foundation for all of their support and efforts to implement the One ILSI strategy over the past two years. The One ILSI strategy was developed by the ILSI Board and professional staff during 2012-2013 and was formally launched at the beginning of his two-year term as ILSI President. Referring to the One ILSI Implementation Plan, which was included in the trustee briefing book, Dr. Hjelle described the components of the plan and its focus on foresight to increase ILSI's credibility and vision.

Four thematic areas were identified that together cover most of the scientific areas addressed by the organization. Dr. Hjelle specifically thanked the professional staff from the branches who had volunteered to lead these four thematic areas over the past two years. Professional development for key staff in the branches and the Research Foundation is a fundamental part of the implementation plan as well.

Dr. Hjelle said that he enjoyed visiting the various branches during his term as ILSI President. This experience allowed him to understand more clearly what a truly remarkable organization ILSI is. He

found his term as ILSI President to be personally gratifying and he thanked the trustees for their support.

#### IV. Progress with Implementation of the One ILSI Strategy

a. ILSI Board Science Advisory Group – Dr. Boobis reviewed the accomplishments of the Science Advisory Groups, whose members are himself and Dr. Peter van Bladeren, serving as Co-Chairs, Dr. Michael Doyle, Dr. Catherine Field, Dr. Lewis Smith, Dra. Sara Valdés, Dr. Connie Weaver and Dr. Flávio Zambrone. The group interacted with the leaders of the four thematic areas and oversaw the development of the key activities chart which is organized by the four thematic area topics. The advisory group also reviewed the Best Practice Guide for Identification of Emerging Issues and surveyed the branches to assess how they went about identifying emerging issues.

The survey results showed that a range of stakeholders were being consulted in the emerging issues identification process, though who is involved varies from branch to branch. The process of prioritization was even more variable with fewer branches involving external stakeholders. The survey results and the issues identified were included in the trustee briefing books. There is substantial overlap among the emerging issues identified by different branches, thus offering opportunities for collaboration.

Dr. Sushila Chang noted that branches operate in culturally different environments, making it unlikely that one specific process would work for all. The best practice approach which provides guidelines and concrete examples would be more helpful. Other trustees noted that some branches list activities rather than emerging issues. Dr. Lewis Smith commented that governance of the One ILSI strategy was needed to increase visibility. There was general agreement that the branches were communicating more effectively with each other, but cooperative and collaborative activities were still rare. More time during the annual meeting should be devoted to identifying areas of synergy and mechanisms to allow collaboration. Dr. Rhona Applebaum noted that doing so requires the branch staff to build the necessary skill set.

Dr. van Bladeren invited all interested trustees to participate in the Science Advisory Group's meeting with the thematic area leaders on Monday afternoon, January 19 at 5:30 pm. The advisory group relies on Board members to volunteer.

b. ILSI Board Value/Stakeholder Group – This advisory group is led by Dr. Todd Abraham, Dr. Cohen and Mr. Geoff Smith. Dr. Applebaum is also an active member of the group. The group worked with Mr. Michael Shirreffs, ILSI Director of Communications to draft a series of value statements for industry members and public advisors based on an online survey of trustees and academic advisors, interviews with key leaders and branch input.

Dr. Abraham noted that a series of materials (handed out at the meeting) were developed to reflect these value statements. Dr. Cohen commented that ILSI was being more proactive, less reactive in its messaging.

Mr. Shirreffs briefly reviewed the materials that were distributed. All are intended to be used as development materials and use a modular approach. There are three versions

of the fold-out document to demonstrate how it can be tailored to different audiences. One of the examples is in Korean, showing that languages other than English may be used. Such materials allow ILSI to centrally control the message, i.e., ensure that everyone speaks with one voice, as long as the translations are accurate. The set of program guides – linked to the four thematic areas – are still in draft so that the branches can comment on them. The objective of these documents is to present what ILSI is doing in a specific area, e.g., healthy aging, in an easy-to-read format. The final document is a case study on caffeine, which provides more detail on what ILSI accomplished with a body of work on a single topic. Additional case studies will be developed. Mr. Shirreffs is still developing the best practices guide for development that will go along with these communications tools.

Dr. Doyle suggested that more detail was needed in the program guide for food and water safety as the current text does not include all that ILSI is doing. Dr. Abraham acknowledged that the guides were still in draft and that he wanted to see the thematic area leaders take ownership of what goes in each guide.

In response to a question about how these materials will be used, Dr. Abraham said that this would be part of the advisory group's work for 2015. He acknowledged that it is hard to know all the ways the materials could be used at the local level and that some customization will be needed. This is why the modular approach was selected. Dr. Hjelle suggested that a master list of contacts made each year be compiled and metrics be developed to track the effectiveness of the materials for each of these contacts.

In 2015, the advisory group's priorities will be to validate the value statements, update the program guides based on branch feedback, identify specific topics for additional case studies highlighting ILSI science, prioritizing additional stakeholders for targeted outreach, and setting outreach goals with measures of success. Dr. Abraham ended his report by asking for volunteers.

**c.** Thematic area collaborations – Dr. Suzie Harris briefly reviewed the outcome of the thematic area discussions during the ILSI Branch Staff Meeting on the previous day. All four groups experienced good cross-branch participation.

**Food and Water Safety** – This group is led by Dr. Eric Hentges, ILSI North America, and Mr. Keng Ngee Teoh, ILSI Southeast Asia Region. In 2015, the branches involved in this thematic area will continue to focus on capacity building on food safety risk assessment in Asia and Africa. Several ILSI branches are involved with the World Bank Global Food Safety Partnership (GSFP) and will undertake pilot testing of a new training module being developed by GSFP. This work links with the Toxicology/Risk Science thematic area as well. The two thematic areas are communicating with each other to leverage each's activity to the greatest extent possible. ILSI Europe volunteered to take on the leadership of the iFoodExposure project and proposed that interested branches join with them to support the expansion of the GUIDEA database of dietary intake/exposure methods beyond Europe. ILSI Japan Center for Health Promotion made a presentation to the group on Project SWAN, a community-based clean water activity.

**Sustainable Agriculture and Nutrition Security** – This group is led by Dra. Mariela Berezovsky, ILSI Brasil, and Dr. Morven McLean, ILSI Research Foundation. The group discussed further the plan to help the ILSI Research Foundation Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security (CIMSANS) in identifying data in countries around the world that could be used to assess sustainable nutrition security for the very first time.

**Nutrition, Health and Well-being** – This group is led by Dr. Diána Bánáti, ILSI Europe, and Mrs. Yeong Boon Yee, ILSI Southeast Asia Region. The group discussed their ongoing effort to collect information on successful healthy aging interventions and to compile these into a public database for others to use in deciding how to support healthy aging. They are planning to organize a session during the 2015 SLAN (Latin American Nutrition Society) meeting and the 2017 International Union of Nutritional Scientists (IUNS) meeting. In addition to this work, the group agreed to explore two other important nutrition topics – nutrition for the first 1000 days of life and nutritional impact on the microbiome. This group also plans to update the matrix of branch activities for this thematic area.

**Toxicology and Risk Science** – This group is led by Ms. Syril Pettit and Dr. Michelle Embry, ILSI Health and Environmental Sciences Institute (HESI). The Risk Science Forum, a branch staff group, is up and running with an online portal. The forum is designed as a way to enhance the understanding of state-of-the-art risk science by the branch staff. The branches involved in the thematic area are also contributing information about risk assessment training courses being offered in their regions. This information will be added to the WHO Risk Assessment Network database, which is managed by HESI. As a new activity the branches involved in this thematic area decided to try to identify groups for which such training is needed and to contribute to planning a workshop to identify best practices for such training.

Dr. Hjelle commented that there was a very high level of participation by the branches and, especially the thematic area leaders, during the discussions on the previous day. He urged trustees to volunteer as "champions" to help the thematic area groups identify potential funding sources. Shortening the period to raise funds will greatly impact the success of these programs.

**d. One ILSI accountability** – Having annual performance evaluation goals linked to One ILSI for branch executive directors is part of the One ILSI Strategic Plan. Dr. Harris noted that this topic was addressed during the ILSI Branch Staff Meeting and all branches were encouraged to develop performance goals for the executive directors and for other staff, if feasible. At present not all branches use an annual performance evaluation system. The branch board should be responsible for ensuring that the branch executive director has a performance goal related to implementation of One ILSI.

Dr. Abraham asked that a common goal be developed, especially for the One ILSI thematic leaders, so that performance can be evaluated across the branch network.

#### V. Communications
Mr. Shirreffs began his report by acknowledging the help he receives from the Value/Stakeholder Advisory Group. He urged other trustees to volunteer to join this group, noting that he would like to have Latin America represented in the group. The primary components of the communications program are: developing messages, crafting strategies to deliver these messages, creating online and print materials, enhancing and maintaining the website, conducting outreach via social media, responding to the media, and improving search engine optimization (SEO) for ILSI. There are three communications tracks – traditional, internal or corporate, and development (the ask).

In 2014, a development kit was initiated. The process of developing the ILSI promotional materials pointed to the need to develop a case study on how to go about developing such materials, a project which he plans to take on this year. In addition, ILSI's social media program, which includes Facebook, Twitter, YouTube and LinkedIn, was enhanced. ILSI's presence on various social media platforms is steadily increasing. Videos of ILSI scientific programs posted on YouTube are popular, with over 69,000 viewing minutes recorded in 2014. In terms of ILSI's media presence, the organization is still not pursuing a proactive media program.

In 2015, Mr. Shirreffs will accelerate ILSI's social media program by adding more scientific content, exploring the feasibility of blogging and developing best practices. Dr. Applebaum endorsed blogging as a tool ILSI should use more. Mr. Shirreffs suggested that a guest editorial approach may be the way to begin. The focus of such blogs would be on science communication. In response to a question from Dr. Boobis about benchmarks for social media, Mr. Shirreffs said that he planned to track the return on investment of the social media tools to determine what is working and what is not. The communications budget includes funding for Mr. Shirreffs to attend several large scientific meetings in 2015, where he will tweet to enhance ILSI's presence on this platform. The Research Foundation and several branches have individuals who do the same for meetings they attend.

Mr. Shirreffs will focus on reenergizing ILSI EXTRA and refreshing the ILSI website, using information collected through surveys of users. ILSI has contracted with a professional web design group to oversee the refresh and a technology group to take care of the technical needs. The transition from the current site to the new one will be managed by him and Mr. Steve Parker, ILSI Information Technology Manager. The transition should be seamless over the course of 2015. The branch staff has been invited to participate in a meeting on Monday afternoon, January 19, with the professional design group to discuss what the branches need and want. The return on investment will be tracked for these communications tools, too. Further into the future, Mr. Shirreffs plans to work closely with ILSI's Information Technology department to determine the feasibility of a customer relations management database more suited to ILSI's communications needs than the current one.

Dr. Adam Drewnowski suggested that the re-fresh process should also include the needs of various international groups with whom ILSI works or wants to work. Mr. Shirreffs acknowledged this potential audience and noted that many were currently "following" ILSI through social media. Personal contact was suggested by Dr. Cohen as another way to reach the broader stakeholder audience.

Dr. John O'Brien complemented Mr. Shirreffs for developing such a clear path to enhancing ILSI's impact, but he also asked for more.

### VI. **Report from the Publications Committee**

Dr. Connie Weaver, Chair of the Publications Committee, thanked the other members of the committee, Dr. Chang, Dr. Field, Dr. Michael Knowles, Dr. M.T. Kuwata, Mr. Felipe Rodriguez, Dra. Valdés, and Dr. Zambrone, for their help throughout the past year. The committee will meet on Monday, January 19, and other trustees are welcome to attend. Dr. Weaver also thanked Ms. Allison Worden, ILSI Publications Manager, for all of her work over the past year.

In 2014, the committee oversaw the search and selection process for a new publishing partner for *Nutrition Reviews*. One of the primary reasons was to improve financial returns from the journal. The committee also began exploring the potential benefits and risks of open data and open access initiatives with the goal of developing best practices guidelines. The committee also provided input toward the development of a new textbook, *Present Knowledge in Food Safety*.

Dr. Naomi Fukagawa is the current editor-in-chief of *Nutrition Reviews* and has been in this position since 2009. Beginning in January 2015, the journal will be published in partnership with Oxford University Press. The new publishing agreement included a signing bonus (\$100,000), increased royalty payments, and increased annual stipend for ILSI's costs associated with preparing manuscripts for publication. Dr. Weaver noted that *Nutrition Reviews* is the most highly cited monthly review journal in nutrition (Impact Factor = 5.541). ISI ranks *Nutrition Reviews* as fifth out of 78 journals in nutrition and dietetics. The journal is being translated into Japanese, Chinese, and Spanish by ILSI branches. Furthermore, as shown in Appendix A of the committee's report, *Nutrition Reviews* makes a profit for ILSI (\$87,386 projected in 2014). Dr. Abraham asked for information about how ILSI's revenue from *Nutrition Reviews* compares to that of other journals.

ILSI's other publication, *Present Knowledge in Nutrition (PKN), Tenth Edition,* was published in print and electronic formats in 2012. It is an essential reference text for researchers, health professionals, policy experts, educators and students. Dr. Weaver said that work on the eleventh edition is expected to begin in 2015. This work will include evaluating potential publishers, beginning a search and selection process for the new edition's editors, and conducting a market analysis to optimize the new edition for current research and teaching methods.

Dr. Knowles was given credit by Dr. Weaver for developing an exciting proposal for a new textbook, *Present Knowledge in Food Safety.* He serves as the lead editor for this proposed publication, which is intended to serve as a reference and teaching tool in the model of PKN. A publishing proposal will be sent to potential publishers in 2015.

Ms. Worden also led the initiative to find new metrics with which to measure the impact of ILSI scientific publications. She gave a well-received presentation on a new tool, Altmetric, during the ILSI Branch Staff meeting on Friday, January 16. Some of the Oxford University Press signing bonus will be used to subscribe to Altmetric and track the coverage of ILSI publications in social media, traditional media and government policy documents. These data will be used by each of ILSI's entities to set their own goals.

The committee recently began looking at issues related to open access and open data in an effort to understand the trends and potential implications for ILSI's publications. In line with most journals, *Nutrition Reviews* provides an opportunity for authors to purchase instant open access for their articles as well as gratis online space for sharing supplementary data sets related to their articles. To convert the journal to an entirely open access model in the current pricing environment would not be financially sustainable. Since the issues of open access and open data affect much of ILSI's work beyond

publications ILSI owns, the committee will draft best practice guidelines for open data and open access projects and share them with the ILSI Board for review.

Thus, the future work of the committee includes overseeing *Nutrition Reviews'* progress under its new publisher, overseeing development of *Present Knowledge in Food Safety* and the eleventh edition of PKN, monitoring evolving trends in scholarly publishing, proposing best practice guidelines for open data and open access endeavors, overseeing selection of metric tools to measure the impact of ILSI's scientific outputs, and exploring other publishing opportunities.

### VII. Report of the Financial Oversight Committee

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began her report by thanking the members of the committee – Dr. Abraham, Dr. Chang, Dr. Gerhard Eisenbrand, Dr. Joanne Lupton, Mr. Rodriguez, and Dr. Lewis Smith. She also thanked Ms. Beth-Ellen Berry, ILSI Chief Financial Officer, for her excellent work throughout the year. The committee's report and ILSI financial statements were distributed to the trustees electronically prior to the meeting and were included in the trustee briefing book. The financial statements were the balance sheet as of November 30, 2014 and the functional activity statement with 2014 year-end projections and 2015 proposed budget. Also included in the briefing books was a document titled, "How to Read Your ILSI Financial Statements."

Beginning with the balance sheet, which shows assets, liabilities and net assets on November 30, 2014, Dr. Westring noted that the final balances for the year were not provided. However, the November 30, 2014 balances provide a reasonable indication of ILSI's financial health. The year-end balances will be prepared and will be audited in early 2015. The November 30, 2014 balances show that ILSI is maintaining sufficient liquidity and has healthy assets in both the ILSI unrestricted and restricted activities.

ILSI has a Board-designated reserve fund which was officially established in 2013, with a target balance of 50 percent of the annual unrestricted budget (~\$600,000). The investment policy for this reserve fund was revised by the Financial Oversight Committee in the fourth quarter of 2014. Going forward the asset allocation will change from being 100 percent invested in fixed income instruments to 40 percent equity and 60 percent fixed income. While this change to a more diversified portfolio will increase opportunities for long-term growth, it will also mean that month-to-month volatility is more likely. The Board-designated reserve fund is invested in broad market index funds with low fees. On December 31, 2014, the balance was \$576,229 with earnings of 1.7 percent for the year.

Moving to the revenue and expenses (income statement) by functional area, Dr. Westring first focused on the unrestricted activities of ILSI Governance and Coordination (GC), Communications and Press. ILSI GC covers the international network of branches, the ILSI Board of Trustees, and ILSI's portion of the annual meeting. Communications covers proactive outreach, the ILSI website and the branch extranet. ILSI Press covers *Nutrition Reviews*, ILSI's monthly scientific journal, and *Present Knowledge in Nutrition*, 10<sup>th</sup> edition. Looking at the subtotal for the ILSI unrestricted functions, Dr. Westring noted that revenue in 2014 exceeded budget by 9 percent, primarily due to the \$100,000 signing bonus from Oxford University Press, the new publisher for *Nutrition Reviews*, beginning in 2015. In response to a question about advertising revenue, Ms. Berry said that banner ads are being run in the online journal. Such revenue is included in the publishing agreement with Oxford University Press.

Expenses exceeded budget by 7 percent due to two unbudgeted grants for One ILSI projects, one to ILSI Health and Environmental Sciences Institute (HESI) and the other to ILSI Southeast Asia Region. Funds were raised in 2013 to provide support for the One ILSI projects in the thematic areas, although the particular projects and necessary funding were not mapped out at the time the 2014 budget was developed. ILSI is projected to end 2014 with net assets of \$1,078,256, which will be a decline in net assets of \$2,901 from the beginning of 2014.

In comparing 2014 projections to the 2015 proposed budget, Dr. Westring noted that ILSI had been sharing an executive director with the ILSI Research Foundation and received reimbursement for the foundation's share of salary/benefit expenses. This is shown in the "fee for service" line under revenue. In 2015, Dr. Harris will move to 60 percent effort for ILSI only and the foundation will employ its own full-time executive director. Thus, both salary/benefit expenses and "fee for service" revenue will be reduced in 2015 by approximately \$95,000. Small increases for operating costs have been included in the 2015 budget and the annual meeting expenses have been increased to account for a more expensive venue, compared to 2014. The proposed 2015 budget shows year end net assets of \$1,103,893 compared to \$1,078,256 at the projected 2014 year-end net assets.

Turning to the restricted functions, which include functions mandated by branch leadership, steering committees, or outside donors, Dr. Westring reminded the ILSI Board of Trustees that these funds are not available to fund unrestricted activities and these accounts must maintain positive net assets. The current restricted functions are:

- Platform for International Partnerships (PIP) -- manages ILSI's interactions with WHO and FAO
- Global Travel Fund supports branch staff travel to other branches
- Developing Food and Water Safety Capacity in Sub-Saharan Africa and Asia supports training and internship programs in developing countries
- Malaspina Travel Award supports outreach to young scientists
- International Branch Activity supports local activities for ILSI Focal Point in China and Latin American branches coordination
- Shared Services support human resources, accounting, legal, and information technology for the ILSI corporations based in Washington, DC, USA.

The revenue from contributions in 2014 exceeded the budget by 25 percent. In addition to annual contributions from ILSI member companies, PIP received a one-time contribution from the Industry Council for Development (ICD). The Coca-Cola Company contributed \$325,000 for 2014 and \$350,000 for 2015 to fund PIP activities, food and water safety programs, the Malaspina International Scholar Travel Award, and a coordination position to strengthen the ILSI branch network in Latin America. Plans for the restricted programs were not developed at the time that the 2014 budget was prepared, thus expenses exceed what was included in the budget by 13 percent. The projected 2014 year-end net assets for the restricted functions are \$857,355 compared to the budget value of \$539,225.

Comparing the projected 2014 year-end restricted functions to the proposed 2015 budget, Dr. Westring noted that revenue from contributions is down by 22 percent, though substantial contributions made in 2014 were for 2015 activities. Annual contributions from ILSI member companies for PIP and the Sub-Saharan Africa program are expected to continue. Expenses are budgeted to be down by four percent, as program plans are still being developed for some of the 2015 restricted activities. The proposed 2015

budget shows net assets at the end of the year of \$769,003, compared to the projected 2014 year-end net assets of \$857,355.

Summarizing the total ILSI functional activity statement, the 2014 projected year-end net assets are \$1,935,610, compared to the year-end net assets for the 2014 budget, which were \$1,585,236. The proposed 2015 budget shows total year-end net assets of \$1,872,897.

### VIII. Adoption of the ILSI Budget

**Action:** Dr. Westring moved that the 2015 ILSI budget be approved as presented to the board. The motion was seconded and passed unanimously.

### IX. Report from the ILSI Research Foundation

Dr. Adam Drewnowski, Chair, ILSI Research Foundation Board of Trustees, began his report by thanking the members of the ILSI Research Foundation Executive Director Search Committee, several of whom are ILSI Trustees. He also congratulated Dr. Morven McLean, who accepted the offer to become the first full-time executive director for the foundation.

A written report of the foundation's accomplishments in 2014 was included in the trustees' briefing book. Dr. Drewnowski described the ILSI Research Foundation as an international entity that works both independently and in concert with other ILSI entities, to advance the mission of ILSI. In 2014, the foundation had four centers of excellence – Center for Environmental Risk Assessment (CERA), Center for Risk Science Innovation and Application (RSIA), Center for Safety Assessment of Food and Feed (CSAFF), and the Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security CIMSANS). There was also a program on nutrition and health.

To date, CERA has focused largely on applied research, related to improving how genetically-modified crops are evaluated for potential adverse environmental impacts. Developing environmental risk assessment tools for low exposure scenarios continues to be an important topic for CERA as the disproportionate focus on hazard assessment has led to trade disruptions as well as limitations on research and development. The so-called "low-level presence" occurs when small amounts of genetically-modified grain that has been commercially approved in the country of export is subsequently discovered in shipments to countries of import where approval for the specific grain is absent or pending.

CERA also works collaboratively with multiple public and private sector organizations to improve and standardize the risk assessment methods applied to evaluating the potential environmental impacts that a transgenic protein may have on non-target organisms. This work has been translated into hands-on field and lab training programs, with attendees from many of the developing countries where CERA is active. CERA developed a conceptual framework that provides a scientifically defensible process for evaluating if existing data from experimental field trials are relevant and/or sufficient for environmental risk assessments conducted in other countries. Additionally, it promotes a strategic approach to identifying field trial site locations, so that field data will be transportable from one regulatory jurisdiction to another.

Capacity building is a key function for CERA, making sure that the good science being done at ILSI and elsewhere is accessible to the people who need it to support their work. The Partnership Project in

Biosafety Risk Assessment & Regulation, which ended in 2014, was active in eight countries (Bangladesh, Colombia, Kenya, Paraguay, Tanzania, Uruguay, Uganda, and Vietnam). Having met all of its milestones, the project is now undergoing an external assessment as part of the funding agreement with the World Bank.

CSAFF promotes science-based approaches to the safety assessment of food and feed, with a strong emphasis on improved knowledge dissemination and capacity building. A tripartite scientific advisory council is being established to provide scientific guidance to the center, in line with the councils that have been put together for CERA and CIMSANS.

CSAFF also maintains the ILSI Crop Composition Database, a valuable tool for comparative food safety assessment. The most recent update (Version 5.0) contains over 800,000 data points for comparative assessment, covering 3150 compositional components for six crops, including newly added canola, sweet corn and rice.

In 2014, CSAFF organized a tripartite, multi-stage capacity building program on toxicity testing relevant to safety assessment of genetically modified foods. This work was supported by a grant from the U. S. Agency for International Development and with materials donated by DuPont Pioneer. The first phase of the training, in New Delhi, India, included classroom lectures and practical exercises for food safety training. The second phase, which took place at the Stine Haskell Research Facility in Newark, Delaware, USA, involved actual laboratory experience related to toxicity testing.

The primary mission of CIMSANS is to foster new public-private partnerships on integrated modeling that improve both scientific understanding and public policy around the growing impacts of climate change and resource scarcity – especially water – on sustainable nutrition security (SNS). Through a series of peer-reviewed publications, the center has already helped release private-sector maize breeding trial data as Open Data and has produced improved assessment methodologies for maize and other major row crops. As with other ILSI entities, CIMSANS has quickly become an important global partner, engaging hundreds of influential scientists among dozens of key organizations within academia, governments, and the private sector. CIMSANS has co-hosted a series of conferences with increasing levels of global impact. CIMSANS is now gathering the partners and resources needed to produce the first credible, comprehensive, global SNS assessment that includes all of the world's most important staple and non-staple foods.

Active partnerships include GEOSHARE and SUSFANS, which also includes ILSI Europe. CIMSANS is partnering with several public and private sector organizations to finalize the metrics that will be included in the sustainable nutrition security assessment. A workshop is scheduled for February 17, Washington to "co-create" with a broad set of stakeholders, including the International Food Policy Research Institute (IFPRI), mathematical expressions for the nutrition metrics. These expressions will then be added to the available integrated models. A paper describing the finalized SNS metrics will be published in the peer-reviewed scientific literature.

RSIA was active with two major topics in 2014. The center provided a grant to the Harvard Center for Risk Analysis to support a conference and development of a series of case studies on risk of risk perception. After publishing a series of papers on how to go about measuring the release of nanomaterial in various products, RSIA handed off the standard methods development to the U.S. National Institute for Occupational Safety and Health and the National Institute of Standards and Technology. RSIA ceased operation at the end of 2014.

Dr. Drewnowski reported that 59 percent of the foundation's funding came from the public sector in 2014, with 36 percent from the private sector, 2 percent from foundations, 2 percent from other ILSI entities and 1 percent from nongovernmental organizations. The foundation actively collaborated with nine ILSI branches in 2014 – Argentina, Brasil, Europe, India, Korea, North America, North Andean, South Andean, and Southeast Asia Region. He also called attention to the foundation's output during the past year – 35 conferences, meetings and workshops and 18 peer-reviewed publications.

Going forward, Dr. Drewnowski described the focus of the Research Foundation as agriculture, food safety, sustainability and nutrition security. In his view, health and non-communicable disease prevention easily fit within these topics. In the future, he suggested that there would be more emphasis on understanding dietary intake, both from the risk assessment and the nutrition perspectives.

Dr. Knowles pointed out that the Horizon 2020 program in Europe is actively seeking to increase international partnerships, particularly with the United States, BRIC countries, Africa and Latin America. He encouraged the foundation to utilize this interest to their advantage.

In response to trustee questions about why RSIA activities were terminated and what would be done with the remaining funds, Dr. Harris said that she made the decision to close RSIA because the center was not able to fund its programs. The ILSI Research Foundation Board of Trustees set a policy of maintaining positive net assets for all centers. RSIA had not been able to meet this criterion for several years and plans for 2015 did not show that meeting the criterion would be feasible. Any remaining funding commitments made by RSIA will be honored.

### X. Report from the ILSI Platform for International Partnerships

A written report on the 2014 activities of the ILSI Platform for International Partnerships (PIP) was included in the trustee briefing book.

Dr. Harris asked the ILSI Board of Trustees to consider an amendment to the membership section of the ILSI bylaws as a way of addressing a concern recently raised by the World Health Organization (WHO). ILSI's status as a recognized nongovernmental organization is up for renewal as part of an ongoing three-year cycle used by WHO. ILSI provided the requested information about its performance under the 2012-2014 WHO/ILSI Plan of Work and developed a new three-year plan of work with various parts of WHO. These materials were all submitted on time. In late December, Dr. Harris received an email request to update an informational database which included a question about whether ILSI had members that were involved with tobacco. ILSI answered the question accurately, saying that one member – ITC Food Businesses – was part of a conglomerate that included a tobacco company. ITC actually stands for Indian Tobacco Company. This company has been a member of ILSI-India for many years and ILSI has repeatedly acknowledge them as a member and told WHO that ILSI-India and ILSI were not in any way involved with tobacco.

About one week prior to the ILSI Annual Meeting, Dr. Harris learned that the WHO Secretariat's report on the "Review of nongovernmental organizations in official relations with WHO" (EB136/NGO/WP/1) specifically called attention to the fact that "a member company of one of its branches is owned by a company that manufactures and sells tobacco products." The secretariat report goes on to recommend that ILSI's status be renewed. In talking with the ILSI assigned technical officer at WHO, Dr. Harris was encouraged to take action to resolve the problem – membership by a tobacco-associated company. Hence, with help from Mr. Shawn Sullivan, ILSI Legal Counsel, and others, an amendment to the bylaws (attached) was drafted and was distributed to the ILSI Board of Trustees for consideration.

During the discussion that followed several trustees expressed frustration that this member was being singled-out unfairly as the member was not involved in tobacco production, manufacturing, marketing or sales. Others noted that this is a serious issue. Dr. Boobis said that as an academic working at a United Kingdom university, he is required to annually certify that he is not involved with any organization associated with tobacco. Failure to do so would limit his ability to receive government funding. Dr. Peter van Bladeren said that if ILSI were to be publicly linked with tobacco, his company, Nestlé, would seriously consider dropping out of the organization. Others suggested that ILSI should carefully monitor its relations with WHO.

**Action:** A motion was made to amend Article II: Membership of the ILSI bylaws to add the proposed two final sentences. The motion was seconded and passed by a hand vote of 28 in favor and one abstention.

Dr. Harris thanked the Board for their swift and decisive action and said that she would report this action to WHO immediately. She then turned to a second, and perhaps more difficult issue, of how ILSI may be categorized by WHO in the draft non-State actors framework. The draft being considered by the WHO Executive Board has four categories – nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions. ILSI categorized itself as a scientific/academic entity in an online questionnaire distributed by WHO. The WHO Secretariat states in their "Review of nongovernmental organizations in official relations with WHO" (EB136/NGO/WP/1; para 7) that ILSI should be listed as a private sector entity. Such a categorization by WHO is unacceptable to ILSI, because ILSI is incorporated as a public charity. Should WHO insist on calling ILSI a private sector entity, ILSI may have to end all activities with WHO to avoid such a classification. ILSI is preparing a letter to WHO explaining its concerns and asking for a meeting at which to discuss them.

Before moving on to the next agenda item, Dr. Cohen called attention to the new Malaspina International Scholar Travel Award. Ten such awards were given this first year and nine of the ten awardees have come to the 2015 ILSI Annual Meeting. These scholars were nominated by the branches in the region where the scholar lives and the final list of awardees was chosen by a selection committee composed of mostly ILSI trustees. The scholars are at a mid-level point in their careers and will hopefully gain a good appreciation of ILSI from the annual meeting experience. Dr. Cohen acknowledged The Coca-Cola Company for supporting this award. He also encouraged all trustees to meet the awardees. They will be recognized during the ILSI Assembly of Members meeting on Sunday, January 18, 2015.

### XI. Report of the ILSI Nomination Review Committee

Dr. Takeshi Kimura, Chair, ILSI Nomination Review Committee, began his report by thanking the members of the committee – Dr. Cohen, Dr. Knowles, Dr. Weaver, and Dr. Flávio Zambrone – for their assistance with the committee's tasks. The committee's report was included in the trustees briefing book.

The first of the three tasks given to the ILSI Nomination Review Committee was to review the nominees for seats on the ILSI Board of Trustees. Three trustees will retire from the board – Mr. Felipe Rodriguez, Dr. P.K. Seth, and Dr. Geoff Thompson (resigned mid-year). Dr. Kimura asked the board members to acknowledge the service of these three trustees with a round of applause.

The following individuals were re-nominated by the branches in the respective regions for additional three-year terms on the ILSI Board of Trustees:

Asia-Pacific North	Dr. Takeshi Kimura (I)	
Europe/Africa	Dr. John O'Brien (I)	
	Dr. Peter van Bladeren (I)	
HESI	Dr. Alan Boobis (P)	
	Dr. Lewis Smith (P)	
Latin America	Dr. Flávio Zambrone (P)	
North America	Dr. Todd Abraham (I)	
	Dr. Michael Doyle (P)	
	Dr. Catherine Field (P)	
	Dr. Joanne Lupton (P)	
Research Foundation	Dr. Adam Drewnowski (P)	

New Nominees offered by the branches are:

Asia Pacific South	Dr. B. Sesikeran (P)
Europe/Africa	Dr. Peter Weber (I)
Latin America	Mr. Ary Bucione (I)

Bios for the new nominees were included in the trustee briefing book. Dr. Kimura reminded the trustees that in January 2013, the ILSI Board of Trustees elected Dr. Applebaum as the ILSI Vice-President. She was added to the ILSI Board of Trustees in a special 32<sup>nd</sup> seat as allowed under the bylaws (Article IV, Section 1). But this special seat is only valid for a year at a time, so it is necessary to re-elect her for this year.

The ILSI Nomination Review Committee approved all of these nominations and Dr. Kimura will present these names to the ILSI Assembly of members meeting on Sunday, January 18, 2015, for election.

To allow Dr. Applebaum to remain on the ILSI Board, Dr. Kimura asked that the ILSI Board approve the expansion of the Board by one seat, as allowed by the bylaws. The number of public sector trustees will still exceed the number of private sector trustees with Dr. Applebaum's election to this additional seat.

**Action:** Dr. Kimura moved that the ILSI Board of Trustees be expanded by one seat to 32 seats to allow Dr. Rhona Applebaum to remain a member of the ILSI Board of Trustees. The motion was seconded and passed unanimously.

The second task for the ILSI Nomination Review Committee was to nominate officers of the board and at-large members of the ILSI Executive Committee. Officers serve two-year terms; at-large members are elected annually. The succession plan adopted several years ago calls for the Vice President and Vice Chair to move up to the positions of President and Chair, if acceptable. The Nomination Review Committee agreed that the current Vice President, Rhona Applebaum, should become the ILSI President. The committee also agreed to nominate Dr. Peter van Bladeren as the new Vice President. If elected both are willing to serve.

In January 2014, Dr. Alan Boobis agreed to move into the Chair role in January 2015, assuming the next Nomination Review Committee agreed. Dr. Kimura reported that the committee did agree. The committee also agreed to nominate Dr. Connie Weaver as the ILSI Vice Chair for one year. Both Dr. Boobis and Dr. Weaver are being proposed for one-year terms to return to the regular rotation cycle in January 2016. Both may be re-elected at that time for full two-year terms as Chair and Vice Chair, respectively. Both were willing to serve.

The committee nominated Dr. Flavio Zambrone for a two-year term as Secretary. Dr. Zambrone was willing to serve, if elected. The committee nominated Dr. Marion Ehrich, Dr. Tamotsu Kuwata, Mr. Geoff Smith and Dr. Peter Weber for one-year terms as At-Large Members of the ILSI Executive Committee. All agreed to serve, if elected.

Action: Dr. Kimura moved the election of Dr. Applebaum as President, Dr. van Bladeren as Vice President, Dr. Boobis as Chair for one year, Dr. Weaver for Vice Chair for one year, Dr. Zambrone for Secretary, and Drs. Ehrich, Weber, and Kuwata and Mr. Geoff Smith as At-Large Members, with the understanding that Dr. Applebaum and Dr. Weber would be elected to the Board by the Assembly of Members on Sunday, January 18, 2015. The motion was seconded and carried unanimously.

The third and final task of the ILSI Nomination Review Committee was to nominate candidates for threeyear terms on the ILSI Research Foundation Board of Trustees. Nominees submitted by the ILSI Research Foundation Nominating Committee were reviewed by the ILSI Nomination Review Committee and approved. The nominees were Dr. Jerry Hjelle (renomination), Dr. Ronald Kleinman, and Dr. Ivonne Rietjens. Bios for Drs. Kleinman and Rietjens were included in the trustee briefing book. Dr. Applebaum, as ILSI President, has an assigned seat on the ILSI Research Foundation Board of Trustees.

**Action:** Dr. Kimura moved the election of Drs. Hjelle, Kleinman and Rietjens each for a three-year term on the ILSI Research Foundation Board of Trustees. The motion was seconded and passed unanimously.

Dr. Kimura also recognized the ILSI Research Foundation trustees whose terms expired at the end of the 2015 ILSI Annual Meeting -- Dr. Dennis Bier, Dr. Jim Bus, and Dr. John Peters.

### XII. Comments from the ILSI President and ILSI Board Chair

Dr. Applebaum thanked the ILSI Board of Trustees for their support, saying that she was honored to serve as president for ILSI, an organization about which she was passionate. She said that she would operate with an "open-door" policy and encouraged trustees to contact her with questions, comments or concerns at any time. She described her belief in the strength of "threes", such as ILSI's tripartite nature. She likes to use scorecards to follow complex and competitive tasks. Though she admitted that she would not be able to fill Dr. Hjelle's shoes, she will focus on collaboration, value and communication as the three areas she will strengthen during her two-year tenure as the ILSI President.

Dr. Boobis also thanked the ILSI Board of Trustees for their support. He noted that leading ILSI presents a substantial challenge. The organization is dynamic and not afraid to ask itself tough questions. ILSI carries out substantial work with very small resources. He noted that ILSI needs to think carefully about the challenges it faces, as the organization is still under attack. Dr. Boobis also complimented Dr. Cohen on his outstanding service to ILSI as the chair for the past three years. He described Dr. Cohen as a leader who makes ILSI an organization worth being involved with. Dr. Cohen is also a strong leader who executes with kindness and tact. He presented Dr. Cohen with a gift.

In turning over the chairmanship of the ILSI Board of Trustees to Dr. Boobis, Dr. Cohen stated that he greatly enjoyed serving as the board chair and noted that working with ILSI has given him the opportunity to work with the "most phenomenal people in the world."

### XIII. Other Business

a. New Branch Proposals – Dr. Knowles, Chair of the ILSI Branch Development Committee, briefly described the application for branch status from the study group in the Middle East. The ILSI Branch Development Committee reviewed the application in detail during their meeting on Friday evening, January 16. The committee members present (Mike Knowles, P.K. Seth, and Geoff Smith) agreed that the study group had satisfied the eight criteria for forming a new branch. While the proposed branch constitution still needs some editorial revisions, the committee recommended that the new branch, ILSI Middle East, as described in the written motion distributed at the meeting (attached), be approved.

Action: Dr. Knowles moved adoption of the motion. There was a second and the motion carried unanimously.

Dr. Knowles also reminded the board that the former branch, ILSI North Africa and Gulf Region, had been closed. There is some interest in North African countries like Morocco, especially among academics to develop ILSI-led collaborations. He will monitor this situation and report back to the ILSI Board of Trustees.

ILSI South Africa is still interested in expanding to cover more of Sub-Saharan Africa and they may establish a study group to explore which countries and the timetable for such expansion. Dr. Knowles said there was substantial external interest in such an expansion.

b. Proposal from ILSI Japan Center for Health Promotion – Mr. Takashi Togami, Director, ILSI Japan Center for Health Promotion (CHP), was invited by the chair to make a presentation about the center's work to the ILSI Board of Trustees. Mr. Togami's presentation was distributed to the trustees prior to the meeting.

Mr. Togami reviewed the significant outcomes from three programs managed by his center – Project IDEA, Project SWAN and Project PAN, all of which are contributing to improving public health in one or more Asian countries. To date ILSI Japan CHP has been supported by strong links with respected academic and administrative networks in these countries. ILSI Southeast Asia has been an important collaborator for ILSI Japan CHP. Other opportunities have been suggested especially in Africa. However, ILSI Japan CHP is facing a critical shortage of resources – funds and professional manpower. The annual budget of ILSI Japan CHP has been in the range of \$300,000 – 500,000 in recent years. This funding has come from members of ILSI Japan and public funds from the government of Japan. Mr. Togami said that the programs now need a broader funding base.

Over the past 15 years, ILSI Japan CHP showed that ILSI could contribute to and improve the public health and directly benefit at-risk populations. Especially, ILSI Japan CHP has

shown that ILSI's tripartite partnership can effectively work to solve public health problems based on scientific evidence. Mr. Togami asked the ILSI Board of Trustees to study whether ILSI organizations can initiate and participate in social programs and how ILSI fundraising, financial operation, and collaboration with international organizations could contribute.

Several trustees suggested possible partners for ILSI Japan CHP, including the International Water Association (IWA) for Project SWAN and the International Finance Corporation (IFC) at the World Bank.

Dr. Boobis suggested that Dr. van Bladeren lead a study group with the following members – Dr. Hjelle, Mr. Geoff Smith and Mr. Togami – to review the information provided by Mr. Togami and report back to the ILSI Board of Trustees.

### c. Plans for 2016, 2017, and 2018 ILSI Annual Meetings

Dr. Harris referred the trustees to the flyer at the back of the trustees briefing book for the dates and venues for these three meetings:

22-26 January 2016 – Renaissance Vinoy Resort & Golf Club, St. Petersburg , FL, USA 20-25 January 2017 – Hilton La Jolla Torrey Pines, LaJolla, CA, USA 19-24 January 2018 – Fairmont Southampton, Southampton, Bermuda

Mr. Geoff Smith suggested that staff investigate having the ILSI Annual Meeting outside of the United States.

### XIV. Adjournment

As there was not further business, Dr. Boobis thanked the trustees for their active participation and adjourned the meeting at noon.

Signed:	Date:
- 0	

## ILSI Board of Trustees Meeting

### Saturday, 17 January 2015 8:00 am –Noon Chandler, Arizona

### AGENDA

	Ι.	Call to Order	Dr. Sam Cohen
	11.	Approval of Minutes from the July 14, 2014 ILSI Board of Trustees Conference Call	Dr. Sam Cohen
	III.	President's Report	Dr. Jerry Hjelle
	IV.	<ul> <li>Progress with Implementation of the One ILSI Strategy</li> <li>a. ILSI Board Science Advisory Group Dr. Peter van Bladeren/Dr. Alan Boobis</li> <li>b. ILSI Board Value/Stakeholder Group - Dr. Todd Abraham/Dr. Sam Cohen/Mr. Geoff Smith</li> <li>c. Thematic area collaborations</li> <li>d. One ILSI accountability</li> </ul>	
	V.	Impact of Communications	Mr. Michael Shirreffs
	VI.	Report from the Publications Committee	Dr. Connie Weaver
	VII.	Report of the Financial Oversight Committee	Dr. Liz Westring
		a. 2014 Year-end Projections and 2015 Budget	
	VIII.	Adoption of the ILSI Budget for 2015	Dr. Sam Cohen
BREAK – PHOTO (30 minutes)			
	IX.	Report from the ILSI Research Foundation	Dr. Adam Drewnowski
	Х.	Report from the ILSI Platform for International Partnerships	Dr. Suzie Harris
	XI.	<ul><li>Report of the Nomination Review Committee</li><li>a. Introduction of Nominees to the ILSI Board of Trustees</li><li>b. Election of Officers and Executive Committee Members</li><li>c. Election of Trustees to the ILSI Research Foundation Board</li></ul>	Dr. Takeshi Kimura
	XII.	Comments from the ILSI Board Chair and Comments from the ILSI President	Dr. Alan Boobis Dr. Rhona Applebaum

- a. New Branch Proposal
- b. Proposal from ILSI Japan
- c. Plans for 2016 and 2017 Annual Meetings

Dr. Michael Knowles Mr. Takashi Togami Dr. Suzie Harris

IX. Adjournment



# ILSI Board of Trustees Meeting

# Saturday, 17 January 2015 Chandler, Arizona, USA

# ATTENDEES

Dr. Todd Abraham Mondelēz International HQ

Dr. Rhona Applebaum The Coca-Cola Company

Dr. Scott Belanger The Procter & Gamble Company

Ms. Beth-Ellen Berry ILSI

Dr. Alan Boobis Imperial College London

Mr. Ary Bucione Dupont do Brasil

Dr. Sushila Chang Griffith University

Dr. Samuel Cohen University of Nebraska Medical Center

Frederick H. Degnan, Esq. King & Spalding

Dr. Dennis Devlin Exxon Mobil Corporation

Dr. Michael Doyle University of Georgia

Dr. Adam Drewnowski University of Washington Dr. Marion Ehrich VA-MD Regional College of Veterinary Medicine

Prof. Gerhard Eisenbrand University of Kaiserslautern

Dr. Catherine Field University of Alberta

Dr. Jerry Hjelle Monsanto Company

Dr. Suzanne Harris ILSI

Dr. Takeshi Kimura Ajinomoto Co., Inc.

Dr. Michael E. Knowles (retired) The Coca-Cola Company

Dr. Tamotsu Kuwata University of Human Arts and Sciences

Dr. Joanne Lupton Texas A&M University

Prof . John O'Brien Nestlé Research Center

Prof. Gerhard Rechkemmer Max Rubner-Institute (Federal Research Institute of Nutrition and Food) Mr. John Ruff ILSI Past President

Dr. Prahlad K. Seth Lucknow Biotechology Park

Mr. Michael Shirreffs

Mr. Geoff Smith Nutrition Strategies International

Dr. Lewis Smith (retired) University of Leicester

Mr. Shawn N. Sullivan ILSI

Dr. Sara Valdés Martínez Universidad National Autonoma de Mexico

Dr. Peter van Bladeren Nestec S.A

Prof Kendall Wallace University of Minnesota Med School

Dr. Connie Weaver Purdue University

Prof. Peter Weber DSM Nutritionals

Dr. Elizabeth Westring General Mills

Dr. Flávio A.D. Zambrone Planitox

### OBSERVERS

Prof. Lucia Anelich ILSI South Africa

Ms. Vivian Aranda ILSI South Andean

Prof. Dianá Bánáti ILSI Europe

Ms. Mariela Berezovsky ILSI Brazil

Mr. Javier Castellanos ILSI Latin America Coordinator

Dr. Morven McLean ILSI Research Foundation Mrs. Olga Mora ILSI North Andean

Ms. Syril Pettit HESI

Dr. Andrew Roberts ILSI Research Foundation/CERA

Ms. Rekha Sinha ILSI-India

Mr. Takashi Togami ILSI Japan

Ms. Allison Worden ILSI Dr. Ryuji Yamaguchi ILSI Japan

Mrs. Boon Yee Yeong ILSI Southeast Asia Region

Dr. Myeong-Ae Yu ILSI Korea

## ILSI Board of Trustees Mid-year Conference Call

# Thursday, July 9, 2015 9:00 – 11:00 a.m. Eastern Daylight Time

# AGENDA

I.	Call to Order	Dr. Alan Boobis
II.	Approval of Minutes from the 17 January ILSI Board of Trustees Meeting	Dr. Alan Boobis
III.	President's Report	Dr. Rhona Applebaum
IV.	Progress with Implementing the One ILSI Strategy	
	<ul> <li>a. Science Advisory Group</li> <li>b. Value/Stakeholder Group</li> <li>c. Thematic area activities</li> <li>d. Governance policies and best practices</li> </ul>	Dr. Peter van Bladeren Dr. Sam Cohen Dr. Suzie Harris Mr. Shawn Sullivan
V.	Impact of Communications	Mr. Michael Shirreffs
VI.	Report from the Publications Committee	Dr. Connie Weaver
VII.	Report of the Financial Oversight Committee	Dr. Liz Westring
VIII.	Update on Branch Development	Dr. Michael Knowles
IX.	Report from the ILSI Research Foundation	Dr. Adam Drewnowski
X.	Report from the ILSI Platform for International Partnerships	Dr. Suzie Harris
XI.	Other Business	
	<ul><li>a. Follow-up on Center for Health Promotion proposal</li><li>b. Malaspina International Scholars Travel Award</li><li>c. Plans for 2016 Annual Meeting</li></ul>	Dr. Peter van Bladeren Dr. Suzie Harris Dr. Suzie Harris
VII	A 11	

XII. Adjournment

# ILSI<sup>®</sup> INTERNATIONAL LIFE SCIENCES INSTITUTE

# ILSI Board of Trustees 2015 Mid-year Conference Call Information

# The conference room number for all calls is 476-399-389 #

Country	Toll Free Dial-In	Note
Australia	1 800 064 762	NOLE
Australia	1-800-004-782	
Brazil	0800-047-4905	
Canada	1-888-299-2873	
Germany	0-800-723-5123	
Greece	00-800-4414-2827	
India	000-800-852-1446	
Japan	0-120-615-800	
Korea	0806140880	
Mexico	01-800-083-5534	
Singapore	800-852-3903	
Switzerland	0-800-002-347	41-(0)-225-3311-19 – long distance
United		
Kingdom	0-800-169-0430	
United States	1-888-585-9008	

If you are calling from a country not listed, please contact Beth Brueggemeyer

From:

Sent: To: Cc: Subject: onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of nutritionreviews@ilsi.org Wednesday, June 17, 2015 2:33 AM Joanne Lupton sdonovan@illinois.edu Reminder: Review Due Today

17-Jun-2015

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you kindly agreed to review Manuscript ID NUTR-REV-088-LA-04-2015, entitled "Consumption of whole grains and cereal fiber in relation to cancer risk: a systematic review of longitudinal studies." This e-mail is a reminder that your review is now due. Please complete and submit your review via ScholarOne Manuscripts at <a href="https://mc.manuscriptcentral.com/nutr-rev">https://mc.manuscriptcentral.com/nutr-rev</a>.

To directly access the manuscript for review, with no need to enter log in details, please click the link below:

https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=fca275cf606646f5932dc6635ff4f2f2

To log in to your account on the reviewing site, please go to <u>https://mc.manuscriptcentral.com/nutr-rev</u>. Your casesensitive USER ID is <u>ilupton@tamu.edu</u>. For security purposes, your password is not listed in this email. If you are unsure of your password, you may click the link below to set a new password.

https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=d9f4844cc7ac4bd5aa68878d1c330a87

Your participation in our peer-review process is most sincerely appreciated. If you encounter any difficulties completing your review or accessing the reviewing site, please contact me directly.

With kind regards,

Allison Worden Publications Manager

Nutrition Reviews E-mail: <u>nutritionreviews@ilsi.org</u>

Present Knowledge in Nutrition E-mail:

cc. Dr. Sharon Donovan Editor

[email ref: ENR-SW-6-b]

From:	Suzanne Harris	
Sent:	Tuesday, June 16, 2015 3:59 PM	
То:	's.chang@griffith.edu.au'; 'Catherine Field	; Joanne Lupton;
	'kwallace@	d.umn.edu'
Cc:	'carmel.james@griffith.edu.au'	
Subject:	REMINDER: Survey for ILSI Public Sector Trustees	

I hope you will complete the short survey that I sent you several weeks ago. Your input is very important. The deadline was last Friday, so please let me know if you are able to respond this week.

Thank you.

Suzie
From: Suzanne Harris
Sent: Tuesday, May 26, 2015 3:05 PM
To: ; s.chang@griffith.edu.au; scohen@unmc.edu; mdoyle@uga.edu;
'adamdrew@u.washington.edu'; marion@vt.edu; Catherine Field
Joanne Lupton (Joanne.Lupton@agnet.tamu.edu); john.c.peters@ucdenver.edu;
kwallace@d.umn.edu;
'Flavio Zambrone'
Cc: carmel.james@griffith.edu.au; jbradford@unmc.edu; 'Haan,
Dawn E'; Michael Shirreffs
Subject: Survey for ILSI Public Sector Trustees

TO: ILSI Public Sector Trustees

FROM: Suzie Harris

The ILSI Board of Trustees Science Advisory Group, led by Dr. Alan Boobis and Dr. Peter van Bladeren, asked that we gather some information about the areas of expertise held by the ILSI public sector trustees and then by the branch public sector trustees and science advisors. With input from the ILSI Executive Committee, some questions were also added to get an idea of how involved you are with other science-based organizations like FAO and WHO.

We are using you as guinea pigs for this effort. I hope you will use this link

https://www.surveymonkey.com/r/Adviser\_Expertise

to access the survey and to complete it. At the end there are two questions to gauge what you thought of the earlier questions.

Please let me know if you have any questions. It would be very helpful if you would complete the survey by **Friday, June 12, 2015.** Thank you.

From: Sent: Subject: Attachments: John Faulkner Thursday, June 11, 2015 10:58 AM Your ILSI North America Science Briefs for May 2015 Food Safety Briefs May 2015.pdf; Nutrition Briefs May 2015.pdf

Hello!

Attached for your summer reading pleasure are your **Food Safety** and **Nutrition** Science Briefs for the month of **May**.

Each month we review the most recent articles published in the major journals of nutrition and those from the fields of chemical and microbiology food safety and select those for inclusion that we believe will be of the greatest interest to ILSI North America's technical and project committees.

As always, these briefs, along with prior science briefs, are accessible via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will be happy to add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126 <u>ifaulkner@ilsi.ora</u>



# **Nutrition Briefs**

# May 2015

### **Cardiovascular Disease**

### Effects of the Pure Flavonoids Epicatechin and Quercetin on Vascular Function and Cardiometabolic Health: A Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

J.I. Dower, J.M. Geleijnse, L. Gijsbers, P.L. Zock, D. Kromhout, P.C.H. Hollman American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 914–921, 2015 doi: 10.3945/ajcn.114.098590

Link to full text: Click here

**Significance:** Epicatechin may in part contribute to the cardioprotective effects of cocoa and tea by improving insulin resistance, but it is unlikely that quercetin plays an important role in the cardioprotective effects of tea.

This randomized, double-blind, placebo-controlled, crossover trial investigated the effects of supplementation of pure epicatechin and quercetin on vascular function and cardiometabolic health in 37 apparently healthy adults aged 40-80 y with a systolic blood pressure (BP) between 125 and 160 mm Hg at screening. Participants received (-)-epicatechin (100 mg/d), quercetin-3-glucoside (160 mg/d), or placebo capsules for 4 wk in random order. The primary outcome was the change in flow-mediated dilation from pre- to post-intervention. Results showed that epicatechin supplementation did not change flow-mediated dilation significantly (1.1% absolute; 95% CI: -0.1%, 2.3%; P = 0.07). Epicatechin supplementation improved fasting plasma insulin ( $\Delta$  insulin: -1.46 mU/L; 95% CI: -2.74, -0.18 mU/L; P = 0.03) and insulin resistance ( $\Delta$  homeostasis model assessment of insulin resistance: -0.38; 95% CI: -0.74, -0.01; P = 0.04) and had no effect on fasting plasma glucose. Epicatechin did not change BP, arterial stiffness, nitric oxide, endothelin 1, or blood lipid profile. Quercetin-3-glucoside supplementation had no effect on flow-mediated dilation, insulin resistance, or other CVD risk factors.

### How Effective Are Current Dietary Guidelines for Cardiovascular Disease Prevention in Healthy Middle-Aged and Older Men and Women? A Randomized Controlled Trial

D.P. Reidlinger, J. Darzi, W.L. Hall, P.T. Seed, P.J. Chowienczyk, T.A.B. Sanders on behalf of the Cardiovascular disease risk REduction Study (CRESSIDA) investigators

American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 922-930, 2015

doi: 10.3945/ajcn.114.097352

Link to full text: Click here

**Significance:** Selecting a diet consistent with current dietary guidelines lowers blood pressure and lipids, which would be expected to reduce the risk of CVD by one-third in healthy middle-aged and older men and women.

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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This parallel-designed randomized controlled trial compared effects on vascular and lipid cardiovascular disease (CVD) risk factors of following the United Kingdom dietary guidelines (treatment) with a traditional British diet (control). In 165 healthy nonsmoking men and women (aged 40-70 y), ambulatory blood pressure (BP), vascular function, and CVD risk factors were measured at baseline and during 12 wk after random assignment to treatment. In the treatment group (n=80) compared with control (n=82), daytime systolic BP was 4.2 mm Hg lower (95% CI: 1.7, 6.6 mm Hg; P<0.001), the total cholesterol:HDL cholesterol ratio was 0.13 lower (95% CI: 0, 0.26; P=0.044), pulse wave velocity was 0.29 m/s lower (95% CI: 0.07, 0.52 m/s; P=0.011), high-sensitivity C-reactive protein was 36% lower (95% CI: 7%, 48%; P=0.017), and body weight was 1.9 kg lower (95% CI: 1.3, 2.5 kg; P<0.001). Treatment effect on flow-mediated dilation and Revised Quantitative Insulin Sensitivity Check Index was not significant. Causal mediated effects analysis based on urinary sodium excretion indicated that sodium reduction explained 2.4 mm Hg (95% CI: 1.0, 3.9 mm Hg) of the fall in blood pressure.

### Orange Juice–Derived Flavanone and Phenolic Metabolites Do Not Acutely Affect Cardiovascular Risk Biomarkers: A Randomized, Placebo-Controlled, Crossover Trial in Men at Moderate Risk of Cardiovascular Disease

M.Y. Schär, P.J. Curtis, S. Hazim, L.M. Ostertag, C.D. Kay, J.F. Potter, et al. American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 931–938, 2015 doi: 10.3945/ajcn.114.104364

Link to full text: Click here

**Significance:** After single-dose flavanone intake within orange juice, circulating flavanone and phenolic metabolites collectively reached a concentration of 15.20  $\pm$  2.15 µmol/L, but no effects were observed on cardiovascular risk biomarkers.

In an acute, randomized, placebo-controlled crossover trial, the effects of orange juice (OJ) or a dose-matched hesperidin supplement on plasma concentrations of established and novel flavanone metabolites and their effects on cardiovascular risk biomarkers were examined in 16 men (aged 51–69 y) at moderate CVD risk. Subjects received OJ or a hesperidin supplement (both providing 320 mg hesperidin) or control (all matched for sugar and vitamin C content). Before each intervention, a diet low in flavonoids, nitrate/nitrite, alcohol, and caffeine was followed, and a standardized low-flavonoid evening meal was consumed. Results showed that OJ intake significantly increased (mean  $\pm$  SEM) plasma concentrations of 8 flavanone (1.75  $\pm$  0.35 µmol/L, P<0.0001) and 15 phenolic (13.27  $\pm$  2.22 µmol/L, P<0.0001) metabolites compared with control at 5 h postconsumption. Despite increased plasma flavanone and phenolic metabolite concentrations, cardiovascular risk biomarkers were unaltered. After hesperidin supplement intake, flavanone metabolites were not different from the control, suggesting altered absorption/metabolism compared with the OJ matrix.

### **Diabetes**

#### Partial Meal Replacement Plan and Quality of the Diet at 1 Year: Action for Health in Diabetes (Look AHEAD) Trial

H.A. Raynor, A.M. Anderson, G.D. Miller, R. Reeves, L.M. Delahanty, M.Z. Vitolins, et al.

Journal of the Academy of Nutrition and Dietetics, Vol. 115, No. 5; pp. 731–742, 2015 doi: 10.1016/j.jand.2014.11.003

#### Link to full text: Click here

**Significance:** The partial meal replacement plan consumed by Intensive Lifestyle Intervention participants was related to superior diet quality.

This randomized controlled trial compared dietary intake and percent meeting fat-related and food group dietary recommendations in Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups at 0 and 12 months from 16 U.S. sites. Participants were aged 45-76 years, overweight or obese, with type 2 diabetes. Complete 0- and 12-month dietary assessments (collected between 2001 and 2004) were available for 2,397 participants (1,186 randomized to DSE group and 1,211 randomized to ILI group). Results showed that at 12 months, ILI participants had a significantly lower fat and cholesterol intake and greater fiber intake than DSE participants. ILI participants consumed more servings per day of fruits; vegetables; and milk, yogurt, and cheese; and fewer servings per day of fats, oils, and sweets than DSE participants. A greater percentage of ILI participants than DSE participants met fat-related and most food group recommendations. Within ILI, a greater percentage of participants consuming two or more meal replacements per day than participants consuming less than one meal replacement per day met most fat-related and food group recommendations.

### Substitution of Red Meat With Legumes in the Therapeutic Lifestyle Change Diet Based on Dietary Advice Improves Cardiometabolic Risk Factors in Overweight Type 2 Diabetes Patients: A Cross-Over Randomized Clinical Trial

S. Hosseinpour-Niazi, P. Mirmiran, M. Hedayati, F. Azizi European Journal of Clinical Nutrition, Vol. 69, No. 5; pp. 592–597, 2015 doi:10.1038/ejcn.2014.228

Link to full text: Click here

**Significance:** Dietary advice given for substituting red meat with legumes within a TLC diet, improved lipid profiles and glycemic control among diabetes patients.

This randomized, controlled, cross-over trial determined the effects of substituting red meat with legumes in the Therapeutic Lifestyle Change (TLC) diet on cardiometabolic risk factors in 31 type 2 diabetes patients (age:  $58.1\pm6.0$  years) based on dietary education. Subjects were randomly assigned to consume a control diet (legume-free TLC diet) and legume-based TLC diet (intervention diet) for 8 weeks. The legume-based TLC group was advised to replace two servings of red meat with legumes, 3 days/week. After the interventional period, a washout period was conducted for 4 weeks. The groups were then advised to follow the alternate treatment for 8 weeks. Compared with the control diet, the intervention diet significantly decreased fasting blood glucose (P=0.04), fasting insulin (P=0.04), triglyceride concentrations (P=0.04) and LDL-cholesterol (P=0.02). Total cholesterol concentrations decreased after consumption of both TLC diet and legume TLC diet; however, the data did not differ significantly between the two diets.

### Egg Consumption and Risk of Incident Type 2 Diabetes in Men: The Kuopio Ischaemic Heart Disease Risk Factor Study

J.K. Virtanen, J. Mursu, T-P. Tuomainen, H.E.K. Virtanen, S. Voutilainen American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 1088–1096, 2015 doi: 10.3945/ ajcn.114.104109

#### Link to full text: Click here

**Significance:** Higher egg intake was associated with a lower risk of type 2 diabetes in this cohort of middle-aged and older men.

The association between egg consumption and risk of incident type 2 diabetes (T2D) was investigated in 2332 men (42–60 y) in the prospective, population-based Kuopio Ischaemic Heart Disease Risk Factor Study. Dietary intakes were assessed with 4-d food records at baseline. During an average follow-up of 19.3 y, 432 men developed T2D. After adjustment for potential confounders, those in the highest compared with the lowest egg intake quartile had a 38% (95% CI: 18%, 53%; P-trend across quartiles <0.001) lower risk of incident T2D. Analyses with metabolic risk markers also suggested an inverse association with fasting plasma glucose and serum C-reactive protein but not with serum insulin. The associations between cholesterol intake and risk of T2D, plasma glucose, serum insulin, and C-reactive protein were mainly nonsignificant, especially after accounting for egg consumption.

### Increased Protein Intake Is Associated With Uncontrolled Blood Pressure by 24-Hour Ambulatory Blood Pressure Monitoring in Patients With Type 2 Diabetes.

C.B. Mattos, L.V. Viana, T.P. Paula, R.A. Sarmento, J.C. Almeida, J.L. Gross, et al. Journal of the American College of Nutrition, Vol. 34, No. 3; pp. 232–239, 2015 doi: 10.1080/07315724.2014.926155

Link to full text: Click here

**Significance:** High protein intake and meat consumption were associated with high daytime ambulatory blood pressure monitoring values in patients with type 2 diabetes.

This cross-sectional study analyzed possible associations of dietary components, especially protein intake, with blood pressure (BP) during ambulatory BP monitoring (ABPM) in 121 patients (aged 62.3 years; 54.5% women) with type 2 diabetes. Patients were divided into 2 groups according to their daytime ABPM: uncontrolled BP (systolic BP  $\geq$  135 mmHg or diastolic BP  $\geq$  85 mmHg) and controlled BP (systolic BP < 135 mmHg and diastolic BP < 85 mmHg). The uncontrolled BP group had higher glycated hemoglobin (HbA1C) values (8.4  $\pm$  2.0 vs 7.6  $\pm$  1.3%; p=0.04) and consumed more protein (20.0  $\pm$  3.8 vs 18.2  $\pm$  3.6% of energy; p=0.01) and meat, (2.6 [1.45, 2.95] vs 2.0 [1.49, 2.90] g/kg weight; p=0.04) than the controlled BP group. In a multivariate analysis, protein intake (% of energy) increased the chance for uncontrolled BP (odds ratio [OR] = 1.16; 95% CI, 1.02, 1.30; p=0.02), adjusted for BMI, HbA1C, LDL-cholesterol, number of antihypertensive medications, and ethnicity. Meat consumption higher than 3.08 g/kg weight/day more than doubled the chance for uncontrolled BP (OR = 2.53; 95% CI, 1.01, 7.60; p=0.03).

### Caffeine

# Trends in Intake and Sources of Caffeine in the Diets of US Adults: 2001–2010

V.L. Fulgoni, D.R. Keast, H.R. Lieberman American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 1081–1087, 2015 doi: 10.3945/ ajcn.113.080077 Link to full text: Click here **Significance:** Although new caffeine-containing products were introduced into the U.S. food supply, total per capita intake was stable from 2001 to 2010.

This study obtained an up-to-date, nationally representative estimate of caffeine consumption in adults. Dietary intake data from NHANES from 2001 to 2010 for adults  $\geq$ 19 y of age were used (n=24,808). Acute and usual intake of caffeine was estimated from all caffeine-containing foods and beverages. Trends in consumption and changes in sources of caffeine were also examined. Eighty-nine percent of the adult US population consumed caffeine, with equal prevalence in men and women. Usual mean ± SE per capita caffeine consumption when nonusers were included was  $186 \pm 4 \text{ mg/d}$ , with men consuming more than women ( $211 \pm 5$  vs.  $161 \pm 3$  mg/d, P<0.05). Usual intake in consumers was 211  $\pm 3 \text{ mg/d}$ , with 240  $\pm 4 \text{ mg/d}$  in men and 183  $\pm 3 \text{ mg/d}$  in women (P<0.05); 46% was consumed in a single consumption event. In consumers, acute 90th and 99th percentiles of intake were 436 and 1066 mg/d, respectively. Consumption was highest in men aged 31-50 y and lowest in women aged 19-30 y. Beverages provided 98% of caffeine consumed, with coffee (~64%), tea (~16%), and soft drinks ( $\sim 18\%$ ) predominant sources; energy drinks provided <1%, but their consumption increased substantially from 2001 to 2010.

### **Blood Pressure**

### The Effect of Tree Nut, Peanut, and Soy Nut Consumption on Blood Pressure: A Systematic Review and Meta-Analysis of Randomized Controlled Clinical Trials

N. Mohammadifard, A. Salehi-Abargouei, J. Salas-Salvadó, M. Guasch-Ferré, K. Humphries, N. Sarrafzadegan

American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 966–982, 2015

doi: 10.3945/ ajcn.114.091595

Link to full text: Click here

**Significance:** Total nut consumption lowered systolic blood pressure in participants without type 2 diabetes; however, pistachios seemed to have the strongest effect on reducing blood pressure.

This systematic review and meta-analysis of published randomized controlled trials (RCTs) estimated the effect of nut consumption (tree nuts, peanuts, and soy nuts) on blood pressure (BP). MEDLINE, SCOPUS, ISI Web of Science, and Google Scholar were searched for RCTs carried out between 1958 and October 2013 that reported the effect of consuming single or mixed nuts (including walnuts, almonds, pistachios, cashews, hazelnuts, macadamia nuts, pecans, peanuts, and soy nuts) on systolic BP (SBP) or diastolic BP (DBP) as primary or secondary outcomes in adults. Studies that evaluated the effects for <2 wk or in which the control group ingested different healthy oils were excluded. Twentyone RCTs met the inclusion criteria. Nut consumption leads to a significant reduction in SBP in participants without type 2 diabetes [mean difference (MD): -1.29; 95% CI: -2.35, -0.22; P=0.02] but not in the total population. Pistachios, but not other nuts, significantly reduce SBP (MD: -1.82; 95% CI: -2.97, -0.67; P = 0.002). Our study suggests that pistachios (MD: -0.80; 95% CI: -1.43, -0.17; P = 0.01) and mixed nuts (MD: -1.19; 95% CI: -2.35, -0.03; P = 0.04) have a significant reducing effect on DBP.

### Flavonoids

#### Flavonoid Intake and All-Cause Mortality

K.L. Ivey, J.M Hodgson, K.D. Croft, J.R. Lewis, R.L. Prince American Journal of Clinical Nutrition, Vol. 101, No. 5; pp. 1012–1020, 2015 doi: 10.3945/ ajcn.113.073106 Link to full text: Click here

**Significance:** High consumption of flavonoids is associated with reduced risk of mortality in older women.

The association between flavonoid intake and risk of 5-y mortality from all causes was explored using 2 comprehensive food composition databases to assess flavonoid intake. The study population included 1063 randomly selected women aged >75 y. All-cause, cancer, and cardiovascular mortalities were assessed over 5 y of follow-up. Two estimates of flavonoid intake (total flavonoid<sub>USDA</sub> and total flavonoid<sub>PE</sub>) were determined by using food composition data from the USDA and the Phenol-Explorer (PE) databases, respectively. During follow-up, 129 (12%) deaths were documented. Participants with high total flavonoid intake were at lower risk [multivariate-adjusted HR (95% CI)] of 5-y all-cause mortality than those with low total flavonoid consumption [total flavonoid<sub>USDA</sub>: 0.37 (0.22, 0.58); total flavonoid<sub>PE</sub>: 0.36 (0.22, 0.60)]. Similar beneficial relations were observed for both CVD mortality [total flavonoid<sub>USDA</sub>: 0.34 (0.17, 0.69); flavonoid<sub>PE</sub>: 0.32 (0.16, 0.61)] and cancer mortality [total flavonoid<sub>USDA</sub>: 0.25 (0.10, 0.62); flavonoid<sub>PE</sub>: 0.26 (0.11, 0.62)].

### Food Allergy

# Sublingual Immunotherapy for Peanut Allergy: Long-Term Follow-Up of a Randomized Multicenter Trial

A.W. Burks, R.A. Wood, S.M. Jones, S.H. Sicherer, D.M. Fleischer, A.M. Scurlock, et al. for the Consortium of Food Allergy Research (CoFAR)

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1240–1248.e3, 2015 doi: dx.doi.org/10.1016/j.jaci.2014.12.1917

Link to full text: Click here

**Significance:** Peanut sublingual immunotherapy induced a modest level of desensitization, decreased immunologic activity over 3 years in responders, and had an excellent long-term safety profile.

This study sought to provide long-term (3-year) clinical and immunologic outcomes for the peanut sublingual immunotherapy (SLIT) trial. Key end points were (1) percentage of responders at 2 years (ie, could consume 5 g of peanut powder or a 10-fold increase from baseline), (2) percentage reaching desensitization at 3 years, (3) percentage attaining sustained unresponsiveness after 3 years, (4) immunologic end points, and (5) assessment of safety parameters. Response to treatment was evaluated in 40 subjects aged 12-40 years by performing a 10-g peanut powder oral food challenge after 2 and 3 years of daily peanut SLIT therapy. At 3 years, SLIT was discontinued for 8 weeks, followed by another 10-g oral food challenge and an open feeding of peanut butter to assess sustained unresponsiveness. Approximately 98% of the 18,165 doses were tolerated without adverse reactions beyond the oropharynx, with no severe symptoms or uses of epinephrine. A high rate (>50%) discontinued therapy. By study's end, 4 (10.8%) of 37 SLIT-treated participants were fully desensitized to 10 g of peanut powder, and all 4 achieved sustained unresponsiveness. Responders at 2 years showed a significant decrease in peanut-specific basophil activation and skin prick test titration compared with nonresponders.

# Natural History of Peanut Allergy and Predictors of Resolution in the First 4 Years of Life: A Population-Based Assessment

R.L. Peters, K.J. Allen, S.C. Dharmage, J.J. Koplin, T. Dang, K.P. Tilbrook, et al. for the HealthNuts Study

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1257–1266.e2, 2015 doi: dx.doi.org/10.1016/j.jaci.2015.01.002

Link to full text: Click here

**Significance:** In this study, thresholds for SPT and sIgE levels were generated in which all participants underwent oral food challenges at both diagnosis and follow-up, irrespective of SPT and sIgE results.

This study sought to describe the natural history of peanut allergy between 1 and 4 years of age and develop thresholds for skin prick test (SPT) results and specific IgE (sIgE) levels measured at age 1 and 4 years that have 95% positive predictive value (PPV) or negative predictive value for the persistence or resolution of peanut allergy. One-year-old infants with challenge-confirmed peanut allergy (n=156) were followed up at 4 years of age with repeat oral food challenges, SPTs, and sIgE measurements (n=103). Peanut allergy resolved in 22% (95% CI, 14% to 31%) of children by age 4 years. Decreasing wheal size predicted tolerance, and increasing wheal size was associated with persistence. Thresholds for SPT responses and sIgE levels at age 1 year with a 95% PPV for persistent peanut allergy are an SPT-induced response of  $\geq$ 13 mm and an sIgE level of  $\geq$  5.0 kU/L. Thresholds for SPT and sIgE results at age 4 years with a 95% PPV for persistent peanut allergy are an SPT response of  $\geq 8$  mm and an sIgE level of  $\geq$ 2.1 kU/L. Ara h 2, tree nut, and house dust mite sensitization; coexisting food allergies; eczema; and asthma were not predictive of persistent peanut allergy.

### A Randomized, Double-Blind, Placebo-Controlled Pilot Study of Sublingual Versus Oral Immunotherapy for the Treatment of Peanut Allergy

S.D. Narisety, P.A. Frischmeyer-Guerrerio, C.A. Keet, M. Gorelik, J. Schroeder, R.G. Hamilton, et al.

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1275–1282.e6, 2015 doi: dx.doi.org/10.1016/j.jaci.2014.11.005

Link to full text: Click here

**Significance:** Oral immunotherapy appeared far more effective than sublingual immunotherapy for the treatment of peanut allergy, but was also associated with significantly more adverse reactions and early study withdrawal.

This double-blind study compared the safety, efficacy, and mechanistic correlates of peanut oral immunotherapy (OIT) and sublingual immunotherapy (SLIT) in children with peanut allergy (PA). Twenty-one subjects (7 to 13 years) were randomized to receive active SLIT/placebo OIT or active OIT/placebo SLIT. Doses were escalated to 3.7 mg/d (SLIT) or 2000 mg/d (OIT), and subjects were rechallenged after 6 and 12 months of maintenance. After unblinding, therapy

was modified per protocol to offer an additional 6 months of therapy. Subjects who passed challenges at 12 or 18 months were taken off treatment for 4 weeks and rechallenged. Five subjects discontinued therapy; of the remaining 16, all had a >10-fold increase in challenge threshold after 12 months. The increased threshold was significantly greater in the active OIT group (141- vs 22-fold, P=.01). Significant within-group changes in skin test results and peanut-specific IgE and IgG4 levels were found, with overall greater effects with OIT. Adverse reactions were generally mild but more common with OIT (P<.001), including moderate reactions and doses requiring medication. Four subjects had sustained unresponsiveness at study completion.

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ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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# **Food Safety Briefs**

# May 2015

# E. Coli

### Prevalence and Characteristics of Shiga Toxin-Producing Escherichia Coli Isolated From Retail Raw Meats in China

X. Bai, H. Wang, Y. Xin, R. Wei, X. Tang, A. Zhao, et al. International Journal of Food Microbiology, Vol. 200, 4 May 2015; pp. 31–38, 2015 doi: 10.1016/j.ijfoodmicro.2015.01.018 Link to full text: Click here

**Significance:** There is a high genetic diversity of Shiga toxin-producing Escherichia coli in retail raw meats, some of which have potential to cause human diseases.

This study evaluated the prevalence of Shiga toxin-producing Escherichia coli (STEC) from retail raw meats collected from two geographical regions in China. The results revealed that 166 out of 853 samples were stx-positive; 63 STEC isolates were recovered from 58 stx-positive samples including pork (4.4%, 14/318), beef (11.0%, 21/191), mutton (20.6%, 26/126), chicken (0.5%, 1/205), and duck (7.7%, 1/13). Twenty-six O serogroups and 33 O:H serotypes were identified. All three stx<sub>1</sub> subtypes and five stx<sub>2</sub> subtypes (2a to 2e) were found in the 63 STEC isolates, among which stx<sub>2e</sub>-positive STEC isolates were the most predominant (39.7%), followed by stx<sub>1c</sub> only (20.6%), stx<sub>1c</sub> + stx<sub>2b</sub> (14.3%), and stx<sub>1a</sub> only (9.5%). STEC isolates carried virulence genes eae (6.3%), ehxA (36.5%), katP (4.8%), astA (11.1%), and subA (36.5%). Of the four adherence-associated genes tested, toxB was absent, whereas saa, paa, and efa1 were present in 28, three, and one STEC isolates respectively. The STEC isolates were divided into 50 PFGE patterns and 33 sequence types. STEC from different sources and geographical regions were separated by PFGE and MLST.

### Decontamination Method Using Heat and Relative Humidity for Radish Seeds Achieves a 7-Log Reduction of Escherichia Coli O157:H7 Without Affecting Product Quality

Y.B. Kim, H.W. Kim, M.K. Song, M.S. Rhee

International Journal of Food Microbiology, Vol. 201, 18 May 2015; pp. 42–46, 2015

doi: 10.1016/j.ijfoodmicro.2015.02.015

Link to full text: Click here

**Significance:** This decontamination method uses only heat and relative humidity without chemicals, and is thus applicable as a general decontamination procedure in spout-producing plants where the use of growth chambers is the norm.

A novel decontamination method was developed to inactivate Escherichia coli O157:H7 on radish seeds without adversely affecting seed germination or product quality. The use of heat (55, 60, and 65 °C) combined with relative humidity (RH; 25, 45, 65, 85, and 100%) for 24 h was evaluated for effective microbial

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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reduction and preservation of seed germination rates. A significant two-way interaction of heat and RH was observed for both microbial reduction and germination rate (P < 0.0001). Increases in heat and RH were associated with corresponding reductions in E. coli O157:H7 and in germination rate (P < 0.05). The order of lethality for the different treatments was as follows: no treatment < 55 °C/25–65% RH = 60 °C/25–45% RH = 65 °C/25% RH < 55 °C/85% RH = 60 °C/65% RH < 55 °C/100% RH = 60 °C/85–100% RH = 65 °C/45–100% RH. The most effective condition, 65 °C/45% RH, completely inactivated E. coli O157:H7 on the seeds (7.0 log CFU/g reduction) and had no significant effect on the germination rate (85.4%; P > 0.05) or product quality.

# Genetically Marked Strains of Shiga Toxin–Producing O157:H7 and Non-O157 Escherichia coli: Tools for Detection and Modeling

G.C. Paoli, C. Wijey, G.A. Uhlich Journal of Food Protection, Vol. 78, No. 5; pp. 888–901, 2015 doi: 10.4315/0362-028X.JFP-14-472 Link to full text: Click here

**Significance:** Genetically marked strains could be used to enumerate and model the growth of STEC in the presence of foodborne background flora.

In this study, positive control (PC) strains for the detection of Shiga toxin-producing E. coli (STEC) O157:H7 and the six USDA-regulated non-O157 STEC (serogroups O26, O45, O103, O111, O121, and O145) were constructed. To ensure that the food testing samples were not cross-contaminated by the PC sample, it is important that the STEC-PC strains were distinguishable from STEC isolated from test samples. End-point and real-time PCR assays were developed for the specific detection of the PC strains and were tested using 93 strains of E. coli (38 STEC O157:H7, at least 6 strains of each of the USDA-regulated non-O157 STEC, and 2 commensal E. coli) and 51 strains of other bacteria (30 species from 20 genera). The PCR assays demonstrated high specificity for the unique target sequence. The target sequence was detectable by PCR after 10 culture passages (~100 generations). In addition, the strains were tested for their potential use in modeling the growth of STEC. Plating the PC strains mixed with ground beef flora on modified rainbow agar containing spectinomycin (Sp), eliminated the growth of the background flora that grew on modified rainbow agar without Sp.

### Control of the Biofilms Formed by Curli- and Cellulose-Expressing Shiga Toxin–Producing Escherichia coli Using Treatments With Organic Acids and Commercial Sanitizers

Y.J. Park, J. Chen Journal of Food Protection, Vol. 78, No. 5; pp. 990–995, 2015 doi: 10.4315/0362-028X.JFP-14-382 Link to full text: Click here

**Significance:** Bacterial surface components and cell contact surfaces can influence both biofilm formation and the efficacy of sanitizing treatments.

This study was conducted to quantify biofilms formed by different Shiga toxinproducing Escherichia coli (STEC) strains on polystyrene and stainless steel surfaces and to determine the effectiveness of sanitizing treatments in control of these biofilms. STEC producing various amounts of cellulose (n=6) or curli (n=6) were allowed to develop biofilms on polystyrene and stainless steel surfaces at 28°C for 7 days. The biofilms were treated with 2% acetic or lactic acid and manufacturer-recommended concentrations of acidic or alkaline sanitizers, and residual biofilms were quantified. Treatments with the acidic and alkaline sanitizers were more effective than those with the organic acids for removing the biofilms. Compared with their counterparts, cells expressing a greater amount of cellulose or curli formed more biofilm mass and had greater residual mass after sanitizing treatments on polystyrene than on stainless steel.

### Thermal Inactivation of Shiga Toxin–Producing Escherichia coli Cells Within Cubed Beef Steaks Following Cooking on a Griddle

R.S. Swartz, J.B. Luchansky, M. Kulas, B.A. Shoyer, L.E. Shane, H. Strasser, et al. Journal of Food Protection, Vol. 78, No. 5; pp. 1013–1017, 2015

doi: 10.4315/0362-028X.JFP-14-454

Link to full text: Click here

**Significance:** Cooking single or double cubed steak on a nonstick aluminum griddle heated at 191.5°C for at least 1.25 and 3.0 min/side, respectively, was sufficient to achieve a 5.0log reduction in the levels of the single strains from each of the eight target STEC serogroups tested.

Thermal inactivation of Shiga toxin-producing Escherichia coli (STEC) cells within knitted/cubed beef steaks following cooking on a nonstick griddle was quantified. Both faces of each beef cutlet (ca. 64 g; ca. 8.5 cm length by 10.5 cm width by 0.75 cm height) were surface inoculated (ca.  $6.6 \log CFU/g$ ) with 250 µl of a rifampin-resistant cocktail composed of single strains from each of eight target serogroups of STEC: O26:H11, O45:H2, O103:H2, O104:H4, O111:H2, O121:H19, O145:NM, and O157:H7. Single-cubed steaks (SCS) and double cubed steaks (DCS) were individually cooked for  $\leq$  3.5 min/side in 30 ml of extra virgin olive oil heated to 191.5°C on a hard-anodized aluminum nonstick griddle using a flat-surface electric ceramic hot plate. Regardless of single versus double cubed, the longer the cooking time, the higher the final internal temperature, and the greater the inactivation of STEC cells within cubed steaks. The average final internal temperatures of SCS and DCS (cooked for ≤2.5 min and 3.5 min, respectively) ranged from 59.8-94.7°C and 40.3-82.2°C, respectively. Cooking SCS and DCS on an aluminum griddle set at ca. 191.5°C for 0.5 to 2.5 min and 1.0 to 3.5 min per side, respectively, resulted in total reductions in pathogen levels of ca. 1.0 to  $\geq 6.8 \log CFU/g$ .

### Salmonella

### In-Feed Supplementation of trans-Cinnamaldehyde Reduces Layer-Chicken Egg-Borne Transmission of Salmonella enterica Serovar Enteritidis

I. Upadhyaya, A. Upadhyay, A. Kollanoor-Johny, S. Mooyottu, S.A. Baskaran, H-B. Yin, et al.

Applied and Environmental Microbiology, Vol. 81, No. 9; pp. 2985–2994, 2015 doi: 10.1128/AEM.03809-14

doi: 10.1120/AEI0.03007-1

Link to full text: Click here

**Significance:** Trans-cinnamaldehyde may potentially be used as a feed additive to reduce egg-borne transmission of S. Enteritidis.

This study investigated the efficacy of in-feed supplementation with transcinnamaldehyde (TC) in reducing Salmonella enterica serovar Enteritidis cecal colonization and systemic spread in layers. Additionally, the effect of TC on S. Enteritidis virulence factors critical for macrophage survival and oviduct colonization was investigated in vitro. Supplementation of TC in feed for 66 days at 1 or 1.5% (vol/wt) for 40- or 25-week-old layer chickens decreased the amounts of S. Enteritidis on eggshell and in yolk (P<0.001). Additionally, S. Enteritidis persistence in the cecum, liver, and oviduct in TC-supplemented birds was decreased compared to that in controls (P<0.001). In vitro cell culture assays revealed that TC reduced S. Enteritidis adhesion to and invasion of primary chicken oviduct epithelial cells and reduced S. Enteritidis survival in chicken macrophages (P 0.001). Follow-up gene expression analysis using real-time quantitative PCR (qPCR) showed that TC downregulated the expression of S. Enteritidis virulence genes critical for chicken oviduct colonization (P<0.001).

### **Foodborne Pathogens**

### Previous Physicochemical Stress Exposures Influence Subsequent Resistance of Escherichia Coli O157:H7, Salmonella Enterica, and Listeria Monocytogenes to Ultraviolet-C in Coconut Liquid Endosperm Beverage

A.A. Gabriel

International Journal of Food Microbiology, Vol. 201, 18 May 2015; pp. 7–16, 2015 doi: 10.1016/j.ijfoodmicro.2015.02.003

Link to full text: Click here

**Significance:** The D and  $D_{UV-C}$  values of S. enterica after previous exposure to sequential acid and desiccation stresses were found significantly greatest, making the organism and physiological state an appropriate reference organism for the establishment of UV-C pasteurization process for the beverage.

This study investigated the influences of prior exposures to common physicochemical stresses encountered by microorganisms in food and food processing ecologies on their subsequent susceptibility towards UV-C treatment in coconut liquid endosperm beverage. Cocktails of Escherichia coli O157:H7, Salmonella enterica, and Listeria monocytogenes were separately subjected to gradually acidifying environment (final pH 4.46), exposed to abrupt desiccation by suspension in saturated NaCl solution ( $a_w = 0.85$ ) for 4, 8, and 24 h, and sequential acidic and desiccated stresses before suspending in the coconut beverage for UV-C challenge. Non-stressed cells had exposure time (D) values of 3.2–3.5 s, and corresponding UV-C energy dose values ( $D_{UV-C}$ ) values of 8.4–9.1 mJ/cm<sup>2</sup>. Cells exposed to previous acid stress had D values of 4.1–4.8 s and corresponding  $D_{UV-C}$  values of 10.7–12.5 mJ/cm<sup>2</sup>. Prior exposure to desiccation resulted in D values of 5.6–7.9 s and  $D_{UV-C}$  values of 14.7–20.6 mJ/cm<sup>2</sup>, while exposure to combined acid and desiccation stresses resulted in D values of 6.1–8.1 s and  $D_{UV-C}$  values of 15.9–21.0 mJ/cm<sup>2</sup>.

### Reduction of Surrogates for Escherichia coli O157:H7 and Salmonella During the Production of Nonintact Beef Products by Chemical Antimicrobial Interventions

C.J. Ulbrich, L.M. Lucia, A.N. Arnold, T.M. Taylor, J.W. Savell, K.B. Gehring Journal of Food Protection, Vol. 78, No. 5; pp. 881–887, 2015 doi: 10.4315/0362-028X.JFP-14-344 Link to full text: Click here **Significance:** Producers of non-intact beef products should focus on use of validated antimicrobial sprays that maximize microbial reduction and minimize internalization of surface bacteria into the finished product.

The efficacy of chemical antimicrobials for controlling Escherichia coli O157:H7 and Salmonella during production of marinated non-intact beef products was evaluated using nonpathogenic surrogates. Boneless beef strip loins were inoculated with either approximately 5.8 (high) or 1.9 (low) log CFU/cm2 of nonpathogenic rifampin-resistant E. coli, chilled at 2°C for 24 h, vacuum packaged, and aged for 7-24 days at 2°C. After aging, strip loins received no treatment (control) or one of five antimicrobial spray treatments: 2.5% L-lactic acid (pH 2.6), 5.0% L-lactic acid (pH 2.4), 1,050 ppm of acidified sodium chlorite (pH 2.8), 205 ppm of peroxyacetic acid (pH 5.2), or tap water (pH 8.6). Mean application temperatures were 53, 26, 20, and 18°C for lactic acid, water, peroxyacetic acid, and acidified sodium chlorite treatments, respectively. For high-inoculation strip loins, the 5.0% L-lactic acid treatment was most effective for reducing surrogates on meat surfaces before marination, producing a 2.6-log mean reduction. Peroxyacetic acid treatment resulted in the greatest reduction of surface-located surrogate microorganisms in marinated product. Water treatment resulted in greater internalization of surrogate microorganisms compared with the control, as determined by enumeration of surrogates from cored samples.

### Norovirus

#### A Comparative Study of Digital RT-PCR and RT-qPCR for Quantification of Hepatitis A Virus and Norovirus in Lettuce and Water Samples

C. Coudray-Meunier, A. Fraisse, S. Martin-Latil, L. Guillier, S. Delannoy, P. Fach, et al.

International Journal of Food Microbiology, Vol. 201, 18 May 2015; pp. 17–26, 2015 doi: 10.1016/j.ijfoodmicro.2015.02.006

Link to full text: Click here

**Significance:** This absolute quantitation approach may be useful to standardize quantification of enteric viruses in bottled water and lettuce samples and may be extended to quantifying other human pathogens in food samples.

The performance of microfluidic digital RT-PCR (RT-dPCR) was compared to RT-qPCR for detecting the main viruses responsible for foodborne outbreaks (human Noroviruses (NoV) and Hepatitis A virus (HAV)) in spiked lettuce and bottled water. Two process controls (Mengovirus and Murine Norovirus) were used and external amplification controls (EAC) were added to examine inhibition of RT-qPCR and RT-dPCR. For detecting viral RNA and cDNA, the sensitivity of the RT-dPCR assays was either comparable to that of RT-qPCR (RNA of HAV, NoV GI, Mengovirus) or slightly (around 1 log<sub>10</sub>) decreased (NoV GII and MNV-1 RNA and of HAV, NoV GI, NoV GII cDNA). The number of genomic copies determined by dPCR was always from 0.4 to 1.7 log<sub>10</sub> lower than the expected numbers of copies calculated by using the standard qPCR curve. Viral recoveries calculated by RT-dPCR were found to be significantly higher than by RT-qPCR for NoV GI, HAV and Mengovirus in water, and for NoV GII and HAV in lettuce samples. The RT-dPCR assay proved to be more tolerant to inhibitory substances present in lettuce samples.

#### Listeria

Development of Predictive Models for the Growth Kinetics of Listeria monocytogenes on Fresh Pork Under Different Storage Temperatures

K. Luo, S-S. Hong, J. Wang, M-J. Chung, D-H. Oh Journal of Food Protection, Vol. 78, No. 5; pp. 921–926, 2015 doi: 10.4315/0362-028X.JFP-14-428 Link to full text: Click here

**Significance:** The model developed in this study was capable of predicting the growth of L. monocytogenes under various isothermal conditions.

This study was conducted to develop a predictive model to estimate the growth of Listeria monocytogenes on fresh pork during storage at constant temperatures (5, 10, 15, 20, 25, 30, and 35°C). The Baranyi model was fitted to growth data (log CFU/gram) to calculate the specific growth rate (SGR) and lag time (LT) with a high coefficient of determination (R 2 > 0.98). As expected, SGR increased with a decline in LT with rising temperatures in all samples. Secondary models were then developed to describe the variation of SGR and LT as a function of temperature. Subsequently, the developed models were validated with additional independent growth data collected at 7, 17, 27, and 37°C and from published reports using proportion of relative errors and proportion of standard error of prediction. The proportion of relative errors of the SGR and LT models developed herein were 0.79 and 0.18, respectively. In addition, the standard error of prediction values of the SGR and LT of L. monocytogenes ranged from 25.7 to 33.1% and from 44.92 to 58.44%, respectively.

### Comparative Efficacy of Potassium Levulinate With and Without Potassium Diacetate and Potassium Propionate Versus Potassium Lactate and Sodium Diacetate for Control of Listeria monocytogenes on Commercially Prepared Uncured Turkey Breast

A.C.S. Porto-Fett, S.G. Campano, B.A. Shoyer, D. Israeli, A. Oser, J.B. Luchansky

Journal of Food Protection, Vol. 78, No. 5; pp. 927–933, 2015

doi: 10.4315/0362-028X.JFP-14-467

Link to full text: Click here

**Significance:** Potassium levulinate is at least as effective as potassium propionate and potassium diacetate as an antilisterial agent.

The efficacy of potassium levulinate (KLEV; 0.0, 1.0, 1.5, and 2.0%) with and without a blend of potassium propionate (0.1%) and potassium diacetate (0.1%) (KPD) versus a blend of potassium lactate (1.8%) and sodium diacetate (0.125%) (KLD) were evaluated for inhibiting Listeria monocytogenes on commercially prepared, uncured turkey breast during refrigerated storage. Product formulated with KLD or KLEV (1.5%) was also subsequently surface treated with 44 ppm of a solution of lauric arginate (LAE). Without inclusion of antimicrobials in the formulation, pathogen levels increased by ca. 5.2 log CFU/slice, whereas with the inclusion of 1.0-2.0% KLEV pathogen levels increased by only ca. 2.9 to 0.8 log CFU/slice after 90 days at 4°C. When 1.0% KLEV and KPD were included as ingredients, pathogen levels increased by ca. 0.8 log CFU/slice after storage at 4°C for 90 days, whereas a decrease of ca. 0.7 log CFU/slice was observed when 1.5 or 2.0% KLEV and KPD were included as ingredients. KLD was effective at suppressing L. monocytogenes in uncured turkey breast. When uncured turkey

breast was formulated with KLD or KLEV (1.5%) or without antimicrobials and subsequently surface treated with LAE, pathogen levels decreased by ca. 1.0 log CFU/package within 2 h. Results validate the use of KLEV to inhibit outgrowth of L. monocytogenes during refrigerated storage of uncured turkey breast.

### Acrylamide

# Effect of Pretreatments and Air-Frying, a Novel Technology, on Acrylamide Generation in Fried Potatoes

M. Sansano, M. Juan-Borrás, I. Escriche, A. Andrés, A. Heredia Journal of Food Science, Vol. 80, No. 5; pp. T1120–T1128, 2015 doi: 10.1111/1750-3841.12843 Link to full text: Click here

Link to full text: Click here

**Significance:** Air-frying reduced acrylamide content by about 90% compared with conventional deep-oil-frying.

This paper investigated the effect of air-frying technology, in combination with a pretreatment based of soaking the samples in different chemical agent solutions (citric acid, glycine, calcium lactate, sodium chloride, or nicotinic acid [vitamin B3]), on the generation of acrylamide in fried potatoes. The influence of reducing sugars on the development of surface's color was also analyzed. The experiments were conducted at 180 °C by means of air-frying and deepoil-frying, as a reference technology. Based on the evolution of color crust with frying time, it could be concluded that the rate of Maillard reaction decreased as the initial reducing sugars content increased in the raw material, and was also lower for deep-oil-frying than for air-frying regardless of pretreatments applied. Air-frying reduced acrylamide content by about 90% compared with conventional deep-oil-frying without pretreatment. However, deep-oil fried potatoes pretreated with solutions of nicotinic acid, citric acid, glycine at 1%, and NaCl at 2% presented much lower acrylamide levels (up to 80% to 90% reduction) than nonpretreated samples.

### Food Allergy

# Sublingual Immunotherapy for Peanut Allergy: Long-Term Follow-Up of a Randomized Multicenter Trial

A.W. Burks, R.A. Wood, S.M. Jones, S.H. Sicherer, D.M. Fleischer, A.M. Scurlock, et al. for the Consortium of Food Allergy Research (CoFAR)

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1240–1248.e3, 2015

doi: 10.1016/j.jaci.2014.12.1917

Link to full text: Click here

**Significance:** Peanut sublingual immunotherapy induced a modest level of desensitization, decreased immunologic activity over 3 years in responders, and had an excellent long-term safety profile.

This study sought to provide long-term (3-year) clinical and immunologic outcomes for the peanut sublingual immunotherapy (SLIT) trial. Key end points were (1) percentage of responders at 2 years (ie, could consume 5 g of peanut powder or a 10-fold increase from baseline), (2) percentage reaching desensitization at 3 years, (3) percentage attaining sustained unresponsiveness after 3 years, (4) immunologic end points, and (5) assessment of safety parameters.
Response to treatment was evaluated in 40 subjects aged 12-40 years by performing a 10-g peanut powder oral food challenge after 2 and 3 years of daily peanut SLIT therapy. At 3 years, SLIT was discontinued for 8 weeks, followed by another 10-g oral food challenge and an open feeding of peanut butter to assess sustained unresponsiveness. Approximately 98% of the 18,165 doses were tolerated without adverse reactions beyond the oropharynx, with no severe symptoms or uses of epinephrine. A high rate (>50%) discontinued therapy. By study's end, 4 (10.8%) of 37 SLIT-treated participants were fully desensitized to 10 g of peanut powder, and all 4 achieved sustained unresponsiveness. Responders at 2 years showed a significant decrease in peanut-specific basophil activation and skin prick test titration compared with nonresponders.

# Natural History of Peanut Allergy and Predictors of Resolution in the First 4 Years of Life: A Population-Based Assessment

R.L. Peters, K.J. Allen, S.C. Dharmage, J.J. Koplin, T. Dang, K.P. Tilbrook, et al. for the HealthNuts Study

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1257–1266.e2, 2015 doi: 10.1016/j.jaci.2015.01.002

Link to full text: Click here

**Significance:** In this study, thresholds for SPT and sIgE levels were generated in which all participants underwent oral food challenges at both diagnosis and follow-up, irrespective of SPT and sIgE results.

This study sought to describe the natural history of peanut allergy between 1 and 4 years of age and develop thresholds for skin prick test (SPT) results and specific IgE (sIgE) levels measured at age 1 and 4 years that have 95% positive predictive value (PPV) or negative predictive value for the persistence or resolution of peanut allergy. One-year-old infants with challenge-confirmed peanut allergy (n=156) were followed up at 4 years of age with repeat oral food challenges, SPTs, and sIgE measurements (n=103). Peanut allergy resolved in 22% (95% CI, 14% to 31%) of children by age 4 years. Decreasing wheal size predicted tolerance, and increasing wheal size was associated with persistence. Thresholds for SPT responses and sIgE levels at age 1 year with a 95% PPV for persistent peanut allergy are an SPT-induced response of  $\geq 13$  mm and an sIgE level of  $\geq$  5.0 kU/L. Thresholds for SPT and sIgE results at age 4 years with a 95% PPV for persistent peanut allergy are an SPT response of  $\geq 8$  mm and an sIgE level of  $\geq 2.1$  kU/L. Ara h 2, tree nut, and house dust mite sensitization; coexisting food allergies; eczema; and asthma were not predictive of persistent peanut allergy.

#### A Randomized, Double-Blind, Placebo-Controlled Pilot Study of Sublingual Versus Oral Immunotherapy for the Treatment of Peanut Allergy

S.D. Narisety, P.A. Frischmeyer-Guerrerio, C.A. Keet, M. Gorelik, J. Schroeder, R.G. Hamilton, et al.

Journal of Allergy and Clinical Immunology, Vol. 135, No. 5; pp. 1275–1282.e6, 2015 doi: 10.1016/j.jaci.2014.11.005

Link to full text: Click here

**Significance:** Oral immunotherapy appeared far more effective than sublingual immunotherapy for the treatment of peanut allergy, but was also associated with significantly more adverse reactions and early study withdrawal.

This double-blind study compared the safety, efficacy, and mechanistic correlates of peanut oral immunotherapy (OIT) and sublingual immunotherapy (SLIT) in children with peanut allergy (PA). Twenty-one subjects (7 to 13 years) were randomized to receive active SLIT/placebo OIT or active OIT/placebo SLIT. Doses were escalated to 3.7 mg/d (SLIT) or 2000 mg/d (OIT), and subjects were rechallenged after 6 and 12 months of maintenance. After unblinding, therapy was modified per protocol to offer an additional 6 months of therapy. Subjects who passed challenges at 12 or 18 months were taken off treatment for 4 weeks and rechallenged. Five subjects discontinued therapy; of the remaining 16, all had a >10-fold increase in challenge threshold after 12 months. The increased threshold was significantly greater in the active OIT group (141- vs 22-fold, P=.01). Significant within-group changes in skin test results and peanut-specific IgE and IgG4 levels were found, with overall greater effects with OIT. Adverse reactions were generally mild but more common with OIT (P<.001), including moderate reactions and doses requiring medication. Four subjects had sustained unresponsiveness at study completion.

#### About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

From: Sent: To:

Cc:

**Delia Murphy** Wednesday, June 10, 2015 9:36 AM ; DAllison@uab.edu fergc@foodsci.umass.edu; @od.nih.gov; jwerdman@illinois.edu; james.hill@ucdenver.edu; dblund@wisc.edu; Joanne Lupton;

Shawn Sullivan;

weavercm@purdue.edu; Alison Kretser Subject: Reminder: ACTION ITEM: ILSI North America Scientific Integrity Working Group **Attachments:** 5-27-15\_Plan of Work for Scientific Integrity.docx; Scientific Integrity Work by Various Organizations and in the Current Li....docx

Good morning,

As a reminder, if you have not already provided comments or edits to the draft plan of work for the ILSI North America Scientific Integrity Working Group, they are due by COB this Friday 12 June.

Please let me know if you have any questions.

Best. Delia

Delia Murphy Science Program Associate **ILSI North America** 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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From: Delia Murphy			
Sent: Wednesday, May 2	7, 2015 1:35 PM		
То: '	'; 'DAllison@uab.edu';		1, 1 7
'fergc@foodsci.umass.edu'; '			'mdoyle@uga.edu'; 'dwyerj1@od.nih.gov';
'jwerdman@illinois.edu';			Eric Hentges; 'james.hill@ucdenver.edu';
			dblund@wisc.edu';
'jlupton@tamu.edu'; '		';	'trains@eggnutritioncenter.org';
			'; Shawn
Sullivan;	;		; 'weavercm@purdue.edu';

Cc: Alison Kretser Subject: ILSI North America Scientific Integrity Working Group

To: ILSI North America Scientific Integrity Working Group Re: Draft Plan of Work

Please find attached the draft plan of work for the ILSI North America Scientific Integrity Working Group which reflects the discussion at the 30 April meeting of the Working Group. Also attached is the Compilation of Scientific Integrity Work by Various Organizations and in the Current Literature presented at the meeting and referenced in the plan of work.

<u>Please read the document and provide comments or edits to the draft by COB Friday, 12 June.</u> The revised document will then be re-distributed to the Working Group for final approval.

The draft plan of work will be shared with the ILSI North America Board of Trustees' Executive Committee on a conference call on 2 June. It will be clearly stated that this current version is a draft and has not been finalized by the Working Group.

The meeting minutes from the 30 April meeting are nearing completion and will be distributed to the Working Group as soon as possible.

Please let Alison and I know if you have any questions.

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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## **Scientific Integrity Working Group**

#### Background/Recommendations from the Scientific Integrity Working Group from 30 April Meeting

- 1. Given the extensive work being done by federal agencies and other organizations on scientific integrity (see Compilation of Scientific Integrity Work by Various Organizations document completed by ILSI North America), why is there still an issue with scientific integrity? What are the reasons for an apparent increase in scientific fraud and misuse of scientific data? What are the pressures that result in these actions? What can be done to instill scientific integrity in all researchers?
- 2. ILSI North America should synthesize the Compilation document into a framework (science, research, and people) and publish it to shine a light on the work that has been done by the federal agencies and other organizations. ILSI North America should then develop a set of principles/best practices on scientific integrity from existing efforts.
- 3. ILSI North America's focus should be on implementation of these principles/best principles. To accomplish this goal, ILSI North America will bring visibility to the published principles/best practices by hosting a "tournament" on an annual basis to identify outstanding papers within specific categories that can be held up as examples and model publications. The following categories are under consideration as they were identified in the ILSI North America membership survey on scientific integrity: study design, statistical analysis, reporting fidelity, open source data sets, best reviewer, and best in class. This "tournament" would show the principles/best practices in action by focusing on the strengths and weaknesses in each category.
- 4. The Working Group feels that ILSI North America should seek a broader group of collaborators than we have previously worked with in order to have a greater impact; ones that have impeccable reputations and are not focused on area of science. Possible candidates are:
  - a. American Association for the Advancement of Science (AAAS)
  - b. Association of Public and Land-grant Universities (APLU)
  - c. National Science Foundation (NSF)
  - d. Association of American Universities (AAU)
  - e. The National Academies (NAS)
- 5. As the COI Summit Consortium has agreed to reconvene in two years, ILSI North America could introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

#### Proposed Plan of Work for the Scientific Integrity Working Group

- 1. A Compilation of Scientific Integrity Work by Federal Agencies and Other Organizations was completed in April 2015. This information will be placed into a framework using three categories that encompass scientific integrity (science, research, and people.)
  - a. This work will be submitted to a peer reviewed journal as the first manuscript in order to have it published in a timely manner while the other scientific integrity work is

undertaken. Dr. Fergus Clydesdale has offered to publish this manuscript in *Critical Reviews in Food Science and Nutrition*.

- b. This compilation should remain a living document. With the journal, explore the possibility of an online version of the publication, capturing activities on scientific integrity on a regular basis.
- 2. Develop a second paper in collaboration with AAAS and/or APLU that builds on the first manuscript. The paper will synthesize a set of principles/best practices for scientific integrity using the framework (science, research, and people) to establish the first "rulebook" on scientific integrity and will describe how to implement them. Incorporate sports analogies to better illustrate this issue. Examine case studies of scientific misconduct (worst practices) to incorporate into the manuscript (NSF and HHS Office of Research Integrity jointly issue a list of case summaries of scientific misconduct each year <a href="https://ori.hhs.gov/case\_summary">https://ori.hhs.gov/case\_summary</a>). Highlight the punishments that are currently being dispensed for scientific misconduct. A goal of the publication will be to raise awareness of the real consequences of scientific misconduct, i.e. the "penalty phase." Little attention has been given to this area within the scientific community.
  - a. The ILSI North America body of work on conflict of interest can be highlighted in the "people" section of the framework. For example, an individual researcher should be aware that he/she has certain conflicts of interest which can affect their personal integrity.
- 3. In collaboration with AAAS, APLU, and/or NSF, begin development of an annual "tournament" to identify outstanding papers within specific categories across all scientific disciplines. Begin development of criteria/rubric for grading papers at the "tournament" with collaborators (review current grading scales, i.e. HHS NIH National Cancer Institute, USDA National Institute of Food and Agriculture. Dr. David Allison has also begun to outline the procedure for evaluating papers.) The first "tournament" will be held in late 2017-early 2018.
  - a. Nutrition, food science, and food safety professional societies may be interested in sponsoring specific categories within the "tournament" (i.e. award prize money for winners of "tournament".)
- 4. Present the new framework and principles/best practices at major professional society meetings beginning in 2016-2017, educating attendees on the components of scientific integrity (i.e. learning to throw the baseball before you play the game.) The session would outline current efforts in scientific integrity, what it means for institutions and researchers, and where it is going and will bring to light how it applies to your professional organization. (If an individual researcher does not implement the principles/best practices, it can ruin one's career.) The case studies used would be specific to the professional meeting. The session will also include a description of the "tournament" and the proposed criteria/rubric developed for grading the papers for additional feedback from attendees.
  - a. Potential Meetings to Present the Framework and Principles/Best Practices:
    - i. American Association for Advancement of Science (AAAS)
    - ii. Association of Public and Land-grant Universities (APLU)
    - iii. Association of American Universities (AAU)
    - iv. World Conference on Research Integrity
    - v. American Society of Nutrition- Experimental Biology (EB)
    - vi. International Association for Food Protection (IAFP)
    - vii. Academy of Nutrition and Dietetics FNCE
    - viii. Canadian Nutrition Society (CNS)
    - ix. Society of Toxicology (SOT)
    - x. Society for Risk Analysis (SRA)
    - xi. Institute of Food Technologists (IFT)
    - xii. International Union of Food Science and Technology (IUFoST)
    - xiii. International Society for Behavioral Nutrition and Physical Activity (ISBNPA)

- 5. Finalize the criteria/rubric for grading papers and train the "referees" for the "tournament," recognizing that over time, the principles/best practices may evolve, as demonstrated in sports.
- 6. Hold "tournament" in Washington, DC.
- 7. Post winning papers in the different "tournament" categories to NIH PubMed Commons for recognition.
- 8. When the COI Summit Consortium reconvenes in two years, ILSI North America will introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

#### **Proposed Timeline for Plan of Work:**

- 1. Presentation of plan of work to the ILSI North America Board of Trustees: July 2015
- 2. Meet with AAAS and APLU to share Plan of Work: Summer 2015
- 3. First manuscript on Compilation of Scientific Integrity Work: Submission September 2015
- 4. Second manuscript on principles/best practices, developed in collaboration with AAAS and/or APLU: mid-2016
- 5. Roadshow at Major Professional Society Meetings: 2016-2017
- 6. Second COI Summit Consortium Meeting: December 2016- early 2017
- 7. First Annual "Tournament": late 2017-early 2018



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## <u>Compilation of Scientific Integrity Work by Various Organizations and in the</u> <u>Current Literature</u>

## **Scientific Integrity Work by Federal Agencies**

#### **Presidential Memorandum for the Heads of Executive Departments and Agencies** March 9, 2009

https://www.whitehouse.gov/the\_press\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/

#### Office of Science and Technology Policy (OSTP)

Directive on Scientific Integrity- December 17, 2010 This document is the implementation guide for the federal agencies to respond to the Presidential Memorandum. https://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

Scientific Integrity Report Card

As of July 2013, fifteen agencies have released final scientific integrity policies. http://www.peer.org/assets/docs/About SI Report Card and Disclaimer.pdf

#### **National Science Foundation**

The National Science Foundation (NSF) is an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense..." With an annual budget of \$7.3 billion (FY 2015), we are the funding source for approximately 24 percent of all federally supported basic research conducted by America's colleges and universities. In many fields such as mathematics, computer science and the social sciences, NSF is the major source of federal backing.

NSF Scientific Integrity Policy- released after December 2010

It is the policy of NSF to maintain a culture of scientific integrity in accordance with the President's March 9, 2009 Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity and the implementation guidance in the Office of Science and Technology Policy (OSTP) December 17, 2010 Memorandum. NSF's policy applies to civil service employees; visiting scientists, engineers, and educators; those working at NSF under the Intergovernmental Personnel Act; and political appointees.

http://www.nsf.gov/bfa/dias/policy/si/sipolicy.pdf

Responsible Conduct of Research (RCR)- released after August 2007 when the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act was signed into law. http://www.nsf.gov/bfa/dias/policy/rcr.jsp

NSF's Research Misconduct regulation is found at 45 CFR 689.

The above regulation only applies to conduct that occurred on or after April 17th, 2002. For alleged misconduct that occurred before April 17, 2002, we use <u>this</u> definition and follow the procedure described in 45 CFR 689 above.



Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up results and recording or reporting them
- Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit,
- Policy defines "research" and "research record"

https://www.nsf.gov/oig/session.pdf

Searches for "scientific integrity" and "research integrity" grants results included many grants awarded in the 1990s but it seems that not as many have been funded more recently

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22scientific+integrity%22+%22research+integrity%22+&ActiveAwards=true&ExpiredAwards=true

<u>Collaborative Research: Foundations of Social and Ethical Responsibility Among Undergraduate</u> <u>Engineering Students: Comparing Across Time, Institutions, and Interventions</u>

Award Number: 1449479; Principal Investigator: Brent Jesiek; Co-Principal Investigator: Carla Zoltowski; Organization: Purdue University; NSF Organization: SES Start Date: 05/15/2015; Award Amount: \$260,491.00; Relevance: 29.51;

Research grants for "research misconduct" have taken place recently, including:

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22research+misconduct%22

#### The Nature of Ethical Decision-Making in Research

Award Number:0924751; Principal Investigator: R. Wayne Fuqua; Co-Principal Investigator: David Hartmann, Thomas Van Valey; Organization: Western Michigan University; NSF Organization: SES Start Date:10/01/2009; Award Amount:\$357,073.00; Relevance:77.79;

#### **Gaming Against Plagiarism**

Award Number:1033002; Principal Investigator: Michelle Foss Leonard; Co-Principal Investigator: Amy Buhler, Margeaux Johnson, James Oliverio, Douglas Levey, Benjamin DeVane; Organization: University of Florida; NSF Organization: IIS Start Date:09/01/2010; Award Amount:\$298,660.00; Relevance:72.24; <a href="http://digitalworlds.ufl.edu/projects/gap/">http://digitalworlds.ufl.edu/projects/gap/</a>

#### **Department of Health and Human Services (HHS)**

Policies and Principles for Assuring Scientific Integrity Published in 2011 http://aspe.hhs.gov/sp/scientificintegrity/principles/index.cfm

**Office of Research Integrity** 

https://ori.hhs.gov/

In 2000, ORI began the <u>Research on Research Integrity (RRI) Program</u> and the biennial <u>Research Conferences on</u> <u>Research Integrity</u> to expand the knowledge base and develop a research community focused on the responsible conduct of research, research integrity, and research misconduct. That same year ORI started the <u>Rapid Response</u> <u>for Technical Assistance</u> to provide early and direct assistance to institutions assessing research misconduct allegations.



In 2002, ORI launched the Responsible Conduct Research (RCR) <u>RCR Resource Development Program</u> and the <u>RCR Program for Academic Societies</u>. The former program was designed to facilitate the development of materials for teaching the responsible conduct of research by the research community for use in the research community. The latter program, a collaboration with the Association of American Medical Colleges, supported activities within academic societies designed to promote the responsible conduct of research among their members. The first RCR Expo was held in 2003 to call attention to the new RCR materials. ORI published the <u>ORI Introduction to the Responsible Conduct of Research</u> in 2004 and began the <u>RCR Program for Graduate Schools</u> in collaboration with the Council of Graduate Schools to institutionalize RCR education in graduate training.

A new regulation, <u>PHS Policies on Research Misconduct (pdf)</u>, became effective on June 16, 2005. The regulation is codified at 42 C.F.R. Part 93. ORI began developing a training program for institutional research integrity officers (RIOs) in 2005 that produced an orientation video in 2006 and boot camps in 2007. In 2007, ORI also began the <u>RCR Program for Postdocs</u> and took another step toward the creation of a laboratory management training program in collaboration with the Laboratory Management Institute at the University of California-Davis to develop on-line instruction on laboratory management. Previously, ORI organized the first national conference on the management of biomedical research laboratories in 1998 in collaboration with the University of Arizona and supported the development of instructional resources on laboratory management through its RCR Resource Development Program.

"The Lab: Avoiding Research Misconduct": An Interactive Movie on Research Misconduct In "The Lab: Avoiding Research Misconduct," you become the lead characters in an interactive movie and make decisions about integrity in research that can have long-term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices. http://ori.hhs.gov/THELAB

The National Science Foundation and the Office of Research Integrity at the Department of Health and Human Services jointly confirm about 20 cases a year of research misconduct, according to Steneck. The actual number could be 10 times that or more, he said, because some researchers suspect but do not report misconduct, some institutions fail to undertake rigorous investigations and some journals find but do not report misconduct.

#### National Institutes of Health (NIH)

NIH Policies and Procedures for Promoting Scientific Integrity November 2012 http://www.nih.gov/about/director/sci-int-nov2012.pdf

NIH has not yet finalized the most recent language providing guidance to reviewers <u>http://enhancing-peer-review.nih.gov/guidance\_reviewers.html</u> <u>http://grants.nih.gov/grants/peer/peer.htm</u>

NIH hosts a workshop with journals to unite on reproducibility:

A group of editors representing more than 30 major journals; representatives from funding agencies; and scientific leaders assembled at the American Association for the Advancement of Science's headquarters in June 2014 to discuss principles and guidelines for preclinical biomedical research. The gathering was convened by the US National Institutes of Health, *Nature* and *Science* (see *Science* **346**, 679; 2014). The discussion ranged from what journals were already doing to address reproducibility — and the effectiveness of those measures — to the magnitude of the problem and the cost of solutions. The attendees agreed on a common set of Principles and Guidelines in Reporting Preclinical Research



(see go.nature.com/ezjl1p) that list proposed journal policies and author reporting requirements in order to promote transparency and reproducibility.

NIH plans to enhance reproducibility:

- NIH is developing a training module on enhancing reproducibility and transparency of research findings, with an emphasis on good experimental design.
- Several of the NIH's institutes and centres are also testing the use of a checklist to ensure a more systematic evaluation of grant applications.
- A pilot was launched last year that we plan to complete by the end of this year to assess the value of assigning at least one reviewer on each panel the specific task of evaluating the 'scientific premise' of the application: the key publications on which the application is based (which may or may not come from the applicant's own research efforts).
- Big Data initiative, the NIH has requested applications to develop a Data Discovery Index (DDI) to allow investigators to locate and access unpublished, primary data (see go.nature.com/rjjfoj).
- in mid-December, the NIH launched an online forum called PubMed Commons (see go.nature.com/8m4pfp) for open discourse about published articles.
- NIH is contemplating modifying the format of its 'biographical sketch' form, which grant applicants are required to complete, to emphasize the significance of advances resulting from work in which the applicant participated, and to delineate the part played by the applicant.
- NIH is examining ways to anonymize the peer-review process to reduce the effect of unconscious bias (see go.nature.com/g5xr3c)

http://www.nature.com/news/policy-nih-plans-to-enhance-reproducibility-1.14586

NIH Regional Consultation Meeting on Peer Review

October 22, 2007 – Washington, D.C. Meeting Summary: <u>http://enhancing-peer-review.nih.gov/meetings/102207-summary.html</u>

#### Food and Drug Administration (FDA)

http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm

FDA has a long and continuing history of promoting an environment of robust scientific debate, where the integrity of information is ensured, all views are carefully considered, and scientific decisions are protected from political influence. In 2009, we established **FDA's Office of Scientific Integrity** (OSI). OSI works to:

- 1. ensure that FDA's policies and procedures are current and applied across the Agency;
- 2. resolve scientific disputes that may arise internally or externally and that are not resolved at the Agency's Center levels; and
- 3. advise the Chief Scientist and other senior FDA leaders on appropriate responses.

#### **Centers for Disease Control and Prevention (CDC)**

The Office of the Associate Director for Science (OADS) provides service and support to the CDC scientists as they work to protect people's health and improve the quality of their lives. Our focus is on strengthening the quality and integrity of CDC's science. Furthermore, by fostering innovative and successful scientific collaborations and partnerships we are also working towards enhancing the relevance of our science and its health impact.

Our office is also a home to the Office of Science Quality (OSQ) which is responsible for advancing the quality of CDC's science and championing the translation of research through the development of science policies and best practices (e.g., authorship, scientific clearance, peer review, and extramural research policies); and the Office of Scientific Integrity, which ensures that CDC science and research activities comply with various federal laws,



regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.

http://www.cdc.gov/od/science/aboutus/index.htm

#### **Environmental Protection Agency (EPA)**

EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote scientific and ethical standards and to create a proactive culture to support them. The policy establishes a Scientific Integrity Committee to implement the policy. The Committee consists of Deputy Scientific Integrity Officials that represent each of the Agency's Program Offices and Regions. The Scientific Integrity Official (ScIO) chairs the Committee. The ScIO is the Agency's focal point on scientific integrity and serves as the Agency's expert on such matters.

EPA Scientific Integrity Policy (PDF)

#### http://www2.epa.gov/osa/basic-information-about-scientific-integrity

Definition of Scientific Integrity: Scientific Integrity results from adherence to professional values and practices, when conducting and applying the results of science and scholarship. It ensures:

- Objectivity
- Clarity
- Reproducibility
- Utility

Scientific Integrity is important because it provides insulation from:

- Bias
- Fabrication
- Falsification
- Plagiarism
- Outside interference
- Censorship
- Inadequate procedural and information security

#### Principles of Scientific Integrity

In 1999, the Agency published its Principles of Scientific Integrity, developed in conjunction with the EPA's National Partnership Council, which is comprised of representatives of Agency labor unions and management. The Principles laid out the basic rules for ethical behavior by all EPA employees in:

- Conducting scientific research
- Interpreting and presenting results
- Using scientific information and data

Principles of Scientific Integrity

Community of Practice for Statistics- January 2014

Initiative to strengthen statistics, consideration, and study design and to ensure these same factors are evaluation during the review and approval of study protocols. 3 Working Groups were formed to raise awareness of the importance of statistical issues and provide a forum for robust discussion. The 3 Working Groups developed process and guidance

documents. http://www.ncbi.nlm.nih.gov/pubmed/25795653



Revising The Agency's Peer Review Handbook: The Agency's Peer Review Handbook was first issued in 1998. It was revised and reissued in 2000 (2nd Edition) and 2006 (3rd Edition). In 2009 an addendum on the "Appearance of a Lack of Impartiality in External Peer Review" was added. The Handbook is currently being updated to incorporate EPA organizational changes, the 2009 addendum, as well as additional processes that have been put into place since 2006.

Peer Review Handbook 3rd Edition, 2006

Addendum to Peer Review Handbook 3rd Edition

#### **United States Department of Agriculture (USDA)**

USDA Scientific Integrity Policy - 2013

To ensure that science at USDA is held to the highest standards possible, Secretary Vilsack issued a Departmental Regulation (DR) on Scientific Integrity. It provides guidance to all employees and contractors on the proper use of scientific findings and the principles of conducting scientific activities, and addresses the White House Office of Science and Technology Policy's request for all federal departments to write these policies. See below for the policy and the handbook, which describes how the policy will be implemented.

- USDA Scientific Integrity Policy (DR 1074-001) (PDF, 262KB)
- USDA Scientific Integrity Policy Handbook (PDF, 879KB)
- Annual USDA Scientific Integrity Allegations Summary Report (May 2013 April 2014) (PDF, 179KB)
- USDA Agency Scientific Integrity Officers

Research misconduct - an important subset of scientific integrity violation - is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. To ensure that the public can trust the objectivity of its science, USDA established policies and procedures for handling research misconduct that occurs in research that is either funded or conducted by USDA.

• View a list of USDA Research Integrity Officers

Anyone who suspects USDA researchers or researchers performing USDA-funded research of engaging in research misconduct is encouraged to make a formal allegation of research misconduct to USDA's Office of the Inspector General (OIG)



## **Scientific Integrity Work by Non-Profit Organizations**

**The National Academies** 

#### **Institute of Medicine**

Does the Public Trust Science? Trust and Confidence at the Intersections of the Life Sciences and Society A workshop of the Roundtable on Public Interfaces of the Life Sciences May 5-6, 2015 National Academy of Sciences 2101 Constitution Avenue N.W., Lecture Room Washington, D.C. http://nas-sites.org/publicinterfaces/roundtable/events/trust/

2002: Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct This report focuses on the research environment and attempts to define and describe those elements that allow and encourage unique individuals, regardless of their role in the research organization or their backgrounds on entry, to act with integrity. The committee's goal was to define the desired outcomes and set forth a set of initiatives that it believes will enhance integrity in the research environment. The committee considered approaches that can be used to ensure integrity and methods that can be used to assess the effectiveness of those efforts.

Several overarching conclusions emerged as the committee addressed the desire of the Department of Health and Human Services' Office of Research Integrity for means to assess and track the state of integrity in the research environment:

- Attention to issues of integrity in scientific research is very important to the public, scientists, the institutions in which they work, and the scientific enterprise itself.
- No established measures for assessing integrity in the research environment exist.
- Promulgation of and adherence to policies and procedures are necessary, but they are not sufficient means to ensure the responsible conduct of research.
- There is a lack of evidence to definitively support any one way to approach the problem of promoting and evaluating research integrity.
- Education in the responsible conduct of research is critical, but if it is not done appropriately and in a creative way, it is likely to be of only modest help and may be ineffective.
- Institutional self-assessment is one promising approach to assessing and continually improving integrity in research.

https://www.iom.edu/Reports/2002/Integrity-in-Scientific-Research-Creating-an-Environment-That-Promotes-Responsible-Conduct.aspx

RESPONSIBLE SCIENCE Ensuring the Integrity of the Research Process VOLUME I Panel on Scientific Responsibility and the Conduct of Research Committee on Science, Engineering, and Public Policy National Academy of Sciences National Academy of Engineering Institute of Medicine NATIONAL ACADEMY PRESS Washington, D.C. 1992 http://www.nap.edu/openbook.php?record\_id=1864&page=R1



"Conflict of Interest and Medical Innovation:

Ensuring Integrity While Facilitating Innovation in Medical Research: Workshop Summary" (2014) <u>http://www.nap.edu/catalog/18723/conflict-of-interest-and-medical-innovation-ensuring-integrity-while-facilitating</u>

Scientific advances such as the sequencing of the human genome have created great promise for improving human health by providing a greater understanding of disease biology and enabling the development of new drugs, diagnostics, and preventive services. However, the translation of research advances into clinical applications has so far been slower than anticipated. This is due in part to the complexity of the underlying biology as well as the cost and time it takes to develop a product. Pharmaceutical companies are adapting their business models to this new reality for product development by placing increasing emphasis on leveraging alliances, joint development efforts, early-phase research partnerships, and public-private partnerships. These collaborative efforts make it possible to identify new drug targets, enhance the understanding of the underlying basis of disease, discover novel indications for the use of already approved products, and develop biomarkers for disease outcomes or directed drug use. While the potential benefits of collaboration are significant, the fact that the relationships among development partners are often financial means that it is vital to ensure trust by identifying, disclosing, and managing any potential sources of conflict that could create bias in the research being performed together.

## **Scientific Integrity Work by Foundations**

#### John Templeton Foundation

Increasing Scientific Openness and Integrity

Project Leader(s): Brian Nosek, Jeffrey Spies

Grantee(s): <u>Center for Open Science</u> (see below additional projects under the Arnold Foundation) Description: An academic scientist's professional success depends on publishing. Publishing norms emphasize novel, positive, tidy results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that maximize publishability even at the expense of accuracy. This challenges scientists' character because professional success is enhanced by pursuing suboptimal scientific practices. As such, disciplinary norms guide researchers toward practices that are contrary to personal and scientific values. The end result is inflation of error in published science, and interference with knowledge accumulation. Scientific integrity can be improved with strategies that make the fundamental but abstract accuracy motive—getting it right—competitive with the more tangible and concrete incentive—getting it published. We are building infrastructure (http://openscienceframework.org/) to alter the incentives, increase openness and accountability, and provide a

(http://openscienceframework.org/) to alter the incentives, increase openness and accountability, and provide a means of instilling habits that embody scientific values in the daily behavior of practicing scientists. Also, we are building communities around open science values, and means of providing credit for practicing those values. Ultimately, we aim to enhance the credibility and integrity of individual scientists, the scientific community, and the knowledge base that they produce. We will meet these goals in this grant with three activities: (1) building the Open Science Framework to provide features that provide value to the scientist's existing workflow and enables or automates good practices, (2) building community, training and outreach to facilitate use of the Open Science Framework, and (3) connecting a variety of tools (e.g., data repositories, data visualization tools, analytic tools)



through the OSF to support the entire research lifecycle and facilitate documentation and archival of research materials and data. Grant Amount: \$2,109,856 Start Date: January 2014, End Date: October 2016 Grant ID: 46545 http://www.templeton.org/what-we-fund/grants/increasing-scientific-openness-and-integrity

#### **MacArthur Foundation**

The <u>Center for Scientific Integrity</u> operates <u>Retraction Watch</u> through a generous grant from the MacArthur Foundation. <u>http://retractionwatch.com/the-retraction-watch-faq/</u>

The goals of the Center fall under four broad areas:

- A database of retractions, expressions of concern and related publishing events, generated by the work of Retraction Watch. The database will be freely available to scientists, scholars and anyone else interested in analyzing the information.
- Long-form, larger-impact writing, including magazine-length articles, reports and books.
- Aid and assistance to groups and individuals whose interests in transparency and accountability intersect with ours, and who could benefit from shared expertise and resources.

http://retractionwatch.com/the-center-for-scientific-integrity/

#### **Arnold Foundation**

The Arnold Foundation has 4 areas of focus, one is research integrity. LJAF's Research Integrity initiative aims to improve the reliability and validity of scientific evidence across fields that inform governmental policy, philanthropic endeavors, and individual decision making. As a society, we often rely on published scientific research to guide our policy, health, and lifestyle choices. Although some published research is rigorous and reliable, some is not. Worse, the unreliability of research is often difficult or impossible to ascertain. LJAF is currently working to address this problem by supporting organizations that are committed to improving the openness, transparency, and quality of research. All research projects sponsored in full or in part by LJAF must follow the Guidelines for Investments in Research. See Guidelines for Investments in Research

Between 2011-2014, the Arnold Foundation granted \$66,859,986 in grant dollars for Research Integrity projects, including grants to:

#### American Association for the Advancement of Science (AAAS) (see more on AAAS below)

\$100,000 to foster open, reliable, and rigorous scientific research by sponsoring three workshops on publication standards. The grant runs from 2014-2016.

#### **Nutrition Science Initiative**

Two grants for a total of up to \$44 million running from 2012-2018 to improve the quality of science in nutrition and obesity research.

The mission of Nutrition Science Initiative is to reduce the individual, social, and economic costs of obesity, diabetes, and their related diseases by improving the quality of science in nutrition and obesity research. The Nutrition Science Initiative is currently focusing on 3 projects:

1. Boston Children's Hospital: This study will determine whether reduced calorie intake or a change in the proportions of fat and carbohydrates is the most effective strategy for maintaining a reduced body weight.



- 2. Energy Balance Consortium: This highly controlled laboratory study will help determine whether it's the total amount of calories you eat or the proportion of fat and carbohydrate in the diet that most importantly drives body weight gain.
- 3. Stanford University: This study compares the effects of a very low-carbohydrate and very-low fat diets on body weight in free-living obese patients over a year's time and examines whether genetic or metabolic factors can predict the response to the different diets.

#### Center for Open Science, Inc. (COS)

(see above for more information under the John Templeton Foundation) Several million dollars to the Center for Open Science, Inc.

COS Communities blur the boundary between COS and the many individual and organizational contributors to improving scientific practices. COS Communities form around particular products or services to define specifications, maximize applicability, promote adoption, and facilitate evaluation and improvement. There are 4 buckets of COS communities:

Publishing Initiatives

- Badges to Acknowledge Open Practices: Badges incentivize open research by rewarding authors with visual acknowledgements on published manuscripts. Currently, badges can be earned for three distinct practices: open data, open materials, and preregistration. Badges appear directly on publications along with information regarding where the relevant data, materials, or registration can be found. The badges and their criteria are developed and maintained as a community-driven initiative of the Center for Open Science.
- 2. Registered Reports: Registered Reports offer journals an alternative structure to the current publishing format to promote transparency and reproducibility in scientific research. In this model, peer review occurs twice. Each study procedure and analysis plan are evaluated prior to data collection for in-principle acceptance; if accepted, the final manuscript is essentially guaranteed publication regardless of the reported outcome, with a second peer review to ensure the accepted methodology was conducted.

Metascience

- 1. Reproducibility Project: Psychology (RP:P): The RP:P is a collaborative community effort to replicate published psychology experiments from three important journals. Replication teams follow a standard protocol to maximize consistency and quality across replications, and the accumulated data, materials and workflow are to be open for critical review on OSF. The RP:P is coordinated at the Center for Open Science and involves volunteer scientists from all over the world.
- 2. Reproducibility Project: Cancer Biology (RP:CB): The RP:CB is an initiative to conduct direct replications of 50 high-impact cancer biology studies. The project anticipates learning more about predictors of reproducibility, common obstacles to conducting replications, and how the current scientific incentive structure affects research practices by estimating the rate of reproducibility in a sample of published cancer biology literature. The RP:CB is a collaborative effort between the Center for Open Science and network provider Science Exchange.
- 3. Many Labs I: Many Labs I project was a crowdsourced replication study in which the same 13 psychological effects were examined in 36 independent samples to examine variability in replicability across sample and setting.
  - a. Results:
    - i. Variations in sample and setting had little impact on observed effect magnitudes



- ii. When there was variation in effect magnitude across samples, it occurred in studies with large effects, not studies with small effects
- iii. Replicability was much more dependent on the effect of study rather than the sample or setting in which it was studied
- iv. Replicability held even across lab-web and across nations
- v. Two effects in a subdomain with substantial debate about reproducibility (flag and currency priming) showed no evidence of an effect in individual samples or in the aggregate.
- 4. Many Labs II: Conducted in Fall of 2014, Many Labs II employed the same model as Many Labs I but with almost 30 effects, more than 100 laboratories, and including samples from more than 20 countries. The findings should be released in mid-2015.
- 5. Many Labs III: Many psychologists rely on undergraduate participant pools as their primary source of participants. Most participant pools are made up of undergraduate students taking introductory psychology courses over the course of a semester. Also conducted in Fall of 2014, Many Labs III systematically evaluated time-of-semester effects for 10 psychological effects across many participant pools. Twenty labs administered the same protocol across the academic semester. The aggregate data will provide evidence as to whether the time-of-semester moderates the detectability of effects.
- 6. Collaborative Replications and Education Project (CREP): The Collaborative Replications and Education Project facilitates student research training through conducting replications. The community-led team composed a list of studies that could be replicated as part of research methods courses, independent studies, or bachelor theses. Replication teams are encouraged to submit their results to an information commons for aggregation for potential publication. This integrates learning and substantive contribution to research.
- 7. Crowdsourcing a Dataset: Crowdsourcing a dataset is a method of data analysis in which multiple independent analysts investigate the same research question on the same data set in whatever manner they consider to be best. This approach should be particularly useful for complex data sets in which a variety of analytic approaches could be used, and when dealing with controversial issues about which researchers and others have very different priors. This first crowdsourcing project establishes a protocol for independent simultaneous analysis of a single dataset by multiple teams, and resolution of the variation in analytic strategies and effect estimates among them.

#### Infrastructure

 Open Source Developers: The Center for Open Science is a Python-based, open source development shop. Developers who want to support open science should definitely consider contributing to our open source community. The Open Science Framework, the flagship platform of the Center for Open Science, is a web application for supporting the research workflow. Essentially, the Center for Open Science wants to bring the core philosophy of open source development to science. Developers have the opportunity to contribute to maturing products, like the Open Science Framework, or to new projects that help make science better.

#### Interest Groups

1. Ambassadors: Center for Open Science ambassadors act as the local authority on the Center for Open Science, the Open Science Framework, and open science practices in their community. They are trained to talk about the Center for Open Science, lead Open Science Framework demonstrations, and represent us at conferences and meetings. Researchers in any field and from



any country can become COS Ambassadors. This is a great opportunity to promote open science in your community and help us work to increase openness, integrity, and reproducibility across scientific domains.

2. Open Science Collaboration: The Open Science Collaboration is a network of researchers, professionals, citizen scientists, and others with an interest in open science, metascience, and good scientific practices. The goal of the Open Science Collaboration is to promote open collaboration of scientific ideas. Collaboration and broadcasting of problems increases the odds a person with the right expertise will see it and be able to solve it easily. In the same vein, collaboration can lead to novel solutions to problems being found. Collaboration also means that projects can be more ambitious, as more people with a variety of expertise and experience are involved to help distribute the work.

Workshop held at the Center for Open Science in 2014 aimed at creating standards for promoting reproducible research in the social-behavioral sciences. Representatives from across disciplines (economics, political science, psychology, sociology, medicine), from funders (NIH, NSF, Laura and John Arnold Foundation, Sloan Foundation), publishers (Science/AAAS, APA, Nature Publishing Group), editors (American Political Science Review, Psychological Science, Perspectives on Psychological Science, Science), data archivists (ICPSR), and researchers from over 40 leading institutions (UC Berkeley, MIT, University of Michigan, University of British Columbia, UVA, UPenn, Northwestern, among many others) came together to push forward on specific action items researchers and publishers can do to promote transparent and reproducible research. http://bitss.org/2014/11/06/creating-standards-for-reproducible-research-overview-of-cos-meeting/

#### **Robert Wood Johnson Foundation (RWJ)**

http://www.rwjf.org/reports/grr/038967.htm#int\_biblio

Anderson F. "Science Advocacy and Scientific Due Process." Issues in Science and Technology, 16(Summer): 71–76, 2000.

Reports

Anderson F, Edens G and Sargeant T. Science Advocacy and Scientific Due Process: Sourcebook of Materials. Washington: Cadwalader, Wickersham & Taft, 2000.

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib A Case Study of Industry Documents From Rofecoxib Litigation <u>http://www.rwjf.org/en/library/research/2008/04/guest-authorship-and-ghostwriting-in-publications-related-to-rof.html</u>

What's Behind Large Disparities in NIH Research Funding

In 2011, the National Institutes of Health revealed, through their own research, that only 16 percent of grant applications submitted by African American researchers were funded. The number for White researchers was 29 percent. Here, Robert Wood Johnson Foundation (RWJF) experts answer questions about the problem, possible solutions and how researchers should proceed.

http://www.rwjf.org/en/library/articles-and-news/2011/12/breaking-new-ground-in-research/whats-behind-largedisparities-in-nih-research-funding.html

#### **Sloan Foundation**

Opportunities: Big Data is a Big Deal (beginning on page 15)

Launched in 2011 and led by Program Director Joshua M. Greenberg, the Foundation's Digital Information Technology program aims to leverage developments in digital information technology to empower scientists, enable new forms of data intensive research, and improve and expand the dissemination and evaluation of



scholarship. The program has two dimensions, one outward- and one inward-facing. In its outward-facing dimension, the program works directly with researchers, technologists, engineers, academic publishers, and university administrators to speed the development and adoption of tools, standards, norms, and practices that will enable researchers to better communicate with one another and more effectively work with large datasets. It also aims to facilitate the creation of career paths for data scientists and to educate the scholarly community about new big data opportunities, methods, and challenges. In its inward-facing dimension, the program seeks to support and encourage the effective use of new datasets, data repositories, data dissemination, and computational techniques across Sloan's other grant making programs. Big data makes it possible to both improve the quality of existing research and expand the set of questions amendable to scientific investigation and analysis. http://www.sloan.org/fileadmin/media/files/annual\_reports/2013-Annual-Report.pdf

<u>http://www.sloan.org/major-program-areas/?L=0</u> (See funding work under Center for Open Science, Inc. above)

### **Scientific Integrity Work by Associations**

American Association for the Advancement of Science (AAAS) http://www.aaas.org/page/scientific-integrity

In 2006, at the 31st annual AAAS Forum on Science and Technology Policy, a Forum panel that explored the subtle dilemmas of science ethics and integrity http://www.aaas.org/news/aaas-panel-explores-subtle-dilemmas-science-ethics-and-integrity

"Forbidding science? Balancing freedom, security, innovation, & precaution" Workshop held on January 12-13, 2006 Conference cosponsored with AAAS that explored whether and how restrictions on scientific research should be imposed [2006]

#### **Council of Science Editors**

The Council of Science Editors (CSE) is an international membership organization for editorial professionals publishing in the sciences. Our purpose is to serve over 800 members in the scientific, scientific publishing, ad information science communities by fostering networking, education, discussion, and exchange. Our aim is to be an authoritative resource on current and emerging issues in the communication of scientific information.

CSE has an Editorial Policy Committee- The Editorial Policy Committee serves as a resource regarding editorial and publishing policies applying to publications in the sciences. The committee studies and analyzes procedural, ethical, legal, and economic policies and recommends policies and/or guidelines that relate to the editing, review, and publication of manuscripts in books and journals in the sciences. The committee may suggest policy to the CSE board of directors affecting CSE's own publications. Policy guidelines developed by the committee will be presented to the membership via publication in Science Editor and the Web site, by presentation at CSE annual meetings, or in other ways, and after appropriate revision in consultation with the board, may be published and disseminated by CSE through the Publications, Education, Membership, and Program Committees.



White Paper on Publication Ethics CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update (approved by the CSE Board of Directors on March 30, 2012) **PDF of the** <u>entire White Paper</u>

#### Introduction to White Paper:

The Council of Science Editors and its Editorial Policy Committee encourage everyone involved in the journal publishing process to take responsibility for promoting integrity in scientific journal publishing. This paper will serve as a basis for developing and improving effective practices to achieve that goal. We first wrote this white paper in 2006 and it was last updated in 2009. For the 2012 Update, we substantially revised and updated each section; included information on citation manipulation, publication planning by study sponsors, and ethical conduct of sponsors; reorganized the section on reporting suspect manuscripts; updated information on international models for responding to research misconduct; and provided more recent examples of corrections, retractions, and expressions of concern. Through this White Paper and other activities, the Editorial Policy Committee aims to open dialogue about ethical publishing practices, inform those involved in the editorial process, and foster informed decision-making by editors. We intend to work with other professional organizations to shape the scientific journal environment so the integrity of our publications is upheld. With the understanding that what may be appropriate for one discipline or organization may not be so for another, the White Paper intends to inform and guide rather than direct. Where there is more published information available from the biomedical community on some of the topics in this paper, more references or examples in those areas are given. However, our intention is to provide information that is useful to all the sciences. Please help us to keep this living document current by pointing out areas that need to be expanded or updated. We will build on the work of this White Paper through the continued work of the Committee and your contributions. Please send comments and suggestions to CSE@CouncilScienceEditors.org and include "Editorial Policy Committee" in the subject line

#### **American Chemical Society (ACS)**

Scientific Integrity in Public Policy ACS Position Statement http://www.acs.org/content/acs/en/policy/publicpolicies/promote/scientificintegrity.html

#### "Catching Errors: Peer Review and Retractions in Publishing"

#### Thursday, April 16, 2015, 2:00-3:00 PM ET

We have all seen the headlines where unintentional errors and falsified data have caused papers to be retracted. These instances can damage the reputation of the researchers, journals, and the institutions associated with the erroneous research. Join Dr. Ivan Oransky of *Retraction Watch*, Dr. Charon Pierson of the Governing Council of the Committee on Publication Ethics (see more on this organization below), and Dr. James DuBois of the Center for Clinical Research Ethics (see more on this organization below) as they discuss the efforts that are being made to combat this issue as well as what could be changed to improve the review process.

#### Center for Science in the Public Interest (CSPI)

Integrity in Science Project 2006

Promoting Disclosure http://www.cspinet.org/integrity/disclosure.html

The Integrity in Science project promotes full disclosure of conflicts of interest when scientists publish in journals, are quoted in the press or appear before legislative or regulatory bodies at all levels of government. The project and its allies in the scientific community believe total disclosure of conflicts of interest is mandatory if the public is to maintain its faith in the integrity of the scientific process, and the government is to remain a fair and



impartial arbiter of scientific disputes that determine the laws and regulations that affect the health and safety of the American people.

## **Scientific Integirty Work by Other Organizations**

#### Center for Clinical Research Ethics (CCRE)

The **Center for Clinical Research Ethics** (CCRE) was established through a partnership between the Institute of Clinical and Translational Sciences (ICTS) at Washington University and the Center for Health Care Ethics at Saint Louis University, both in St. Louis, MO.

The Center for Clinical Research Ethics (CCRE):

- Helps ensure that all ICTS trainees receive training in clinical research ethics (CRE) and the responsible conduct of research (RCR) that exceeds the minimum standards set by NIH;
- Conducts and supports collaborative research on clinical research ethics, research integrity, and the intersection of ethics and community engagement; and
- Shares expertise in research ethics with individuals, policy committees, and others through consulting activities.

#### **CCRE** Education

- CCRE aims to help ensure that all ICTS trainees receive **training in clinical research ethics** (**CRE**) **and the responsible conduct of research** (**RCR**)that exceeds the minimum standards set by the National Institutes of Health. We accomplish this aim by directing the course, M17-510 "Ethical and Regulatory Issues in Clinical Research" and by providing speakers in the "Research Ethics Lecture Series" of the Human Research Protections Office at Washington University.
- The <u>Professional Integrity</u> (PI) program (previously known as Restoring Professionalism and Integrity in Research or RePAIR) provides intensive professional development education for investigators who have engaged in wrongdoing or unprofessional behavior. The PI Program will also sponsor a webinar series on institutional strategies for preventing wrongdoing and fostering professionalism in research.
- We also offer a library of research case studies.
- The Institute for Clinical and Translational Sciences (ICTS) and the Office of the Vice Chancellor for Research (OVCR) at Washington University in St. Louis jointly sponsor a course on the responsible conduct of research (RCR). The RCR course is designed to satisfy the National Institutes of Health Requirement for Instruction in the Responsible Conduct of Research. It may also be incorporated into plans to satisfy National Science Foundation RCR training requirements.

**CCRE** Consultations



- Consultation on Training: We consult with training grant program directors to assist them in developing, identifying, or describing training in the Responsible Conduct of Research (RCR) or Clinical Research Ethics (CRE). Ongoing collaboration with CCRE faculty on funded training programs should be budgeted into grant applications.
- Consultation on Research Design: We consult on the design of research on ethical issues in human subjects research, research integrity, and ELSI in genetics. An initial consultation is funded by the CTSA. Ongoing collaboration with CCRE faculty on funded research projects should be budgeted into grant applications.

#### Current Projects

CCRE faculty have ongoing research and scholarly projects in the areas of mental health research ethics, understanding and preventing wrongdoing in research, community engagement strategies for addressing questions of research ethics, disclosure of results of genetic testing, and first-in-human research. CCRE faculty research has received support from the US Office of Research Integrity, the National Institutes of Health, the Greenwall Foundation, and other agencies. See the recent CCRE **publications** and a list of **grants and contracts**.

- DuBois, J.M. "The Role of Culture and Experience in the Perception of Research Regulations, Norms and Values," Office of Research Integrity, HHS (IR-ORI-14-001-018712). 8/1/2014-7/31/2016. \$98,360. Principal Investigator.
- DuBois, J.M. "Validating Outcome Measures for Remediation of Research Wrongdoing," Office of Research Integrity, HHS (1 ORIIR 130002-01-00). 9/1/2013-8/31/2015. \$277,700. Principal Investigator.
- DuBois, J.M. "Preventing Ethical Disasters in the Practice of Medicine," NIH National Institute of Aging (1R01AG043527-01). 6/1/2013-5/31/2018. \$1,258,500. Principal Investigator.
- DuBois, J. M. "Restoring Professionalism and Integrity in Research (RePAIR)," \$500,000 funded by NIH (Administrative Supplement to WU ICTS). September 17, 2007-May 31, 2012. DuBois is serving as Project Director for this project and PI of the SLU subaward (\$476,564). The project involves developing a curriculum for a remediation training program for investigators caught violating the rules for the responsible conduct of research.
- DuBois, J. M. "ORI Research Integrity Casebook," \$155,579 funded by the Office of Research Integrity . March 1, 2011-September 30, 2012. *The major goal of this project is to produce a casebook that is suitable for use in face-to-face training in the responsible conduct of research.*
- Solomon, S. Sarah Gehlert (Site PI for WU) "Development of a Nationally Implementable, Locally Deliverable Human Research Participants Training Workshop for Community-Based Researchers, Collaborators and Staff." (2011). Supplement to the CTSA from the National Center for Research Resources, National Institutes of Health to Michigan Institute for Clinical and Health Research (MICHR), \$34,513
- DuBois, J. M. "Environmental Factors Predictive of Misbehavior in Collaborative Health Research," National Institutes of Health (1R21RR026313-01). 9/25/2009-8/31/2010. \$376,000. Principal Investigator.
- DuBois, J. M. "Environmental Factors Associated with Professional Misconduct in Medical Research and Practice," BF Foundation. 1/1/2009-12/31/2011. \$100,000. Principal Investigator.



- DuBois, J. M. "Responsible Conduct of Research Instructional Assessment Program. Part II," Office of Research Integrity, Contract, 7/1/2008-9/30/2009. \$60,000, Principal Investigator.
- DuBois, J. M. "Center for Clinical Research Ethics," within the Washington University of St. Louis, Institute for Clinical and Translational Science. (NIH: 1 U54 RR023496-01A1, Principal Investigator: Polonsky, K.) 9/1/2007-8/31/2012. Role: 15% effort as Director. \$500,000 subcontract with St. Louis University, DuBois, Principal Investigator.
- DuBois, J. M. "Best Practices in Mental Health Research Ethics Conference Series," National Institute of Mental Health (1R13MH079690). 9/1/2007 8/31/2011. \$200,000. Principal Investigator.

#### **Committee on Publication Ethics (COPE)**

The Committee on Publication Ethics (COPE) was established in 1997 by a small group of medical journal editors in the UK but now has over 9000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics. Several major publishers (including <u>Elsevier</u>, <u>Wiley–Blackwell</u>, <u>Springer</u>, <u>Taylor & Francis, Palgrave</u> <u>Macmillan</u> and <u>Wolters Kluwer</u>) have signed up some, if not all, of their journals as COPE members.

COPE provides advice to editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases. COPE does not investigate individual cases but encourages editors to ensure that cases are investigated by the appropriate authorities (usually a research institution or employer).

All COPE members are expected to follow the Code of Conduct for Journal Editors.

COPE has produced an eLearning course for new editors. Eleven modules in total, the course currently includes: An Introduction to Publication Ethics, Plagiarism, and Authorship among others. COPE also funds <u>research</u> on publication ethics, organizes <u>annual seminars</u> globally and has created an <u>audit tool</u> for members to measure compliance with its <u>Code of Conduct and Best Practice Guidelines for Journal Editors</u>.

- COPE Code of Conduct and Best Practice Guidelines for Journal Editors
- <u>Flowcharts</u> on how to handle common ethical problems
- Other <u>COPE guidelines</u> (eg on retractions)
- <u>Sample letters</u> (to adapt for use)
- <u>Database of all cases</u> discussed at COPE Forum (including podcasts of the discussion (where available), the advice given and the outcome of cases)



## **Scientific Integrity Literature Review**

A search through PubMed using the guidelines of publications in the past ten years (2005-2015) and the key terms "scientific integrity", "research integrity", and "misconduct", resulted in 835 publications. We have not evaluated all these publications but instead narrowed the search terms to the following:

# Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND research integrity; scientific integrity; transparency; misconduct; ethics Results: 13

Protecting our science. Seixas NS. Ann Occup Hyg. 2013 Oct;57(8):963-5. doi: 10.1093/annhyg/met056. PMID: 24130260 Related citations

Transparency for each research article. Institutions must also be accountable for research integrity.

Cosentino M, Picozzi M. BMJ. 2013 Sep 10;347:f5477. doi: 10.1136/bmj.f5477. No abstract available. PMID: 24022040 Related citations

Conflicts of interest for medical publishers and editors: protecting the integrity of **scientific**scholarship. Desai SS, Shortell CK. J Vasc Surg. 2011 Sep;54(3 Suppl):59S-63S. doi: 10.1016/j.jvs.2011.05.111. PMID: 21872119 Related citations

Misinformation in the medical literature: what role do error and fraud play?

Steen RG. J Med **Ethics**. 2011 Aug;37(8):498-503. doi: 10.1136/jme.2010.041830. Epub 2011 Feb 22. PMID: 21343631 <u>Related citations</u>

Editors' overview: topics in the responsible management of **research** data. Giffels J, Vollmer SH, Bird SJ. Sci Eng **Ethics**. 2010 Dec;16(4):631-7. doi: 10.1007/s11948-010-9243-1. Epub 2010 Oct 28. PMID: 20981506

<u>Rethinking the meaning of being a scientist--the role of scientific integrity boards and some thoughts</u> about scientific culture.

Werner-Felmayer G. Med Law. 2010 Sep;29(3):329-39. PMID: 22145555 Related citations

Publication ethics. Morton NS.



Paediatr Anaesth. 2009 Oct;19(10):1011-3. doi: 10.1111/j.1460-9592.2009.03086.x. Epub 2009 Jun 13. Review. PMID: 19619189 Related citations

Role of editors and journals in detecting and preventing **scientific** misconduct: strengths, weaknesses, opportunities, and threats.

Marusic A, Katavic V, Marusic M. Med Law. 2007 Sep;26(3):545-66. PMID: 17970252 Related citations

When conflict-of-interest is a factor in **scientific** misconduct.

Krimsky S. Med Law. 2007 Sep;26(3):447-63. PMID: 17970245 <u>Related citations</u>

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

**Research** integrity and pharmaceutical industry sponsorship.

Gøtzsche PC. Med J Aust. 2005 Jun 6;182(11):549-50. PMID: 15938676 Related citations

The IARC monographs program: changing attitudes towards public health. Tomatis L. Int J Occup Environ Health. 2002 Apr-Jun;8(2):144-52. PMID: 12019681 Related citations

The Medical **Research** Council's approach to allegations of **scientific** misconduct. Evans I. Sci Eng **Ethics**. 2000 Jan;6(1):91-4. PMID: 11273442 Related citations

Research misconduct definitions adopted by U.S. research institutions. Resnik DB, Neal T, Raymond A, Kissling GE. Account Res. 2015;22(1):14-21. doi: 10.1080/08989621.2014.891943. PMID: 25275621 Related citations



#### Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND scientific integrity; research integrity; quality of papers Results: 78 We have highlighted 12 of the publications that are most relevant.

Research ethics education for community-engaged research: a review and research agenda. Anderson EE, Solomon S, Heitman E, DuBois JM, Fisher CB, Kost RG, Lawless ME, Ramsey C, Jones B, Ammerman A, Ross LF. J Empir Res Hum Res Ethics. 2012 Apr;7(2):3-19. doi: 10.1525/jer.2012.7.2.3. Review. PMID: 22565579 Related citations

Professional ethics: an overview from health research ethics point of view.

Nyika A. Acta Trop. 2009 Nov;112 Suppl 1:S84-90. doi: 10.1016/j.actatropica.2009.07.033. Epub 2009 Aug 7. Review. PMID: 19665439 Related citations

Fraud and misconduct in science: the stem cell seduction: Implications for the peer-review process. van der Heyden MA, van de Ven T, Opthof T. Neth Heart J. 2009 Jan;17(1):25-9. PMID: 19148335 <u>Related citations</u> "The (anonymous) peer review process serves as goalkeeper of scientific quality rather than scientific integrity."

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

Making sense of research: A guide for critiquing a paper.

Stockhausen L, Conrick M. Contemp Nurse. 2002 Dec;14(1):38-48. Review. PMID: 16114192 Related citations

Beyond conflict of interest: the responsible conduct of **research**. Rhoades LJ. Sci Eng Ethics. 2002 Jul;8(3):459-68. Review. PMID: 12353376



#### Related citations

Maintaining data integrity in randomized clinical trials. Moody LE, McMillan S. Nurs Res. 2002 Mar-Apr;51(2):129-33. PMID: 11984384 <u>Related citations</u>

[Quality assurance of data collection and data processing in epidemiologic study data]. Greiner M, Baumann MP, Zessin KH. Dtsch Tierarztl Wochenschr. 2001 Nov;108(11):443-9. German. PMID: 11765598 <u>Related citations</u>

#### Guidelines for quality assurance in multicenter trials: a position paper.

Knatterud GL, Rockhold FW, George SL, Barton FB, Davis CE, Fairweather WR, Honohan T, Mowery R, O'Neill R. Control Clin Trials. 1998 Oct;19(5):477-93. PMID: 9741868 <u>Related citations</u>

**Quality** data: what are they?

Sforza VA. Ann Ist Super Sanita. 1994;30(4):439-43. PMID: 7762939 <u>Related citations</u>

#### Research data integrity: a result of an integrated information system.

Cranmer MF, Lawrence LR, Konvicka AK, Taylor DW, Herrick SS. J Toxicol Environ Health. 1976 Nov;2(2):285-99. PMID: 1011288 Related citations

A guide to critiquing a research paper on clinical supervision: enhancing skills for practice. Fothergill A, Lipp A. J Psychiatr Ment Health Nurs. 2014 Nov;21(9):834-40. doi: 10.1111/jpm.12161. Epub 2014 May 13. PMID: 24818837 Related citations

#### **Other Notable Publications Found**

<u>Peer review.</u> **Twaij H**, Oussedik S, Hoffmeyer P. Bone Joint J. 2014 Apr;96-B(4):436-41. doi: 10.1302/0301-620X.96B4.33041. Review. PMID: 24692607 <u>Related citations</u>



Peer review: a view based on recent experience as an author and reviewer. Clark RK. Br Dent J. 2012 Aug;213(4):153-4. doi: 10.1038/sj.bdj.2012.721. PMID: 22918342 Related citations

<u>Good practice in reviewing and publishing studies on herbal medicine, with special emphasis on traditional Chinese medicine and Chinese materia medica.</u>

**Chan K**, **Shaw D**, Simmonds MS, Leon CJ, Xu Q, Lu A, Sutherland I, Ignatova S, Zhu YP, Verpoorte R, Williamson EM, Duez P. J Ethnopharmacol. 2012 Apr 10;140(3):469-75. doi: 10.1016/j.jep.2012.01.038. Epub 2012 Feb 11. Review. PMID: 22330011

Related citations

From:onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of<br/>nutritionreviews@ilsi.orgSent:Wednesday, June 10, 2015 2:23 AMTo:Joanne LuptonCc:Subject:Reminder: Review Due in One Week

10-Jun-2015

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you kindly agreed to review Manuscript ID NUTR-REV-088-LA-04-2015, entitled "Consumption of whole grains and cereal fiber in relation to cancer risk: a systematic review of longitudinal studies." The manuscript is located in your Reviewer Center at <a href="https://mc.manuscriptcentral.com/nutr-rev">https://mc.manuscriptcentral.com/nutr-rev</a>.

This e-mail is simply a reminder that your review is due in one week. To directly access just the manuscript for review, with no need to enter log in details, please click the link below:

#### https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=ab753309935c41128ed555c4e4f4f00a

To log in to your account on the reviewing site, please go to <u>https://mc.manuscriptcentral.com/nutr-rev</u>. Your casesensitive USER ID is <u>ilupton@tamu.edu</u>. For security purposes, your password is not listed in this email. If you are unsure of your password, you may click the link below to set a new password.

#### https://mc.manuscriptcentral.com/nutr-rev?URL MASK=4f117d42fb584ecaad649911180a2b58

Your assistance in helping us deliver a timely evaluation to our authors is most sincerely appreciated. If you encounter any difficulties completing your review or accessing the reviewing site, please contact me directly.

With kind regards,

Allison Worden Publications Manager

Nutrition Reviews E-mail: <u>nutritionreviews@ilsi.org</u>

Present Knowledge in Nutrition E-mail:

cc. Dr. Sharon Donovan Editor

[email ref: ENR-SW-6-a]

From: Sent: To:	Suzanne Harris Tuesday. June 09. 2015 10:37 AM s.chang@griffith.edu.au; eisenbra@rhrk.uni-kl.de; Catherine Joanne Lupton;
Cc: Subject:	john.c.peters@ucdenver.edu; kwallace@d.umn.edu; weavercm@purdue.edu; carmel.james@griffith.edu.au; hemm REMINDER: Survey for ILSI Public Sector Trustees

I hope you will complete the short survey that I sent you two weeks ago. Your input is very important. Please respond by the deadline of **June 12, 2015**, if you can.

Thank you.

Suzie			
From: Suzanne	Harris		
Sent: Tuesday	May 26 2015 3:05 PM		
	s.chang@griffith.edu.au; scohe	en@unmc.edu; mdoyle@uga.edu;	
'adamdrew@u.w	vashington.edu':	Catherine Field	
	Joanne Lupton (Joanne.Lupto	on@agnet.tamu.edu); john.c.peters@ucdenver.edu;	
	;	; ; <u>kwallace@d.umn.edu</u> ;	
weavercm@purc	<u>due.edu</u> ; 'Flavio Zambrone'		
Cc: carmel.jame	es@griffith.edu.au; jbradford@unmc.edu;	; 'Haan	I,
Dawn E'; Michae	el Shirreffs		
Subject: Surve	y for ILSI Public Sector Trustees		
TO:	ILSI Public Sector Trustees		
FROM:	Suzie Harris		

The ILSI Board of Trustees Science Advisory Group, led by Dr. Alan Boobis and Dr. Peter van Bladeren, asked that we gather some information about the areas of expertise held by the ILSI public sector trustees and then by the branch public sector trustees and science advisors. With input from the ILSI Executive Committee, some questions were also added to get an idea of how involved you are with other science-based organizations like FAO and WHO.

We are using you as guinea pigs for this effort. I hope you will use this link

https://www.surveymonkey.com/r/Adviser Expertise

to access the survey and to complete it. At the end there are two questions to gauge what you thought of the earlier questions.

Please let me know if you have any questions. It would be very helpful if you would complete the survey by **Friday, June 12, 2015.** Thank you.

From:	onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of
	nutritionreviews@ilsi.org
Sent:	Tuesday, June 02, 2015 12:54 AM
То:	Joanne Lupton
Cc:	
Subject:	Second reminder: Request to review

02-Jun-2015

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited by Dr. Sharon Donovan to review a manuscript entitled "Consumption of whole grains and cereal fiber in relation to cancer risk: a systematic review of longitudinal studies" [Manuscript ID NUTR-REV-088-LA-04-2015]. A follow-up to that invitation was also sent, but we do not seem to have received a response.

In order to ensure your preference with regard to this invitation is recorded, and to avoid any undue delay in the processing of the submission, we would be grateful if you could indicate your ability to assist by clicking on the appropriate link below:

Agreed: https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=89b808e325ca4cd395fdb6bc9bcca3db

Declined: https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=f676b24130a04f36a9bfa873c7e74f67

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Your opinion on the suitability of this submission for possible publication in Nutrition Reviews will be highly valued by the editors. Please let us know if your schedule will permit you to accept.

Kind regards,

Nutrition Reviews nutritionreviews@ilsi.org

cc. Dr. Sharon Donovan [email ref: SE-33-a] From: Sent: To: Delia Murphy Monday, June 01, 2015 2:17 PM DAllison@uab.edu;

mdoyle@uga.edu; dwyerj1@od.nih.gov; jwerdman@illinois.edu; ; Eric Hentges; james.hill@ucdenver.edu;

dblund@wisc.edu; Joanne Lupton;

	weavercm@purdue.edu;
Cc:	Alison Kretser
Subject:	ILSI North America Invite to June 16 Public-Private Partnership Principles Unveiling

To: ILSI North America Scientific Integrity Working Group

Re: Invitation to the Public Unveiling of A Transparent, Actionable Framework for Food and Nutrition Research Public-Private Partnerships

Below is the invitation to the Public Unveiling of A Transparent, Actionable Framework for Food and Nutrition Research Public-Private Partnerships. This is the public unveiling of the set of principles for research public-private partnerships that were agreed upon and endorsed by a group of federal agencies and nutrition, food science, and food safety professional societies at a meeting held in December 2014. At this meeting at the National Academy of Sciences building on June 16, the set of principles (based on the ILSI North America set of principles published in October 2013 in *Nutrition Reviews*) will be shared. The full agenda is available by click on the link below.

If Working Group members would like to attend the Unveiling, we encourage you to RSVP to the invitation below.

Thank you, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America:

From: American Society for Nutrition [mailto:sohlhorst@nutrition.org]
Sent: Thursday, May 21, 2015 2:03 PM
To: Delia Murphy
Subject: Invite to June 16 Public-Private Partnership Principles Unveiling



Hosted by

American Society for Nutrition ASN Foundation	



EX SafeUnsubscribe

This email was sent to <u>dmurphy@ilsi.org</u> by <u>sohlhorst@nutrition.org</u> | <u>Update Profile/Email Address</u> | Rapid removal with <u>SafeUnsubscribe</u><sup>™</sup> | <u>Privacy Policy</u>.



American Society for Nutrition | 9650 Rockville Pike | Bethesda | MD | 20814

From:	onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of nutritionreviews@ilsi.org
Sent:	Sunday, May 31, 2015 12:56 AM
То:	Joanne Lupton
Cc:	
Subject:	Reminder: Request to review

31-May-2015

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited to review a manuscript entitled "Consumption of whole grains and cereal fiber in relation to cancer risk: a systematic review of longitudinal studies" [Manuscript ID NUTR-REV-088-LA-04-2015] for Nutrition Reviews, but a response to that invitation has not yet been received.

In order to ensure the review process proceeds in a timely fashion, this invitation is being extended again. To automatically register your response, please click on the appropriate link below:

Agreed: https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=2e6afa84b6454931a8e09941482f2553

Declined: https://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=23c5df32a38144059bbce7d7c61f0db1

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Thank you for considering this invitation. I hope your schedule will allow you to accept.

Sincerely,

Sharon Donovan Associate Editor, Nutrition Reviews 2013 Impact Factor 5.541 www.nutritionreviewsjournal.com

[email ref: SE-32-a]
From: Sent: To:	Delia Murphy Wednesday, May 27, 2015 12:34 PM DAllison@uab.edu; @foodsci.umass.edu; mdoyle@uga.edu; dwyerj1@od.nih.gov; jwerdman@illinois.edu; m; Eric Hentges; james.hill@ucdenver.edu;	
	; dblund@wisc.edu; Joanne Lupton;	;
Cc: Subject: Attachments:	Sullivan; weavercm@purdue.edu; Alison Kretser ILSI North America Scientific Integrity Working Group 5-27-15_Plan of Work for Scientific Integrity.docx; Scientific Integrity Organizations and in the Current Literature.docx	; Shawn ; y Work by Various

To: ILSI North America Scientific Integrity Working Group Re: Draft Plan of Work

Please find attached the draft plan of work for the ILSI North America Scientific Integrity Working Group which reflects the discussion at the 30 April meeting of the Working Group. Also attached is the Compilation of Scientific Integrity Work by Various Organizations and in the Current Literature presented at the meeting and referenced in the plan of work.

<u>Please read the document and provide comments or edits to the draft by COB Friday, 12 June.</u> The revised document will then be re-distributed to the Working Group for final approval.

The draft plan of work will be shared with the ILSI North America Board of Trustees' Executive Committee on a conference call on 2 June. It will be clearly stated that this current version is a draft and has not been finalized by the Working Group.

The meeting minutes from the 30 April meeting are nearing completion and will be distributed to the Working Group as soon as possible.

Please let Alison and I know if you have any questions.

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America:



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

# <u>Compilation of Scientific Integrity Work by Various Organizations and in the</u> <u>Current Literature</u>

# **Scientific Integrity Work by Federal Agencies**

#### **Presidential Memorandum for the Heads of Executive Departments and Agencies** March 9, 2009

https://www.whitehouse.gov/the\_press\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/

#### Office of Science and Technology Policy (OSTP)

Directive on Scientific Integrity- December 17, 2010 This document is the implementation guide for the federal agencies to respond to the Presidential Memorandum. https://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

Scientific Integrity Report Card

As of July 2013, fifteen agencies have released final scientific integrity policies. http://www.peer.org/assets/docs/About SI Report Card and Disclaimer.pdf

#### **National Science Foundation**

The National Science Foundation (NSF) is an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense..." With an annual budget of \$7.3 billion (FY 2015), we are the funding source for approximately 24 percent of all federally supported basic research conducted by America's colleges and universities. In many fields such as mathematics, computer science and the social sciences, NSF is the major source of federal backing.

NSF Scientific Integrity Policy- released after December 2010

It is the policy of NSF to maintain a culture of scientific integrity in accordance with the President's March 9, 2009 Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity and the implementation guidance in the Office of Science and Technology Policy (OSTP) December 17, 2010 Memorandum. NSF's policy applies to civil service employees; visiting scientists, engineers, and educators; those working at NSF under the Intergovernmental Personnel Act; and political appointees.

http://www.nsf.gov/bfa/dias/policy/si/sipolicy.pdf

Responsible Conduct of Research (RCR)- released after August 2007 when the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act was signed into law. http://www.nsf.gov/bfa/dias/policy/rcr.jsp

NSF's Research Misconduct regulation is found at 45 CFR 689.

The above regulation only applies to conduct that occurred on or after April 17th, 2002. For alleged misconduct that occurred before April 17, 2002, we use <u>this</u> definition and follow the procedure described in 45 CFR 689 above.



Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up results and recording or reporting them
- Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit,
- Policy defines "research" and "research record"

https://www.nsf.gov/oig/session.pdf

Searches for "scientific integrity" and "research integrity" grants results included many grants awarded in the 1990s but it seems that not as many have been funded more recently

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22scientific+integrity%22+%22research+integrity%22+&ActiveAwards=true&ExpiredAwards=true

**Collaborative Research: Foundations of Social and Ethical Responsibility Among Undergraduate Engineering Students: Comparing Across Time, Institutions, and Interventions** 

Award Number: 1449479; Principal Investigator: Brent Jesiek; Co-Principal Investigator: Carla Zoltowski; Organization: Purdue University; NSF Organization: SES Start Date: 05/15/2015; Award Amount: \$260,491.00; Relevance: 29.51;

Research grants for "research misconduct" have taken place recently, including:

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22research+misconduct%22

#### The Nature of Ethical Decision-Making in Research

Award Number:0924751; Principal Investigator: R. Wayne Fuqua; Co-Principal Investigator: David Hartmann, Thomas Van Valey; Organization: Western Michigan University; NSF Organization: SES Start Date:10/01/2009; Award Amount:\$357,073.00; Relevance:77.79;

#### **Gaming Against Plagiarism**

Award Number:1033002; Principal Investigator: Michelle Foss Leonard; Co-Principal Investigator: Amy Buhler, Margeaux Johnson, James Oliverio, Douglas Levey, Benjamin DeVane; Organization: University of Florida; NSF Organization: IIS Start Date:09/01/2010; Award Amount:\$298,660.00; Relevance:72.24; <a href="http://digitalworlds.ufl.edu/projects/gap/">http://digitalworlds.ufl.edu/projects/gap/</a>

#### **Department of Health and Human Services (HHS)**

Policies and Principles for Assuring Scientific Integrity Published in 2011 http://aspe.hhs.gov/sp/scientificintegrity/principles/index.cfm

**Office of Research Integrity** 

https://ori.hhs.gov/

In 2000, ORI began the <u>Research on Research Integrity (RRI) Program</u> and the biennial <u>Research Conferences on</u> <u>Research Integrity</u> to expand the knowledge base and develop a research community focused on the responsible conduct of research, research integrity, and research misconduct. That same year ORI started the <u>Rapid Response</u> <u>for Technical Assistance</u> to provide early and direct assistance to institutions assessing research misconduct allegations.



In 2002, ORI launched the Responsible Conduct Research (RCR) <u>RCR Resource Development Program</u> and the <u>RCR Program for Academic Societies</u>. The former program was designed to facilitate the development of materials for teaching the responsible conduct of research by the research community for use in the research community. The latter program, a collaboration with the Association of American Medical Colleges, supported activities within academic societies designed to promote the responsible conduct of research among their members. The first RCR Expo was held in 2003 to call attention to the new RCR materials. ORI published the <u>ORI Introduction to the Responsible Conduct of Research</u> in 2004 and began the <u>RCR Program for Graduate Schools</u> in collaboration with the Council of Graduate Schools to institutionalize RCR education in graduate training.

A new regulation, <u>PHS Policies on Research Misconduct (pdf)</u>, became effective on June 16, 2005. The regulation is codified at 42 C.F.R. Part 93. ORI began developing a training program for institutional research integrity officers (RIOs) in 2005 that produced an orientation video in 2006 and boot camps in 2007. In 2007, ORI also began the <u>RCR Program for Postdocs</u> and took another step toward the creation of a laboratory management training program in collaboration with the Laboratory Management Institute at the University of California-Davis to develop on-line instruction on laboratory management. Previously, ORI organized the first national conference on the management of biomedical research laboratories in 1998 in collaboration with the University of Arizona and supported the development of instructional resources on laboratory management through its RCR Resource Development Program.

"The Lab: Avoiding Research Misconduct": An Interactive Movie on Research Misconduct In "The Lab: Avoiding Research Misconduct," you become the lead characters in an interactive movie and make decisions about integrity in research that can have long-term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices. http://ori.hhs.gov/THELAB

The National Science Foundation and the Office of Research Integrity at the Department of Health and Human Services jointly confirm about 20 cases a year of research misconduct, according to Steneck. The actual number could be 10 times that or more, he said, because some researchers suspect but do not report misconduct, some institutions fail to undertake rigorous investigations and some journals find but do not report misconduct.

#### National Institutes of Health (NIH)

NIH Policies and Procedures for Promoting Scientific Integrity November 2012 http://www.nih.gov/about/director/sci-int-nov2012.pdf

NIH has not yet finalized the most recent language providing guidance to reviewers <u>http://enhancing-peer-review.nih.gov/guidance\_reviewers.html</u> <u>http://grants.nih.gov/grants/peer/peer.htm</u>

NIH hosts a workshop with journals to unite on reproducibility:

A group of editors representing more than 30 major journals; representatives from funding agencies; and scientific leaders assembled at the American Association for the Advancement of Science's headquarters in June 2014 to discuss principles and guidelines for preclinical biomedical research. The gathering was convened by the US National Institutes of Health, *Nature* and *Science* (see *Science* **346**, 679; 2014). The discussion ranged from what journals were already doing to address reproducibility — and the effectiveness of those measures — to the magnitude of the problem and the cost of solutions. The attendees agreed on a common set of Principles and Guidelines in Reporting Preclinical Research



(see go.nature.com/ezjl1p) that list proposed journal policies and author reporting requirements in order to promote transparency and reproducibility.

NIH plans to enhance reproducibility:

- NIH is developing a training module on enhancing reproducibility and transparency of research findings, with an emphasis on good experimental design.
- Several of the NIH's institutes and centres are also testing the use of a checklist to ensure a more systematic evaluation of grant applications.
- A pilot was launched last year that we plan to complete by the end of this year to assess the value of assigning at least one reviewer on each panel the specific task of evaluating the 'scientific premise' of the application: the key publications on which the application is based (which may or may not come from the applicant's own research efforts).
- Big Data initiative, the NIH has requested applications to develop a Data Discovery Index (DDI) to allow investigators to locate and access unpublished, primary data (see go.nature.com/rjjfoj).
- in mid-December, the NIH launched an online forum called PubMed Commons (see go.nature.com/8m4pfp) for open discourse about published articles.
- NIH is contemplating modifying the format of its 'biographical sketch' form, which grant applicants are required to complete, to emphasize the significance of advances resulting from work in which the applicant participated, and to delineate the part played by the applicant.
- NIH is examining ways to anonymize the peer-review process to reduce the effect of unconscious bias (see go.nature.com/g5xr3c)

http://www.nature.com/news/policy-nih-plans-to-enhance-reproducibility-1.14586

NIH Regional Consultation Meeting on Peer Review

October 22, 2007 – Washington, D.C. Meeting Summary: <u>http://enhancing-peer-review.nih.gov/meetings/102207-summary.html</u>

#### Food and Drug Administration (FDA)

http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm

FDA has a long and continuing history of promoting an environment of robust scientific debate, where the integrity of information is ensured, all views are carefully considered, and scientific decisions are protected from political influence. In 2009, we established **FDA's Office of Scientific Integrity** (OSI). OSI works to:

- 1. ensure that FDA's policies and procedures are current and applied across the Agency;
- 2. resolve scientific disputes that may arise internally or externally and that are not resolved at the Agency's Center levels; and
- 3. advise the Chief Scientist and other senior FDA leaders on appropriate responses.

#### **Centers for Disease Control and Prevention (CDC)**

The Office of the Associate Director for Science (OADS) provides service and support to the CDC scientists as they work to protect people's health and improve the quality of their lives. Our focus is on strengthening the quality and integrity of CDC's science. Furthermore, by fostering innovative and successful scientific collaborations and partnerships we are also working towards enhancing the relevance of our science and its health impact.

Our office is also a home to the Office of Science Quality (OSQ) which is responsible for advancing the quality of CDC's science and championing the translation of research through the development of science policies and best practices (e.g., authorship, scientific clearance, peer review, and extramural research policies); and the Office of Scientific Integrity, which ensures that CDC science and research activities comply with various federal laws,



regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.

http://www.cdc.gov/od/science/aboutus/index.htm

#### **Environmental Protection Agency (EPA)**

EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote scientific and ethical standards and to create a proactive culture to support them. The policy establishes a Scientific Integrity Committee to implement the policy. The Committee consists of Deputy Scientific Integrity Officials that represent each of the Agency's Program Offices and Regions. The Scientific Integrity Official (ScIO) chairs the Committee. The ScIO is the Agency's focal point on scientific integrity and serves as the Agency's expert on such matters.

EPA Scientific Integrity Policy (PDF)

#### http://www2.epa.gov/osa/basic-information-about-scientific-integrity

Definition of Scientific Integrity: Scientific Integrity results from adherence to professional values and practices, when conducting and applying the results of science and scholarship. It ensures:

- Objectivity
- Clarity
- Reproducibility
- Utility

Scientific Integrity is important because it provides insulation from:

- Bias
- Fabrication
- Falsification
- Plagiarism
- Outside interference
- Censorship
- Inadequate procedural and information security

#### Principles of Scientific Integrity

In 1999, the Agency published its Principles of Scientific Integrity, developed in conjunction with the EPA's National Partnership Council, which is comprised of representatives of Agency labor unions and management. The Principles laid out the basic rules for ethical behavior by all EPA employees in:

- Conducting scientific research
- Interpreting and presenting results
- Using scientific information and data

Principles of Scientific Integrity

Community of Practice for Statistics- January 2014

Initiative to strengthen statistics, consideration, and study design and to ensure these same factors are evaluation during the review and approval of study protocols. 3 Working Groups were formed to raise awareness of the importance of statistical issues and provide a forum for robust discussion. The 3 Working Groups developed process and guidance

documents. http://www.ncbi.nlm.nih.gov/pubmed/25795653



Revising The Agency's Peer Review Handbook: The Agency's Peer Review Handbook was first issued in 1998. It was revised and reissued in 2000 (2nd Edition) and 2006 (3rd Edition). In 2009 an addendum on the "Appearance of a Lack of Impartiality in External Peer Review" was added. The Handbook is currently being updated to incorporate EPA organizational changes, the 2009 addendum, as well as additional processes that have been put into place since 2006.

Peer Review Handbook 3rd Edition, 2006

Addendum to Peer Review Handbook 3rd Edition

#### **United States Department of Agriculture (USDA)**

USDA Scientific Integrity Policy - 2013

To ensure that science at USDA is held to the highest standards possible, Secretary Vilsack issued a Departmental Regulation (DR) on Scientific Integrity. It provides guidance to all employees and contractors on the proper use of scientific findings and the principles of conducting scientific activities, and addresses the White House Office of Science and Technology Policy's request for all federal departments to write these policies. See below for the policy and the handbook, which describes how the policy will be implemented.

- USDA Scientific Integrity Policy (DR 1074-001) (PDF, 262KB)
- USDA Scientific Integrity Policy Handbook (PDF, 879KB)
- Annual USDA Scientific Integrity Allegations Summary Report (May 2013 April 2014) (PDF, 179KB)
- USDA Agency Scientific Integrity Officers

Research misconduct - an important subset of scientific integrity violation - is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. To ensure that the public can trust the objectivity of its science, USDA established policies and procedures for handling research misconduct that occurs in research that is either funded or conducted by USDA.

• View a list of USDA Research Integrity Officers

Anyone who suspects USDA researchers or researchers performing USDA-funded research of engaging in research misconduct is encouraged to make a formal allegation of research misconduct to USDA's Office of the Inspector General (OIG)



# **Scientific Integrity Work by Non-Profit Organizations**

**The National Academies** 

#### **Institute of Medicine**

Does the Public Trust Science? Trust and Confidence at the Intersections of the Life Sciences and Society A workshop of the Roundtable on Public Interfaces of the Life Sciences May 5-6, 2015 National Academy of Sciences 2101 Constitution Avenue N.W., Lecture Room Washington, D.C. http://nas-sites.org/publicinterfaces/roundtable/events/trust/

2002: Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct This report focuses on the research environment and attempts to define and describe those elements that allow and encourage unique individuals, regardless of their role in the research organization or their backgrounds on entry, to act with integrity. The committee's goal was to define the desired outcomes and set forth a set of initiatives that it believes will enhance integrity in the research environment. The committee considered approaches that can be used to ensure integrity and methods that can be used to assess the effectiveness of those efforts.

Several overarching conclusions emerged as the committee addressed the desire of the Department of Health and Human Services' Office of Research Integrity for means to assess and track the state of integrity in the research environment:

- Attention to issues of integrity in scientific research is very important to the public, scientists, the institutions in which they work, and the scientific enterprise itself.
- No established measures for assessing integrity in the research environment exist.
- Promulgation of and adherence to policies and procedures are necessary, but they are not sufficient means to ensure the responsible conduct of research.
- There is a lack of evidence to definitively support any one way to approach the problem of promoting and evaluating research integrity.
- Education in the responsible conduct of research is critical, but if it is not done appropriately and in a creative way, it is likely to be of only modest help and may be ineffective.
- Institutional self-assessment is one promising approach to assessing and continually improving integrity in research.

https://www.iom.edu/Reports/2002/Integrity-in-Scientific-Research-Creating-an-Environment-That-Promotes-Responsible-Conduct.aspx

RESPONSIBLE SCIENCE Ensuring the Integrity of the Research Process VOLUME I Panel on Scientific Responsibility and the Conduct of Research Committee on Science, Engineering, and Public Policy National Academy of Sciences National Academy of Engineering Institute of Medicine NATIONAL ACADEMY PRESS Washington, D.C. 1992 http://www.nap.edu/openbook.php?record\_id=1864&page=R1



"Conflict of Interest and Medical Innovation:

Ensuring Integrity While Facilitating Innovation in Medical Research: Workshop Summary" (2014) <u>http://www.nap.edu/catalog/18723/conflict-of-interest-and-medical-innovation-ensuring-integrity-while-facilitating</u>

Scientific advances such as the sequencing of the human genome have created great promise for improving human health by providing a greater understanding of disease biology and enabling the development of new drugs, diagnostics, and preventive services. However, the translation of research advances into clinical applications has so far been slower than anticipated. This is due in part to the complexity of the underlying biology as well as the cost and time it takes to develop a product. Pharmaceutical companies are adapting their business models to this new reality for product development by placing increasing emphasis on leveraging alliances, joint development efforts, early-phase research partnerships, and public-private partnerships. These collaborative efforts make it possible to identify new drug targets, enhance the understanding of the underlying basis of disease, discover novel indications for the use of already approved products, and develop biomarkers for disease outcomes or directed drug use. While the potential benefits of collaboration are significant, the fact that the relationships among development partners are often financial means that it is vital to ensure trust by identifying, disclosing, and managing any potential sources of conflict that could create bias in the research being performed together.

# **Scientific Integrity Work by Foundations**

#### John Templeton Foundation

Increasing Scientific Openness and Integrity

Project Leader(s): Brian Nosek, Jeffrey Spies

Grantee(s): <u>Center for Open Science</u> (see below additional projects under the Arnold Foundation) Description: An academic scientist's professional success depends on publishing. Publishing norms emphasize novel, positive, tidy results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that maximize publishability even at the expense of accuracy. This challenges scientists' character because professional success is enhanced by pursuing suboptimal scientific practices. As such, disciplinary norms guide researchers toward practices that are contrary to personal and scientific values. The end result is inflation of error in published science, and interference with knowledge accumulation. Scientific integrity can be improved with strategies that make the fundamental but abstract accuracy motive—getting it right—competitive with the more tangible and concrete incentive—getting it published. We are building infrastructure (http://openscienceframework.org/) to alter the incentives, increase openness and accountability, and provide a

(http://openscienceframework.org/) to alter the incentives, increase openness and accountability, and provide a means of instilling habits that embody scientific values in the daily behavior of practicing scientists. Also, we are building communities around open science values, and means of providing credit for practicing those values. Ultimately, we aim to enhance the credibility and integrity of individual scientists, the scientific community, and the knowledge base that they produce. We will meet these goals in this grant with three activities: (1) building the Open Science Framework to provide features that provide value to the scientist's existing workflow and enables or automates good practices, (2) building community, training and outreach to facilitate use of the Open Science Framework, and (3) connecting a variety of tools (e.g., data repositories, data visualization tools, analytic tools)



through the OSF to support the entire research lifecycle and facilitate documentation and archival of research materials and data. Grant Amount: \$2,109,856 Start Date: January 2014, End Date: October 2016 Grant ID: 46545 http://www.templeton.org/what-we-fund/grants/increasing-scientific-openness-and-integrity

#### **MacArthur Foundation**

The <u>Center for Scientific Integrity</u> operates <u>Retraction Watch</u> through a generous grant from the MacArthur Foundation. <u>http://retractionwatch.com/the-retraction-watch-faq/</u>

The goals of the Center fall under four broad areas:

- A database of retractions, expressions of concern and related publishing events, generated by the work of Retraction Watch. The database will be freely available to scientists, scholars and anyone else interested in analyzing the information.
- Long-form, larger-impact writing, including magazine-length articles, reports and books.
- Aid and assistance to groups and individuals whose interests in transparency and accountability intersect with ours, and who could benefit from shared expertise and resources.

http://retractionwatch.com/the-center-for-scientific-integrity/

#### **Arnold Foundation**

The Arnold Foundation has 4 areas of focus, one is research integrity. LJAF's Research Integrity initiative aims to improve the reliability and validity of scientific evidence across fields that inform governmental policy, philanthropic endeavors, and individual decision making. As a society, we often rely on published scientific research to guide our policy, health, and lifestyle choices. Although some published research is rigorous and reliable, some is not. Worse, the unreliability of research is often difficult or impossible to ascertain. LJAF is currently working to address this problem by supporting organizations that are committed to improving the openness, transparency, and quality of research. All research projects sponsored in full or in part by LJAF must follow the Guidelines for Investments in Research. See Guidelines for Investments in Research

Between 2011-2014, the Arnold Foundation granted \$66,859,986 in grant dollars for Research Integrity projects, including grants to:

#### American Association for the Advancement of Science (AAAS) (see more on AAAS below)

\$100,000 to foster open, reliable, and rigorous scientific research by sponsoring three workshops on publication standards. The grant runs from 2014-2016.

#### **Nutrition Science Initiative**

Two grants for a total of up to \$44 million running from 2012-2018 to improve the quality of science in nutrition and obesity research.

The mission of Nutrition Science Initiative is to reduce the individual, social, and economic costs of obesity, diabetes, and their related diseases by improving the quality of science in nutrition and obesity research. The Nutrition Science Initiative is currently focusing on 3 projects:

1. Boston Children's Hospital: This study will determine whether reduced calorie intake or a change in the proportions of fat and carbohydrates is the most effective strategy for maintaining a reduced body weight.



- 2. Energy Balance Consortium: This highly controlled laboratory study will help determine whether it's the total amount of calories you eat or the proportion of fat and carbohydrate in the diet that most importantly drives body weight gain.
- 3. Stanford University: This study compares the effects of a very low-carbohydrate and very-low fat diets on body weight in free-living obese patients over a year's time and examines whether genetic or metabolic factors can predict the response to the different diets.

#### Center for Open Science, Inc. (COS)

(see above for more information under the John Templeton Foundation) Several million dollars to the Center for Open Science, Inc.

COS Communities blur the boundary between COS and the many individual and organizational contributors to improving scientific practices. COS Communities form around particular products or services to define specifications, maximize applicability, promote adoption, and facilitate evaluation and improvement. There are 4 buckets of COS communities:

Publishing Initiatives

- Badges to Acknowledge Open Practices: Badges incentivize open research by rewarding authors with visual acknowledgements on published manuscripts. Currently, badges can be earned for three distinct practices: open data, open materials, and preregistration. Badges appear directly on publications along with information regarding where the relevant data, materials, or registration can be found. The badges and their criteria are developed and maintained as a community-driven initiative of the Center for Open Science.
- 2. Registered Reports: Registered Reports offer journals an alternative structure to the current publishing format to promote transparency and reproducibility in scientific research. In this model, peer review occurs twice. Each study procedure and analysis plan are evaluated prior to data collection for in-principle acceptance; if accepted, the final manuscript is essentially guaranteed publication regardless of the reported outcome, with a second peer review to ensure the accepted methodology was conducted.

Metascience

- 1. Reproducibility Project: Psychology (RP:P): The RP:P is a collaborative community effort to replicate published psychology experiments from three important journals. Replication teams follow a standard protocol to maximize consistency and quality across replications, and the accumulated data, materials and workflow are to be open for critical review on OSF. The RP:P is coordinated at the Center for Open Science and involves volunteer scientists from all over the world.
- 2. Reproducibility Project: Cancer Biology (RP:CB): The RP:CB is an initiative to conduct direct replications of 50 high-impact cancer biology studies. The project anticipates learning more about predictors of reproducibility, common obstacles to conducting replications, and how the current scientific incentive structure affects research practices by estimating the rate of reproducibility in a sample of published cancer biology literature. The RP:CB is a collaborative effort between the Center for Open Science and network provider Science Exchange.
- 3. Many Labs I: Many Labs I project was a crowdsourced replication study in which the same 13 psychological effects were examined in 36 independent samples to examine variability in replicability across sample and setting.
  - a. Results:
    - i. Variations in sample and setting had little impact on observed effect magnitudes



- ii. When there was variation in effect magnitude across samples, it occurred in studies with large effects, not studies with small effects
- iii. Replicability was much more dependent on the effect of study rather than the sample or setting in which it was studied
- iv. Replicability held even across lab-web and across nations
- v. Two effects in a subdomain with substantial debate about reproducibility (flag and currency priming) showed no evidence of an effect in individual samples or in the aggregate.
- 4. Many Labs II: Conducted in Fall of 2014, Many Labs II employed the same model as Many Labs I but with almost 30 effects, more than 100 laboratories, and including samples from more than 20 countries. The findings should be released in mid-2015.
- 5. Many Labs III: Many psychologists rely on undergraduate participant pools as their primary source of participants. Most participant pools are made up of undergraduate students taking introductory psychology courses over the course of a semester. Also conducted in Fall of 2014, Many Labs III systematically evaluated time-of-semester effects for 10 psychological effects across many participant pools. Twenty labs administered the same protocol across the academic semester. The aggregate data will provide evidence as to whether the time-of-semester moderates the detectability of effects.
- 6. Collaborative Replications and Education Project (CREP): The Collaborative Replications and Education Project facilitates student research training through conducting replications. The community-led team composed a list of studies that could be replicated as part of research methods courses, independent studies, or bachelor theses. Replication teams are encouraged to submit their results to an information commons for aggregation for potential publication. This integrates learning and substantive contribution to research.
- 7. Crowdsourcing a Dataset: Crowdsourcing a dataset is a method of data analysis in which multiple independent analysts investigate the same research question on the same data set in whatever manner they consider to be best. This approach should be particularly useful for complex data sets in which a variety of analytic approaches could be used, and when dealing with controversial issues about which researchers and others have very different priors. This first crowdsourcing project establishes a protocol for independent simultaneous analysis of a single dataset by multiple teams, and resolution of the variation in analytic strategies and effect estimates among them.

#### Infrastructure

 Open Source Developers: The Center for Open Science is a Python-based, open source development shop. Developers who want to support open science should definitely consider contributing to our open source community. The Open Science Framework, the flagship platform of the Center for Open Science, is a web application for supporting the research workflow. Essentially, the Center for Open Science wants to bring the core philosophy of open source development to science. Developers have the opportunity to contribute to maturing products, like the Open Science Framework, or to new projects that help make science better.

#### Interest Groups

1. Ambassadors: Center for Open Science ambassadors act as the local authority on the Center for Open Science, the Open Science Framework, and open science practices in their community. They are trained to talk about the Center for Open Science, lead Open Science Framework demonstrations, and represent us at conferences and meetings. Researchers in any field and from



any country can become COS Ambassadors. This is a great opportunity to promote open science in your community and help us work to increase openness, integrity, and reproducibility across scientific domains.

2. Open Science Collaboration: The Open Science Collaboration is a network of researchers, professionals, citizen scientists, and others with an interest in open science, metascience, and good scientific practices. The goal of the Open Science Collaboration is to promote open collaboration of scientific ideas. Collaboration and broadcasting of problems increases the odds a person with the right expertise will see it and be able to solve it easily. In the same vein, collaboration can lead to novel solutions to problems being found. Collaboration also means that projects can be more ambitious, as more people with a variety of expertise and experience are involved to help distribute the work.

Workshop held at the Center for Open Science in 2014 aimed at creating standards for promoting reproducible research in the social-behavioral sciences. Representatives from across disciplines (economics, political science, psychology, sociology, medicine), from funders (NIH, NSF, Laura and John Arnold Foundation, Sloan Foundation), publishers (Science/AAAS, APA, Nature Publishing Group), editors (American Political Science Review, Psychological Science, Perspectives on Psychological Science, Science), data archivists (ICPSR), and researchers from over 40 leading institutions (UC Berkeley, MIT, University of Michigan, University of British Columbia, UVA, UPenn, Northwestern, among many others) came together to push forward on specific action items researchers and publishers can do to promote transparent and reproducible research. http://bitss.org/2014/11/06/creating-standards-for-reproducible-research-overview-of-cos-meeting/

#### **Robert Wood Johnson Foundation (RWJ)**

http://www.rwjf.org/reports/grr/038967.htm#int\_biblio

Anderson F. "Science Advocacy and Scientific Due Process." Issues in Science and Technology, 16(Summer): 71–76, 2000.

Reports

Anderson F, Edens G and Sargeant T. Science Advocacy and Scientific Due Process: Sourcebook of Materials. Washington: Cadwalader, Wickersham & Taft, 2000.

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib A Case Study of Industry Documents From Rofecoxib Litigation <u>http://www.rwjf.org/en/library/research/2008/04/guest-authorship-and-ghostwriting-in-publications-related-to-rof.html</u>

What's Behind Large Disparities in NIH Research Funding

In 2011, the National Institutes of Health revealed, through their own research, that only 16 percent of grant applications submitted by African American researchers were funded. The number for White researchers was 29 percent. Here, Robert Wood Johnson Foundation (RWJF) experts answer questions about the problem, possible solutions and how researchers should proceed.

http://www.rwjf.org/en/library/articles-and-news/2011/12/breaking-new-ground-in-research/whats-behind-largedisparities-in-nih-research-funding.html

#### **Sloan Foundation**

Opportunities: Big Data is a Big Deal (beginning on page 15)

Launched in 2011 and led by Program Director Joshua M. Greenberg, the Foundation's Digital Information Technology program aims to leverage developments in digital information technology to empower scientists, enable new forms of data intensive research, and improve and expand the dissemination and evaluation of



scholarship. The program has two dimensions, one outward- and one inward-facing. In its outward-facing dimension, the program works directly with researchers, technologists, engineers, academic publishers, and university administrators to speed the development and adoption of tools, standards, norms, and practices that will enable researchers to better communicate with one another and more effectively work with large datasets. It also aims to facilitate the creation of career paths for data scientists and to educate the scholarly community about new big data opportunities, methods, and challenges. In its inward-facing dimension, the program seeks to support and encourage the effective use of new datasets, data repositories, data dissemination, and computational techniques across Sloan's other grant making programs. Big data makes it possible to both improve the quality of existing research and expand the set of questions amendable to scientific investigation and analysis. http://www.sloan.org/fileadmin/media/files/annual\_reports/2013-Annual-Report.pdf

<u>http://www.sloan.org/major-program-areas/?L=0</u> (See funding work under Center for Open Science, Inc. above)

### **Scientific Integrity Work by Associations**

American Association for the Advancement of Science (AAAS) http://www.aaas.org/page/scientific-integrity

In 2006, at the 31st annual AAAS Forum on Science and Technology Policy, a Forum panel that explored the subtle dilemmas of science ethics and integrity http://www.aaas.org/news/aaas-panel-explores-subtle-dilemmas-science-ethics-and-integrity

"Forbidding science? Balancing freedom, security, innovation, & precaution" Workshop held on January 12-13, 2006 Conference cosponsored with AAAS that explored whether and how restrictions on scientific research should be imposed [2006]

#### **Council of Science Editors**

The Council of Science Editors (CSE) is an international membership organization for editorial professionals publishing in the sciences. Our purpose is to serve over 800 members in the scientific, scientific publishing, ad information science communities by fostering networking, education, discussion, and exchange. Our aim is to be an authoritative resource on current and emerging issues in the communication of scientific information.

CSE has an Editorial Policy Committee- The Editorial Policy Committee serves as a resource regarding editorial and publishing policies applying to publications in the sciences. The committee studies and analyzes procedural, ethical, legal, and economic policies and recommends policies and/or guidelines that relate to the editing, review, and publication of manuscripts in books and journals in the sciences. The committee may suggest policy to the CSE board of directors affecting CSE's own publications. Policy guidelines developed by the committee will be presented to the membership via publication in Science Editor and the Web site, by presentation at CSE annual meetings, or in other ways, and after appropriate revision in consultation with the board, may be published and disseminated by CSE through the Publications, Education, Membership, and Program Committees.



White Paper on Publication Ethics CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update (approved by the CSE Board of Directors on March 30, 2012) **PDF of the** <u>entire White Paper</u>

#### Introduction to White Paper:

The Council of Science Editors and its Editorial Policy Committee encourage everyone involved in the journal publishing process to take responsibility for promoting integrity in scientific journal publishing. This paper will serve as a basis for developing and improving effective practices to achieve that goal. We first wrote this white paper in 2006 and it was last updated in 2009. For the 2012 Update, we substantially revised and updated each section; included information on citation manipulation, publication planning by study sponsors, and ethical conduct of sponsors; reorganized the section on reporting suspect manuscripts; updated information on international models for responding to research misconduct; and provided more recent examples of corrections, retractions, and expressions of concern. Through this White Paper and other activities, the Editorial Policy Committee aims to open dialogue about ethical publishing practices, inform those involved in the editorial process, and foster informed decision-making by editors. We intend to work with other professional organizations to shape the scientific journal environment so the integrity of our publications is upheld. With the understanding that what may be appropriate for one discipline or organization may not be so for another, the White Paper intends to inform and guide rather than direct. Where there is more published information available from the biomedical community on some of the topics in this paper, more references or examples in those areas are given. However, our intention is to provide information that is useful to all the sciences. Please help us to keep this living document current by pointing out areas that need to be expanded or updated. We will build on the work of this White Paper through the continued work of the Committee and your contributions. Please send comments and suggestions to CSE@CouncilScienceEditors.org and include "Editorial Policy Committee" in the subject line

#### **American Chemical Society (ACS)**

Scientific Integrity in Public Policy ACS Position Statement http://www.acs.org/content/acs/en/policy/publicpolicies/promote/scientificintegrity.html

#### "Catching Errors: Peer Review and Retractions in Publishing"

#### Thursday, April 16, 2015, 2:00-3:00 PM ET

We have all seen the headlines where unintentional errors and falsified data have caused papers to be retracted. These instances can damage the reputation of the researchers, journals, and the institutions associated with the erroneous research. Join Dr. Ivan Oransky of *Retraction Watch*, Dr. Charon Pierson of the Governing Council of the Committee on Publication Ethics (see more on this organization below), and Dr. James DuBois of the Center for Clinical Research Ethics (see more on this organization below) as they discuss the efforts that are being made to combat this issue as well as what could be changed to improve the review process.

#### Center for Science in the Public Interest (CSPI)

Integrity in Science Project 2006

Promoting Disclosure http://www.cspinet.org/integrity/disclosure.html

The Integrity in Science project promotes full disclosure of conflicts of interest when scientists publish in journals, are quoted in the press or appear before legislative or regulatory bodies at all levels of government. The project and its allies in the scientific community believe total disclosure of conflicts of interest is mandatory if the public is to maintain its faith in the integrity of the scientific process, and the government is to remain a fair and



impartial arbiter of scientific disputes that determine the laws and regulations that affect the health and safety of the American people.

# **Scientific Integirty Work by Other Organizations**

#### Center for Clinical Research Ethics (CCRE)

The **Center for Clinical Research Ethics** (CCRE) was established through a partnership between the Institute of Clinical and Translational Sciences (ICTS) at Washington University and the Center for Health Care Ethics at Saint Louis University, both in St. Louis, MO.

The Center for Clinical Research Ethics (CCRE):

- Helps ensure that all ICTS trainees receive training in clinical research ethics (CRE) and the responsible conduct of research (RCR) that exceeds the minimum standards set by NIH;
- Conducts and supports collaborative research on clinical research ethics, research integrity, and the intersection of ethics and community engagement; and
- Shares expertise in research ethics with individuals, policy committees, and others through consulting activities.

#### **CCRE** Education

- CCRE aims to help ensure that all ICTS trainees receive **training in clinical research ethics** (**CRE**) **and the responsible conduct of research** (**RCR**)that exceeds the minimum standards set by the National Institutes of Health. We accomplish this aim by directing the course, M17-510 "Ethical and Regulatory Issues in Clinical Research" and by providing speakers in the "Research Ethics Lecture Series" of the Human Research Protections Office at Washington University.
- The <u>Professional Integrity</u> (PI) program (previously known as Restoring Professionalism and Integrity in Research or RePAIR) provides intensive professional development education for investigators who have engaged in wrongdoing or unprofessional behavior. The PI Program will also sponsor a webinar series on institutional strategies for preventing wrongdoing and fostering professionalism in research.
- We also offer a library of research case studies.
- The Institute for Clinical and Translational Sciences (ICTS) and the Office of the Vice Chancellor for Research (OVCR) at Washington University in St. Louis jointly sponsor a course on the responsible conduct of research (RCR). The RCR course is designed to satisfy the National Institutes of Health Requirement for Instruction in the Responsible Conduct of Research. It may also be incorporated into plans to satisfy National Science Foundation RCR training requirements.

**CCRE** Consultations



- Consultation on Training: We consult with training grant program directors to assist them in developing, identifying, or describing training in the Responsible Conduct of Research (RCR) or Clinical Research Ethics (CRE). Ongoing collaboration with CCRE faculty on funded training programs should be budgeted into grant applications.
- Consultation on Research Design: We consult on the design of research on ethical issues in human subjects research, research integrity, and ELSI in genetics. An initial consultation is funded by the CTSA. Ongoing collaboration with CCRE faculty on funded research projects should be budgeted into grant applications.

#### Current Projects

CCRE faculty have ongoing research and scholarly projects in the areas of mental health research ethics, understanding and preventing wrongdoing in research, community engagement strategies for addressing questions of research ethics, disclosure of results of genetic testing, and first-in-human research. CCRE faculty research has received support from the US Office of Research Integrity, the National Institutes of Health, the Greenwall Foundation, and other agencies. See the recent CCRE **publications** and a list of **grants and contracts**.

- DuBois, J.M. "The Role of Culture and Experience in the Perception of Research Regulations, Norms and Values," Office of Research Integrity, HHS (IR-ORI-14-001-018712). 8/1/2014-7/31/2016. \$98,360. Principal Investigator.
- DuBois, J.M. "Validating Outcome Measures for Remediation of Research Wrongdoing," Office of Research Integrity, HHS (1 ORIIR 130002-01-00). 9/1/2013-8/31/2015. \$277,700. Principal Investigator.
- DuBois, J.M. "Preventing Ethical Disasters in the Practice of Medicine," NIH National Institute of Aging (1R01AG043527-01). 6/1/2013-5/31/2018. \$1,258,500. Principal Investigator.
- DuBois, J. M. "Restoring Professionalism and Integrity in Research (RePAIR)," \$500,000 funded by NIH (Administrative Supplement to WU ICTS). September 17, 2007-May 31, 2012. DuBois is serving as Project Director for this project and PI of the SLU subaward (\$476,564). The project involves developing a curriculum for a remediation training program for investigators caught violating the rules for the responsible conduct of research.
- DuBois, J. M. "ORI Research Integrity Casebook," \$155,579 funded by the Office of Research Integrity . March 1, 2011-September 30, 2012. *The major goal of this project is to produce a casebook that is suitable for use in face-to-face training in the responsible conduct of research.*
- Solomon, S. Sarah Gehlert (Site PI for WU) "Development of a Nationally Implementable, Locally Deliverable Human Research Participants Training Workshop for Community-Based Researchers, Collaborators and Staff." (2011). Supplement to the CTSA from the National Center for Research Resources, National Institutes of Health to Michigan Institute for Clinical and Health Research (MICHR), \$34,513
- DuBois, J. M. "Environmental Factors Predictive of Misbehavior in Collaborative Health Research," National Institutes of Health (1R21RR026313-01). 9/25/2009-8/31/2010. \$376,000. Principal Investigator.
- DuBois, J. M. "Environmental Factors Associated with Professional Misconduct in Medical Research and Practice," BF Foundation. 1/1/2009-12/31/2011. \$100,000. Principal Investigator.



- DuBois, J. M. "Responsible Conduct of Research Instructional Assessment Program. Part II," Office of Research Integrity, Contract, 7/1/2008-9/30/2009. \$60,000, Principal Investigator.
- DuBois, J. M. "Center for Clinical Research Ethics," within the Washington University of St. Louis, Institute for Clinical and Translational Science. (NIH: 1 U54 RR023496-01A1, Principal Investigator: Polonsky, K.) 9/1/2007-8/31/2012. Role: 15% effort as Director. \$500,000 subcontract with St. Louis University, DuBois, Principal Investigator.
- DuBois, J. M. "Best Practices in Mental Health Research Ethics Conference Series," National Institute of Mental Health (1R13MH079690). 9/1/2007 8/31/2011. \$200,000. Principal Investigator.

#### **Committee on Publication Ethics (COPE)**

The Committee on Publication Ethics (COPE) was established in 1997 by a small group of medical journal editors in the UK but now has over 9000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics. Several major publishers (including <u>Elsevier</u>, <u>Wiley–Blackwell</u>, <u>Springer</u>, <u>Taylor & Francis, Palgrave</u> <u>Macmillan</u> and <u>Wolters Kluwer</u>) have signed up some, if not all, of their journals as COPE members.

COPE provides advice to editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases. COPE does not investigate individual cases but encourages editors to ensure that cases are investigated by the appropriate authorities (usually a research institution or employer).

All COPE members are expected to follow the Code of Conduct for Journal Editors.

COPE has produced an eLearning course for new editors. Eleven modules in total, the course currently includes: An Introduction to Publication Ethics, Plagiarism, and Authorship among others. COPE also funds <u>research</u> on publication ethics, organizes <u>annual seminars</u> globally and has created an <u>audit tool</u> for members to measure compliance with its <u>Code of Conduct and Best Practice Guidelines for Journal Editors</u>.

- COPE Code of Conduct and Best Practice Guidelines for Journal Editors
- <u>Flowcharts</u> on how to handle common ethical problems
- Other <u>COPE guidelines</u> (eg on retractions)
- <u>Sample letters</u> (to adapt for use)
- <u>Database of all cases</u> discussed at COPE Forum (including podcasts of the discussion (where available), the advice given and the outcome of cases)



# **Scientific Integrity Literature Review**

A search through PubMed using the guidelines of publications in the past ten years (2005-2015) and the key terms "scientific integrity", "research integrity", and "misconduct", resulted in 835 publications. We have not evaluated all these publications but instead narrowed the search terms to the following:

# Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND research integrity; scientific integrity; transparency; misconduct; ethics Results: 13

Protecting our science. Seixas NS. Ann Occup Hyg. 2013 Oct;57(8):963-5. doi: 10.1093/annhyg/met056. PMID: 24130260 Related citations

Transparency for each research article. Institutions must also be accountable for research integrity.

Cosentino M, Picozzi M. BMJ. 2013 Sep 10;347:f5477. doi: 10.1136/bmj.f5477. No abstract available. PMID: 24022040 Related citations

Conflicts of interest for medical publishers and editors: protecting the integrity of **scientific**scholarship. Desai SS, Shortell CK. J Vasc Surg. 2011 Sep;54(3 Suppl):59S-63S. doi: 10.1016/j.jvs.2011.05.111. PMID: 21872119 Related citations

Misinformation in the medical literature: what role do error and fraud play?

Steen RG. J Med **Ethics**. 2011 Aug;37(8):498-503. doi: 10.1136/jme.2010.041830. Epub 2011 Feb 22. PMID: 21343631 <u>Related citations</u>

Editors' overview: topics in the responsible management of **research** data. Giffels J, Vollmer SH, Bird SJ. Sci Eng **Ethics**. 2010 Dec;16(4):631-7. doi: 10.1007/s11948-010-9243-1. Epub 2010 Oct 28. PMID: 20981506

<u>Rethinking the meaning of being a scientist--the role of scientific integrity boards and some thoughts</u> about scientific culture.

Werner-Felmayer G. Med Law. 2010 Sep;29(3):329-39. PMID: 22145555 Related citations

Publication ethics. Morton NS.



Paediatr Anaesth. 2009 Oct;19(10):1011-3. doi: 10.1111/j.1460-9592.2009.03086.x. Epub 2009 Jun 13. Review. PMID: 19619189 Related citations

Role of editors and journals in detecting and preventing **scientific** misconduct: strengths, weaknesses, opportunities, and threats.

Marusic A, Katavic V, Marusic M. Med Law. 2007 Sep;26(3):545-66. PMID: 17970252 Related citations

When conflict-of-interest is a factor in **scientific** misconduct.

Krimsky S. Med Law. 2007 Sep;26(3):447-63. PMID: 17970245 <u>Related citations</u>

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

**Research** integrity and pharmaceutical industry sponsorship.

Gøtzsche PC. Med J Aust. 2005 Jun 6;182(11):549-50. PMID: 15938676 Related citations

The IARC monographs program: changing attitudes towards public health. Tomatis L. Int J Occup Environ Health. 2002 Apr-Jun;8(2):144-52. PMID: 12019681 Related citations

The Medical **Research** Council's approach to allegations of **scientific** misconduct. Evans I. Sci Eng **Ethics**. 2000 Jan;6(1):91-4. PMID: 11273442 Related citations

Research misconduct definitions adopted by U.S. research institutions. Resnik DB, Neal T, Raymond A, Kissling GE. Account Res. 2015;22(1):14-21. doi: 10.1080/08989621.2014.891943. PMID: 25275621 Related citations



#### Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND scientific integrity; research integrity; quality of papers Results: 78 We have highlighted 12 of the publications that are most relevant.

Research ethics education for community-engaged research: a review and research agenda. Anderson EE, Solomon S, Heitman E, DuBois JM, Fisher CB, Kost RG, Lawless ME, Ramsey C, Jones B, Ammerman A, Ross LF. J Empir Res Hum Res Ethics. 2012 Apr;7(2):3-19. doi: 10.1525/jer.2012.7.2.3. Review. PMID: 22565579 Related citations

Professional ethics: an overview from health research ethics point of view.

Nyika A. Acta Trop. 2009 Nov;112 Suppl 1:S84-90. doi: 10.1016/j.actatropica.2009.07.033. Epub 2009 Aug 7. Review. PMID: 19665439 Related citations

Fraud and misconduct in science: the stem cell seduction: Implications for the peer-review process. van der Heyden MA, van de Ven T, Opthof T. Neth Heart J. 2009 Jan;17(1):25-9. PMID: 19148335 <u>Related citations</u> "The (anonymous) peer review process serves as goalkeeper of scientific quality rather than scientific integrity."

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

Making sense of research: A guide for critiquing a paper.

Stockhausen L, Conrick M. Contemp Nurse. 2002 Dec;14(1):38-48. Review. PMID: 16114192 Related citations

Beyond conflict of interest: the responsible conduct of **research**. Rhoades LJ. Sci Eng Ethics. 2002 Jul;8(3):459-68. Review. PMID: 12353376



#### Related citations

Maintaining data integrity in randomized clinical trials. Moody LE, McMillan S. Nurs Res. 2002 Mar-Apr;51(2):129-33. PMID: 11984384 <u>Related citations</u>

[Quality assurance of data collection and data processing in epidemiologic study data]. Greiner M, Baumann MP, Zessin KH. Dtsch Tierarztl Wochenschr. 2001 Nov;108(11):443-9. German. PMID: 11765598 <u>Related citations</u>

#### Guidelines for quality assurance in multicenter trials: a position paper.

Knatterud GL, Rockhold FW, George SL, Barton FB, Davis CE, Fairweather WR, Honohan T, Mowery R, O'Neill R. Control Clin Trials. 1998 Oct;19(5):477-93. PMID: 9741868 <u>Related citations</u>

**Quality** data: what are they?

Sforza VA. Ann Ist Super Sanita. 1994;30(4):439-43. PMID: 7762939 <u>Related citations</u>

#### Research data integrity: a result of an integrated information system.

Cranmer MF, Lawrence LR, Konvicka AK, Taylor DW, Herrick SS. J Toxicol Environ Health. 1976 Nov;2(2):285-99. PMID: 1011288 Related citations

A guide to critiquing a research paper on clinical supervision: enhancing skills for practice. Fothergill A, Lipp A. J Psychiatr Ment Health Nurs. 2014 Nov;21(9):834-40. doi: 10.1111/jpm.12161. Epub 2014 May 13. PMID: 24818837 Related citations

#### **Other Notable Publications Found**

<u>Peer review.</u> **Twaij H**, Oussedik S, Hoffmeyer P. Bone Joint J. 2014 Apr;96-B(4):436-41. doi: 10.1302/0301-620X.96B4.33041. Review. PMID: 24692607 <u>Related citations</u>



Peer review: a view based on recent experience as an author and reviewer. Clark RK. Br Dent J. 2012 Aug;213(4):153-4. doi: 10.1038/sj.bdj.2012.721. PMID: 22918342 Related citations

<u>Good practice in reviewing and publishing studies on herbal medicine, with special emphasis on traditional Chinese medicine and Chinese materia medica.</u>

**Chan K**, **Shaw D**, Simmonds MS, Leon CJ, Xu Q, Lu A, Sutherland I, Ignatova S, Zhu YP, Verpoorte R, Williamson EM, Duez P. J Ethnopharmacol. 2012 Apr 10;140(3):469-75. doi: 10.1016/j.jep.2012.01.038. Epub 2012 Feb 11. Review. PMID: 22330011

Related citations



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

# **Scientific Integrity Working Group**

#### Background/Recommendations from the Scientific Integrity Working Group from 30 April Meeting

- 1. Given the extensive work being done by federal agencies and other organizations on scientific integrity (see Compilation of Scientific Integrity Work by Various Organizations document completed by ILSI North America), why is there still an issue with scientific integrity? What are the reasons for an apparent increase in scientific fraud and misuse of scientific data? What are the pressures that result in these actions? What can be done to instill scientific integrity in all researchers?
- 2. ILSI North America should synthesize the Compilation document into a framework (science, research, and people) and publish it to shine a light on the work that has been done by the federal agencies and other organizations. ILSI North America should then develop a set of principles/best practices on scientific integrity from existing efforts.
- 3. ILSI North America's focus should be on implementation of these principles/best principles. To accomplish this goal, ILSI North America will bring visibility to the published principles/best practices by hosting a "tournament" on an annual basis to identify outstanding papers within specific categories that can be held up as examples and model publications. The following categories are under consideration as they were identified in the ILSI North America membership survey on scientific integrity: study design, statistical analysis, reporting fidelity, open source data sets, best reviewer, and best in class. This "tournament" would show the principles/best practices in action by focusing on the strengths and weaknesses in each category.
- 4. The Working Group feels that ILSI North America should seek a broader group of collaborators than we have previously worked with in order to have a greater impact; ones that have impeccable reputations and are not focused on area of science. Possible candidates are:
  - a. American Association for the Advancement of Science (AAAS)
  - b. Association of Public and Land-grant Universities (APLU)
  - c. National Science Foundation (NSF)
  - d. Association of American Universities (AAU)
  - e. The National Academies (NAS)
- 5. As the COI Summit Consortium has agreed to reconvene in two years, ILSI North America could introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

#### Proposed Plan of Work for the Scientific Integrity Working Group

- 1. A Compilation of Scientific Integrity Work by Federal Agencies and Other Organizations was completed in April 2015. This information will be placed into a framework using three categories that encompass scientific integrity (science, research, and people.)
  - a. This work will be submitted to a peer reviewed journal as the first manuscript in order to have it published in a timely manner while the other scientific integrity work is

undertaken. Dr. Fergus Clydesdale has offered to publish this manuscript in *Critical Reviews in Food Science and Nutrition*.

- b. This compilation should remain a living document. With the journal, explore the possibility of an online version of the publication, capturing activities on scientific integrity on a regular basis.
- 2. Develop a second paper in collaboration with AAAS and/or APLU that builds on the first manuscript. The paper will synthesize a set of principles/best practices for scientific integrity using the framework (science, research, and people) to establish the first "rulebook" on scientific integrity and will describe how to implement them. Incorporate sports analogies to better illustrate this issue. Examine case studies of scientific misconduct (worst practices) to incorporate into the manuscript (NSF and HHS Office of Research Integrity jointly issue a list of case summaries of scientific misconduct each year <a href="https://ori.hhs.gov/case\_summary">https://ori.hhs.gov/case\_summary</a>). Highlight the punishments that are currently being dispensed for scientific misconduct. A goal of the publication will be to raise awareness of the real consequences of scientific misconduct, i.e. the "penalty phase." Little attention has been given to this area within the scientific community.
  - a. The ILSI North America body of work on conflict of interest can be highlighted in the "people" section of the framework. For example, an individual researcher should be aware that he/she has certain conflicts of interest which can affect their personal integrity.
- 3. In collaboration with AAAS, APLU, and/or NSF, begin development of an annual "tournament" to identify outstanding papers within specific categories across all scientific disciplines. Begin development of criteria/rubric for grading papers at the "tournament" with collaborators (review current grading scales, i.e. HHS NIH National Cancer Institute, USDA National Institute of Food and Agriculture. Dr. David Allison has also begun to outline the procedure for evaluating papers.) The first "tournament" will be held in late 2017-early 2018.
  - a. Nutrition, food science, and food safety professional societies may be interested in sponsoring specific categories within the "tournament" (i.e. award prize money for winners of "tournament".)
- 4. Present the new framework and principles/best practices at major professional society meetings beginning in 2016-2017, educating attendees on the components of scientific integrity (i.e. learning to throw the baseball before you play the game.) The session would outline current efforts in scientific integrity, what it means for institutions and researchers, and where it is going and will bring to light how it applies to your professional organization. (If an individual researcher does not implement the principles/best practices, it can ruin one's career.) The case studies used would be specific to the professional meeting. The session will also include a description of the "tournament" and the proposed criteria/rubric developed for grading the papers for additional feedback from attendees.
  - a. Potential Meetings to Present the Framework and Principles/Best Practices:
    - i. American Association for Advancement of Science (AAAS)
    - ii. Association of Public and Land-grant Universities (APLU)
    - iii. Association of American Universities (AAU)
    - iv. World Conference on Research Integrity
    - v. American Society of Nutrition- Experimental Biology (EB)
    - vi. International Association for Food Protection (IAFP)
    - vii. Academy of Nutrition and Dietetics FNCE
    - viii. Canadian Nutrition Society (CNS)
    - ix. Society of Toxicology (SOT)
    - x. Society for Risk Analysis (SRA)
    - xi. Institute of Food Technologists (IFT)
    - xii. International Union of Food Science and Technology (IUFoST)
    - xiii. International Society for Behavioral Nutrition and Physical Activity (ISBNPA)

- 5. Finalize the criteria/rubric for grading papers and train the "referees" for the "tournament," recognizing that over time, the principles/best practices may evolve, as demonstrated in sports.
- 6. Hold "tournament" in Washington, DC.
- 7. Post winning papers in the different "tournament" categories to NIH PubMed Commons for recognition.
- 8. When the COI Summit Consortium reconvenes in two years, ILSI North America will introduce the principles/best practices for scientific integrity and seek endorsement from the nutrition, food science, and food safety professional societies.

#### **Proposed Timeline for Plan of Work:**

- 1. Presentation of plan of work to the ILSI North America Board of Trustees: July 2015
- 2. Meet with AAAS and APLU to share Plan of Work: Summer 2015
- 3. First manuscript on Compilation of Scientific Integrity Work: Submission September 2015
- 4. Second manuscript on principles/best practices, developed in collaboration with AAAS and/or APLU: mid-2016
- 5. Roadshow at Major Professional Society Meetings: 2016-2017
- 6. Second COI Summit Consortium Meeting: December 2016- early 2017
- 7. First Annual "Tournament": late 2017-early 2018

From: Sent: To:	Suzanne Harris Tuesday, May 26, 2015 2:05 PM s.chang@griffith.edu.au; scohen@unmc.edu; mdoyle@uga.edu: 'adamdrew@u washington edu': marion@yt.edu;
	Joanne
	Lupton; john.c.peters@ucdenver.edu;
	; kwallace@d.umn.edu; weavercm@purdue.edu;
	'Flavio Zambrone'
Cc:	carmel.james@griffith.edu.au; jbradford@unmc.edu;
	; 'Haan, Dawn E'; Michael Shirreffs
Subject:	Survey for ILSI Public Sector Trustees
TO:	ILSI Public Sector Trustees

FROM: Suzie Harris

The ILSI Board of Trustees Science Advisory Group, led by Dr. Alan Boobis and Dr. Peter van Bladeren, asked that we gather some information about the areas of expertise held by the ILSI public sector trustees and then by the branch public sector trustees and science advisors. With input from the ILSI Executive Committee, some questions were also added to get an idea of how involved you are with other science-based organizations like FAO and WHO.

We are using you as guinea pigs for this effort. I hope you will use this link https://www.surveymonkey.com/r/Adviser Expertise

to access the survey and to complete it. At the end there are two questions to gauge what you thought of the earlier questions.

Please let me know if you have any questions. It would be very helpful if you would complete the survey by **Friday**, **June 12**, **2015**. Thank you.

From: Sent: Subject: Attachments: John Faulkner Tuesday, May 19, 2015 10:12 AM Your ILSI North America Science Briefs for April 2015 Food Safety Briefs April 2015.pdf; Nutrition Briefs April 2015.pdf

Hello!

Attached are your Food Safety and Nutrition Science Briefs for the month of April.

Each month the most recent articles published in the major journals of nutrition and those from the fields of chemical and microbiology food safety are reviewed and we select those for inclusion that we believe will be of the greatest interest to ILSI North America's technical and project committees.

As always, these briefs, along with prior science briefs, are accessible via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will be happy to add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Food Safety Briefs**

# April 2015

#### E. Coli

Multifactorial Effects of Ambient Temperature, Precipitation, Farm Management, and Environmental Factors Determine the Level of Generic Escherichia coli Contamination on Preharvested Spinach

S. Park, S. Navratil, A. Gregory, A. Bauer, I. Srinath, B. Szonyi, et al. Applied and Environmental Microbiology, Vol. 81, No. 7; pp. 2635–2650, 2015 doi: 10.1128/AEM.03793-14

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**Significance:** Farm management, the environment and weather factors determined the odds of a contamination event in spinach.

A repeated cross-sectional study was conducted to identify farm management, environment, weather, and landscape factors that predict the count of generic Escherichia coli on spinach at the preharvest level. E. coli was enumerated for 955 spinach samples collected on 12 farms in Texas and Colorado between 2010 and 2012. Farm management and environmental characteristics were surveyed using a questionnaire. Weather and landscape data were obtained from National Resources Information databases. A two-part mixed-effect negative binomial hurdle model was used to identify factors affecting E. coli counts on spinach. Results indicated that the odds of a contamination event (non-zero versus zero counts) vary by state (odds ratio [OR] = 108.1). Odds of contamination decreased with implementation of hygiene practices (OR = 0.06) and increased with an increasing average precipitation amount (mm) in the past 29 days (OR = 3.5) and the application of manure (OR = 52.2). On contaminated spinach, E. coli counts increased with the average precipitation amount over the past 29 days. The relationship between E. coli count and the average maximum daily temperature over the 9 days prior to sampling followed a quadratic function with the highest bacterial count at around 24°C.

#### Salmonella

#### Survival of Salmonella on Chamomile, Peppermint, and Green Tea during Storage and Subsequent Survival or Growth following Tea Brewing

S.E. Keller, C.N. Stam, D.R. Gradl, Z. Chen, E.L. Larkin, S.R. Pickens, et al. Journal of Food Protection, Vol. 78, No. 4; pp. 661–667, 2015 doi: 10.4315/0362-028X.JFP-14-508

Link to full text: Click here

**Significance:** If Salmonella survives after storage, it may also survive and grow after a home brewing process.

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

The survival of Salmonella on dried chamomile flowers, peppermint leaves, and green tea leaves stored under different conditions was examined. Survival and growth of Salmonella was also assessed after subsequent brewing using dried inoculated teas. A Salmonella enterica serovar cocktail was inoculated onto different dried tea leaves or flowers to give starting populations of approximately 10 log CFU/g. The inoculum was allowed to dry prior to storage under 25 and 35°C at low (<30% relative humidity [RH]) and high (>90% RH) humidity levels. Under the four storage conditions tested, survival followed the order: 25°C with low RH > 35°C with low RH > 25°C with high RH > 35°C with high RH. Salmonella losses at 25°C with low RH occurred primarily during drying. In contrast, Salmonella decreased below detection after 45 days at 35°C and high RH in all teas tested. The thermal resistance of Salmonella was assessed at 55°C immediately after inoculation of tea leaves or flowers, after drying (24 h) onto tea leaves or flowers, and after 28 days of storage at 25°C with low RH. All conditions resulted in similar D-values ( $2.78 \pm 0.12$ ,  $3.04 \pm 0.07$ , and  $2.78 \pm 0.56$ , at 0 h, 24 h, and 28 days, respectively), indicating thermal resistance of Salmonella in brewed tea did not change after desiccation and 28 days of storage. In addition, all brewed teas tested supported the growth of Salmonella.

#### **Foodborne Pathogens**

Survival of Salmonella and Escherichia coli O157:H7 on Strawberries, Basil, and Other Leafy Greens during Storage S. Delbeke, S. Ceuppens, L. Jacxsens, M. Uyttendaele Journal of Food Protection, Vol. 78, No. 4; pp. 652–660, 2015 doi: 10.4315/0362-028X.JFP-14-354 Link to full text: Click here

**Significance:** Avoiding contamination at cultivation is important as Salmonella and E. coli O157:H7 survive during storage, and strawberries, basil, and other leafy green leaves are consumed without inactivation treatment.

The survival of Salmonella and Escherichia coli O157:H7 on strawberries, basil leaves, and other leafy greens was assessed at cold (<7°C) and ambient temperatures. All commodities were spot inoculated with E. coli O157:H7 or Salmonella to obtain an initial inoculum of 5-6 log and 4-5 log CFU/g for strawberries and leafy greens, respectively. Both Salmonella and E. coli O157:H7 showed a gradual decrease in numbers if inoculated on strawberries, with a similar reduction observed at 4, 10, and 15°C (2-3 log after 5 days). However, at 15°C (and 10°C for E. coli O157:H7), the survival experiment stopped before day 7, as die-off of both pathogens below the lower limit of detection was achieved or spoilage occurred. At 22°C, strawberries were moldy after 2 or 4 days. At that time, a 1- to 2-log reduction of both pathogens had occurred. A restricted die-off (on average 1.0 log) and increase (on average, 0.5 log) of both pathogens on basil leaves occurred after 7 days of storage at 7 and 22°C, respectively. On leafy greens, a comparable decrease as on basil was observed after 3 days at 7°C. At 22°C, both pathogens increased to higher numbers on fresh-cut iceberg and butterhead lettuce leaves (on average 1.0 log).

Evaluation of Novel Micronized Encapsulated Essential Oil–Containing Phosphate and Lactate Blends for Growth Inhibition of Listeria monocytogenes and Salmonella on Poultry Bologna, Pork Ham, and Roast Beef Ready-to-Eat Deli Loaves

G. Casco, T.M. Taylor, C. Alvarado



Journal of Food Protection, Vol. 78, No. 4; pp. 698–706, 2015 doi: 10.4315/0362-028X.JFP-14-273 Link to full text: Click here

**Significance:** The encapsulated essential oil with phosphate version 2 at 0.60% can function to replace potassium lactate to limit growth of Salmonella and Listeria monocytogens in ready-to-eat deli products.

Two proprietary noncommercial essential oil-containing phosphate blends were evaluated for antimicrobial activity against Salmonella enterica cocktail (SC)and Listeria monocytogenes (Lm)-inoculated deli meat products made from pork, poultry, or beef. Four treatments were tested: nonencapsulated essential oil with phosphate version 1 at 0.45% of final batch (EOV145; chicken and pork, or EEOV245 beef), micronized encapsulated essential oil with phosphate version 2 at 0.60% of final batch (EEOV260), a 2.0% potassium lactate (PL) control, and a negative control (CN) with no applied antimicrobial agent. Compared with the CN, none of the antimicrobial agents (EEOV260, EOV145, PL) successfully limited Lm or SC growth to <2.0 log cycles over 49 days or 35 days of refrigerated storage, respectively. The PL and EEOV260-treated ham loaves did show Lm growth limiting ability of up to 1 log cycle by days 35 and 42. On formed roast beef, the EEOV260 was able to extend the lag phase and inhibited the growth of Lm in the same manner as the PL. For SC-treated samples, a lag-phase extension was observed through 35 days of storage in poultry bologna treated with EEOV260 compared with the other samples. For pork deli loaves, the EEOV260 inhibited growth of SC at days 21 and 28 to the same level of efficacy as PL (0.5 log cycle). In roast beef samples, on day 35, the SC growth was inhibited ca. 0.5 log CFU/g by EEOV260 when compared with the CN.

#### The Growing Season, but Not the Farming System, Is a Food Safety Risk Determinant for Leafy Greens in the Mid-Atlantic Region of the United States

S.C. Marine, S. Pagadala, F. Wang, D.M. Pahl, M.V. Melendez, W.L. Kline, et al. Applied and Environmental Microbiology, Vol. 81, No. 7; pp. 2395–2407, 2015 doi: 10.1128/AEM.00051-15

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**Significance:** Seasonal events, weather conditions, and proximity of compost piles might be important factors contributing to microbial contamination on farms growing leafy greens.

To assess farm-level risk factors, bacterial indicators, Salmonella enterica and Shiga toxin-producing Escherichia coli (STEC) from 32 organic and conventional farms were analyzed. A total of 577 leafy greens, irrigation water, compost, field soil, and pond sediment samples were collected. Salmonella was recovered from 2.2% of leafy greens (n=369) and 7.7% of sediment (n=13) samples. There was an association between Salmonella recovery and growing season (fall versus spring) (P=0.006) but not farming system (organic or conventional) (P=0.920) or region (P=0.991). No STEC was isolated. In all, 10% of samples were positive for E. coli: 6% of leafy greens, 18% of irrigation water, 10% of soil, 38% of sediment, and 27% of compost samples. Farming system was a significant factor for total coliforms (TC) (P<0.001), with higher counts from organic farm samples. Growing season was a factor for aerobic mesophiles on leafy greens (P=0.004), with higher levels in fall than in spring. Water source was a factor for all indicator bacteria (P<0.001).



#### Survival and Growth of Salmonella Typhimurium, Escherichia coli O157:H7 and Staphylococcus aureus in Eggplant Dip During Storage

T.M. Osaili, A.A. Al-Nabulsi, Z. Jaradat, R.R. Shaker, D.Z. Alomari, M.M. Al-Dabbas, et al.

International Journal of Food Microbiology, Vol. 198, 2 April 2015; pp. 37–42, 2015

doi: 10.1016/j.ijfoodmicro.2014.12.025

Link to full text: Click here

**Significance:** The use of citric acid at 0.4–0.8% can inhibit the growth of S. aureus in eggplant dip, but adequate refrigeration is essential to minimize risk from this and other pathogens in this product.

This study examined the effects of citric acid on the survival of pathogenic microorganisms (Salmonella Typhimurium, Escherichia coli O157:H7 and Staphylococcus aureus) and naturally present organisms (lactic acid bacteria [LAB], aerobic bacteria [APC], and yeast and mold [YM]) in eggplant dip during storage. Eggplant dip with 0, 0.2, 0.4, 0.6 or 0.8% citric acid was inoculated with S. Typhimurium, E. coli O157:H7 or S. aureus and stored at 4, 10 and 21 °C for  $\leq$  15 d. The survival of the inoculated microorganisms was monitored, and LAB, APC, YM numbers and pH were determined. There was no significant effect of citric acid on inoculated S. Typhimurium and E. coli O157:H7. Salmonella and E. coli O157:H7 survived > 7 d with little reduction in viability. Reduction of S. aureus viability increased with citric acid concentration and reached > 3.0 log10 CFU/g by 15 d at 4 °C. At 21 °C, 0.6 and 0.8% citric acid significantly reduced LAB. Citric acid had significant effects on samples stored at 10 and 21 °C.

#### Norovirus

#### Efficacy and Mechanisms of Murine Norovirus Efficacy and Mechanisms of Murine Norovirus Inhibition by Pulsed-Light Technology

A. Vimont, I. Fliss, J. Jean Applied and Environmental Microbiology, Vol. 81, No. 8; pp. 2950–2957, 2015 doi: 10.1128/AEM.03840-14 Link to full text: Click here

**Significance:** Pulsed-light technology could provide an effective alternative means of inactivating noroviruses in wastewaters, in clear beverages, in drinking water, or on food-handling surfaces in the presence or absence of biofilms.

Pulse light was investigated for its efficacy in inactivating murine norovirus 1 (MNV-1) as a human norovirus surrogate in phosphate-buffered saline, hard water, mineral water, turbid water, and sewage treatment effluent and on food contact surfaces, including high-density polyethylene, polyvinyl chloride, and stainless steel, free or in an alginate matrix. The pulsed-light device emitted a broadband spectrum (200 to 1,000 nm) at a fluence of 0.67 J cm–2 per pulse, with 2% UV at 8 cm beneath the lamp. Reductions in viral infectivity exceeded 3 log10 in < 3 s (5 pulses; 3.45 J cm–2) in clear suspensions and on clean surfaces, and in 6 s (11 pulses; 7.60 J cm–2) on fouled surfaces except for stainless steel (2.6 log10). The presence of protein or bentonite interfered with viral inactivation. Pulsed light appeared to disrupt MNV-1 structure and degrade viral protein and RNA.



#### Electron Beam Inactivation of Tulane Virus on Fresh Produce, and Mechanism of Inactivation of Human Norovirus Surrogates by Electron Beam Irradiation

A. Predmore, G.C. Sanglay, E. DiCaprio, J. Li, R.M. Uribe, K. Le International Journal of Food Microbiology, Vol. 198, 2 April 2015; pp. 28–36, 2015 doi: 10.1016/j.ijfoodmicro.2014.12.024

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**Significance:** The mechanism of inactivation of electron beam was likely the same as gamma irradiation as the damage to viral constituents led to inactivation.

This study had three distinct goals: 1) to evaluate the sensitivity of a human norovirus surrogate, Tulane virus (TV), to electron beam (e-beam) irradiation in foods, 2) to compare the difference in sensitivity of TV and murine norovirus (MNV-1) to e-beam irradiation, and 3) to determine the mechanism of inactivation of these two viruses by e-beam irradiation. TV was reduced from 7 log10 units to undetectable levels at target doses of  $\geq 16$  kGy in strawberries and lettuce. MNV-1 was more resistant to e-beam treatment than TV. At target doses of 4 kGy, e-beam provided a 1.6 and 1.2 log reduction of MNV-1 in phosphate buffered saline (PBS) and Dulbecco's Modified Eagle Medium (DMEM), compared to a 1.5 and 1.8 log reduction of TV in PBS and Opti-MEM, respectively. Transmission electron microscopy revealed that increased e-beam doses negatively affected the structure of both viruses. Analysis of viral proteins by SDS-PAGE found that irradiation also degraded viral proteins. Using RT-PCR, irradiation was shown to degrade viral genomic RNA.

#### Norovirus Cross-Contamination during Preparation of Fresh Produce

S.F. Grove, A. Suriyanarayanan, B. Puli, H. Zhao, M. Li, D. Li, et al. International Journal of Food Microbiology, Vol. 198, 2 April 2015; pp. 43–49, 2015 doi: 10.1016/j.ijfoodmicro.2014.12.023 Link to full text: Click here

**Significance:** Virions are transferred from one hand to the other during washing with and without soap.

This study examined cross-contamination of a human norovirus (HuNoV) surrogate, murine norovirus (MNV-1), during common procedures used in preparing fresh produce in a food service setting, including turning water spigots, handling and chopping Romaine lettuce, and washing hands. MNV-1 transfer coefficients varied by surface type, and a greater affinity for human hands and chopped lettuce was observed. During the chopping of Romaine lettuce, MNV-1 was transferred from either a contaminated cutting board (25% or 1.4-log transfer %) or knife (~ 100% or 2.0-log transfer %) to lettuce at a significantly greater rate than from contaminated lettuce to the board (2.1% or 0.3-log transfer %) and knife (1.2% or 0.06-log transfer %). For handwashing trials, only one hand was inoculated with MNV-1 prior to washing. The handwashing methods included rubbing hands under tap water for at least 5 s (average 2.8-log reduction) or washing hands for at least 20 s with liquid soap (average 2.9-log reduction) or foaming soap (average 3.0-log reduction). Despite the reductions of MNV-1 observed, residual virions were detected on both hands after washing in every replicate trial. MNV-1 transfers readily between common surfaces during food preparation.



#### Listeria

#### Antimicrobial Effects of Essential Oils, Nisin, and Irradiation Treatments against Listeria monocytogenes on Ready-to-Eat Carrots

A. Ndoti-Nembe, K.D. Vu, N. Doucet, M. Lacroix Journal of Food Science, Vol. 80, No. 4; pp. M795–M799, 2015 doi: 10.1111/1750-3841.12832 Link to full text: Click here

**Significance:** Combined treatments using nisin + carvacrol or nisin + mountain savory and irradiation at 1.0 kGy could be used as an effective method for controlling Listeria monocytogenes in minicarrots.

The study aimed at using essential oil (EO) alone or combined EO with nisin and low dose  $\gamma$ -irradiation to evaluate their antibacterial effect against Listeria monocytogenes during storage of carrots at 4 °C. Minicarrots were inoculated with L. monocytogenes at a final concentration of approximately 7 log CFU/g. Inoculated samples were coated by nisin at final concentration of 103 International Unit (IU)/mL or individual mountain savory EO or carvacrol at final concentration of 0.35%, w/w) or nisin + EO. The samples were then irradiated at 0, 0.5, and 1.0 kGy. The treated samples were kept at 4 °C and microbial analysis of samples were conducted at days 1, 3, 6, and 9. The results showed that coating carrots by carvacrol + nisin or mountain savory + nisin and then irradiating coated carrots at 1 kGy could reduce L. monocytogenes by more than 3 log at day 1 and reduced it to undetectable level from day 6.

#### **Mycotoxins**

#### Occurrence of Ochratoxin A Contamination and Detection of Ochratoxigenic Aspergillus Species in Retail Samples of Dried Fruits and Nuts

J.D. Palumbo, T.L. O'Keeffe, Y.S. Ho, C.J. Santillan Journal of Food Protection, Vol. 78, No. 4; pp. 836–842 doi: 10.4315/0362-028X.JFP-14-471 Link to full text: Click here

**Significance:** Raisins are more frequently contaminated with low levels of ochratoxin A than other dried fruits and nuts, and Aspergillus species are the likely source of that contamination.

To determine the incidence of ochratoxin A (OTA) contamination in dried fruits and tree nuts, retail packaged and bulk raisins, dates, figs, prunes, almonds, pistachios, and walnuts were collected from small and large supermarkets in seven areas of the US between 2012 and 2014. Of the 665 samples analyzed, OTA was detected in 48 raisin samples, 4 fig samples, 4 pistachio samples, and 1 date sample, and ranged from 0.28 to 15.34 ng/g in dried fruits and 1.87 to 890 ng/g in pistachios; two raisin samples and one pistachio sample exceeded the European Union regulatory limit of 10 ng/g. PCR detection of potential OTA-producing Aspergillus species revealed the presence of A. niger, A. welwitschiae, and A. carbonarius in 20, 7, and 7 of the 57 OTA-contaminated samples, respectively. However, OTA-producing A. carbonarius was isolated from only one raisin sample.



#### **Infant Formula**

# Exposure to Di-2-Ethylhexyl Phthalate, Di-N-Butyl Phthalate and Bisphenol A through Infant Formulas

T. Cirillo, G. Latini, M.A. Castaldi, L. Dipaola, E. Fasano, F. Esposito, et al. Journal of Agricultural and Food Chemistry, Vol. 63, No. 12; pp. 3303–3310, 2015 doi: 10.1021/jf505563k

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**Significance:** There are potential hazards for infants fed with baby formulas and the contamination seems more related to the production of formulas than to a release from containers.

The aim of this study was to test the presence of di-2-ethylhexyl phthalate (DEHP), di-n-butyl phthalate (DnBP), and bisphenol A (BPA) in infant formulas. DEHP, DnBP, and BPA concentrations were measured in 22 liquid and 28 powder milks by gas chromatography with flame ionization detection and high performance liquid chromatography with fluorimetric detection, respectively. DEHP concentrations were between 0.005 and 5.088  $\mu$ g/g (median 0.906  $\mu$ g/g), DnBP concentrations were between 0.008 and 1.297  $\mu$ g/g (median 0.053  $\mu$ g/g), and BPA concentrations were between 0.003 and 0.375  $\mu$ g/g (median 0.015  $\mu$ g/g). Concentrations of the investigated contaminants in liquid and powder milks were not significantly different, even though samples were packed in different types of containers.

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The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org


# **Nutrition Briefs**

## April 2015

## **Cardiovascular Disease**

#### The Effect of a Low-Fat Spread With Added Plant Sterols on Vascular Function Markers: Results of the Investigating Vascular Function Effects of Plant Sterols (INVEST) Study

R.T. Ras, D. Fuchs, W.P. Koppenol, U. Garczarek, A. Greyling, C. Keicher, et al. American Journal of Clinical Nutrition, Vol. 101, No. 4; pp. 733–741, 2015 doi: 10.3945/ajcn.114.102053

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**Significance:** The intake of a low-fat spread with added plant sterols neither improved nor worsened flow mediated dilation or other vascular function markers in hypercholesterolemic men and women.

This double-blind, randomized, placebo-controlled, parallel design study examined the effects of a low-fat spread with added plant sterols (PSs) on brachial artery endothelial function (as measured by flow-mediated dilation [FMD]), arterial stiffness, blood pressure, serum lipids, and plasma PS concentrations. The authors hypothesized that PSs would not worsen FMD but would rather modestly improve FMD. After a 4-wk run-in period, 240 hypercholesterolemic but otherwise healthy men and women consumed 20 g/d of low-fat spread without (control) or with added PSs (3 g/d) during 12 wk; 232 participants completed the study. PS intake did not affect FMD (+0.01 percentage points; 95% CI: -0.73, 0.75) compared with control. Measures of arterial stiffness and blood pressure were also not significantly changed compared with control. After PS intervention, LDL-cholesterol significantly decreased on average by 0.26 mmol/L (95% CI: -0.40, -0.12) or 6.7% compared with control. Plasma sitosterol and campesterol concentrations significantly increased in the PS group up to on average 11.5 µmol/L and 13.9 µmol/L (expressed as geometric means), respectively.

#### Emerging Risk Factors as Markers for Carotid Intima Media Thickness Scores

S.C. Masley, R. Roetzheim, L.V. Masley, T. McNamara, D.D. Schocken Journal of the American College of Nutrition, Vol. 34, No. 2; pp. 100–107, 2015 doi: 10.1080/07315724.2014.916238

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**Significance:** Aerobic fitness and dietary intake of fiber, fish, magnesium, and zinc are inversely associated with carotid IMT scores, while systolic blood pressure, fasting glucose, body composition, and total cholesterol/HDL ratio have a direct relationship with mean carotid IMT.

This prospective, cross-sectional analysis of 592 subjects aimed to determine which lifestyle factors were associated with mean carotid intima media thickness

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

(IMT), a safe and reliable predictor of future cardiovascular disease (CVD) risk. Measures were made of body composition, anthropometric measures, fitness, diet (measured with a 3-day food diary), laboratory results, and mean carotid IMT. Multivariate analyses showed that higher mean IMT values were associated with increasing age (p < 0.0001), male gender (p = 0.0002), higher systolic blood pressure (BP; p = 0.0008), higher BMI (p = 0.0005), and lower intake of zinc (p = 0.0001). Bivariate analyses (controlling for age and gender, with and without statin use), showed that higher mean IMT scores were statistically associated with higher diastolic BP (p = 0.007), higher total cholesterol/HDL ratio (p < 0.0001), higher triglyceride/HDL ratio (p = 0.0001), lower aerobic capacity measures (p = 0.0007), higher body fat percentage and waist circumference (p < 0.0001), higher fasting glucose level (p = 0.028), and lower intake of magnesium (p = 0.019), fish (p = 0.007), and fiber (p = 0.02).

#### Diabetes

#### Low Circulating 25-Hydroxyvitamin D Concentrations Are Associated with Defects in Insulin Action and Insulin Secretion in Persons with Prediabetes

F. Abbasi, C. Blasey, D. Feldman, M.P. Caulfield, F.M. Hantash, G.M. Reaven Journal of Nutrition, Vol. 145, No. 4; pp. 714–719, 2015 doi: 10.3945/jn.114.209171 Link to full text: Click here

Significance: Nondiabetics with prediabetes and low circulating 25(OH)D concentrations are the most insulin resistant and have impaired  $\beta$ -cell function, attributes that put them at enhanced risk of type 2 diabetes.

This cross-sectional study determined whether low circulating 25-hydroxyvitamin D [25(OH)D] concentrations are associated with defects in insulin action and insulin secretion in persons with prediabetes (PreDM). Nondiabetic subjects were stratified (n=488) on PreDM or normal fasting glucose (NFG) and a 25(OH)D concentration  $\leq$  20 ng/mL (deficient) or >20 ng/mL (sufficient). Insulin resistance (IR) by steady state plasma glucose (SSPG) concentration and homeostasis model assessment of insulin resistance (HOMA-IR) and insulin secretion by HOMA of  $\beta$ -cell function (HOMA- $\beta$ ) were determined. IR and secretion measures in PreDM and NFG groups; 25(OH)D-deficient and 25(OH) D-sufficient groups; and PreDM-deficient, PreDM-sufficient, NFG-deficient, and NFG-sufficient subgroups were compared, adjusting for covariates. In the PreDM group, mean SSPG concentration and HOMA-IR were higher and mean HOMA- $\beta$  was lower than in the NFG group (P<0.001 for all comparisons). In the 25(OH)D-deficient group, mean SSPG concentration was higher (P<0.001), but neither mean HOMA-IR nor HOMA- $\beta$  was significantly different from that in the 25(OH)D-sufficient group. In the PreDMdeficient subgroup, mean (95% CI) SSPG concentration was higher (P<0.01) than in the PreDM-sufficient, NFG-deficient, and NFG-sufficient subgroups [192 (177-207) mg/dL vs. 166 (155-177) mg/dL, 148 (138-159) mg/dL, and 136 (127–144) mg/dL, respectively].

#### A High–Glycemic Index, Low-Fiber Breakfast Affects the Postprandial Plasma Glucose, Insulin, and Ghrelin Responses of Patients with Type 2 Diabetes in a Randomized Clinical Trial

F.M. Silva, C.K. Kramer, D. Crispim, M.J. Azevedo Journal of Nutrition, Vol. 145, No. 4; pp. 736–741, 2015



doi: 10.3945/jn.114.195339

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**Significance:** Plasma glucose, insulin, and ghrelin responses were least favorable when patients with type 2 diabetes consumed a breakfast with a high GI and low fiber.

This randomized 4-intervention crossover investigated the effect of 4 breakfasts with a different glycemic index (GI) and amount of fiber on postprandial plasma glucose, insulin, and appetite in 14 patients with type 2 diabetes [7 men; ages  $65.8 \pm 5.2$  y; glycated hemoglobin:  $6.6 \pm 0.9\%$ ; BMI:  $27.2 \pm 3.1$ ]. The breakfasts were as follows: a high GI ( $60.4 \pm 0.1\%$ ) and high fiber ( $6.0 \pm 0.3$  g) (HGI-HF), a high GI (60.9  $\pm$  1.7%) and low fiber (2.5  $\pm$  0.4 g) (HGI-LF), a low GI (37.7  $\pm$  0.1%) and high fiber (6.2  $\pm$  0.3 g) (LGI-HF), and a low GI (39.8  $\pm$  1.3%) and low fiber  $(2.0 \pm 0.1 \text{ g})$  (LGI-LF). The area under the curve (AUC) [mean (95% CI)] for plasma glucose (mmol/L  $\times$  min) was higher after patients consumed the HGI-LF breakfast [9.62 (8.39, 10.84)] than after the LGI-HF breakfast [8.95 (7.71, 10.18)] (P  $\leq$  0.05). Insulin AUC ( $\mu$ IU/mL  $\times$  min) after patients consumed the HGI-LF meal [65.72 (38.24, 93.19)] was higher than after the HGI-HF meal [57.24 (32.44, 82.04)] ( $P \le 0.05$ ). The other observed difference was higher insulin AUC after the consumption of the LGI-LF breakfast [61.54 (36.61, 86.48)] compared with the AUC after the LGI-HF breakfast [54.16 (31.43, 76.88)] (P  $\leq$  0.05). Plasma ghrelin decreased in comparison with baseline only after patients consumed the LGI-HF and LGI-LF breakfasts.

#### Purified Anthocyanin Supplementation Reduces Dyslipidemia, Enhances Antioxidant Capacity, and Prevents Insulin Resistance in Diabetic Patients

D. Li, Y. Zhang, Y. Liu, R. Sun, M. Xia Journal of Nutrition, Vol. 145, No. 4; pp. 742–748, 2015 doi: 10.3945/jn.114.205674 Link to full text: Click here

**Significance:** Anthocyanin supplementation exerts beneficial metabolic effects in subjects with type 2 diabetes by improving dyslipidemia, enhancing antioxidant capacity, and preventing insulin resistance.

This randomized, placebo-controlled, double-blind trial investigated the effects of purified anthocyanins on dyslipidemia, oxidative status, and insulin sensitivity in 58 patients with type 2 diabetes. Patients were given 160 mg of anthocyanins twice daily or placebo (n = 29/group) for 24 wk. Anthocyanin supplementation significantly decreased serum LDL-cholesterol (by 7.9%), triglycerides (by 23.0%), apolipoprotein (apo) B-48 (by 16.5%), and apo C-III (by 11.0%) and increased HDL-cholesterol (by 19.4%) compared with placebo. In addition, patients in the anthocyanin group showed higher total radical-trapping antioxidant parameter and ferric ion reducing antioxidant power values than did patients in the placebo group. Serum concentrations of 8-iso-prostaglandin F2a, 13-hydroxyoctadecadienoic acid, and carbonylated proteins in patients in the anthocyanin group were significantly less than in patients in the placebo group (23.4%, 25.8% and 20%, respectively). Furthermore, supplementation with anthocyanin lowered fasting plasma glucose (by 8.5%) and homeostasis model assessment for insulin resistance index (by 13%), and elevated serum adiponectin (by 23.4%) and β-hydroxybutyrate (by 42.4%) concentrations significantly compared with placebo supplementation.



#### The Association Between a Biomarker Score for Fruit and Vegetable Intake and Incident Type 2 Diabetes: The EPIC-Norfolk Study

A.J.M. Cooper, S.J. Sharp, R.N. Luben, K-T. Khaw, N.J. Wareham, N.G. Forouhi

European Journal of Clinical Nutrition, Vol. 69, No. 4; pp. 449–454, 2015 doi: 10.1038/ejcn.2014.246

Link to full text: Click here

**Significance:** A combination of biomarkers representing the intake of a mixed fruit and vegetable diet was strongly inversely associated with incident diabetes.

This study aimed to examine the prospective association between a composite score comprised of three biomarkers of mixed fruit and vegetable (FV) intake in 318 incident diabetics (cases) and 926 free-living controls. Subjects aged 40–79 years at baseline (1993–1997) completed a 7-day prospective food diary and had plasma vitamin C and carotenoid measures. A composite biomarker score (CB-score) comprising the sum of plasma vitamin C, beta-carotene and lutein was derived. A strong inverse association was found between the CB-score and incident diabetes. The ORs (95% CI) of diabetes comparing quartiles Q2, Q3 and Q4 of the CB-score with Q1 (reference category) were 0.70 (0.49, 1.00), 0.34 (0.23, 0.52) and 0.19 (0.12, 0.32), respectively, and 0.49 (0.40, 0.58) per s.d. change in CB-score in a model adjusted for demographic and lifestyle factors. The association was marginally attenuated after additionally adjusting for body mass index and waist circumference (0.60 (0.49 and 0.74) per s.d. change in CB-score).

#### Consumption of Fatty Foods and Incident Type 2 Diabetes in Populations From Eight European Countries

B. Buijsse, H. Boeing, D. Drogan, M.B. Schulze, E.J. Feskens, P. Amiano European Journal of Clinical Nutrition, Vol. 69, No. 4; pp. 455–461, 2015 doi: 10.1038/ejcn.2014.249 Link to full text: Click here

**Significance:** Fatty foods were generally not associated with type 2 diabetes, apart from weak positive association for margarine.

This case control study, nested within 8 countries with 12,403 incident type 2 diabetes (T2D) cases and a subcohort of 16,835 people, assessed whether the intake of vegetable oil, butter, margarine, nuts and seeds, and cakes and cookies is related to incident T2D. Diet was assessed at baseline (1991–1999) by countryspecific questionnaires. Country-specific hazard ratios (HRs) across four categories of fatty foods (nonconsumers and tertiles among consumers) were combined with random-effects meta-analysis. After adjustment not including BMI, nonconsumers of butter, nuts and seeds and cakes and cookies were at higher T2D risk compared with the middle tertile of consumption. Among consumers, cakes and cookies were inversely related to T2D (HRs across increasing tertiles 1.14, 1.00 and 0.92, respectively; P-trend < 0.0001). All these associations attenuated upon adjustment for BMI, except the higher risk of nonconsumers of cakes and cookies (HR 1.57). Higher consumption of margarine became positively associated after BMI adjustment (HRs across increasing consumption tertiles: 0.93, 1.00 and 1.12; P-trend 0.03). Within consumers, vegetable oil, butter and nuts and seeds were unrelated to T2D.



#### The Effect of a High-Egg Diet on Cardiovascular Risk Factors in People With Type 2 Diabetes: The Diabetes and Egg (DIABEGG) Study—A 3-Mo Randomized Controlled Trial

N.R. Fuller, I.D. Caterson, A. Sainsbury, G. Denyer, M. Fong, J. Gerofi, et al. American Journal of Clinical Nutrition, Vol. 101, No. 4; pp. 705–713, 2015

doi: 10.3945/ajcn.114.096925

Link to full text: Click here

**Significance:** A high-egg diet can be included safely as part of the dietary management of patients with type 2 diabetes, and it may provide greater satiety.

This randomized controlled study aimed to determine whether a high-egg diet (2 eggs/d for 6 d/wk) compared with a low-egg diet (<2 eggs/wk) affected circulating lipid profiles, particularly HDL-cholesterol, in 140 overweight or obese people with prediabetes or type 2 diabetes (T2D). Subjects were randomly assigned to one of the 2 diets as part of a 3-mo weight maintenance study. Results found no significant difference in the change in HDL-cholesterol from screening to 3 mo between groups; the mean difference (95% CI) between high- and low-egg groups was +0.02 mmol/L (-0.03, 0.08 mmol/L; P = 0.38). No between-group differences were shown for total cholesterol, LDL-cholesterol, triglycerides, or glycemic control. Both groups were matched for protein intake, but the high-egg group reported less hunger and greater satiety postbreakfast. Polyunsaturated fatty acid (PUFA) and monounsaturated fatty acid (MUFA) intakes significantly increased from baseline in both groups. High egg consumption did not have an adverse effect on the lipid profile of people with T2D in the context of increased MUFA and PUFA consumption.

#### Sugar-Sweetened Beverages

Changing Beverage Consumption Patterns Have Resulted in Fewer Liquid Calories in the Diets of US Children: National Health and Nutrition Examination Survey 2001-2010

M.S.C. Mesirow, J.A. Welsh

Journal of the Academy of Nutrition and Dietetics, Vol. 115, No. 4; pp. 559–566.e4, 2015

doi: 10.1016/j.jand.2014.09.004

Link to full text: Click here

**Significance:** Changing beverage consumption patterns reflect positive trends in the form of reduced intake of sugar-sweetened beverages, whole milk, and total calories from beverages in US children.

This study described recent trends in consumption of all commonly consumed beverages among US children aged 2 to 19 years. Twenty-four-hour dietary recalls from 18,541 participants in the 2001-2010 NHANES were used to assess beverage intake, including sugar-sweetened beverages (SSBs), milks, 100% juices, low-/no-calorie beverages, alcohol-containing beverages; and plain water (during 2005-2010 only). Weighted mean intakes (percent total energy and total ounces) and consumption prevalence were estimated. Results found that between 2001-2002 and 2009-2010, total daily beverage consumption (excluding water) decreased from 24.4% to 21.1% energy (32.0 to 27.9 oz). Significant decreases (P<0.05) occurred in sugar-sweetened sodas (13.5% to 10.2% energy), whole milk (2.7% to 1.6% energy), fruit juices with sugar added (2.3% to 2.1% energy), and fruit-flavored drinks (1.6% to 0.8% energy). Significant increases



occurred for sweetened coffees/teas, energy drinks, sport drinks, and unsweetened juices though the contribution of each to total energy intake remained <1%. Low-/no-calorie drink consumption also increased, rising from 0.2 to 1.3 oz/day.

## Mothers' Child-Feeding Practices Are Associated with Children's Sugar-Sweetened Beverage Intake

S. Park, R. Li, L. Birch Journal of Nutrition, Vol. 145, No. 4; pp. 806–812, 2015 doi: 10.3945/jn.114.207233 Link to full text: Click here

**Significance:** The odds of daily sugar-sweetened beverage intake were lower among children whose mothers set limits on sweets/junk foods regardless of the child's weight but were higher among underweight/normal-weight children whose mothers restricted the child's favorite food intake.

This study examined the association between mothers' child-feeding practices and sugar-sweetened beverage (SSB) intake among 1350 6-y-old children. Data from the Year 6 Follow-up of the Infant Feeding Practices Study II were evaluated. The outcome variable was child's SSB intake. The exposure variables were 4 child-feeding practices of mothers: setting limits on sweets or junk foods, regulating their child's favorite food intake to prevent overconsumption, pressuring their child to eat enough, and pressuring their child to "clean the plate." The consumption of SSBs ≥1 time/d was observed among 17.1% of underweight/ normal-weight children and in 23.2% of overweight/obese children. Adjusted ORs (aORs) of consuming SSBs  $\geq 1$  time/d (vs. no SSB consumption) were significantly lower in children whose mothers reported setting limits on sweets/junk foods (aOR: 0.29; 95% CI: 0.15, 0.58 for underweight/normal-weight children; aOR: 0.16; 95% CI: 0.03, 0.79 for overweight/obese children). SSB intake was higher among underweight/normal-weight children whose mothers reported trying to keep the child from eating too much of their favorite foods (aOR: 2.03; 95% CI: 1.25, 3.29). Mothers' tendency to pressure their children to consume more food or to "clean the plate" was not associated with child's SSB intake.

#### Caffeine

Urine Excretion of Caffeine and Select Caffeine Metabolites Is Common in the US Population and Associated with Caffeine Intake

M.E. Rybak, M.R. Sternberg, C-I. Pao, N. Ahluwalia, C.M. Pfeiffer Journal of Nutrition, Vol. 145, No. 4; pp. 766–774, 2015 doi: 10.3945/jn.114.205476 Link to full text: Click here

**Significance:** Excretion of caffeine and its metabolites in urine is common in the US population.

This study described urine caffeine and caffeine metabolite concentrations (n = 2466) and excretion rates (n = 2261) in the US population  $\geq$ 6 y by age, sex, race-ethnicity, and caffeine intake (from foods, beverages, and dietary supplements). Caffeine and 14 of its metabolites were measured in spot urine samples from the NHANES 2009–2010 by use of LC-tandem mass spectrometry. Results found that caffeine and its metabolites were detectable in the urine of most persons, generally at concentrations  $\geq$ 1 µmol/L. Median concentrations (95% CI) ranged from 0.560 (0.497, 0.620) µmol/L to 58.6 (48.6, 67.2) µmol/L;



median excretion rates from 0.423 (0.385, 0.468) nmol/min to 46.0 (40.7, 50.2) nmol/min. Urine concentrations and excretion rates for 9 analytes had moderate correlations with caffeine intake (Spearman  $\rho = 0.55-0.68$ , P < 0.0001); the remaining analytes had low correlations ( $\rho = 0.15-0.33$ , P < 0.0001). Larger differences in geometric mean concentrations and excretion rates between the highest vs. lowest quartiles of caffeine intake for the 9 compounds than the rest were observed. Consistent with dietary caffeine intake, urine concentrations and excretion rates for most compounds were significantly higher in men than women, non-Hispanic whites than Hispanics and non-Hispanic blacks, and highest in persons aged 40–59 y.

#### **Blood Pressure**

#### Flaxseed Consumption May Reduce Blood Pressure: A Systematic Review and Meta-Analysis of Controlled Trials

S. Khalesi, C. Irwin, M. Schubert

Journal of Nutrition, Vol. 145, No. 4; pp. 758-765, 2015

doi: 10.3945/jn.114.205302

Link to full text: Click here

**Significance:** Consumption of flaxseed may lower blood pressure slightly but it may be greater when it is consumed as a whole seed and for a duration of >12 wk.

The effect of flaxseed consumption on blood pressure and the influence of baseline blood pressure, type of flaxseed supplementation, and duration of flaxseed supplementation on blood pressure were explored. PubMed, CINAHL, and Cochrane Library were searched through July 2014 for studies in which humans supplemented their habitual diet with flaxseed or its extracts (i.e., oil, lignans, fiber) for  $\geq 2$  wk. A total of 11 studies (14 trials) were included in the analysis. Random-effects meta-analyses were conducted for the mean difference in blood pressure. Results indicated that flaxseed supplementation reduced systolic blood pressure (-1.77 mm Hg; 95% CI: -3.45, -0.09 mm Hg; P = 0.04) and diastolic blood pressure (-1.58 mm Hg; 95% CI: -2.64, -0.52 mm Hg; P = 0.003). These results were not influenced by categorization of participants into higher baseline blood pressure ( $\geq 130$  mm Hg). An improvement in diastolic blood pressure was observed in subgroup analysis for consuming whole flaxseed (-1.93 mm Hg; 95% CI: -3.65, -0.21 mm Hg; P < 0.05) and duration of consumption  $\geq 12$  wk (-2.17 mm Hg; 95% CI: -3.44, -0.89 mm Hg; P < 0.05).

#### Fiber

## Dietary Fiber Intake and Risk of Ischemic and Hemorrhagic Stroke in the UK Women's Cohort Study

D.E. Threapleton, V.J. Burley, D.C. Greenwood, J.E. Cade European Journal of Clinical Nutrition, Vol. 69, No. 4; pp. 467–474, 2015 doi: 10.1038/ejcn.2014.260 Link to full text: Click here

**Significance:** Greater total fiber and fiber from cereals are associated with a lower stroke risk, and associations were more consistent with ischemic stroke.

This study examined the association of fiber intake with a reduced stroke risk and in different stroke types (i.e., total, ischemic or hemorrhagic stroke). A total of 27,373 disease-free women were followed up for 14.4 years. Diet was assessed



with a 217-item food frequency questionnaire and stroke cases were identified using English Hospital Episode Statistics and mortality records. A total of 135 hemorrhagic and 184 ischemic stroke cases were identified in addition to 138 cases where the stroke type was unknown or not recorded. Greater intake of total fiber, higher fiber density and greater soluble fiber, insoluble fiber and fiber from cereals were associated with a significantly lower risk for total stroke. For total stroke, the hazard ratio per 6 g/day total fiber intake was 0.89 (95% CI: 0.81–0.99). Different findings were observed for hemorrhagic and ischemic stroke in healthy-weight or overweight women. Total fiber, insoluble fiber and cereal fiber were inversely associated with hemorrhagic stroke risk in overweight/obese participants, and in healthy-weight women greater cereal fiber was associated with a lower ischemic stroke risk. In non-hypertensive women, higher fiber density was associated with lower ischemic stroke risk.

## About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

From:Beth BrueggemeyerSent:Wednesday, April 29, 2015 10:54 AMTo:Joanne LuptonSubject:RE: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

Joanne.

LOL! Practice makes perfect.

Β.

-----Original Message-----From: Joanne Lupton [mailto:Joanne.Lupton@agnet.tamu.edu] Sent: Wednesday, April 29, 2015 11:41 AM To: Beth Brueggemeyer; Katie Stuart Subject: RE: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

Beth, It will be next January until I get this straight. Nothing like retirement! Joanne

Joanne R. Lupton, Ph.D.

-----Original Message-----From: Beth Brueggemeyer Sent: Wednesday, April 29, 2015 8:54 AM To: Katie Stuart; Donald Clark; Joanne Lupton Subject: FW: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

Good morning Joanne and Katie,

I am writing about the reimbursement of expenses from the 2015 ILSI Annual Meeting. Thank you for the receipts - they arrived in good shape.

There is a dinner charge for January 21 - at the Sheraton Wild Pass Hotel for the amount of \$148.42. You provided the credit card statement with this dinner highlighted. For the ILSI accounting purposes, we ask if you can send us a copy of the restaurant receipt from the dinner. If you charged the dinner to your hotel room and then paid upon checkout from the hotel, do you have the Hotel statement at the time of check-out?

My apologies for the inconvenience of this request.

Thanks, Beth

-----Original Message-----From: Donald Clark [mailto Sent: Tuesday, April 14, 2015 10:33 AM To: Beth Brueggemeyer Subject: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting Hello Ms. Brueggemeyer!

Ok, I believe we have the files set up where you can view them now.

Thank you, and please feel free to contact me with any questions.

Katie Stuart

From: Sent: To: Subject: Joanne Lupton Wednesday, April 29, 2015 10:41 AM Beth Brueggemeyer; Katie Stuart RE: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

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Katie Stuart

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Katie Stuart

## COMPLETE AND APPEND TO YOUR REIMBURSEMENT FORM:

Please indicate if the reimbursement is to be provided by:  $\underline{X}$  Cheque \_\_\_\_\_Bank Draft

Please note that some banks charge processing fees to receive bank drafts. These fees are the responsibility of the payee and will not be reimbursed by ILSI.

For reimbursement by CHEQUE, please provide the	ne following:	
Name: Journe Lupton		30
Street Address:		
City:		
Province/State:		
Country: USA		
Postal/zip code:		
Telephone number:		
For reimbursement by WIRE TRANSFER, please p	rovide the following:	
Bank Name:		
Bank Address:		
Account Number:	-	
Account Holder's Name:		
ABA Routing Number (US Accounts):		
Sort/Swift Code (non-US Accounts):		
IBAN Number (non-US Accounts):		
Bank Identifier Code (non-US Accounts):		
Preferred currency:		



International Life Sciences Institute 1156 Fifteenth Street, NW1.202.6Suite 2001.202.6Washington, DC 20005www.ils

1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

## International Life Sciences Institute Expense Reimbursement Form

Name: Dr	Joan	ne Li	iptor	)		Travel Date	e(s): 1-16	e-15 thru 1-20-2015
Purpose of tr	avel: IL	SI 21	015 An	inual V	neeting	Travel loca	tion(s): P	hoenix, AZ
	Itemized ex	penses	1.1		0			
Date	Breakfast	Lunch	Dinner	Lodging	Travel	Other	Daily Total	Description of other expenses and currency
1-16-15		7.90			358.70		366.60	
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-20-15		Le.87	10000				6.87	
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Date submitted: 4-7-15	Signature of claimant: Joanne Lupton
Date approved:	Signture of ILSI RF authorising party:

PLEASE ATTACH RECEIPTS FOR ALL ITEMS OF \$25USD OR MORE (or equivalent)

(Mileage is reimbursed at the rate of 56¢ per mile – or prevailing US gov't rate in effect in January 2015)

8-7.48-548
p. 3/10

atinum	Card®

JOANNE R LUPTON Closing Date 02/11/15

Account Ending

**Payments and Credits** 

Description

FAST FOOD RESTAURAN

Summary

	Total
Payments	\$0.00
Total Payments and Credits	
Detail *Indicates posting date	
Payments	Amount
01/23/15* JOANNE R LUPTON ONLINE PAYMENT - THANK YOU	
New Charges	
Summary	Total
JOANNE R LUPTON	
Total New Charges	
Detail	
JOANNE R LUPTON Card Ending	Amount
01/16/15 PANDA EXPRESS #2239 HOUSTON TX ILS I	\$7.90

Continued on reverse

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UNITED	Manage your account online: www.chase.com/united	Customer Service: 1-800-323-6252	Mobile: Visit chase.com on your mobile browser
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Date of Transaction	Merchant Name or Transaction Desc	ription	\$ Amount
01/16 IN *TRANST	YLE TRANSPOR 800-4105479 AZ	Cur Service	93.00

#### JOANNE R LUPTON

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Account Ending 3-04009

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Detail Contin	nued	
		Amount
20/15 PARA	DISE BAKERYCAFE PHOENIX AZ TLSI FOOD RESTAURANT	\$6.87
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01/10 0000 LODO	0000 Meals	

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JOANNER LUPTON	Account Ending	60°

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1	Passenger Name: LUPTON	/JOANNEDR			
1	Document Type: PASSENC	GER TICKET			 

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Continued on next page

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From:	Suzanne Harris
Sent:	Tuesday, April 28, 2015 4:12 PM
То:	Joanne Lupton
Subject:	RE: Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight Committee conference call Tuesday, April 28, 2015

Thanks, Joanne.

Suzie

From: Joanne Lupton [mailto:Joanne.Lupton@agnet.tamu.edu]
Sent: Tuesday, April 28, 2015 5:06 PM
To: Suzanne Harris
Subject: RE: Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight Committee conference call -- Tuesday, April 28, 2015

Suzie, I'm so sorry, I didn't have this on my calendar (don't know why). I'm going to ILSI tomorrow for the COI meeting. I'll read what you sent and send comments back to you if I have any. Joanne

From: Suzanne Harris		
Sent: Tuesday, April 28, 2015 8:01 AM		
То: '	's.chang@griffith.edu.au';	; Joanne
Lupton;		
Cc:	'carmel.james@griffith.edu.au'; '	;

**Subject:** Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight Committee conference call - Tuesday, April 28, 2015

#### Call is beginning!

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The first conference call in 2015 for the ILSI Financial Oversight Committee is scheduled for **Tuesday, April 28, 2015**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour and the dial-in instructions are provided at the bottom of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the October 27, 2014 conference call

Agenda Item III. 2015 Year-to-date financial report; first quarter 2015 Raffa investment report

Please let me know if you have any questions. If you will not be able to join the conference call on April 28, you are welcome to send your comments and questions either to me to distribute to the committee or directly to the committee.

### **Dial-in Instructions**

If you are calling from:	Please dial:
Australia	1-800-064-762
Germany	0-800-723-5123
United Kingdom	0-800-169-0430
United States	1-888-585-9008

The conference room number for everyone is 476-399-389 #.

If you will be calling in from another country, please let me know which one so I can send you the appropriate toll-free number.

From: Sent:	Suzanne Harris Tuesday, April 28, 2015 8:01 AM						
То:	's chang@griffith edu au'						
	Joanne Lupton;						
Cc:	; 'carmel.james@griffith.edu.au';						
	'; Chelsea L. Bishop; Beth-Ellen Berry; Shawn Sullivan; Beth						
	Brueggemeyer						
Subject:	Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight						
-	Committee conference call Tuesday, April 28, 2015						
Attachments:	FOC 2015-04-28 agd.doc; FOC 2014-10-27 minutes BEB.docx; ILSI Financial Statement 03312015.pdf; ILSI Performance.pdf						

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## March 2015 Portfolio Performance & Activity

ILSI - Board Designated Reserve 1156 15th Street, NW Washington, DC 20005

Description	March	YTD
Beginning Value	588,168.89	576,229.31
Net Contributions	0.00	0.00
Capital Appreciation	-1,580.06	9,988.60
Income	1,101.74	1,610.89
Management Fees	0.00	-138.23
Other Expenses	0.00	0.00
Ending Value	587,690.57	587,690.57
Total Investment Gain/Loss	-478.32	11,461.26
Time Weighted (gross)	-0.08	2.01
Time Weighted (net)	-0.08	1.99



## March 2015 Portfolio Performance & Activity

ILSI - Operating Reserve 1156 15th Street, NW Washingon, DC 20005

Description	March	YTD
Beginning Value	1,327,356.32	1,321,284.22
Net Contributions	-400,000.00	-400,000.00
Capital Appreciation	1,924.16	6,990.16
Income	1,174.74	2,497.79
Management Fees	0.00	-316.95
Other Expenses	0.00	0.00
Ending Value	930,455.22	930,455.22
Total Investment Gain/Loss	3,098.90	9,171.00
Time Weighted (gross)	0.28	0.76
Time Weighted (net)	0.28	0.74

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS		<u>3/31/2015</u>	_	12/31/2014	-	<u>12/31/2013</u>		<u>12/31/2012</u>		<u>12/31/2011</u>
Current Assets										
Cash	\$	441,355	\$	610,636	\$	229,748	\$	509,439	\$	773,367
Short-Term Investments		930,455		1,321,340		609,414		914,298		911,040
Accounts Receivable		1,639		96,518		104,586		169,244		119,954
		309,098		75,755		522,765		1/1,/82		109,126
Prepaid Annual Meeting Expenses		1,688		77,386		67,461		66,489		60,516
Prepaid Expenses and Other Current Assets		4,529		61,934		27,900		16,979		24,342
lotal Current Assets		1,688,766		2,243,569		1,561,874		1,848,232		1,998,344
Other Assets										
Rent Receivable under Shared Shace Agreement		305 904		310 171		357 566		364 147		356 748
Roard-Designated Reserve Fund		587 691		576 229		566 504		269 608		268 446
Total Other Assets		893 595		895 401		924 070		633 754		625 194
		000,000		000,101		021,010		000,101		020,101
Fixed Assets										
Computer Software and Equipment		308,991		301,242		363,213		594,523		510,315
Office Furniture		114,075		114,075		114,075		114,075		114,075
Leasehold Improvements		723,761		723,761		723,761		723,761		703,909
Accumulated Depreciation		(776,992)		(776,992)		(759,231)		(672,454)		(508,231)
Total Net Fixed Asstes		369,834		362,085		441,818		759,904		820,068
Total Assets	\$	2,952,195	\$	3,501,055	\$	2,927,761	\$	3,241,890	\$	3,443,606
LIABILITES AND NET ASSETS										
<u>Current Liabilities</u>	¢	2 2 2 0	¢	00 000	¢	94 220	¢	00 070	¢	140 947
Accounts Payable	φ	5,550	φ	00,002 70,200	φ	04,320	φ	02,373	φ	140,047
Deferred Appual Meeting Revenue		09,750		154 740		130 205		160 320		138 502
		16 151		260 603		14 315		8 513		8 513
Total Current Liabilities		89 239		573 715		333 608		354 950		368 557
		00,200		010,110		000,000		001,000		000,001
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		634,716		648,885		758,189		833,414		891,432
Total Long-Term Liabilities		880,716		894,885		1,004,189		1,079,414		1,137,432
Total Liabilities		969,955		1,468,600		1,337,796		1,434,364		1,505,989
Net Assets										
Beginning Balance		2,032,456		1,589,965		1,807,526		1,937,617		1,614,525
Current Year Change		(50,216)		442,491		(217,562)		(130,091)		323,092
I OTAL NET ASSETS		1,982,240		2,032,456		1,589,965		1,807,526		1,937,617
Total Liabilities and Not Assets	¢	2 052 105	¢	3 501 055	¢	2 027 761	¢	2 241 900	¢	2 4 4 2 6 0 6
Total Liabilities and Net Assets	φ	2,952,195	φ	3,501,055	φ	2,927,701	φ	5,241,690	φ	3,443,000
Larostricted Operations	¢	520 240	¢	502 220	¢	510 792	¢	656 029	¢	550 947
Board-Designated Reserve Fund	φ	587 601	Ψ	576 220	Ψ	566 504	φ	260 602	φ	268 440
Restricted Programs (PIP GTE Africa Other)		520 461		600 828		363 907		133 252		151 425
International Branches (2012 and earlier included IFRiC)		334 740		263 168		148 771		748 628		957 905
Total Net Assets	\$	1.982.240	\$	2.032.456	\$	1.589.965	\$	1.807.526	\$	1.937.617
	<u> </u>	.,	Ŧ	_,,,,,	τ'	.,	*	.,,	٣	.,,
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1.599.527	\$	1.669.855	\$	1.228.266	\$	1,493,282	\$	1.629.787
Current Ratio <sup>(2)</sup>	Ŧ	18 02	Ŧ	3 91	Ŧ	4 68	Ŧ	5 21	Ŧ	5 42
		10.52		0.01		4.50		V.2 I		0.72

<sup>(1)</sup> The 2015 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2015 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

#### Internal Financial Statement

INTERNATIONAL LIFE SCIENCES INSTITUTE		ILSI GC	COMN	IUNICATIONS			LSI PRESS		SUBTOTAL ILSI UNRESTRICTED (1)			
FUNCTIONAL ACTIVITY STATEMENT	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	`% YTD/
For the Three Months Ended March 31, 2015	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENIJE												
		749 000	0%			NI/A			NI/A		749 000	0.0/
BRANCH/INSTITUTE ASSESSMENT	-	746,000	0%	-		IN/A	-	-	IN/A	-	746,000	0%
CONFERENCE/ REGISTRATION FEES	51,969	30,000	173%	-		N/A	-		N/A	51,969	30,000	173%
CONTRIBUTIONS	30,000		N/A	-		N/A	-		N/A	30,000	-	N/A
FEE FOR SERVICES	-		N/A	-		N/A	-		N/A	-	-	N/A
SHARED SERVICES REIMBURSEMENT			N/A	-		N/A	-		N/A			N/A
INVESTMENT AND OTHER INCOME	21,031	26,000	81%	-		N/A	-		N/A	21,031	26,000	81%
PUBLICATIONS - NUTRITION REVIEWS	-		N/A	-		N/A	296,288	402,500	74%	296,288	402,500	74%
TOTAL REVENUE	103,000	804,000	13%	-	-	N/A	296,288	402,500	74%	399,288	1,206,500	33%
EXPENSES												
COMMUNICATIONS	5,861	10,370	57%	5,699	13,875	41%	53	1,910	3%	11,613	26,155	44%
FINANCIAL/PROFESSIONAL FEES	6,830	30,000	23%			N/A			N/A	6,830	30,000	23%
GENERAL & ADMINISTRATIVE												
Shared Services Overhead	29.214	133,700	22%			N/A			N/A	29.214	133,700	22%
Rent	12 841	48 600	26%			N/A			N/A	12 841	48,600	26%
Depreciation	12,041	39,000	0%			NI/A			NI/A	12,041	30,000	0%
Other	2 000	0 110	23%	2 573	6 300	110/5	530	17 855	3%	5 202	33,265	16%
United Indirect Deimburgement	2,030	(070,550)	2370	2,575	161 552	41/0	24.014	11,000	370	5,202	(11.040)	10 %
indirect Reimbursement	(03,073)	(279,556)	23%	33,044	151,555	22%	24,911	110,957	21%	(5,119)	(11,046)	40%
STAFFING	10 500	100 100	000/	00.044	105 000	000/	~~~~	404.000	000/		100.000	000/
Salaries	40,560	182,400	22%	30,641	135,800	23%	22,687	104,800	22%	93,888	423,000	22%
Benefits	20,939	43,776	48%	6,741	32,592	21%	4,991	25,152	20%	32,671	101,520	32%
Outside Services	2,914	2,725	107%			N/A			N/A	2,914	2,725	107%
CONSULTANTS			N/A	10,609	42,000	25%		3,000	0%	10,609	45,000	24%
IT SUPPORT SERVICES			N/A	15,000	30,000	50%			N/A	15,000	30,000	50%
PUBLICATIONS	682	5,000	14%	16,665	15,000	111%	18,652	41,600	45%	35,999	61,600	58%
MEETINGS												
Travel - Board	26,903	63,000	43%			N/A			N/A	26,903	63,000	43%
Travel - Staff	2.501	5.000	50%	3.705	10.000	37%	1.557	8.840	18%	7,763	23.840	33%
Travel - Advisors/Speakers/Invitees	9,552	6,000	159%	-,	,	N/A	1 689	4 000	42%	11 241	10,000	112%
Group Functions/Business Meals	62 520	74 535	84%		1 000	0%	1,000	1,000	/*	62 520	76 935	81%
Other Expenses (Audiovisual/Mant Eee)	50 114	40,500	124%	506	3,000	17%		1,400	N/A	50,610	13,500	116%
Other Expenses (Audiovisidal/Might Fee)	50,114	40,000	12470	500	5,000	17.70			19/5	50,015	43,300	11070
SURTOTAL MEETINGS	151 500	180.035	80%	4 211	14 000	30%	3 2/6	14 240	23%	150.046	217 275	73%
SOBTOTAL MELTINGS	131,380	109,000	00 /8	4,211	14,000	50 %	3,240	14,240	23 /0	159,040	217,275	1370
OTHER PROGRAM EXPENSES	00.000		N1/A			N1/A			N1/A	00.000		N1/A
Grants, Contributions, Research	30,000		N/A			N/A			N/A	30,000	-	N/A
Intracompany Transfers - (Revenue)/Expense			N/A			N/A			N/A	-	-	N/A
TOTAL EXPENSES	239,848	414,229	58%	125,781	441,120	29%	75,079	325,514	23%	395,630	855,349	46%
CHANGE IN NET ASSETS	(136,848)	389,771		(125,781)	(441,120)		221,209	76,986		(41,421)	25,638	
	2 191 500	2 181 500		(2 207 360)	(2 207 360)		1 10/ 212	1 10/ 212		1 168 /60	1 168 /60	
INC 1 ASSETS, DEGININING OF PERIOD	2,101,508	2,101,508		(2,207,300)	(2,207,300)		1,194,312	1,194,312		1,100,400	1,100,400	
NET ASSETS, END OF PERIOD	2,044,660	2,571,280		(2,333,141)	(2,648,480)		1,415,520	1,271,298		1,127,039	1,194,097	
	=======			=======================================						=======		

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC. Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTRICTED PROGRAMS			INT'L	BRANCH ACTIVI	ТҮ	SH	ARED SERVICES		TOTAL		
FUNCTIONAL ACTIVITY STATEMENT	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/
For the Three Months Ended March 31, 2015	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENUE												
BRANCH/INSTITUTE ASSESSMENT	_		N/A	-		N/A	_		N/A	-	748 000	0%
CONFERENCE/ REGISTRATION FEES			N/A	-		N/A	_		N/A	51 969	30,000	173%
CONTRIBUTIONS	80,000	222 000	36%	-		N/A	-		N/A	110,000	222 000	50%
EEE FOR SERVICES		222,000	N/A	-		N/A	_		N/A		-	N/A
SHARED SERVICES REIMBURSEMENT			N/A	-		N/A	322 990	1 513 350	21%	322 990	1 513 350	21%
			N/A	-		N/A	022,000	1,010,000	N/A	21 031	26,000	81%
PUBLICATIONS - NUTRITION REVIEWS			N/A	-		N/A	_		N/A	296 288	402 500	74%
TOTAL REVENUE	80,000	222,000	36%	-	-	N/A	322,990	1,513,350	21%	802,278	2,941,850	27%
	17	1 005	20/		1 200	00/	6.610	50,600	100/	10.040	70 100	220/
COMMUNICATIONS	17	1,005	2%	-	1,360	0%	6,612	50,600	13%	18,243	79,120	23%
FINANCIAL/PROFESSIONAL FEES			N/A			N/A	9,332	50,050	19%	16,162	80,050	20%
GENERAL & ADMINISTRATIVE			N1/A			N1/A			N1/A	00.044	400 700	000/
Shared Services Overhead			N/A			N/A	00.000	450 500	N/A	29,214	133,700	22%
Rent			N/A			N/A	39,800	150,500	26%	52,641	199,100	26%
Depreciation	007	500	N/A			N/A	47.570	20,000	0%	-	59,071	0%
Olilei Indirect Deimburgement	327	500	65%	1 205	E 04E	IN/A	17,579	150,700	12% N/A	23,106	164,400	13%
indirect Reimbursement	3,794	5,603	00%	1,325	5,245	25%			N/A	-	-	IN/A
STAFFING												
Salaries	3,455	5,200	66%	1,206	4,700	26%	199,932	868,000	23%	298,481	1,300,900	23%
Benefits	760	1,248	61%	265	1,128	24%	43,985	200,000	22%	77,682	303,896	26%
Outside Services			N/A			N/A			N/A	2,914	2,725	107%
CONSULTANTS		41,750	0%	9,078	40,932	22%			N/A	19,687	127,682	15%
IT SUPPORT SERVICES			N/A			N/A	919	6,400	14%	15,919	36,400	44%
												500/
PUBLICATIONS			N/A			N/A			N/A	35,999	61,600	58%
MEETINGS												
Travel - Board	-		N/A			N/A			N/A	26,903	63,000	43%
Travel - Staff		5,000	0%	4,448	7,800	57%	4,541	10,000	45%	16,751	46,640	36%
Travel - Advisors/Speakers/Invitees	20,736	142,665	15%	1,268		N/A			N/A	33,245	152,665	22%
Group Functions/Business Meals	3,362	3,055	110%	6,902	6,000	115%	290	7,100	4%	73,074	93,090	78%
Other Expenses (Audiovisual/Mgmt Fee)	2,475	3,400	73%	3,936	3,040	129%			N/A	57,030	49,940	114%
		454 400	170/		16.940		4.024				405 225	 E 1 0/
SUBTUTAL MEETINGS	20,573	154,120	17%		10,040	90%	4,031	17,100	20%	207,004	405,335	51%
OTHER PROGRAM EXPENSES												
Grants, Contributions, Research	25,441	15,000	170%		15,520	0%			N/A	55,441	30,520	182%
Intracompany Transfers - (Revenue)/Expense	100,000	100,000	100%	(100,000)	(100,000)	100%			N/A	-	-	N/A
TOTAL EXPENSES	160,368	324,626	49%	(71,572)	(14,275)	501%	322,989	1,513,350	21%	852,494	3,004,564	28%
CHANGE IN NET ASSETS	(80.360)	(102 626)		71 570	14 275					(50.216)	(62 714)	
	(00,000)	(102,020)		11,572	14,275		0	-		(30,210)	(02,714)	
NET ASSETS, BEGINNING OF PERIOD	600,828	600,828		263,168	263,168		-	-		2,032,456	2,032,456	
NET ASSETS, END OF PERIOD	520,461	498,202		334,740	277,443		0	-		1,982,240	1,969,742	
	=======			======			=============			======		

#### ILSI Board of Trustees Financial Oversight Committee

## Conference Call Monday, October 27, 2014

#### **DRAFT MINUTES**

#### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair, ILSI Financial Oversight Committee, began the conference call at 9:02 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated in the conference call: Dr. Todd Abraham, Dr. Sushila Chang, Dr. Joanne Lupton, Ms. Beth-Ellen Berry, Dr. Suzie Harris, and Mr. Shawn Sullivan. Dr. Lewis Smith was not available for the call, but sent his comments on the various agenda items to the full committee prior to the conference call.

Mr. Mark Murphy, Raffa Wealth Management, joined the call for the discussion of Agenda Item IV. The agenda is attached.

#### II. Approval of Minutes from the July 28, 2014 Conference Call

The minutes were approved as distributed.

#### III. Review of 2014 Year-end Projections and 2015 Budget

Ms. Berry reviewed the two-page document containing the 2014 year-end projections and 2015 budget which was distributed to the committee prior to the conference call (attached). The 2014 year-to-date balance sheet and functional activity statement was also distributed, but not discussed.

For the unrestricted functions, Ms. Berry noted that the main sources of revenue are branch assessments (ILSI Governance and Coordination) and ILSI Press royalty. Focusing on the Subtotal for the Unrestricted functions, Ms. Berry noted that a \$19,000 loss in net assets is projected for year-end compared to the \$35,000 loss budgeted for 2014. Two major changes account for the better than expected performance. First, ILSI received \$100,000 as a bonus from Oxford University Press upon signing a new publishing agreement with them for *Nutrition Reviews*. The unrestricted ILSI functions also had \$80,000 in unbudgeted expenses (two One ILSI grants of \$40,000 each – one to ILSI HESI and the other to ILSI Southeast Asia Region). The remaining components of the unrestricted ILSI functions budget were on target.

The proposed 2015 budget includes a small increase in branch assessments due to new branches beginning to pay the branch assessments. There is no fee for service revenue in the 2015 ILSI GC budget because Dr. Harris will not be the ILSI Research Foundation Executive Director in 2015. ILSI Research Foundation has been reimbursing ILSI for a portion (40 percent) of her salary. In terms of expenses, Dr. Harris will continue to serve as the part-time ILSI Executive Director. The salary line for ILSI GC includes her salary at 60 percent time. No other big changes are included in the ILSI GC budget, other than no credit for annual meeting expenses is expected.

The communications 2015 budget includes funding for consultants to help re-fresh the ILSI website. For ILSI Press, the revenue is the guaranteed minimum in the new agreement with Oxford University Press, though this minimum is not finalized yet. They will provide a larger editorial stipend (\$100,000 vs \$80,000 in the past agreement with Wiley). Expense for copyediting are expected to decline in 2015 as Oxford University Press will take on some of this responsibility. The Press budget is expected to generate \$76,000 in profit. It is possible that this figure will decline once Oxford University Press fully understands the revenue stream likely to be generated by *Nutrition Reviews*.

In response to a question from Dr. Abraham about the risk and opportunity with the ILSI Press budget, Dr. Harris said that the signing bonus would be re-invested in the journal over a period of several years, through subscriptions for new citation tracking tools, support for face-to-face editorial board meetings, support for editor-in-chief search, and professional development for Ms. Allison Worden, ILSI Publications Manager.

In terms of the restricted functions, Ms. Berry noted that the revenue and expenses for these accounts varies more as unexpected contributions are received and expended. The Restricted Programs include the ILSI Platform for International Partnerships and the contributions from The Coca-Cola Company. The latter have been distributed as requested by the donor to specific activities, e.g., Malaspina International Scholars Travel Award, and food safety training in Asia and in Africa. The Branch Staff Travel grant fund is also included in the Restricted Programs. The International Brach Activity includes funding held for the ILSI Focal Point in China (operating funds as well as training funds) and Latin American branches coordination. A new, part-time Latin American branches coordinator position has been established with funding from The Coca-Cola Company. The third restricted function – Shared Services – covers expenses shared by the four corporations that share the Washington office. This function will end 2014 on budget and the 2015 budget includes a one percent increase.

Ms. Berry said that there would likely be minor modifications to both the 2014 year-end projections and the 2015 budget before the 2015 ILSI Board of Trustees meeting. Dr. Lewis email his support for the proposed budget prior to the conference call.

**Action:** Dr. Lupton moved that the 2015 budget be forwarded to the ILSI Board of Trustees for approval during the January 17, 2015 meeting. Dr. Abraham seconded the motion and it carried unanimously.

## IV. Discussion of Revised Investment Policy

Mr. Mark Murphy, Raffa Wealth Management, first reviewed the performance of the Board-designated Reserve Fund over the past quarter. This report along with a quarterly report for the Operating Reserve was distributed to the committee prior to the conference call. He noted that the market had a solid performance for 2014 until mid-September, when equities declined. That trend has reversed and the market has done well over the past few weeks. Page 3 of the report shows that the fixed income portfolio for the ILSI Board-designated Reserve Fund is allocated in line with the investment policy targets. Page 4 shows that the return has been flat for the last month, but has increased by 1.4 percent since the beginning of the year. Mr. Murphy described this as a solid performance for the portfolio. The latter pages of the report show the performance of the various asset classes along with the benchmarks.

At the committee's request, Raffa Wealth Management sent a risk survey out to the committee members and senior staff (Ms. Berry and Dr. Harris). Based on the survey results, Mr. Murphy had recommended to the committee in July that they approve a change in the investment policy to allow a

less conservative portfolio – 40 percent equities and 60 percent bonds. At the committee's request he shared a red-line version of the investment policy for the ILSI Board-designated Reserve Fund that would implement the shift to a less conservative portfolio. While still conservative the new allocation would be liquid but with growth potential. The investment policy goals were revised to state that cash flow is not the primary function and the time horizon is longer term – 5 years – as opposed to 1 year in the current policy.

The asset class allocation recommended includes all areas of equities, domestic and international with the latter having both developed and developing country equities. Benchmarks for the new asset classes were added to the policy as well. Rebalancing is triggered when there is a 20 percent variance to the policy target. This is the same trigger as the current policy and is designed to reduce unnecessary trades. The allocation is evaluated on a quarterly basis.

A performance history for such a portfolio was provided to the committee prior to the conference call. Mr. Murphy pointed out that the model portfolio would have lost 12.5 percent of its value in 2008, but would have been more stable over the past 14 years than the S&P 500 index. While no one can predict future earnings, the past earnings for such a portfolio ranged between 5 and 9 percent, compared to the fixed income portfolio earnings of 1.5-2.00 percent. Mr. Murphy said that a fixed income portfolio could earn as much as 3 percent, but it can also have negative earnings.

In response to a question, Ms. Berry said that she has not had to withdraw funds for operating expenses from the Board-designated Reserve Fund, though the fund has not been in existence for much more than one year.

Action: The committee members present were all in favor of accepting the new investment policy (attached). They asked that Dr. Harris inform the ILSI Board of Trustees Executive Committee of the Financial Oversight Committee's intention to implement the new policy and to ask if there are any objections.

Mr. Murphy commented that support for the new policy was a smart decision.

## V. New Business

None was offered.

## VI. Next Steps

- Dr. Harris will send a message to the ILSI Executive Committee providing details about the proposed investment policy change and ask if there are objections. DONE, no objections received.
- 2015 proposed budget will be distributed to the ILSI Board of Trustees for approval in January 2015.

## VII. Adjournment

As there was no further business, Dr. Westring ended the conference call at approximately 10:00 a.m. Eastern Daylight Time.

Signed:\_\_\_\_\_ Date:\_\_\_\_\_

## ILSI Board of Trustees Financial Oversight Committee

## **Conference Call**

## Monday, October 27, 2014 9:00 – 10:00 am Eastern Daylight Time

## AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the July 28, 2014 Conference Call
- III. Review of 2014 Year-end Projections and 2015 Budget
- IV. Discussion of Revised Investment Policy Raffa Wealth Management
- V. New Business
- VI. Next Steps
- VII. Adjournment

## ILSI Board of Trustees Financial Oversight Committee

## **Conference Call**

## Tuesday, April 28, 2015 9:00 – 10:00 am Eastern Daylight Time

## PROPOSED AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the October 27, 2014 Conference Call
- III. Review of 2015 Year-to-date Financial Statement
- IV. Pursuing an ILSI Annual Meeting Held outside of the United States Financial Implications
- V. New Business
- VI. Next Steps
- VII. Adjournment

From: Sent: Subject: Attachments:

John Faulkner < Monday, April 27, 2015 9:40 AM ILSI Scientific Briefs For Your Reference Attached Food Safety Briefs March 2015.pdf; Nutrition Briefs March 2015.pdf

Hello!

Attached are your **Food Safety** and **Nutrition** Science Briefs for the month of **March** (big apology for the delayed delivery!).

Each month we review the most recent articles published in the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles we select for inclusion are those we believe will be of the greatest interest to ILSI North America's technical and project committees.

As always, these briefs, along with prior science briefs, are accessible via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will be happy to add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Nutrition Briefs**

## March 2015

## **Cardiovascular Disease**

#### A Healthy Diet Is Associated with Less Endothelial Dysfunction and Less Low-Grade Inflammation over a 7-Year Period in Adults at Risk of Cardiovascular Disease

B.C.T. van Bussel, R.M.A. Henry, I. Ferreira, M.M.J. van Greevenbroek, C.J.H. van der Kallen, J.W.R. Twisk, et al.

Journal of Nutrition, Vol. 145, No. 3; pp. 532-540, 2015

DOI: 10.3945/jn.114.201236

Link to full text: Click here

**Significance:** The dietary modification of endothelial dysfunction and low-grade inflammation, processes that are important in atherothrombosis, is possible.

This 7-year longitudinal study investigated the associations between a diet rich in fish, fruit, and vegetables, but moderate in alcohol and low in dairy products and meat and overall biomarker scores of endothelial dysfunction (ED) and low-grade inflammation in 557 participants at increased CVD risk. At baseline, participants were aged 59.6  $\pm$  6.9 y. Measurements were performed then and after 7 y. Biomarkers were combined into overall scores (higher scores indicating worse function). Higher consumption of fish (per 100 g/wk), but not total consumption of vegetables, fruit, alcohol-containing beverages, dairy products, or meat, was associated with a lower overall ED score over 7 y ( $\beta$ : -0.027; 95% CI: -0.051, -0.004). Consumption of more lean fish (per 100 g/wk) and raw vegetables (per 100 g/d), and fewer high-fat dairy products (per 100 g/d) was associated with less ED [(β: -0.038; 95% CI: -0.072, -0.005), (β: -0.095; 95% CI: -0.191, 0.000), and (β: -0.070; 95% CI: -0.131, -0.009), respectively]. Consumption of more fresh fruit (per 100 g/d), wine (per 100 mL/wk), and poultry (per 100 g/d), and fewer high-fat dairy products (per 100 g/d) was associated with less low-grade inflammation [( $\beta$ : -0.074; 95% CI: -0.133, -0.015), (β:-0.006; 95% CI: -0.013, 0.001), (β:-0.247; 95% CI: -0.479, -0.014), and (β:-0.100; 95% CI: -0.182, -0.019), respectively].

#### Multivitamin-Mineral Use Is Associated with Reduced Risk of Cardiovascular Disease Mortality among Women in the United States

R.L. Bailey, T.H. Fakhouri, Y. Park, J.T. Dwyer, P.R. Thomas, J.J. Gahche, et al. Journal of Nutrition, Vol. 145, No. 3; pp. 572–578, 2015

DOI: 10.3945/jn.114.204743

Link to full text: Click here

**Significance:** There is an association between multi-vitamin mineral use of >3 y and reduced CVD mortality risk for women when adjusted for covariates.

The association between multi-vitamin mineral (MVM) and multivitamin (MV) use and cardiovascular disease (CVD)-specific mortality among US adults

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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without CVD was examined using data from NHANES III (1988–1994; n = 8678; age  $\geq$ 40 y) and mortality data from the National Death Index through 2011. No significant association was observed between CVD mortality and users of MVMs or MVs compared with nonusers; however, when users were classified by the reported length of time products were used, a significant association was found with MVM use of >3 y compared with nonusers (HR: 0.65; 95% CI: 0.49, 0.85), specifically among women (HR: 0.56; 95% CI: 0.37, 0.85) but not men (HR: 0.79; 95% CI: 0.44, 1.42). No significant association was observed for MV products and CVD mortality in fully adjusted models.

#### Is Complying with the Recommendations of Sodium Intake Beneficial for Health in Individuals at High Cardiovascular Risk? Findings from the PREDIMED Study

J. Merino, M. Guasch-Ferré, M.A. Martínez-González, D. Corella, R. Estruch, M. Fitó, et al.

American Journal of Clinical Nutrition, Vol. 101, No. 3; pp. 440-448, 2015

DOI: 10.3945/ ajcn.114.096750

Link to full text: Click here

**Significance:** Decreasing sodium intake to <2300 mg/d was associated with a reduced risk of all-cause mortality, whereas increasing the intake to >2300 mg/d was associated with a higher risk of CVD.

This observational prospective study assessed whether reductions in sodium intake to <2300 mg/d were associated with either an increased or a decreased risk of fatal and nonfatal cardiovascular disease (CVD) and all-cause mortality in 3982 participants at high CVD risk. Sodium intake was evaluated with a validated food-frequency questionnaire and categorized as low (<1500 mg/d), intermediate ( $\geq$ 1500 to  $\leq$ 2300 mg/d), high (>2300 to  $\leq$ 3400 mg/d), or very high (>3400 mg/d). Subsequently, 1-y and 3-y changes in sodium intake were calculated. Results documented 125 CVD events and 131 deaths after a 4.8-y median follow-up. Sodium intake <2300 mg/d was associated with a lower risk of all-cause mortality: 48% (HR: 0.52; 95% CI: 0.30, 0.91) and 49% (HR: 0.51; 95% CI: 0.26, 0.98) after 1 and 3 y, respectively. Increasing sodium intake after 1 y was associated with a 72% (HR: 1.72; 95% CI: 1.01, 2.91) higher risk of CVD events. The incidence rate of CVD was reduced for those who reduced their sodium intake and were randomly assigned to the Mediterranean diet interventions [4.1/10,000 (95% CI: 3.1, 8.0) compared with 4.4/10,000 (95% CI: 2.7, 12.4) person-years; P = 0.002].

#### Food Allergy

#### Administration of a Probiotic with Peanut Oral Immunotherapy: A Randomized Trial

M.L.K. Tang, A.-L. Ponsonby, F. Orsini, D. Tey, M. Robinson, E.L. Su, et al. Journal of Allergy and Clinical Immunology, Vol. 135; No. 3; pp. 737–744.e8, 2015 DOI: 10.1016/j.jaci.2014.11.034

Link to full text: Click here

**Significance:** Probiotic and peanut oral immunotherapy was effective in inducing possible sustained unresponsiveness and immune changes that suggest modulation of the peanut-specific immune response.



This double-blind, placebo-controlled randomized trial evaluated a combined therapy of the probiotic Lactobacillus rhamnosus CGMCC 1.3724 and peanut oral immunotherapy (OIT) (probiotic and peanut oral immunotherapy [PPOIT]) in children (1-10 years) with peanut allergy. The primary outcome was induction of sustained unresponsiveness 2 to 5 weeks after discontinuation of treatment (referred to as possible sustained unresponsiveness). Secondary outcomes were desensitization, peanut skin prick test (SPT), and specific IgE and specific IgG4 measurements. Sixty-two children were randomized and stratified by age ( $\leq 5$  and >5 years) and peanut SPT wheal size ( $\leq 10$  and >10mm); 56 reached the trial's end. Possible sustained unresponsiveness was achieved in 82.1% receiving PPOIT and 3.6% receiving placebo (P < .001). Nine children needed to be treated for 7 to achieve sustained unresponsiveness (number needed to treat, 1.27; 95% CI, 1.06-1.59). Of the subjects, 89.7% receiving PPOIT and 7.1% receiving placebo were desensitized (P < .001). PPOIT was associated with reduced peanut SPT responses and peanut-specific IgE levels and increased peanut-specific IgG4 levels (all P < .001). PPOITtreated participants reported a greater number of adverse events, mostly with maintenance home dosing.

#### Diabetes

A High-Protein Breakfast Induces Greater Insulin and Glucose-Dependent Insulinotropic Peptide Responses to a Subsequent Lunch Meal in Individuals with Type 2 Diabetes

Y.-M. Park, T.D. Heden, Y. Liu, L.M. Nyhoff, J.P. Thyfault, H.J. Leidy, et al. Journal of Nutrition, Vol. 145, No. 3; pp. 452–458, 2015 DOI: 10.3945/jn.114.202549 Link to full text: Click here

**Significance:** In type 2 diabetic individuals, consumption of a high-protein breakfast meal attenuates the postprandial glucose response compared with a high-carbohydrate breakfast, and does not magnify the response to the second meal.

The effects of high-protein vs. high-carbohydrate breakfast meals on the metabolic and incretin responses after the breakfast and lunch meals were examined. Twelve type 2 diabetic men and women [age: 21-55 y; BMI: 30-40 kg/m<sup>2</sup>] completed two 7-d breakfast conditions consisting of 500-kcal breakfast meals as protein (35% protein/45% carbohydrate) or carbohydrate (15% protein/65% carbohydrate). On day 7, subjects completed an 8-h testing day. After an overnight fast, the subjects consumed their respective breakfast followed by a standard 500-kcal high-carbohydrate lunch meal 4 h later; blood samples were taken throughout the day. Postbreakfast glucose and glucose-dependent insulinotropic peptide (GIP) area under the curves (AUCs) were lower after the protein vs. carbohydrate condition (17% vs. 23%, respectively) (P < 0.05), whereas postbreakfast insulin, C-peptide, glucagon, and glucagon-like peptide 1 (GLP-1) AUCs were not different between conditions. A protein-rich breakfast may reduce the consequences of hyperglycemia in this population. Postlunch insulin, C-peptide, and GIP AUCs were greater after the protein vs. carbohydrate condition (all, P < 0.05), but postlunch AUCs were not different between conditions. The overall glucose, glucagon, and GLP-1 responses (e.g., 8 h) were greater after the protein vs. carbohydrate condition (all, P < 0.05).



#### Sugar-Sweetened Product Consumption Alters Glucose Homeostasis Compared with Dairy Product Consumption in Men and Women at Risk of Type 2 Diabetes Mellitus

K.C. Maki, K.M. Nieman, A.L. Schild, V.N. Kaden, A.L. Lawless, K.M. Kelley, et al. Journal of Nutrition, Vol. 145, No. 3; pp. 459–466, 2015

DOI: 10.3945/jn.114.204503

Link to full text: Click here

**Significance:** Sugar-sweetened product consumption is associated with less favorable values for homeostasis model assessment 2–insulin sensitivity, liquid meal tolerance test disposition index, HDL-cholesterol, and serum 25(OH)D in men and women at risk of type 2 diabetes vs. baseline values and values during dairy product consumption.

This randomized, 2-period crossover trial compared the effects of dairy and sugar-sweetened product (SSP) consumption on insulin sensitivity and pancreatic  $\beta$ -cell function in men and women at risk of the development of type 2 diabetes mellitus (T2DM) who habitually consume sugar-sweetened beverages. Participants consumed dairy products (474 mL/d 2% milk and 170 g/d low-fat yogurt) and SSPs (710 mL/d nondiet soda and 108 g/d nondairy pudding), each for 6 wk, with a 2-wk washout between treatments. A liquid meal tolerance test (LMTT) was administered at baseline and the end of each period. Changes from baseline were significantly different between dairy product and SSP conditions for median homeostasis model assessment 2–insulin sensitivity (HOMA2–%S) (1.3 vs. –21.3%, respectively, P = 0.009; baseline = 118%), mean LMTT disposition index (–0.03 vs. –0.36, respectively, P = 0.011; baseline = 2.59), mean HDL-cholesterol (0.8 vs. –4.2%, respectively, P = 0.015; baseline = 44.3 mg/dL), and mean serum 25-hydroxyvitamin D [25(OH)D] (11.7 vs. –3.3, respectively, P = 0.022; baseline = 24.5 µg/L).

# Association Between Familial Hypercholesterolemia and Prevalence of Type 2 Diabetes Mellitus

J. Besseling, J.J.P. Kastelein, J.C. Defesche, B.A. Hutten, G.K. Hovingh

Journal of the American Medical Association, Vol. 313, No. 10; pp. 1029–1036, 2015 DOI: 10.1001/jama.2015.1206.

Link to full text: Click here

**Significance:** The prevalence of type 2 diabetes among patients with familial hypercholesterolemia was significantly lower than among unaffected relatives, with variability by mutation type.

The association between type 2 diabetes (T2DM) prevalence and familial hypercholesterolemia was assessed in this cross-sectional study in 63,320 individuals who underwent DNA testing for familial hypercholesterolemia. Deleteriousness and nondeleteriousness of familial hypercholesterolemia mutations were based on literature or laboratory function testing. Low-density lipoprotein (LDL) receptor mutations were considered more severe than apolipoprotein B gene (APOB) mutations, and receptor-negative LDL receptor mutations were considered more severe than receptor-deficient mutations. The prevalence of T2DM was 1.75% in familial hypercholesterolemia patients (n = 440/25,137) vs 2.93% in unaffected relatives (n = 1119/38,183) (P < .001; OR, 0.62 [95% CI, 0.55-0.69]). The adjusted prevalence of T2DM in familial hypercholesterolemia, determined using multivariable regression models, was 1.44% (difference, 1.49% [95% CI, 1.24%-1.71%]) (OR, 0.49 [95% CI, 0.41-0.58]). The adjusted prevalence of



T2DM by APOB vs LDL receptor gene was 1.91% vs 1.33% (OR, 0.65 [95% CI, 0.48-0.87] vs OR, 0.45 [95% CI, 0.38-0.54]), and the prevalence for receptor-deficient vs receptor-negative mutation carriers was 1.44% vs 1.12% (OR, 0.49 [95% CI, 0.40-0.60] vs OR, 0.38 [95% CI, 0.29-0.49]), respectively (P for trend <.001 in both comparisons).

#### **Metabolic Syndrome**

Greater Healthful Food Variety as Measured by the US Healthy Food Diversity Index Is Associated with Lower Odds of Metabolic Syndrome and its Components in US Adults

M. Vadiveloo, N. Parkeh, J. Mattei Journal of Nutrition, Vol. 145, No. 3; pp. 564–571, 2015 DOI: 10.3945/jn.114.199125 Link to full text: Click here

**Significance:** Greater healthful food variety was associated with lower odds of metabolic syndrome (MetS) and some MetS components in the total population, non-Hispanic white and non-Hispanic Black adults.

The US Healthy Food Diversity (HFD) index was used simultaneously to measure dietary variety, quality, and proportionality, hypothesizing a priori that race/ethnicity may moderate associations between diet and health. A representative sample of 7470 adults with two 24-h recalls and complete outcome data from NHANES 2003-2006 were selected. US HFD values were generated using a previously validated equation with a theoretical range from 0 to nearly 1, with higher scores indicative of more varied diets with a higher proportion of healthful food groups. Adults in the third vs. first US HFD tertile had 21% lower odds of metabolic syndrome (MetS) [OR (95% CI): 0.79 (0.64, 0.98)] as well as lower odds of hypertension [0.83 (0.70, 0.995] and elevated waist circumference [0.75 (0.66, 0.86] after multivariable adjustment (P-trend < 0.05). The age- and sex-adjusted odds of low serum HDL-cholesterol and impaired fasting plasma glucose (P-trend < 0.05) were lower in the highest vs. lowest US HFD tertile but attenuated with multivariable adjustment (P = 0.06 and 0.22, respectively). Notably, the US HFD index was only protective against adiposity among non-Hispanic white (NHW) and non-Hispanic black adults, and MetS associations were driven by NHW adults.

#### A Calorie-Restriction Diet Supplemented with Fish Oil and High-Protein Powder is Associated with Reduced Severity of Metabolic Syndrome in Obese Women

European Journal of Clinical Nutrition, Vol. 69, No. 3; pp. 322–328, 2015

H.-Y. Su, H.-C. Lee, W.-Y. Cheng, S.-Y. Huang

DOI: 10.1038/ejcn.2014.196

Link to full text: Click here

**Significance:** A calorie-restriction (CR) dietary intervention combined with various macronutrients can reduce the severity of metabolic syndrome (MetS) in women and increase recovery from MetS by almost twofold in comparison with a CR alone.

The effects of a calorie-restriction diet (CR) supplemented with protein and n-3 polyunsaturated fatty acids (PUFAs) in 143 women with metabolic syndrome (MetS) were evaluated. Subjects were assigned to four dietary interventions:



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1500-kcal CR, calorie-restriction meal-replacement diet (CRMR), calorierestriction diet with fish oil supplementation (CRF) and calorie-restriction meal-replacement diet with fish oil supplementation (CRMRF). The changes in anthropometric measures, metabolic profiles, inflammatory response and the Z-score of severity of MetS were evaluated. Results showed that 136 patients completed the 12-week study. Reductions in body weight (BW), BMI and waist circumference (WC) were observed in all groups. BMI and triglyceride (TG) levels decreased significantly in the CRMR, CRF and CRMRF groups, but not in the CR group. The homeostasis model assessment of insulin resistance (HOMA-IR) had significantly improved in all four groups, and the levels of interleukin-6 (IL-6) and C-reactive protein (CRP) had significantly decreased in the CRF and CRMRF groups. Following the interventions, the changes in WC, mean arterial pressure (MAP), fasting blood glucose (FBG), TGs, HOMA-IR, CRP and IL-6 significantly correlated with the reductions in Z-score of MetS severity.

#### Sugar-Sweetened Beverages

Sugar-Containing Beverage Intake in Toddlers and Body Composition Up to Age 6 Years: The Generation R Study

E.T.M. Leermakers, J.F. Felix, N.S. Erler, A. Ćerimagić, A.I. Wijtzes, A. Hofman, et al.

European Journal of Clinical Nutrition, Vol. 69, No. 3; pp. 314–321, 2015

DOI: 10.1038/ejcn.2015.2

Link to full text: Click here

**Significance:** Higher sugar-containing beverages intake at 13 months was associated with higher BMI up to age 6 years in girls but not in boys.

The association of sugar-containing beverages (SCBs) intake at 13 months with BMI development until 6 years and body composition at age 6 years was examined in 2371 Dutch children from a population-based prospective cohort study. Results showed that in girls, higher SCB intake at 13 months was significantly associated with higher BMI at ages 2, 3, 4 and 6 years (at age 6 years BMI (s.d. score) increase 0.11 (95% CI: +0.00; 0.23), high versus low intake). We observed a tendency towards higher android/gynoid fat ratio in girls with high intake (s.d. increase 0.14 (95% CI -0.02; 0.29), versus low intake) but not with body fat percentage. In boys, there was no association with BMI or body composition, but boys with high SCB intake at 13 months were taller at age 6 years (s.d. increase 0.14 (95% CI +0.00; 0.27), versus low intake).

# A Metabolomics Approach to the Identification of Biomarkers of Sugar-Sweetened Beverage Intake

H. Gibbons, B.A. McNulty, A.P. Nugent, J. Walton, A. Flynn, M.J. Gibney, et al. American Journal of Clinical Nutrition, Vol. 101, No. 3; pp. 471–477, 2015 DOI: 10.3945/ ajcn.114.095604 Link to full text: Click here

**Significance:** The present metabolomics-based strategy proved to be successful in the identification of sugar-sweetened beverage biomarkers.

This study used a metabolomics approach to identify a panel of urinary biomarkers indicative of sugar-sweetened beverage (SSB) consumption from a national food consumption survey and subsequently validated this panel in an acute



intervention study. Heat map analysis was performed to identify correlations between 1H nuclear magnetic resonance (NMR) spectral regions and SSB intakes in 565 participants of the National Adult Nutrition Survey. Metabolites were identified and receiver operating characteristic (ROC) analysis was performed to assess sensitivity and specificity of biomarkers. The panel of biomarkers was validated in an acute study (n = 10). A fasting first-void urine sample and postprandial samples (2, 4, 6 h) were collected after SSB consumption. A panel of 4 biomarkers—formate, citrulline, taurine, and isocitrate—was identified as markers of SSB intake. This panel had an area under the curve of 0.8 for ROC analysis and a sensitivity and specificity of 0.7 and 0.8, respectively. All 4 biomarkers were identified in the SSB sample. After acute consumption of an SSB drink, all 4 metabolites increased in the urine.

### Protein

# Higher-Protein Diets Are Associated with Higher HDL Cholesterol and Lower BMI and Waist Circumference in US Adults

S.M. Pasiakos, H.R. Lieberman, V.L. Fulgoni III Journal of Nutrition, Vol. 145, No. 3; pp. 605–614, 2015 DOI: 10.3945/jn.114.205203 Link to full text: Click here

**Significance:** Americans who consume dietary protein between 1.0 and 1.5 g/kg BW potentially have a lower risk of developing cardiometabolic disease.

This study examined usual protein intake [g/kg body weight (BW)] patterns stratified by weight status and their associations with cardiometabolic risk using data from the NHANES, 2001–2010 (n = 23,876 adults  $\geq$ 19 y of age). Linear and decile trends for association of usual protein intake with cardiometabolic risk factors including blood pressure, glucose, insulin, cholesterol, and triglycerides were determined after controlling for covariates. Results showed that usual protein intake varied across deciles from 0.69 ± 0.004 to 1.51 ± 0.009 g/kg BW (means ± SEs). Usual protein intake was inversely associated with BMI (-0.47 kg/m<sup>2</sup> per decile and -4.54 kg/m<sup>2</sup> per g/kg BW) and waist circumference (-0.53 cm per decile and -2.45 cm per g/kg BW), whereas a positive association was observed between protein intake and HDL-cholesterol (0.01 mmol/L per decile and 0.14 mmol/L per g/kg BW, P < 0.00125).



#### **Hypertension**

Daily Blueberry Consumption Improves Blood Pressure and Arterial Stiffness in Postmenopausal Women with Pre- and Stage 1-Hypertension: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

S.A. Johnson, A. Figueroa, N. Navaei, A. Wong, R. Kalfon, L.T. Ormsbee, et al.

Journal of the Academy of Nutrition and Dietetics, Vol. 115, No. 3; pp. 369–377, 2015

DOI: 10.1016/j.jand.2014.11.001

Link to full text: Click here

**Significance:** Daily blueberry consumption may reduce blood pressure and arterial stiffness, which may be due, in part, to increased nitric oxide production.

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The effects of daily blueberry consumption for 8 weeks on blood pressure and arterial stiffness in 48 postmenopausal women with pre- and stage 1-hypertension were examined in an 8-week, randomized, double-blind, placebo-controlled clinical trial. Participants were randomly assigned to receive either 22 g freeze-dried blueberry powder or 22 g control powder. Resting brachial systolic and diastolic blood pressures were evaluated and arterial stiffness was assessed using carotid-femoral pulse wave velocity and brachial-ankle pulse wave velocity. C-reactive protein, nitric oxide, and superoxide dismutase were measured at baseline, 4 weeks, and 8 weeks. After 8 weeks, systolic blood pressure and diastolic blood pressure (131±17 mm Hg [P<0.05] and 75±9 mm Hg [P<0.01], respectively) and brachial-ankle pulse wave velocity (1,401±122) cm/second; P<0.01) were significantly lower than baseline levels (138±14 mm Hg, 80±7 mm Hg, and 1,498±179 cm/second, respectively), with significant (P<0.05) group×time interactions in the blueberry powder group, whereas there were no changes in the group receiving the control powder. Nitric oxide levels were greater (15.35±11.16 µmol/L; P<0.01) in the blueberry powder group at 8 weeks compared with baseline values (9.11±7.95 µmol/L), whereas there were no changes in the control group.

#### Dietary Phytochemical Index is Inversely Associated With the Occurrence of Hypertension in Adults: A 3-Year Follow-Up (The Tehran Lipid and Glucose Study)

M. Golzarand, Z. Bahadoran, P. Mirmiran, S. Sadeghian-Sharif, F. Azizi European Journal of Clinical Nutrition, Vol. 69, No. 3; pp. 392–398, 2015 DOI: 10.1038/ejcn.2014.233 Link to full text: Click here

Link to full text. Click here

**Significance:** Consumption of phytochemical-rich foods may prevent the development of hypertension.

This prospective study aimed to determine the association of dietary phytochemical index (PI) with the occurrence of hypertension (HTN) after 3 years of follow-up in 1546 non-hypertensive subjects, aged 20–70 years. Dietary PI was calculated as (dietary energy derived from phytochemical-rich foods (kcal)/ total daily energy intake (kcal)) × 100. Blood pressure was measured at baseline and after 3 years of follow-up. The odds of HTN after 3 years in each quartile category of dietary PI were estimated by logistic regression model and adjusted for potential variables. The mean age of participants was  $38.0\pm12.0$  years and 43% were male. The mean dietary PI was  $29.1\pm11.8$ . After 3 years of follow-up, 265 (17.1%) new cases of HTN were identified. No significant changes were observed in the systolic and diastolic blood pressure across quartile categories of dietary PI. After adjustment for confounders, the odds (95% CI) of HTN across quartiles of dietary PI were 1.00, 0.97 (0.62-1.38), 0.69 (0.45-1.07) and 0.52 (0.32-0.84) (P for trend=0.004).

#### **Probiotics**

The Effect of a Multi-Strain Probiotic on the Resistance Toward Escherichia Coli Challenge in a Randomized, Placebo-Controlled, Double-Blind Intervention Study

S.J.M. Ten Bruggencate, S.A. Girard, E.G.M. Floris-Vollenbroek, R. Bhardwaj, T.A. Tompkins

European Journal of Clinical Nutrition, Vol. 69, No. 3; pp. 385–391, 2015 DOI: 10.1038/ejcn.2014.238



Link to full text: Click here

**Significance:** Dietary probiotics did not increase resistance to oral attenuated enterotoxigenic Escherichia coli challenge in human subjects.

A parallel, double-blind, placebo-controlled 4-week intervention was performed in healthy males, to study the effect of a blend of probiotic bacteria (Lactobacillus helveticus Rosell-52, Lactobacillus rhamnosus Rosell-11, Bifidobacterium longum ssp. longum Rosell-175) and a probiotic yeast (Saccharomyces cerevisiae var boulardii CNCM I-1079) on enterotoxigenic Escherichia coli (ETEC) challenge. Primary outcomes studied were fecal ETEC excretion and total fecal output per day. Subjects were randomized to the probiotic (5  $\times$  109 colony-forming units (CFUs); twice daily; n=30) or placebo group (twice daily; n=30). After 2 weeks, subjects were orally challenged with a live attenuated ETEC ( $3 \times 109$  CFU), previously demonstrated to induce mild, short-lived symptoms of a foodborne infection. The ETEC challenge induced a significant increase in fecal ETEC excretion in both groups. However, a statistically significant increase in fecal output was only observed in the probiotic group. ETEC challenge resulted in a decrease in the percentage of fecal dry weight, and an increase in reported Bristol Stool Score, stool frequency and GI complaints. Dietary probiotics significantly decreased the percentage of fecal dry weight. In addition, ETEC increased C-reactive protein, total secretory Immunoglobulin A (IgA) and Immunoglobulin G Colonization Factor Antigen II.

#### **Flavonoids**

Chronic Consumption of Flavanone-Rich Orange Juice Is Associated with Cognitive Benefits: An 8-Wk, Randomized, Double-Blind, Placebo-Controlled Trial in Healthy Older Adults

R.J. Kean, D.J. Lamport, G.F. Dodd, J.E. Freeman, C.M. Williams, J.A. Ellis, et al. American Journal of Clinical Nutrition, Vol. 101, No. 3; pp. 506–514, 2015 DOI: 10.3945/ajcn.114.088518

Link to full text: Click here

**Significance:** Chronic daily consumption of flavanone-rich 100% orange juice over 8 wk is beneficial for cognitive function in healthy older adults.

This study investigated whether 8 wk of daily flavanone-rich orange juice consumption was beneficial for cognitive function in healthy older adults. Highflavanone (305 mg) 100% orange juice and an equicaloric low-flavanone (37 mg) orange-flavored cordial (500 mL) were consumed daily for 8 wk by 37 healthy older adults (mean age: 67 y) according to a crossover, double-blind, randomized design separated by a 4-wk washout. Cognitive function, mood, and blood pressure were assessed at baseline and follow-up by using standardized validated tests. Results showed that global cognitive function was significantly better after 8-wk consumption of flavanone-rich juice than after 8-wk consumption of the low-flavanone control. No significant effects on mood or blood pressure were observed.

Cocoa Flavanol Consumption Improves Cognitive Function, Blood Pressure Control, and Metabolic Profile in Elderly Subjects: The Cocoa, Cognition, and Aging (Cocoa) Study—A Randomized Controlled Trial

D. Mastroiacovo, C. Kwik-Uribe, D. Grassi, S. Necozione, A. Raffaele, L. Pistacchio, et al.



American Journal of Clinical Nutrition, Vol. 101, No. 3; pp. 538–548, 2015 DOI: 10.3945/ ajcn.114.092189

Link to full text: Click here

**Significance:** Regular consumption of cocoa flavanols can reduce some measures of age-related cognitive dysfunction, possibly through an improvement in insulin sensitivity.

This double-blind, controlled, parallel-arm study evaluated the effect of flavanol consumption on cognitive performance in 90 cognitively intact elderly subjects without clinical evidence of cognitive dysfunction. Subjects were randomly assigned to consume daily for 8 wk a drink containing 993 mg [high flavanol (HF)], 520 mg [intermediate flavanol (IF)], or 48 mg [low flavanol (LF)] cocoa flavanols (CFs). Cognitive function was assessed at baseline and after 8 wk by using the Mini-Mental State Examination (MMSE), the Trail Making Test (TMT) A and B, and the Verbal Fluency Test (VFT). The changes in MMSE score in the 3 different treatments were not different. In contrast, there was a positive impact of the intervention on specific aspects of cognitive function. Mean changes (±SEs) in the time required to complete the TMT A and B after consumption of the HF ( $-8.6 \pm 0.4$  and  $-16.5 \pm 0.8$  s, respectively) and IF (-6.7 $\pm$  0.5 and -14.2  $\pm$  0.5 s, respectively) drinks significantly (P < 0.0001) differed from that after consumption of the LF drinks ( $-0.8 \pm 1.6$  and  $-1.1 \pm 0.7$  s, respectively). Similarly, VFT scores significantly improved among all treatment groups, but the magnitude of improvement in the VFT score was significantly (P < 0.0001) greater in the HF group (7.7  $\pm$  1.1 words/60 s) than in the IF (3.6  $\pm$  1.2 words/60 s) and LF (1.3  $\pm$  0.5 words/60 s) groups. Significantly different improvements in insulin resistance, blood pressure, and lipid peroxidation were also observed for the HF and IF groups in comparison with the LF group. Changes in insulin resistance explained ~17% of changes in composite z score (partial  $r^2 = 0.1703$ , P < 0.0001).

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The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

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1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org



# **Food Safety Briefs**

# March 2015

## E. coli

#### Antimicrobial Interventions for O157:H7 and Non-O157 Shiga Toxin– Producing Escherichia coli on Beef Subprimal and Mechanically Tenderized Steaks

Y.-T. Liao, J.C. Brooks, J.N. Martin, A. Echeverry, G.H. Loneragan, M.M. Brashears

Journal of Food Protection, Vol. 78, No. 3; pp. 511-517, 2015

DOI: 10.4315/0362-028X.JFP-14-178

Link to full text: Click here

**Significance:** The reduction of pathogens on surface populations was not sufficient enough to eliminate the pathogen's detection following vacuum storage, mechanical tenderization, and cooking.

The objectives of this study were to: (1) evaluate effects of the spray treatments ambient water, 5% lactic acid (LA), 200 ppm of hypobromous acid (HA), and 200 ppm of peroxyacetic acid (PA)—on the reduction of Escherichia coli O157:H7 or non-O157 Shiga toxin–producing E. coli (STEC) (O26, O103, O111, and O145) with high (106 log CFU/50 cm2) or low (102 log CFU/50 cm2) levels on beef subprimals after vacuum storage for 14 days and (2) evaluate the association of the antimicrobial treatments and cooking (50 or 70°C) on the reduction of the pathogens in blade-tenderized steaks. Treatment effects were only observed on samples taken immediately after spray intervention following inoculation with a high level of O157:H7. The LA and PA treatments significantly reduced low-inoculated non-O157 STEC after spray intervention and resulted in significant reductions of non-O157 STEC on the low-inoculated samples after storage. Although cooking effectively reduced the detection of pathogens in internal steak samples, internalized E. coli O157:H7 and non-O157 STEC were able to survive in steaks cooked to a medium degree of doneness (70°C).

# Transmission of Escherichia coli O157:H7 to Internal Tissues and Its Survival on Flowering Heads of Wheat

B. Martinez, J. Stratton, A. Bianchini, S. Wegulo, G. Weaver Journal of Food Protection, Vol. 78, No. 3; pp. 518–524, 2015 DOI: 10.4315/0362-028X.JFP-14-298 Link to full text: Click here

**Significance:** This study demonstrated the ability of E. coli O157:H7 to reach the phylloplane in wheat.

The study determined (1) whether Escherichia coli O157:H7 could be translocated into the internal tissues of wheat (Triticum aestivum) seedlings from contaminated seed, soil, or irrigation water and (2) whether the bacterium could survive on flowering wheat heads. One hundred plants per treatment were

# **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

sown in pot trays with 50 g of autoclaved soil or purposely contaminated soil, watered every day with 5 ml of water, and harvested 9 days postinoculation. In a fourth experiment, flowering wheat heads were spray inoculated with water containing 4.19 log CFU/ml E. coli O157:H7 and analyzed for survival after 15 days, near the harvest period. Results showed that internalization was possible using contaminated seed, soil, and irrigation water in wheat seedlings, with internalization rates of 2, 5, and 10%, respectively. In the head contamination experiment, all samples tested positive, showing the ability of E. coli O157:H7 to survive on the wheat head.

#### Airborne Dissemination of Escherichia coli in a Dairy Cattle Farm and its Environment

S. Sanz, C. Olarte, R. Martínez-Olarte, E.V. Navajas-Benito, C.A. Alonso, S. Hidalgo-Sanz, et al.

International Journal of Food Microbiology, Vol. 197; pp. 40–44, 2015 Link to full text: Click here

**Significance:** The comparison of genetic profiles suggested that the strains isolated from inside and outside the farm were related, leading to the conclusion that the air is an important vehicle for E. coli dissemination.

The airborne dissemination of Escherichia coli from the inside of a dairy cattle farm to the immediate environment was investigated. The air samples were taken inside the farm (area 0) and from the immediate outside farm surroundings at distances of 50, 100 and 150 m in four directions (north, south, east, and west), at different heights (40 cm, 70 cm and 1 m) and in November and July. E. coli was isolated in both inside and outside air, even in samples taken 150 m from the farm. A seasonal effect was observed with more bacterial isolates when temperature was higher. Regarding the distribution of the isolates, wind direction appeared as a determining factor. In order to verify that E. coli strains isolated from animal housing facilities were identical to those isolated from the air of the immediate farm environment, their genomic DNA profiles were analyzed by pulsed-field gel electrophoresis (PFGE) after digestion with the endonuclease XbaI.

#### Salmonella

#### Fate of Salmonella enterica in a Mixed Ingredient Salad Containing Lettuce, Cheddar Cheese, and Cooked Chicken Meat

F. Bovo, A. De Cesare, G. Manfreda, S. Bach, P. Delaquis Journal of Food Protection, Vol. 78, No. 3; pp. 491–497, 2015 DOI: 10.4315/0362-028X.JFP-14-187

Link to full text: Click here

**Significance:** Rapid growth of bacterial enteric pathogens may occur in mixed ingredient salads; therefore, strict temperature control during the manufacture, distribution, handling, and storage of these products is critical.

A model system was developed to examine the fate of Salmonella enterica (inoculum consisting of S. enterica serovars Agona, Typhimurium, Enteritidis, Brandenberg, and Kentucky) on the surface of romaine lettuce tissues incubated alone and in direct contact with Cheddar cheese or cooked chicken. S. enterica survived but did not grow on lettuce tissues incubated alone or in contact with



Cheddar cheese for 6 days at either 6 or 14°C. In contrast, populations increased from 2.01  $\pm$  0.22 to 9.26  $\pm$  0.22 CFU/cm2 when lettuce washed in water was incubated in contact with cooked chicken at 14°C. Populations on lettuce leaves were reduced to 1.28  $\pm$  0.14 CFU/cm2 by washing with a chlorine solution (70 ppm of free chlorine) but increased to 8.45  $\pm$  0.22 CFU/cm2 after 6 days at 14°C. Experimentation with a commercial product in which one third of the fresh-cut romaine lettuce was replaced with inoculated lettuce revealed that S. enterica populations increased by 4 log CFU/g during storage for 3 days at 14°C.

# Evaluation of the Effects of a Mixture of Organic Acids and Duration of Storage on the Survival of Salmonella on Turkey Carcasses

A. Mikołajczyk Journal of Food Protection, Vol. 78, No. 3; pp. 585–589, 2015 DOI: 10.4315/0362-028X.JFP-14-135 Link to full text: Click here

**Significance:** Treatment of raw turkey breasts with a mixture of organic acids is a promising option for reducing the risk of the presence of Salmonella.

The first part of the study concerned analysis of the influence of the mixtures of organic acids (acetic, ascorbic, citric, lactic, and tartaric) over 15 or 30 min on Salmonella Enteritidis on turkey carcasses. Turkey breast samples were inoculated with Salmonella Enteritidis at 3.7, 2.7, 1.7, 0.7, and 0.07 log CFU. The antibacterial effectiveness of the organic acids differed depending on the initial population of Salmonella on the turkey carcasses. Salmonella was most sensitive to mixtures of equal parts of 1% ascorbic, 1% citric, and 1% tartaric acids. The second part of the study involved determining the influence the organic acid mixtures had on survival of Salmonella Enteritidis was inoculated into a nutrient broth, incubated at 37°C for 24 h, and then added to the diluent in which the turkey breast samples were immersed for 5 min. During storage at 4°C, the Salmonella level in the meat samples decreased. The largest decrease occurred at 4°C after 6 days with equal parts of 1% acetic acid, 1% lactic acid, and 1% tartaric acid.



#### **Foodborne Pathogens**

# Functional Properties of Peanut Fractions on the Growth of Probiotics and Foodborne Bacterial Pathogens

M. Peng, E. Bitsko, D. Biswas Journal of Food Science, Vol. 80, No. 3, pp. M635–M641, 2015 DOI: 10.1111/1750-3841.12785 Link to full text: Click here

**Significance:** Peanut white kernel might assist in improving human gut flora as well as reducing enterohemorrhagic E. coli O157:H7.

The effects of peanut white kernel and peanut skin on 3 strains of Lactobacillus and 3 major foodborne enteric bacterial pathogens were investigated. Significant growth stimulation of Lactobacillus casei and Lactobacillus rhamnosus was observed in the presence of 0.5% peanut flour (PF) made from peanut white kernel, whereas 0.5% peanut skin extract (PSE) exerted the inhibitory effect on

the growth of these beneficial microbes. Within 72 h, PF inhibited growth of enterohemorrhagic Escherichia coli O157:H7 (EHEC), while PSE significantly inhibited Listeria monocytogenes but promoted the growth of both EHEC and Salmonella Typhimurium. The cell adhesion and invasion abilities of 3 pathogens to the host cells were also significantly reduced by 0.5% PF and 0.5% PSE.

#### Efficacy of Antimicrobial Compounds on Surface Decontamination of Seven Shiga Toxin–Producing Escherichia coli and Salmonella Inoculated onto Fresh Beef

N. Kalchayanand, T.M. Arthur, J.M. Bosilevac, J.W. Schmidt, R. Wang, S. Shackelford, et al.

Journal of Food Protection, Vol. 78, No. 3; pp. 503-510, 2015

DOI: 10.4315/0362-028X.JFP-14-268

Link to full text: Click here

**Significance:** Several antimicrobial compounds have been used in commercial meat processing plants for decontamination of pathogens on beef carcasses, but there are many commercially available, novel antimicrobial compounds that may be more effective and suitable for use in beef processing pathogen-reduction programs.

Sixty-four prerigor beef flanks (cutaneous trunci) were used to determine whether hypobromous acid, neutral acidified sodium chlorite, and two citric acid-based antimicrobial compounds effectively reduce seven Shiga toxinproducing Escherichia coli (STEC) serogroups and Salmonella on the surface of fresh beef. Two cocktail mixtures (STEC serogroups O26, O103, O111, O145, and O157 and STEC serogroups O45, O121, and O157 and Salmonella) were inoculated onto prerigor beef flank surfaces. The inoculated fresh beef flanks were subjected to spray treatments with four antimicrobial compounds. Following antimicrobial treatments, both control and treated fresh beef samples were either enumerated immediately or were stored for 48 h at 4°C before enumeration. All four antimicrobial compounds caused 0.7- to 2.0-log reductions of STEC, Salmonella, aerobic plate counts, and Enterobacteriaceae. The four antimicrobial compounds were as effective at reducing the six non-O157 STEC strains as they were at reducing E. coli O157:H7 on the surfaces of fresh beef. The recovery of all seven STEC strains and Salmonella in a low-inoculation study indicated that none of the four antimicrobial compounds eliminated all of the tested pathogens.

#### The Microbiological Quality of Ready-to-Eat Salads in Turkey: A Focus on Salmonella spp. and Listeria monocytogenes

Z. Gurler, S. Pamuk, Y. Yildirim, N. Ertas International Journal of Food Microbiology, Vol. 196; pp. 79–83, 2015 DOI: 10.1016/j.ijfoodmicro.2014.11.021 Link to full text: Click here

**Significance:** Hygienic rules should be implemented in the production chain of readyto-eat foods to ensure microbiological safety and to improve shelf life.

In this study, Listeria monocytogenes and Salmonella spp. were isolated from 15(6%) and 21(8%) samples respectively out of 261 ready-to-eat (RTE) foods commercialized in Turkey. Escherichia coli was present in 10(4%) samples analyzed. Psychrotrophic aerobic populations > 6 log CFU/g were found in 36 (14%) of the samples, while total coliforms were detected in 155 (59%) of samples



analyzed. All of the Salmonella spp. and L. monocytogenes isolates tested, exhibited resistance to one or more antimicrobial agents used. For Salmonella spp. isolates, resistance to penicillin (69%), erythromycin (38%), gentamicin (36%), tetracycline (36%) neomycin (33%), ampicillin (33%), amikacin (33%), vancomycin (33%), streptomycin (29%) cefotaxime (9%) and oxacillin (9%) was observed. For L. monocytogenes isolates, resistance to erythromycin (23%) and cephalothin (20%) was evident. The presence of pathogens and the relatively high resistance among the bacteria tested in RTE foods could pose public health and therapeutic problems in consumers.

#### **Food Allergy**

#### Administration of a Probiotic with Peanut Oral Immunotherapy: A Randomized Trial

M.L.K. Tang, A.-L. Ponsonby, F. Orsini, D. Tey, M. Robinson, E.L. Su, et al. Journal of Allergy and Clinical Immunology, Vol. 135, No. 3; pp. 737–744.e8, 2015 DOI: 10.1016/j.jaci.2014.11.034

Link to full text: Click here

**Significance:** Probiotic and peanut oral immunotherapy was effective in inducing possible sustained unresponsiveness and immune changes that suggest modulation of the peanut-specific immune response.

This double-blind, placebo-controlled randomized trial evaluated a combined therapy of the probiotic Lactobacillus rhamnosus CGMCC 1.3724 and peanut oral immunotherapy (OIT) (probiotic and peanut oral immunotherapy [PPOIT]) in children (1-10 years) with peanut allergy. The primary outcome was induction of sustained unresponsiveness 2 to 5 weeks after discontinuation of treatment (referred to as possible sustained unresponsiveness). Secondary outcomes were desensitization, peanut skin prick test (SPT), and specific IgE and specific IgG4 measurements. Sixty-two children were randomized and stratified by age ( $\leq 5$  and > 5 years) and peanut SPT wheal size ( $\leq 10$  and > 10 mm); 56 reached the trial's end. Possible sustained unresponsiveness was achieved in 82.1% receiving PPOIT and 3.6% receiving placebo (P < .001). Nine children needed to be treated for 7 to achieve sustained unresponsiveness (number needed to treat, 1.27; 95% CI, 1.06-1.59). Of the subjects, 89.7% receiving PPOIT and 7.1% receiving placebo were desensitized (P < .001). PPOIT was associated with reduced peanut SPT responses and peanut-specific IgE levels and increased peanut-specific IgG4 levels (all P < .001). PPOIT-treated participants reported a greater number of adverse events, mostly with maintenance home dosing.

#### **Mycotoxins**

#### Ochratoxin A in Stored U.S. Barley and Wheat

J.A. Kuruc, P. Schwarz, C. Wolf-Hall Journal of Food Protection, Vol. 78, No. 3; pp. 597–601, 2015 DOI: 10.4315/0362-028X.JFP-14-418 Link to full text: Click here

**Significance:** Ochratoxin A is detectable in stored barley and wheat destined for animal feed and human consumption in the U.S.



Ochratoxin A (OTA) is a mycotoxin of significant health concern that is present in a variety of cereal grains and other foods around the world. Although OTA contamination can occur prior to harvest, it is largely considered a storage issue that can be controlled through the implementation of proper storage practices. Barley, durum, and hard red spring wheat samples that had been stored for various lengths of time were collected (n = 262) over a period of 2 years by multiple commercial grain companies located in the northwestern and northern Great Plains regions of the United States. Samples were analyzed for OTA concentration using high-performance liquid chromatography with fluorescence detection. OTA was detected in 12.2% of the samples, and of those samples, 81.3% had been stored for  $\geq 6$  months. One sample of barley and four samples of wheat exceeded 5 ng/g of OTA.

#### **Norovirus**

Consumer Education Needed on Norovirus Prevention and Control: Findings from a Nationally Representative Survey of U.S. Adults

S.C. Cates, K.M. Kosa, J.E. Brophy, A.J. Hall, A. Fraser Journal of Food Protection, Vol. 78, No. 3; pp. 484–490, 2015 DOI: 10.4315/0362-028X.JFP-14-313 Link to full text: Click here

**Significance:** There is the need to educate consumers about how to prevent and control norovirus infection.

A nationally representative Web-enabled panel survey of U.S. adults (n = 1,051) was conducted to collect information on consumers' awareness and knowledge of noroviruses (NoVs). Respondents who had heard of NoVs were asked 22 true-and-false questions on the transmission, prevention, and control of NoVs. Respondents (47%) reported awareness of NoVs, and 85% had heard of the terms "cruise ship virus," "the stomach bug," or "the stomach flu," which are commonly used to describe NoVs. Of those respondents who had previously heard of NoV or other terms used by consumers to describe NoV (n = 948), 36% correctly answered 11 or more of the 22 true-and-false questions, suggesting that consumers have limited knowledge on how to prevent and control NoV infection. Most consumers do not understand that the primary mode of transmission for NoV infection is fecal to oral, and many have the misperception that meat and poultry are sources of NoV infection.

# Effect of Temperature and Relative Humidity on the Survival of Foodborne Viruses during Food Storage

S.J. Lee, J. Si, H.S. Yun, G.P. Ko Applied and Environmental Microbiology, Vol. 81, No. 6; pp. 2075–2081, 2015 DOI: 10.1128/AEM.04093-14

Link to full text: Click here

**Significance:** Major foodborne viruses such as hepatitis A and human norovirus can survive over prolonged periods of time with a limited reduction in numbers.

This study investigated the survival of hepatitis A virus (HAV) and viral surrogates of human norovirus (HuNoV) (bacteriophage MS2 and murine norovirus [MNV]) in food over time. HAV, MNV, and MS2 were inoculated onto either the digestive gland of oysters or the surface of fresh peppers, and their survival



was measured under various temperature (4°C, 15°C, 25°C, and 40°C) and relative humidity (RH) (50% and 70%) conditions. Inoculated viruses were recovered from food samples and quantified by a plaque assay at predetermined time points over 2 weeks (0, 1, 3, 7, 10, and 14 days). Virus survival was influenced primarily by temperature. On peppers at 40°C and at 50% RH, >4- and 6-log reductions of MNV and HAV, respectively, occurred within 1 day. All three viruses survived better on oysters. In addition, HAV survived better at 70% RH than at 50% RH. The survival data for HAV, MS2, and MNV were fit to three different mathematical models (linear, Weibull, and biphasic models). Among them, the biphasic model was optimum in terms of goodness of fit.

#### A Quantitative Exposure Model Simulating Human Norovirus Transmission During Preparation of Deli Sandwiches

A. Stals, L. Jacxsens, L. Baert, E. Van Coillie, M. Uyttendael International Journal of Food Microbiology, Vol. 196; pp. 126–136, 2015 Link to full text: Click here

**Significance:** Good handling practices such as washing hands after a restroom visit, hand gloving, hand disinfection and surface disinfection in deli sandwich bars were an effective way to prevent human norovirus contamination of the prepared foods.

This study aimed to simulate human norovirus (HuNoV) transmission during the preparation of deli sandwiches in a sandwich bar. A quantitative exposure model was developed that included three food handlers working during a three hour shift on a shared working surface where deli sandwiches are prepared. The model consisted of three components: one simulated the preparation of the deli sandwiches and contained the HuNoV reservoirs, locations within the model allowing the accumulation of NoV and the working of intervention measures; another one covered the contamination sources being (1) the initial HuNoV contaminated lettuce used on the sandwiches and (2) HuNoV originating from a shedding food handler; and the third one included four possible intervention measures to reduce HuNoV transmission: hand and surface disinfection during preparation of the sandwiches, hand gloving and hand washing after a restroom visit. A single HuNoV shedding food handler could cause mean levels of  $43 \pm 18$ ,  $81 \pm 37$  and  $18 \pm 7$  HuNoV particles present on the deli sandwiches, hands and working surfaces, respectively. Introduction of contaminated lettuce as the only source of HuNoV resulted in the presence of  $6.4 \pm 0.8$  and  $4.3 \pm 0.4$  HuNoV on the food and hand reservoirs. The inclusion of hand and surface disinfection and hand gloving as a single intervention measure was not effective in the model as only marginal reductions of HuNoV levels were noticeable in the different reservoirs. High compliance of hand washing after a restroom visit did reduce HuNoV presence substantially on all reservoirs.

#### **Special Report**

#### A Risk-Based Strategy for Controlling Chemical Contaminants as Relevant Hazards in Food Ingredients

P.R. Hanlon, J.J. Hlywka, J.A. Scimeca Food Protection Trends, Vol. 35, No. 2; pp. 89–100, 2015 Link to full text: Click here

**Significance:** This paper provides a science-based approach that can serve as an assessment tool to measure, modify and improve management strategies for chemical contaminants in food ingredients and ultimately ensures food safety and regulatory compliance.



The global sourcing of ingredients and distribution of products has dramatically increased over the past decade and so have challenges of food safety. While regulatory values for chemical contaminants can be a guide, formulating a comprehensive program to address chemical contaminants can be complex because of differences in priorities between regulatory agencies. Factors such as the source of contamination, the origin of ingredients, production of contaminants through manufacturing processes and adulteration of food for economic purposes, necessitate considerable effort to control contaminants. Establishing criteria that use scientific principles could be the basis for development of a risk-based program to manage chemical contaminants in ingredients. This would allow for compliance to global regulatory requirements and ensure the production of safe products. Therefore, this paper outlines the use of scientific principles to define the criteria associated with the severity of toxicity caused by chemical contaminants and the probability that a chemical contaminant would be present. Furthermore, the application of science-based criteria to generate rationalized target lists of chemical contaminants specific to ingredient categories can guide the development of analytical methods critical for the control of chemical contaminants.

# About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

From: Sent: To:	Delia Murphy Friday, April 24, 2015 9:25 AM ; DAllison@uab.edu; fergc@foodsci.umass.edu; mdoyle@uga.edu; dwyerj1@od.nih.gov; jwerdman@illinois.edu; Hentges; james.hill@ucdenver.edu;	
	dblund@wisc.edu; Joanne Lupton;	;
_	Sullivan; weavercm@purdue.edu;	; Shawn ;
Cc: Subject:	Eric Hentges; Alison Kretser ILSI North America Conflict of Interest and Scientific Integrity Working Group- 30 April Agenda & Materials	
Attachments:	COI 30 April Agenda.doc; Meeting Minutes_COI 2 Dec Call Agenda.doc; Scientific Integrity Work by Various Organizations and in the Current Lidocx	

To: ILSI North America Conflict of Interest and Scientific Integrity Working Group Re: Agenda and Materials for 30 April In-Person Meeting

Please find attached the agenda for the 30 April in-person meeting of the Conflict of Interest and Scientific Integrity Working Group. Additionally, attached are two documents for Working Group members to review prior to the meeting: the meeting minutes from the 2 December 2014 conference call with the Working Group and a document that compiles Scientific Integrity Work by Various Organizations and in the Current Literature.

If you cannot attend the 30 April meeting in person, a webinar will be available. Please click on the link below to log into the webinar. You will then receive a phone number on your screen to dial into the call. <u>https://gotomeet.me/akretser</u>

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

# **Scientific Integrity Work by Various Organizations and in the Current Literature**

# **Scientific Integrity Work by Federal Agencies**

Presidential Memorandum for the Heads of Executive Departments and Agencies March 9, 2009 <u>https://www.whitehouse.gov/the\_press\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-</u> Agencies-3-9-09/

# Office of Science and Technology Policy (OSTP)

Directive on Scientific Integrity- December 17, 2010 This document is the implementation guide for the federal agencies to respond to the Presidential Memorandum. https://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

### Scientific Integrity Report Card

As of July 2013, fifteen agencies have released final scientific integrity policies. http://www.peer.org/assets/docs/About\_SI\_Report\_Card\_and\_Disclaimer.pdf

#### **National Science Foundation**

The National Science Foundation (NSF) is an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense..." With an annual budget of \$7.3 billion (FY 2015), we are the funding source for approximately 24 percent of all federally supported basic research conducted by America's colleges and universities. In many fields such as mathematics, computer science and the social sciences, NSF is the major source of federal backing.

NSF Scientific Integrity Policy- released after December 2010

It is the policy of NSF to maintain a culture of scientific integrity in accordance with the President's March 9, 2009 Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity and the implementation guidance in the Office of Science and Technology Policy (OSTP) December 17, 2010 Memorandum. NSF's policy applies to civil service employees; visiting scientists, engineers, and educators; those working at NSF under the Intergovernmental Personnel Act; and political appointees.

http://www.nsf.gov/bfa/dias/policy/si/sipolicy.pdf

Responsible Conduct of Research (RCR)- released after August 2007 when the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act was signed into law. http://www.nsf.gov/bfa/dias/policy/rcr.jsp

NSF's Research Misconduct regulation is found at 45 CFR 689.

The above regulation only applies to conduct that occurred on or after April 17th, 2002. For alleged misconduct that occurred before April 17, 2002, we use <u>this</u> definition and follow the procedure described in 45 CFR 689 above.



Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up results and recording or reporting them
- Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit,
- Policy defines "research" and "research record"

https://www.nsf.gov/oig/session.pdf

Searches for "scientific integrity" and "research integrity" grants results included many grants awarded in the 1990s but it seems that not as many have been funded more recently

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22scientific+integrity%22+%22research+integrity%22+&ActiveAwards=true&ExpiredAwards=true

**Collaborative Research: Foundations of Social and Ethical Responsibility Among Undergraduate Engineering Students: Comparing Across Time, Institutions, and Interventions** 

Award Number:1449479; Principal Investigator: Brent Jesiek; Co-Principal Investigator: Carla Zoltowski; Organization: Purdue University; NSF Organization: SES Start Date:05/15/2015; Award Amount:\$260,491.00; Relevance:29.51;

Research grants for "research misconduct" have taken place recently, including:

http://www.nsf.gov/awardsearch/simpleSearchResult?queryText=%22research+misconduct%22

## The Nature of Ethical Decision-Making in Research

Award Number:0924751; Principal Investigator: R. Wayne Fuqua; Co-Principal Investigator: David Hartmann, Thomas Van Valey; Organization: Western Michigan University; NSF Organization: SES Start Date:10/01/2009; Award Amount:\$357,073.00; Relevance:77.79;

#### **Gaming Against Plagiarism**

Award Number:1033002; Principal Investigator: Michelle Foss Leonard; Co-Principal Investigator: Amy Buhler, Margeaux Johnson, James Oliverio, Douglas Levey, Benjamin DeVane; Organization: University of Florida; NSF Organization: IIS Start Date:09/01/2010; Award Amount:\$298,660.00; Relevance:72.24; http://digitalworlds.ufl.edu/projects/gap/

#### **Department of Health and Human Services (HHS)**

Policies and Principles for Assuring Scientific Integrity Published in 2011 http://aspe.hhs.gov/sp/scientificintegrity/principles/index.cfm

**Office of Research Integrity** 

https://ori.hhs.gov/

In 2000, ORI began the <u>Research on Research Integrity (RRI) Program</u> and the biennial <u>Research Conferences on</u> <u>Research Integrity</u> to expand the knowledge base and develop a research community focused on the responsible conduct of research, research integrity, and research misconduct. That same year ORI started the <u>Rapid Response</u> <u>for Technical Assistance</u> to provide early and direct assistance to institutions assessing research misconduct allegations.



In 2002, ORI launched the Responsible Conduct Research (RCR) <u>RCR Resource Development Program</u> and the <u>RCR Program for Academic Societies</u>. The former program was designed to facilitate the development of materials for teaching the responsible conduct of research by the research community for use in the research community. The latter program, a collaboration with the Association of American Medical Colleges, supported activities within academic societies designed to promote the responsible conduct of research among their members. The first RCR Expo was held in 2003 to call attention to the new RCR materials. ORI published the <u>ORI Introduction to the Responsible Conduct of Research</u> in 2004 and began the <u>RCR Program for Graduate Schools</u> in collaboration with the Council of Graduate Schools to institutionalize RCR education in graduate training.

A new regulation, <u>PHS Policies on Research Misconduct (pdf)</u>, became effective on June 16, 2005. The regulation is codified at 42 C.F.R. Part 93. ORI began developing a training program for institutional research integrity officers (RIOs) in 2005 that produced an orientation video in 2006 and boot camps in 2007. In 2007, ORI also began the <u>RCR Program for Postdocs</u> and took another step toward the creation of a laboratory management training program in collaboration with the Laboratory Management Institute at the University of California-Davis to develop on-line instruction on laboratory management. Previously, ORI organized the first national conference on the management of biomedical research laboratories in 1998 in collaboration with the University of Arizona and supported the development of instructional resources on laboratory management through its RCR Resource Development Program.

"The Lab: Avoiding Research Misconduct": An Interactive Movie on Research Misconduct In "The Lab: Avoiding Research Misconduct," you become the lead characters in an interactive movie and make decisions about integrity in research that can have long-term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices. http://ori.hhs.gov/THELAB

The National Science Foundation and the Office of Research Integrity at the Department of Health and Human Services jointly confirm about 20 cases a year of research misconduct, according to Steneck. The actual number could be 10 times that or more, he said, because some researchers suspect but do not report misconduct, some institutions fail to undertake rigorous investigations and some journals find but do not report misconduct.

#### National Institutes of Health (NIH)

NIH Policies and Procedures for Promoting Scientific Integrity November 2012 http://www.nih.gov/about/director/sci-int-nov2012.pdf

NIH has not yet finalized the most recent language providing guidance to reviewers <u>http://enhancing-peer-review.nih.gov/guidance\_reviewers.html</u> <u>http://grants.nih.gov/grants/peer/peer.htm</u>

NIH hosts a workshop with journals to unite on reproducibility:

A group of editors representing more than 30 major journals; representatives from funding agencies; and scientific leaders assembled at the American Association for the Advancement of Science's headquarters in June 2014 to discuss principles and guidelines for preclinical biomedical research. The gathering was convened by the US National Institutes of Health, *Nature* and *Science* (see *Science* **346**, 679; 2014). The discussion ranged from what journals were already doing to address reproducibility — and the effectiveness of those measures — to the magnitude of the problem and the cost of solutions. The attendees agreed on a common set of Principles and Guidelines in Reporting Preclinical Research



(see go.nature.com/ezjl1p) that list proposed journal policies and author reporting requirements in order to promote transparency and reproducibility.

NIH plans to enhance reproducibility:

- NIH is developing a training module on enhancing reproducibility and transparency of research findings, with an emphasis on good experimental design.
- Several of the NIH's institutes and centres are also testing the use of a checklist to ensure a more systematic evaluation of grant applications.
- A pilot was launched last year that we plan to complete by the end of this year to assess the value of assigning at least one reviewer on each panel the specific task of evaluating the 'scientific premise' of the application: the key publications on which the application is based (which may or may not come from the applicant's own research efforts).
- Big Data initiative, the NIH has requested applications to develop a Data Discovery Index (DDI) to allow investigators to locate and access unpublished, primary data (see go.nature.com/rjjfoj).
- in mid-December, the NIH launched an online forum called PubMed Commons (see go.nature.com/8m4pfp) for open discourse about published articles.
- NIH is contemplating modifying the format of its 'biographical sketch' form, which grant applicants are required to complete, to emphasize the significance of advances resulting from work in which the applicant participated, and to delineate the part played by the applicant.
- NIH is examining ways to anonymize the peer-review process to reduce the effect of unconscious bias (see go.nature.com/g5xr3c)

http://www.nature.com/news/policy-nih-plans-to-enhance-reproducibility-1.14586

NIH Regional Consultation Meeting on Peer Review

October 22, 2007 – Washington, D.C. Meeting Summary: <u>http://enhancing-peer-review.nih.gov/meetings/102207-summary.html</u>

### Food and Drug Administration (FDA)

http://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm306446.htm

FDA has a long and continuing history of promoting an environment of robust scientific debate, where the integrity of information is ensured, all views are carefully considered, and scientific decisions are protected from political influence. In 2009, we established **FDA**'s **Office of Scientific Integrity** (OSI). OSI works to:

- 1. ensure that FDA's policies and procedures are current and applied across the Agency;
- 2. resolve scientific disputes that may arise internally or externally and that are not resolved at the Agency's Center levels; and
- 3. advise the Chief Scientist and other senior FDA leaders on appropriate responses.

#### **Centers for Disease Control and Prevention (CDC)**

The Office of the Associate Director for Science (OADS) provides service and support to the CDC scientists as they work to protect people's health and improve the quality of their lives. Our focus is on strengthening the quality and integrity of CDC's science. Furthermore, by fostering innovative and successful scientific collaborations and partnerships we are also working towards enhancing the relevance of our science and its health impact.

Our office is also a home to the Office of Science Quality (OSQ) which is responsible for advancing the quality of CDC's science and championing the translation of research through the development of science policies and best practices (e.g., authorship, scientific clearance, peer review, and extramural research policies); and the Office of Scientific Integrity, which ensures that CDC science and research activities comply with various federal laws,



regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.

http://www.cdc.gov/od/science/aboutus/index.htm

#### **United States Department of Agriculture (USDA)**

USDA Scientific Integrity Policy - 2013

To ensure that science at USDA is held to the highest standards possible, Secretary Vilsack issued a Departmental Regulation (DR) on Scientific Integrity. It provides guidance to all employees and contractors on the proper use of scientific findings and the principles of conducting scientific activities, and addresses the White House Office of Science and Technology Policy's request for all federal departments to write these policies. See below for the policy and the handbook, which describes how the policy will be implemented.

- USDA Scientific Integrity Policy (DR 1074-001) (PDF, 262KB)
- USDA Scientific Integrity Policy Handbook (PDF, 879KB)
- Annual USDA Scientific Integrity Allegations Summary Report (May 2013 April 2014) (PDF, 179KB)
- USDA Agency Scientific Integrity Officers

Research misconduct - an important subset of scientific integrity violation - is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. To ensure that the public can trust the objectivity of its science, USDA established policies and procedures for handling research misconduct that occurs in research that is either funded or conducted by USDA.

• View a list of USDA Research Integrity Officers

Anyone who suspects USDA researchers or researchers performing USDA-funded research of engaging in research misconduct is encouraged to make a formal allegation of research misconduct to USDA's Office of the Inspector General (OIG)

### **Environmental Protection Agency (EPA)**

EPA's Scientific Integrity Policy was issued in February 2012 and provides a framework to promote scientific and ethical standards and to create a proactive culture to support them. The policy establishes a Scientific Integrity Committee to implement the policy. The Committee consists of Deputy Scientific Integrity Officials that represent each of the Agency's Program Offices and Regions. The Scientific Integrity Official (ScIO) chairs the Committee. The ScIO is the Agency's focal point on scientific integrity and serves as the Agency's expert on such matters. EPA Scientific Integrity Policy (PDF)

#### http://www2.epa.gov/osa/basic-information-about-scientific-integrity

Definition of Scientific Integrity: Scientific Integrity results from adherence to professional values and practices, when conducting and applying the results of science and scholarship. It ensures:

- Objectivity
- Clarity



- Reproducibility
- Utility

Scientific Integrity is important because it provides insulation from:

- Bias
- Fabrication
- Falsification
- Plagiarism
- Outside interference
- Censorship
- Inadequate procedural and information security

# Principles of Scientific Integrity

In 1999, the Agency published its Principles of Scientific Integrity, developed in conjunction with the EPA's National Partnership Council, which is comprised of representatives of Agency labor unions and management. The Principles laid out the basic rules for ethical behavior by all EPA employees in:

- Conducting scientific research
- Interpreting and presenting results
- Using scientific information and data

# Principles of Scientific Integrity

Community of Practice for Statistics- January 2014

Initiative to strengthen statistics, consideration, and study design and to ensure these same factors are evaluation during the review and approval of study protocols. 3 Working Groups were formed to raise awareness of the importance of statistical issues and provide a forum for robust discussion. The 3 Working Groups developed process and guidance

documents. http://www.ncbi.nlm.nih.gov/pubmed/25795653

Revising The Agency's Peer Review Handbook: The Agency's Peer Review Handbook was first issued in 1998. It was revised and reissued in 2000 (2nd Edition) and 2006 (3rd Edition). In 2009 an addendum on the "Appearance of a Lack of Impartiality in External Peer Review" was added. The Handbook is currently being updated to incorporate EPA organizational changes, the 2009 addendum, as well as additional processes that have been put into place since 2006.

Peer Review Handbook 3rd Edition, 2006

Addendum to Peer Review Handbook 3rd Edition



# **Scientific Integrity Work by Non-Profit Organizations**

**The National Academies** 

# **Institute of Medicine**

Does the Public Trust Science? Trust and Confidence at the Intersections of the Life Sciences and Society A workshop of the Roundtable on Public Interfaces of the Life Sciences May 5-6, 2015 National Academy of Sciences 2101 Constitution Avenue N.W., Lecture Room Washington, D.C. http://nas-sites.org/publicinterfaces/roundtable/events/trust/

2002: Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct This report focuses on the research environment and attempts to define and describe those elements that allow and encourage unique individuals, regardless of their role in the research organization or their backgrounds on entry, to act with integrity. The committee's goal was to define the desired outcomes and set forth a set of initiatives that it believes will enhance integrity in the research environment. The committee considered approaches that can be used to ensure integrity and methods that can be used to assess the effectiveness of those efforts.

Several overarching conclusions emerged as the committee addressed the desire of the Department of Health and Human Services' Office of Research Integrity for means to assess and track the state of integrity in the research environment:

- Attention to issues of integrity in scientific research is very important to the public, scientists, the institutions in which they work, and the scientific enterprise itself.
- No established measures for assessing integrity in the research environment exist.
- Promulgation of and adherence to policies and procedures are necessary, but they are not sufficient means to ensure the responsible conduct of research.
- There is a lack of evidence to definitively support any one way to approach the problem of promoting and evaluating research integrity.
- Education in the responsible conduct of research is critical, but if it is not done appropriately and in a creative way, it is likely to be of only modest help and may be ineffective.
- Institutional self-assessment is one promising approach to assessing and continually improving integrity in research.

https://www.iom.edu/Reports/2002/Integrity-in-Scientific-Research-Creating-an-Environment-That-Promotes-Responsible-Conduct.aspx

RESPONSIBLE SCIENCE Ensuring the Integrity of the Research Process VOLUME I Panel on Scientific Responsibility and the Conduct of Research Committee on Science, Engineering, and Public Policy National Academy of Sciences National Academy of Engineering Institute of Medicine NATIONAL ACADEMY PRESS Washington, D.C. 1992 http://www.nap.edu/openbook.php?record\_id=1864&page=R1



"Conflict of Interest and Medical Innovation:

Ensuring Integrity While Facilitating Innovation in Medical Research: Workshop Summary" (2014) <u>http://www.nap.edu/catalog/18723/conflict-of-interest-and-medical-innovation-ensuring-integrity-while-facilitating</u>

Scientific advances such as the sequencing of the human genome have created great promise for improving human health by providing a greater understanding of disease biology and enabling the development of new drugs, diagnostics, and preventive services. However, the translation of research advances into clinical applications has so far been slower than anticipated. This is due in part to the complexity of the underlying biology as well as the cost and time it takes to develop a product. Pharmaceutical companies are adapting their business models to this new reality for product development by placing increasing emphasis on leveraging alliances, joint development efforts, early-phase research partnerships, and public-private partnerships. These collaborative efforts make it possible to identify new drug targets, enhance the understanding of the underlying basis of disease, discover novel indications for the use of already approved products, and develop biomarkers for disease outcomes or directed drug use. While the potential benefits of collaboration are significant, the fact that the relationships among development partners are often financial means that it is vital to ensure trust by identifying, disclosing, and managing any potential sources of conflict that could create bias in the research being performed together.

# **Scientific Integrity Work by Foundations**

### John Templeton Foundation

Increasing Scientific Openness and Integrity

Project Leader(s): Brian Nosek, Jeffrey Spies

Grantee(s): <u>Center for Open Science</u> (see below additional projects under the Arnold Foundation) Description: An academic scientist's professional success depends on publishing. Publishing norms emphasize novel, positive, tidy results. As such, disciplinary incentives encourage design, analysis, and reporting decisions that maximize publishability even at the expense of accuracy. This challenges scientists' character because professional success is enhanced by pursuing suboptimal scientific practices. As such, disciplinary norms guide researchers toward practices that are contrary to personal and scientific values. The end result is inflation of error in published science, and interference with knowledge accumulation. Scientific integrity can be improved with strategies that make the fundamental but abstract accuracy motive—getting it right—competitive with the more tangible and concrete incentive—getting it published. We are building infrastructure (http://openscienceframework.org/) to alter the incentives, increase openness and accountability, and provide a means of instilling habits that embody scientific values in the daily behavior of practicing scientists. Also, we are

building communities around open science values, and means of providing credit for practicing scientists. Also, we are building communities around open science values, and means of providing credit for practicing those values. Ultimately, we aim to enhance the credibility and integrity of individual scientists, the scientific community, and the knowledge base that they produce. We will meet these goals in this grant with three activities: (1) building the Open Science Framework to provide features that provide value to the scientist's existing workflow and enables or automates good practices, (2) building community, training and outreach to facilitate use of the Open Science Framework, and (3) connecting a variety of tools (e.g., data repositories, data visualization tools, analytic tools)



through the OSF to support the entire research lifecycle and facilitate documentation and archival of research materials and data. Grant Amount: \$2,109,856 Start Date: January 2014, End Date: October 2016 Grant ID: 46545 http://www.templeton.org/what-we-fund/grants/increasing-scientific-openness-and-integrity

# **MacArthur Foundation**

The <u>Center for Scientific Integrity</u> operates <u>Retraction Watch</u> through a generous grant from the MacArthur Foundation. <u>http://retractionwatch.com/the-retraction-watch-faq/</u>

The goals of the Center fall under four broad areas:

- A database of retractions, expressions of concern and related publishing events, generated by the work of Retraction Watch. The database will be freely available to scientists, scholars and anyone else interested in analyzing the information.
- Long-form, larger-impact writing, including magazine-length articles, reports and books.
- Aid and assistance to groups and individuals whose interests in transparency and accountability intersect with ours, and who could benefit from shared expertise and resources.

http://retractionwatch.com/the-center-for-scientific-integrity/

#### **Arnold Foundation**

The Arnold Foundation has 4 areas of focus, one is research integrity. LJAF's Research Integrity initiative aims to improve the reliability and validity of scientific evidence across fields that inform governmental policy, philanthropic endeavors, and individual decision making. As a society, we often rely on published scientific research to guide our policy, health, and lifestyle choices. Although some published research is rigorous and reliable, some is not. Worse, the unreliability of research is often difficult or impossible to ascertain. LJAF is currently working to address this problem by supporting organizations that are committed to improving the openness, transparency, and quality of research. All research projects sponsored in full or in part by LJAF must follow the Guidelines for Investments in Research. See Guidelines for Investments in Research

Between 2011-2014, the Arnold Foundation granted \$66,859,986 in grant dollars for Research Integrity projects, including grants to:

#### American Association for the Advancement of Science (AAAS) (see more on AAAS below)

\$100,000 to foster open, reliable, and rigorous scientific research by sponsoring three workshops on publication standards. The grant runs from 2014-2016.

#### **Nutrition Science Initiative**

Two grants for a total of up to \$44 million running from 2012-2018 to improve the quality of science in nutrition and obesity research.

The mission of Nutrition Science Initiative is to reduce the individual, social, and economic costs of obesity, diabetes, and their related diseases by improving the quality of science in nutrition and obesity research. The Nutrition Science Initiative is currently focusing on 3 projects:

1. Boston Children's Hospital: This study will determine whether reduced calorie intake or a change in the proportions of fat and carbohydrates is the most effective strategy for maintaining a reduced body weight.



- 2. Energy Balance Consortium: This highly controlled laboratory study will help determine whether it's the total amount of calories you eat or the proportion of fat and carbohydrate in the diet that most importantly drives body weight gain.
- 3. Stanford University: This study compares the effects of a very low-carbohydrate and very-low fat diets on body weight in free-living obese patients over a year's time and examines whether genetic or metabolic factors can predict the response to the different diets.

#### Center for Open Science, Inc. (COS)

(see above for more information under the John Templeton Foundation) Several million dollars to the Center for Open Science, Inc.

COS Communities blur the boundary between COS and the many individual and organizational contributors to improving scientific practices. COS Communities form around particular products or services to define specifications, maximize applicability, promote adoption, and facilitate evaluation and improvement. There are 4 buckets of COS communities:

Publishing Initiatives

- Badges to Acknowledge Open Practices: Badges incentivize open research by rewarding authors with visual acknowledgements on published manuscripts. Currently, badges can be earned for three distinct practices: open data, open materials, and preregistration. Badges appear directly on publications along with information regarding where the relevant data, materials, or registration can be found. The badges and their criteria are developed and maintained as a community-driven initiative of the Center for Open Science.
- 2. Registered Reports: Registered Reports offer journals an alternative structure to the current publishing format to promote transparency and reproducibility in scientific research. In this model, peer review occurs twice. Each study procedure and analysis plan are evaluated prior to data collection for in-principle acceptance; if accepted, the final manuscript is essentially guaranteed publication regardless of the reported outcome, with a second peer review to ensure the accepted methodology was conducted.

Metascience

- 1. Reproducibility Project: Psychology (RP:P): The RP:P is a collaborative community effort to replicate published psychology experiments from three important journals. Replication teams follow a standard protocol to maximize consistency and quality across replications, and the accumulated data, materials and workflow are to be open for critical review on OSF. The RP:P is coordinated at the Center for Open Science and involves volunteer scientists from all over the world.
- 2. Reproducibility Project: Cancer Biology (RP:CB): The RP:CB is an initiative to conduct direct replications of 50 high-impact cancer biology studies. The project anticipates learning more about predictors of reproducibility, common obstacles to conducting replications, and how the current scientific incentive structure affects research practices by estimating the rate of reproducibility in a sample of published cancer biology literature. The RP:CB is a collaborative effort between the Center for Open Science and network provider Science Exchange.
- 3. Many Labs I: Many Labs I project was a crowdsourced replication study in which the same 13 psychological effects were examined in 36 independent samples to examine variability in replicability across sample and setting.
  - a. Results:
    - i. Variations in sample and setting had little impact on observed effect magnitudes



- ii. When there was variation in effect magnitude across samples, it occurred in studies with large effects, not studies with small effects
- iii. Replicability was much more dependent on the effect of study rather than the sample or setting in which it was studied
- iv. Replicability held even across lab-web and across nations
- v. Two effects in a subdomain with substantial debate about reproducibility (flag and currency priming) showed no evidence of an effect in individual samples or in the aggregate.
- 4. Many Labs II: Conducted in Fall of 2014, Many Labs II employed the same model as Many Labs I but with almost 30 effects, more than 100 laboratories, and including samples from more than 20 countries. The findings should be released in mid-2015.
- 5. Many Labs III: Many psychologists rely on undergraduate participant pools as their primary source of participants. Most participant pools are made up of undergraduate students taking introductory psychology courses over the course of a semester. Also conducted in Fall of 2014, Many Labs III systematically evaluated time-of-semester effects for 10 psychological effects across many participant pools. Twenty labs administered the same protocol across the academic semester. The aggregate data will provide evidence as to whether the time-of-semester moderates the detectability of effects.
- 6. Collaborative Replications and Education Project (CREP): The Collaborative Replications and Education Project facilitates student research training through conducting replications. The community-led team composed a list of studies that could be replicated as part of research methods courses, independent studies, or bachelor theses. Replication teams are encouraged to submit their results to an information commons for aggregation for potential publication. This integrates learning and substantive contribution to research.
- 7. Crowdsourcing a Dataset: Crowdsourcing a dataset is a method of data analysis in which multiple independent analysts investigate the same research question on the same data set in whatever manner they consider to be best. This approach should be particularly useful for complex data sets in which a variety of analytic approaches could be used, and when dealing with controversial issues about which researchers and others have very different priors. This first crowdsourcing project establishes a protocol for independent simultaneous analysis of a single dataset by multiple teams, and resolution of the variation in analytic strategies and effect estimates among them.

#### Infrastructure

 Open Source Developers: The Center for Open Science is a Python-based, open source development shop. Developers who want to support open science should definitely consider contributing to our open source community. The Open Science Framework, the flagship platform of the Center for Open Science, is a web application for supporting the research workflow. Essentially, the Center for Open Science wants to bring the core philosophy of open source development to science. Developers have the opportunity to contribute to maturing products, like the Open Science Framework, or to new projects that help make science better.

#### Interest Groups

1. Ambassadors: Center for Open Science ambassadors act as the local authority on the Center for Open Science, the Open Science Framework, and open science practices in their community. They are trained to talk about the Center for Open Science, lead Open Science Framework demonstrations, and represent us at conferences and meetings. Researchers in any field and from



any country can become COS Ambassadors. This is a great opportunity to promote open science in your community and help us work to increase openness, integrity, and reproducibility across scientific domains.

2. Open Science Collaboration: The Open Science Collaboration is a network of researchers, professionals, citizen scientists, and others with an interest in open science, metascience, and good scientific practices. The goal of the Open Science Collaboration is to promote open collaboration of scientific ideas. Collaboration and broadcasting of problems increases the odds a person with the right expertise will see it and be able to solve it easily. In the same vein, collaboration can lead to novel solutions to problems being found. Collaboration also means that projects can be more ambitious, as more people with a variety of expertise and experience are involved to help distribute the work.

Workshop held at the Center for Open Science in 2014 aimed at creating standards for promoting reproducible research in the social-behavioral sciences. Representatives from across disciplines (economics, political science, psychology, sociology, medicine), from funders (NIH, NSF, Laura and John Arnold Foundation, Sloan Foundation), publishers (Science/AAAS, APA, Nature Publishing Group), editors (American Political Science Review, Psychological Science, Perspectives on Psychological Science, Science), data archivists (ICPSR), and researchers from over 40 leading institutions (UC Berkeley, MIT, University of Michigan, University of British Columbia, UVA, UPenn, Northwestern, among many others) came together to push forward on specific action items researchers and publishers can do to promote transparent and reproducible research. http://bitss.org/2014/11/06/creating-standards-for-reproducible-research-overview-of-cos-meeting/

### **Robert Wood Johnson Foundation (RWJ)**

http://www.rwjf.org/reports/grr/038967.htm#int\_biblio

Anderson F. "Science Advocacy and Scientific Due Process." Issues in Science and Technology, 16(Summer): 71–76, 2000.

Reports

Anderson F, Edens G and Sargeant T. Science Advocacy and Scientific Due Process: Sourcebook of Materials. Washington: Cadwalader, Wickersham & Taft, 2000.

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib A Case Study of Industry Documents From Rofecoxib Litigation <u>http://www.rwjf.org/en/library/research/2008/04/guest-authorship-and-ghostwriting-in-publications-related-to-rof.html</u>

What's Behind Large Disparities in NIH Research Funding

In 2011, the National Institutes of Health revealed, through their own research, that only 16 percent of grant applications submitted by African American researchers were funded. The number for White researchers was 29 percent. Here, Robert Wood Johnson Foundation (RWJF) experts answer questions about the problem, possible solutions and how researchers should proceed.

http://www.rwjf.org/en/library/articles-and-news/2011/12/breaking-new-ground-in-research/whats-behind-largedisparities-in-nih-research-funding.html

#### Sloan Foundation

Opportunities: Big Data is a Big Deal (beginning on page 15)

Launched in 2011 and led by Program Director Joshua M. Greenberg, the Foundation's Digital Information Technology program aims to leverage developments in digital information technology to empower scientists, enable new forms of data intensive research, and improve and expand the dissemination and evaluation of



scholarship. The program has two dimensions, one outward- and one inward-facing. In its outward-facing dimension, the program works directly with researchers, technologists, engineers, academic publishers, and university administrators to speed the development and adoption of tools, standards, norms, and practices that will enable researchers to better communicate with one another and more effectively work with large datasets. It also aims to facilitate the creation of career paths for data scientists and to educate the scholarly community about new big data opportunities, methods, and challenges. In its inward-facing dimension, the program seeks to support and encourage the effective use of new datasets, data repositories, data dissemination, and computational techniques across Sloan's other grant making programs. Big data makes it possible to both improve the quality of existing research and expand the set of questions amendable to scientific investigation and analysis. http://www.sloan.org/fileadmin/media/files/annual\_reports/2013-Annual-Report.pdf

<u>http://www.sloan.org/major-program-areas/?L=0</u> (See funding work under Center for Open Science, Inc. above)

# **Scientific Integrity Work by Associations**

American Association for the Advancement of Science (AAAS) http://www.aaas.org/page/scientific-integrity

In 2006, at the 31st annual AAAS Forum on Science and Technology Policy, a Forum panel that explored the subtle dilemmas of science ethics and integrity http://www.aaas.org/news/aaas-panel-explores-subtle-dilemmas-science-ethics-and-integrity

"Forbidding science? Balancing freedom, security, innovation, & precaution" Workshop held on January 12-13, 2006 Conference cosponsored with AAAS that explored whether and how restrictions on scientific research should be imposed [2006]

### **Council of Science Editors**

The Council of Science Editors (CSE) is an international membership organization for editorial professionals publishing in the sciences. Our purpose is to serve over 800 members in the scientific, scientific publishing, ad information science communities by fostering networking, education, discussion, and exchange. Our aim is to be an authoritative resource on current and emerging issues in the communication of scientific information.

CSE has an Editorial Policy Committee- The Editorial Policy Committee serves as a resource regarding editorial and publishing policies applying to publications in the sciences. The committee studies and analyzes procedural, ethical, legal, and economic policies and recommends policies and/or guidelines that relate to the editing, review, and publication of manuscripts in books and journals in the sciences. The committee may suggest policy to the CSE board of directors affecting CSE's own publications. Policy guidelines developed by the committee will be presented to the membership via publication in Science Editor and the Web site, by presentation at CSE annual meetings, or in other ways, and after appropriate revision in consultation with the board, may be published and disseminated by CSE through the Publications, Education, Membership, and Program Committees.



White Paper on Publication Ethics CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update (approved by the CSE Board of Directors on March 30, 2012) **PDF of the** <u>entire White Paper</u>

#### Introduction to White Paper:

The Council of Science Editors and its Editorial Policy Committee encourage everyone involved in the journal publishing process to take responsibility for promoting integrity in scientific journal publishing. This paper will serve as a basis for developing and improving effective practices to achieve that goal. We first wrote this white paper in 2006 and it was last updated in 2009. For the 2012 Update, we substantially revised and updated each section; included information on citation manipulation, publication planning by study sponsors, and ethical conduct of sponsors; reorganized the section on reporting suspect manuscripts; updated information on international models for responding to research misconduct; and provided more recent examples of corrections, retractions, and expressions of concern. Through this White Paper and other activities, the Editorial Policy Committee aims to open dialogue about ethical publishing practices, inform those involved in the editorial process, and foster informed decision-making by editors. We intend to work with other professional organizations to shape the scientific journal environment so the integrity of our publications is upheld. With the understanding that what may be appropriate for one discipline or organization may not be so for another, the White Paper intends to inform and guide rather than direct. Where there is more published information available from the biomedical community on some of the topics in this paper, more references or examples in those areas are given. However, our intention is to provide information that is useful to all the sciences. Please help us to keep this living document current by pointing out areas that need to be expanded or updated. We will build on the work of this White Paper through the continued work of the Committee and your contributions. Please send comments and suggestions to CSE@CouncilScienceEditors.org and include "Editorial Policy Committee" in the subject line

#### **American Chemical Society (ACS)**

Scientific Integrity in Public Policy ACS Position Statement http://www.acs.org/content/acs/en/policy/publicpolicies/promote/scientificintegrity.html

#### "Catching Errors: Peer Review and Retractions in Publishing"

#### Thursday, April 16, 2015, 2:00-3:00 PM ET

We have all seen the headlines where unintentional errors and falsified data have caused papers to be retracted. These instances can damage the reputation of the researchers, journals, and the institutions associated with the erroneous research. Join Dr. Ivan Oransky of *Retraction Watch*, Dr. Charon Pierson of the Governing Council of the Committee on Publication Ethics (see more on this organization below), and Dr. James DuBois of the Center for Clinical Research Ethics (see more on this organization below) as they discuss the efforts that are being made to combat this issue as well as what could be changed to improve the review process.

#### Center for Science in the Public Interest (CSPI)

Integrity in Science Project 2006

Promoting Disclosure http://www.cspinet.org/integrity/disclosure.html

The Integrity in Science project promotes full disclosure of conflicts of interest when scientists publish in journals, are quoted in the press or appear before legislative or regulatory bodies at all levels of government. The project and its allies in the scientific community believe total disclosure of conflicts of interest is mandatory if the public is to maintain its faith in the integrity of the scientific process, and the government is to remain a fair and



impartial arbiter of scientific disputes that determine the laws and regulations that affect the health and safety of the American people.

# **Scientific Integirty Work by Other Organizations**

# Center for Clinical Research Ethics (CCRE)

The **Center for Clinical Research Ethics** (CCRE) was established through a partnership between the Institute of Clinical and Translational Sciences (ICTS) at Washington University and the Center for Health Care Ethics at Saint Louis University, both in St. Louis, MO.

The Center for Clinical Research Ethics (CCRE):

- Helps ensure that all ICTS trainees receive training in clinical research ethics (CRE) and the responsible conduct of research (RCR) that exceeds the minimum standards set by NIH;
- Conducts and supports collaborative research on clinical research ethics, research integrity, and the intersection of ethics and community engagement; and
- Shares expertise in research ethics with individuals, policy committees, and others through consulting activities.

#### **CCRE** Education

- CCRE aims to help ensure that all ICTS trainees receive **training in clinical research ethics** (**CRE**) **and the responsible conduct of research** (**RCR**)that exceeds the minimum standards set by the National Institutes of Health. We accomplish this aim by directing the course, M17-510 "Ethical and Regulatory Issues in Clinical Research" and by providing speakers in the "Research Ethics Lecture Series" of the Human Research Protections Office at Washington University.
- The <u>Professional Integrity</u> (PI) program (previously known as Restoring Professionalism and Integrity in Research or RePAIR) provides intensive professional development education for investigators who have engaged in wrongdoing or unprofessional behavior. The PI Program will also sponsor a webinar series on institutional strategies for preventing wrongdoing and fostering professionalism in research.
- We also offer a library of research <u>case studies</u>.
- The Institute for Clinical and Translational Sciences (ICTS) and the Office of the Vice Chancellor for Research (OVCR) at Washington University in St. Louis jointly sponsor a course on the responsible conduct of research (RCR). The RCR course is designed to satisfy the National Institutes of Health Requirement for Instruction in the Responsible Conduct of Research. It may also be incorporated into plans to satisfy National Science Foundation RCR training requirements.

**CCRE** Consultations



- Consultation on Training: We consult with training grant program directors to assist them in developing, identifying, or describing training in the Responsible Conduct of Research (RCR) or Clinical Research Ethics (CRE). Ongoing collaboration with CCRE faculty on funded training programs should be budgeted into grant applications.
- Consultation on Research Design: We consult on the design of research on ethical issues in human subjects research, research integrity, and ELSI in genetics. An initial consultation is funded by the CTSA. Ongoing collaboration with CCRE faculty on funded research projects should be budgeted into grant applications.

#### Current Projects

CCRE faculty have ongoing research and scholarly projects in the areas of mental health research ethics, understanding and preventing wrongdoing in research, community engagement strategies for addressing questions of research ethics, disclosure of results of genetic testing, and first-in-human research. CCRE faculty research has received support from the US Office of Research Integrity, the National Institutes of Health, the Greenwall Foundation, and other agencies. See the recent CCRE **publications** and a list of **grants and contracts**.

- DuBois, J.M. "The Role of Culture and Experience in the Perception of Research Regulations, Norms and Values," Office of Research Integrity, HHS (IR-ORI-14-001-018712). 8/1/2014-7/31/2016. \$98,360. Principal Investigator.
- DuBois, J.M. "Validating Outcome Measures for Remediation of Research Wrongdoing," Office of Research Integrity, HHS (1 ORIIR 130002-01-00). 9/1/2013-8/31/2015. \$277,700. Principal Investigator.
- DuBois, J.M. "Preventing Ethical Disasters in the Practice of Medicine," NIH National Institute of Aging (1R01AG043527-01). 6/1/2013-5/31/2018. \$1,258,500. Principal Investigator.
- DuBois, J. M. "Restoring Professionalism and Integrity in Research (RePAIR)," \$500,000 funded by NIH (Administrative Supplement to WU ICTS). September 17, 2007-May 31, 2012. DuBois is serving as Project Director for this project and PI of the SLU subaward (\$476,564). The project involves developing a curriculum for a remediation training program for investigators caught violating the rules for the responsible conduct of research.
- DuBois, J. M. "ORI Research Integrity Casebook," \$155,579 funded by the Office of Research Integrity . March 1, 2011-September 30, 2012. *The major goal of this project is to produce a casebook that is suitable for use in face-to-face training in the responsible conduct of research.*
- Solomon, S. Sarah Gehlert (Site PI for WU) "Development of a Nationally Implementable, Locally Deliverable Human Research Participants Training Workshop for Community-Based Researchers, Collaborators and Staff." (2011). Supplement to the CTSA from the National Center for Research Resources, National Institutes of Health to Michigan Institute for Clinical and Health Research (MICHR), \$34,513
- DuBois, J. M. "Environmental Factors Predictive of Misbehavior in Collaborative Health Research," National Institutes of Health (1R21RR026313-01). 9/25/2009-8/31/2010. \$376,000. Principal Investigator.
- DuBois, J. M. "Environmental Factors Associated with Professional Misconduct in Medical Research and Practice," BF Foundation. 1/1/2009-12/31/2011. \$100,000. Principal Investigator.



- DuBois, J. M. "Responsible Conduct of Research Instructional Assessment Program. Part II," Office of Research Integrity, Contract, 7/1/2008-9/30/2009. \$60,000, Principal Investigator.
- DuBois, J. M. "Center for Clinical Research Ethics," within the Washington University of St. Louis, Institute for Clinical and Translational Science. (NIH: 1 U54 RR023496-01A1, Principal Investigator: Polonsky, K.) 9/1/2007-8/31/2012. Role: 15% effort as Director. \$500,000 subcontract with St. Louis University, DuBois, Principal Investigator.
- DuBois, J. M. "Best Practices in Mental Health Research Ethics Conference Series," National Institute of Mental Health (1R13MH079690). 9/1/2007 8/31/2011. \$200,000. Principal Investigator.

#### **Committee on Publication Ethics (COPE)**

The Committee on Publication Ethics (COPE) was established in 1997 by a small group of medical journal editors in the UK but now has over 9000 members worldwide from all academic fields. Membership is open to editors of academic journals and others interested in publication ethics. Several major publishers (including <u>Elsevier</u>, <u>Wiley–Blackwell</u>, <u>Springer</u>, <u>Taylor & Francis,Palgrave</u> <u>Macmillan</u> and <u>Wolters Kluwer</u>) have signed up some, if not all, of their journals as COPE members.

COPE provides advice to editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct. It also provides a forum for its members to discuss individual cases. COPE does not investigate individual cases but encourages editors to ensure that cases are investigated by the appropriate authorities (usually a research institution or employer).

All COPE members are expected to follow the Code of Conduct for Journal Editors.

COPE has produced an eLearning course for new editors. Eleven modules in total, the course currently includes: An Introduction to Publication Ethics, Plagiarism, and Authorship among others. COPE also funds <u>research</u> on publication ethics, organizes <u>annual seminars</u> globally and has created an <u>audit tool</u> for members to measure compliance with its <u>Code of Conduct and Best Practice Guidelines for Journal Editors</u>.

- COPE Code of Conduct and Best Practice Guidelines for Journal Editors
- <u>Flowcharts</u> on how to handle common ethical problems
- Other <u>COPE guidelines</u> (eg on retractions)
- <u>Sample letters</u> (to adapt for use)
- <u>Database of all cases</u> discussed at COPE Forum (including podcasts of the discussion (where available), the advice given and the outcome of cases)



# **Scientific Integrity Literature Review**

A search through PubMed using the guidelines of publications in the past ten years (2005-2015) and the key terms "scientific integrity", "research integrity", and "misconduct", resulted in 835 publications. We have not evaluated all these publications but instead narrowed the search terms to the following:

# Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND research integrity; scientific integrity; transparency; misconduct; ethics Results: 13

Protecting our science. Seixas NS. Ann Occup Hyg. 2013 Oct;57(8):963-5. doi: 10.1093/annhyg/met056. PMID: 24130260 Related citations

Transparency for each research article. Institutions must also be accountable for research integrity.

Cosentino M, Picozzi M. BMJ. 2013 Sep 10;347:f5477. doi: 10.1136/bmj.f5477. No abstract available. PMID: 24022040 Related citations

Conflicts of interest for medical publishers and editors: protecting the integrity of **scientific**scholarship. Desai SS, Shortell CK. J Vasc Surg. 2011 Sep;54(3 Suppl):59S-63S. doi: 10.1016/j.jvs.2011.05.111. PMID: 21872119 Related citations

Misinformation in the medical literature: what role do error and fraud play?

Steen RG. J Med Ethics. 2011 Aug;37(8):498-503. doi: 10.1136/jme.2010.041830. Epub 2011 Feb 22. PMID: 21343631 Related citations

Editors' overview: topics in the responsible management of **research** data. Giffels J, Vollmer SH, Bird SJ. Sci Eng **Ethics**. 2010 Dec;16(4):631-7. doi: 10.1007/s11948-010-9243-1. Epub 2010 Oct 28. PMID: 20981506

<u>Rethinking the meaning of being a scientist--the role of scientific integrity boards and some thoughts</u> about scientific culture.

Werner-Felmayer G. Med Law. 2010 Sep;29(3):329-39. PMID: 22145555 Related citations

Publication ethics. Morton NS.


Paediatr Anaesth. 2009 Oct;19(10):1011-3. doi: 10.1111/j.1460-9592.2009.03086.x. Epub 2009 Jun 13. Review. PMID: 19619189 Related citations

Role of editors and journals in detecting and preventing **scientific** misconduct: strengths, weaknesses, opportunities, and threats.

Marusic A, Katavic V, Marusic M. Med Law. 2007 Sep;26(3):545-66. PMID: 17970252 Related citations

When conflict-of-interest is a factor in scientific misconduct.

Krimsky S. Med Law. 2007 Sep;26(3):447-63. PMID: 17970245 <u>Related citations</u>

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

**Research** integrity and pharmaceutical industry sponsorship.

Gøtzsche PC. Med J Aust. 2005 Jun 6;182(11):549-50. PMID: 15938676 Related citations

The IARC monographs program: changing attitudes towards public health. Tomatis L. Int J Occup Environ Health. 2002 Apr-Jun;8(2):144-52. PMID: 12019681 Related citations

The Medical **Research** Council's approach to allegations of **scientific** misconduct. Evans I. Sci Eng **Ethics**. 2000 Jan;6(1):91-4. PMID: 11273442 Related citations

Research misconduct definitions adopted by U.S. research institutions. Resnik DB, Neal T, Raymond A, Kissling GE. Account Res. 2015;22(1):14-21. doi: 10.1080/08989621.2014.891943. PMID: 25275621 Related citations



#### Search (("1/1/2005"[Date - Publication] : "3000"[Date - Publication])) AND scientific integrity; research integrity; quality of papers Results: 78 We have highlighted 12 of the publications that are most relevant.

Research ethics education for community-engaged research: a review and research agenda. Anderson EE, Solomon S, Heitman E, DuBois JM, Fisher CB, Kost RG, Lawless ME, Ramsey C, Jones B, Ammerman A, Ross LF. J Empir Res Hum Res Ethics. 2012 Apr;7(2):3-19. doi: 10.1525/jer.2012.7.2.3. Review. PMID: 22565579 Related citations

Professional ethics: an overview from health research ethics point of view.

Nyika A. Acta Trop. 2009 Nov;112 Suppl 1:S84-90. doi: 10.1016/j.actatropica.2009.07.033. Epub 2009 Aug 7. Review. PMID: 19665439 Related citations

<u>Fraud and misconduct in science</u>: the stem cell seduction: Implications for the peer-review process. van der Heyden MA, van de Ven T, Opthof T. Neth Heart J. 2009 Jan;17(1):25-9. PMID: 19148335 <u>Related citations</u> "The (anonymous) peer review process serves as goalkeeper of scientific quality rather than scientific integrity."

Issues on research integrity: a perspective.

Pascal CB. Exp Biol Med (Maywood). 2006 Jul;231(7):1262-3. PMID: 16816132 Related citations

Making sense of research: A guide for critiquing a paper.

Stockhausen L, Conrick M. Contemp Nurse. 2002 Dec;14(1):38-48. Review. PMID: 16114192 Related citations

Beyond conflict of interest: the responsible conduct of **research**. Rhoades LJ. Sci Eng Ethics. 2002 Jul;8(3):459-68. Review. PMID: 12353376



### Related citations

Maintaining data integrity in randomized clinical trials. Moody LE, McMillan S. Nurs Res. 2002 Mar-Apr;51(2):129-33. PMID: 11984384 <u>Related citations</u>

[Quality assurance of data collection and data processing in epidemiologic study data]. Greiner M, Baumann MP, Zessin KH. Dtsch Tierarztl Wochenschr. 2001 Nov;108(11):443-9. German. PMID: 11765598 <u>Related citations</u>

### Guidelines for quality assurance in multicenter trials: a position paper.

Knatterud GL, Rockhold FW, George SL, Barton FB, Davis CE, Fairweather WR, Honohan T, Mowery R, O'Neill R. Control Clin Trials. 1998 Oct;19(5):477-93. PMID: 9741868 <u>Related citations</u>

Quality data: what are they?

Sforza VA. Ann Ist Super Sanita. 1994;30(4):439-43. PMID: 7762939 <u>Related citations</u>

### Research data integrity: a result of an integrated information system.

Cranmer MF, Lawrence LR, Konvicka AK, Taylor DW, Herrick SS. J Toxicol Environ Health. 1976 Nov;2(2):285-99. PMID: 1011288 Related citations

A guide to critiquing a research paper on clinical supervision: enhancing skills for practice. Fothergill A, Lipp A. J Psychiatr Ment Health Nurs. 2014 Nov;21(9):834-40. doi: 10.1111/jpm.12161. Epub 2014 May 13. PMID: 24818837 Related citations

### **Other Notable Publications Found**

<u>Peer review.</u> **Twaij H**, Oussedik S, Hoffmeyer P. Bone Joint J. 2014 Apr;96-B(4):436-41. doi: 10.1302/0301-620X.96B4.33041. Review. PMID: 24692607 <u>Related citations</u>



Peer review: a view based on recent experience as an author and reviewer. Clark RK. Br Dent J. 2012 Aug;213(4):153-4. doi: 10.1038/sj.bdj.2012.721. PMID: 22918342 Related citations

<u>Good practice in reviewing and publishing studies on herbal medicine, with special emphasis on traditional Chinese medicine and Chinese materia medica.</u>

Chan K, Shaw D, Simmonds MS, Leon CJ, Xu Q, Lu A, Sutherland I, Ignatova S, Zhu YP, Verpoorte R, Williamson EM, Duez P. J Ethnopharmacol. 2012 Apr 10;140(3):469-75. doi: 10.1016/j.jep.2012.01.038. Epub 2012 Feb 11. Review. PMID: 22330011

Related citations



# Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

Purpose: To update the Working Group on recent activities and discuss future plans.

### I. Welcome and Introductions

A. Kretser

D. Lund

a. Ms. Kretser welcomed Working Group members to the call and Ms. Delia Murphy led introductions.

### II. Approval of 29 May Meeting Minutes

a. Working Group members officially approved the 29 May meeting minutes.

### III. Support of Professional Societies of COI PPP Principles E. Hentges

a. Dr. Eric Hentges shared with the Working Group that ILSI North America has been working with ASN to move this activity forward.

### b. 8 December Meeting

- i. A meeting has been planned for 8 December 2014 where multiple professional societies and federal agencies will attend.
  - 1. Professional Societies:
    - a. American Society for Nutrition
    - b. Academy of Nutrition and Dietetics
    - c. American Gastroenterological Association
    - d. American Heart Association
    - e. American Public Health Association
    - f. Institute of Food Technologists
    - g. International Association for Food Protection

# 2. Federal Agencies:

- a. NIH ODS
- b. NIH NHLBI



- c. NIH NCI
- d. FDA
- e. CDC
- f. USDA ARS
- g. USDA NIFA
- ii. The Statement of Task for the meeting is to jointly endorse a set of principles for public-private partnerships in research. It is anticipated that the group will use the ILSI North America 12 principles published in *Nutrition Reviews* in October 2013 as a starting point but the group may decide to add or edit the list of principles.
- iii. It was noted that all the professional societies who are involved that have journals have pledged to publish the list of principles that result from the meeting in their entirely or in excerpts.
- iv. The principles and the process will be written up after the meeting. Professional societies will then have a chance to endorse the principles.

### c. 12 May Unveiling

- i. The group will hold a meeting at the National Academies of Science building where professional societies and other organizations can formally adopt the principles. A press release will also be issued.
- ii. Dr. Hentges noted that these upcoming meetings and the work done thus far were a culmination of the seven years of hard work on conflict of interest that the Working Group has taken on and thanked the Working Group for their support.

### IV. A Partnership for Public Health: *Branded Food Products Database*

A. Kretser

a. Ms. Kretser noted that 2014 has been an extremely busy year for the Public-Private Partnership.

### b. National Nutrient Databank Conference Proceedings

 In May 2014, the three Partners (USDA, the ATIP Foundation, and ILSI North America) gave a two hour presentation on the Partnership, had a poster in a poster session, and held an informal listening session during lunch at the National Nutrient Databank Conference (NNDC). The Partnership was well received by the Nutrient



Databank Network who saw this Partnership as a high priority for their group to support and remain engaged with to ensure it is a success.

- ii. Proceedings from NNDC will be published in *Procedia Food Science* and the Partners have submitted a draft of their presentation for the proceedings.
- iii. Ms. Kretser noted that the Partners received word after NNDC that USDA approved the funding of the project during the 90 day beta test. A Specific Cooperative Agreement was put in place between USDA and the ATIP Foundation and the transfer of funds took place in early August.

#### c. Beta Test

- i. The Partnership is using FSEnet as the GS1 certified data pool provider and is now beta testing the IT infrastructure with five beta test companies: Campbell Soup Company, Cargill, Incorporated, ConAgra Foods, Inc, General Mills, Inc., and Red Gold, Inc. Red Gold, Inc. is not a North America member but they volunteered to participate in the beta test as they were originally thought to be a non-GS1 member. It has since been discovered that Red Gold is a GS1 member but it is good to have a small to medium sized company in the beta test to see the amount of resources is takes to publish data within their company.
- ii. The product information that manufacturers are providing, including the ingredient list, which is new to the USDA National Nutrient Database, is all present on the product's label, except for the date stamp which is a new feature and will be the date that the data is submitted. The date stamp will be used to archive and track the data.
- iii. Both FDA and UNC Chapel Hill have asked to pilot test the data once it has become publically available in the enhanced USDA National Nutrient Database to test the ease of use of the data. The Partnership will share with them when they can begin to work with the data.

### d. Best Practices Workshop

 ILSI North America held a Best Practices Workshop for its members on 19 November. Representatives from the nutrition/regulatory/labeling section and representatives from the IT/GS1 interface side of all members companies were invited.



- ii. 16 ILSI North America companies participated as well as Red Gold, Inc. GS1 and FSEnet were present as well to answer questions.
- iii. Ms. Kretser noted that it was helpful for member companies to be able to speak to each other about the data submission process and learn best practices from the beta test companies. There was also a discussion about creating a pre-production environment for manufacturers to test the system before submitting all their data. The pre-production environment will be created after the beta test.
- iv. Working Group members were curious whether a risk analysis has been done around the security of the data as the public will be able to easily access it once it is in the USDA National Nutrient Database. Ms. Kretser noted that the security of the data is within the GS1 system. Manufacturers have a history of working with GS1 and trust that GS1 will keep their data secure.
- v. Working Group members also asked about the potential negative effects of the data being made publically available.
  - It was noted that the Partnership has spoken about the potential risks for manufacturers to have their data easily accessible to everyone but manufacturers have made it clear that they feel the value of the database outweighs the risks. Many manufacturers are of the mindset that, "if you don't define, it then it will be defined and you will be reacting to it."
  - 2. Ms. Kretser explained that Food Essentials, a proprietary database, has over 150,000 foods and currently has a contract with FDA. They collect their products by scanning the labels at the grocery store, as do many other proprietary databases such as Mintel. Data on manufacturer's products is already available through these websites but with the Branded Food Products Database, manufacturers are submitting their own data so they can ensure that it is the most up to date and correct. The Partners have heard from several proprietary databases that they would begin to use the data in the Branded Food Products Database rather than collect it on their own.



- 3. It was also noted that several other initiatives, including GMA's Consumer Information Transparency Initiative, are in the developing stages and will ask for this same data from manufacturers.
- 4. ILSI North America does not have a mandate to analyze the data once it is in the Branded Food Products Database and is currently only a part of the project to demonstrate a proof of concept of the principles.

### e. Pledge Letter

- ILSI North America has created a pledge letter to engage its members in a commitment to submit data to the Branded Food Products Database. The pledge letter is an internal document that represents the company's commitment to publish data into the Database. However, it does not mean that the company needs to publish their entire product portfolio and it does not have a timeline associated with it for when the data must be published.
- ii. These companies who sign the pledge letter will be named as inaugural supporters of the initiative along with the financial supporters of the initiative within the press release, which will be released once the beta test is complete. Ms. Kretser noted that members companies will have the opportunity to see the draft press release three weeks in advance of its release to have an opportunity to sign the pledge letter if they have not already.
- iii. To date, 6 member companies have signed the pledge letters and ILSI North America expects to have over 20 members who will ultimately sign the pledge letter.

### f. Outreach Strategy

- i. Ms. Kretser gave an overview of the outreach strategy for the initiative which has been spearheaded by the ATIP Foundation and explained the Value Proposition document which is being used to explain how the Branded Food Products Database will benefit various stakeholders.
- While the ATIP Foundation is the lead in fundraising to sustain the Partnership, ILSI North America has served as a subject matter expert and leveraged its relationships within the 7 categories of stakeholders that have been identified for fundraising. The 7 categories of stakeholders are:



- 1. Federal Research Community
- 2. Nutrition and Food Safety Professional Societies
- 3. Major Foundations
- 4. Proprietary Databases
- 5. Major Food Producing Corporations
- 6. Major Retailers
- 7. Healthcare and Patient Advocacy Groups
- iii. To date, the Partnership has secured funding from several inaugural supporters, including the Academy of Nutrition and Dietetics, the American Heart Association, National Institutes of Health, and the Willett group at the Harvard School of Public Health. Many organizations do not have the funds available to give to the Partnership but are incredibly supportive of the initiative, including the NYC Department of Health, UNC Chapel Hill, and the Society for Nutrition Education and Behavior. The ATIP Foundation and ILSI North America have also spoken with the Pew Foundation and the Robert Wood Johnson Foundation and hope to receive funds from the two foundations. Proprietary databases are also a key stakeholder group that have been contacted and the Partnership anticipates that they will provide funding. Working Group members agreed that proprietary databases will benefit greatly from the data in the Branded Food Products Database so it would be ideal to have them contribute funds.
- iv. The Partners anticipate that the beta test will conclude in Q2 of 2015 and the database will be open for manufacturers to begin submitting their data. Ms. Kretser noted that the Partnership has begun to discuss the formation of a Technical Stakeholder Group that will help with future work, will make sure the data is utilized in the proper manner, etc.
- v. Ms. Kretser noted that ILSI North America held a call with GMA and FMI to share the progress of the initiative and to learn about the progress of their Consumer Information Transparency Initiative as it moved forward. Both initiatives are using the GS1 infrastructure, although the CITI project is geared more towards the consumer. The Phase 1 attributes that the Partnership has identified for manufacturers



to submit to the Branded Food Products Database are most likely a subset of the attributes being asked for by CITI so the initiatives complement each other. GMA and FMI plan to share the progress of the Branded Food Products Database at their board meetings in January 2015.

vi. Ms. Sylvia Rowe and Mr. Nick Alexander continue to document the progress of the Partnership for a case study manuscript.

# V. GRAS Assessment

# E. Hentges

- a. Dr. Hentges notes that this project has not moved forward as ILSI North America is currently short staffed. The project may move forward in the future and IFT has indicated that they would move forward with us if we choose to pursue this project.
- b. The Executive Committee and the Board will be discussing what makes a good GRAS panel and how to reduce bias at the 2015 Annual Meeting.
- c. The Working Group agreed that there is still a need for this work, however, whether ILSI North America can participate meaningfully depends on how FDA proceeds. The Working Group would like to continue to look at this topic in the foreseeable future.

# VI. New Projects

# D. Lund

- a. Dr. Lund reminded the Working Group of a letter that Dr.Rhona Applebaum wrote in 2012 to all ILSI North America member companies about what ILSI North America has been doing in the area of conflict of interest and the next steps for the Working Group.
- b. The Working Group has focused on aspects of conflict of interest for the past 7 years and has amassed a body of work. The Group should promote this work that has been done. The Working Group should also look at the impact this work has had and whether organizations are reacting to or making changes because of the work. Has the IOM or federal committees begun to change their conflict of interest processes?
  - i. This is reflected in the group of federal agencies and major professional societies that are taking part in the endorsement of the principles for research public-private partnerships.



- c. Dr. David Allison recommended that the Working Group shift its focus to research integrity. Many organizations are starting to understand that there are biases. Is there something that ILSI North America can do that would make a positive impact in this area?
  - i. Potential roles that ILSI North America could play/potential projects to take on:
    - 1. ILSI North America could bring people together to discuss scientific integrity.
    - Could provide funding to journals to do a pilot program to grade papers for quality, could do research to look at the quality of reporting in various domains by topic or by journal to provide a benchmark against which progress can be checked, etc.
    - 3. Provide standards for "what good looks like".
    - 4. Quality and scoring of papers that are published. A universal grading system and what the minimum is to be accepted for publication. This would be of high value. Would encourage highly proofed papers. America psychological society badge system for scoring papers- it is just beginning
    - 5. Transparency pledges, raw data depositing
    - 6. Dr Hentges recommended that at the end of COI Summit, all participants will be asked to commit to having a second meeting in 2 years. The Working Group could then have 2 years to build a body of work on research integrity issues and could bring it forward to the group of federal agencies and professional societies.
  - ii. It was noted that getting companies to support these activities is dependent on the nature of the activity. The real challenge will be to develop a business plan with regard to the issues and that is what is going to sell a company to joining and funding the program. It will be incumbent on getting a good description of the project. The Working Group will need to develop project charters.

D. Lund

### VII. Next Steps

a. <u>Action Item:</u> The Working Group will schedule an in-person meeting in Spring 2015 (Completed.)



- b. The Working Group will discuss development of a second harvest roadshow of its work on conflict of interest. It will then shift gears and focus on research integrity.
- c. Potential projects under research integrity:
  - i. Universities funding as a business model
  - ii. Journals accepting payment for publishing papers
  - iii. How to score a successful paper
  - iv. Collaborate with journal editors to create a common declaration of interest form.
- d. The Working Group should work to bring in additional members from ILSI North America's membership. Research integrity is important to many companies so this shift in focus may help the Working Group to gain additional members.

### VIII. Adjournment

A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

#### Attendees

Daryl Lund, chair Todd Abraham David Allison Tom Boileau Fergus Clydesdale Johanna Dwyer John Erdman Eric Hentges Alison Kretser **Richard Lane** Beate Llovd Joanne Lupton Debra Miller Delia Murphy Juan Navia Claudia Riedt David Thomas

#### **Unable to Attend**

Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle Rachel Goldstein James Hill Mark Moorman **Amy Preston** Joseph Ratliff Steven Rizk Kari Ryan Shawn Sullivan Jennifer van de Ligt Connie Weaver Liz Westring

University of Wisconsin, Madison Mondelez International University of Alabama at Birmingham Kraft Foods Group, Inc. University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign **ILSI** North America **ILSI North America** PepsiCo Inc. Coca-Cola Company Texas A&M University The Hershey Company **ILSI** North America McNeill Nutritionals. LLC Dr Pepper Snapple Group Dr Pepper Snapple Group

Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia Mars, Incorporated University of Colorado Health and Wellness Center Kellogg Company The Hershey Company Dr Pepper Snapple Group Mars, Incorporated Kraft Foods Group, Inc. **ILSI North America** Cargill, Incorporated Purdue University General Mills Inc.



# Agenda: Working Group on Conflict of Interest & Scientific Integrity **In-Person Meeting**

Thursday 30 April, 2015, 8:30 am-5:00 pm EDT

### https://gotomeet.me/akretser

# Purpose: to update the Working Group on current projects and to develop a plan of work to shift the Working Group's focus to scientific integrity.

I.	Welcome and Introductions	A. Kretser
II.	Approval of 2 December Meeting Minutes	D. Lund
III.	A Transparent, Actionable Framework for Food and Nutrition Research	Public-Private
	Partnerships	E. Hentges
	a. 8 December Meeting	
	b. 16 June Unveiling of Principles	
IV.	A Partnership for Public Health: Branded Food Products Database	E. Hentges
V.	Altmetric Tracking of Publications	D. Murphy
	BREAK (10:00-10:10 AM EDT)	
VI.	Transition to Scientific Integrity Work	D. Lund/A. Kretser
	a. Results of ILSI North America Membership Survey	A. Kretser
	b. Bibliography of Scientific Integrity Work	A. Kretser
	LUNCH (12:00 PM EDT)	
	c. Presentation of Draft Straw man	D. Lund
	d. Discussion of the Draft Straw man	All
	BREAK (3:15-3:25 PM EDT)	
VII.	Recommendation to Change Name of Working Group	D. Lund
VIII.	Next Steps	D. Lund
IX.	Adjournment	A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Thursday 30 April, 2015, 8:30 am-5:00 pm EDT

### **Attendees**

Todd Abraham	Mondelēz International
Johanna Dwyer	NIH/Tufts University Medical Center
Eric Hentges	ILSI North America
Mitch Kanter	Egg Nutrition Center
Alison Kretser	ILSI North America
Richard Lane	PepsiCo Inc.
Joanne Lupton	Texas A&M University
Debra Miller	The Hershey Company
Delia Murphy	ILSI North America
Joseph Ratliff	Dr Pepper Snapple Group
Claudia Riedt	Dr Pepper Snapple Group
Shawn Sullivan	ILSI North America
Jennifer van de Ligt (tentative if she can attend in person	a) Cargill, Incorporated

### <u>Via Webinar</u>

Daryl Lund, chair Stephanie Atkinson Fergus Clydesdale John Erdman Beate Lloyd Tia Rains Liz Westring

# **Tentative**

Rachel Goldstein

# **Unable to Attend**

David Allison Kerr Dow Michael Doyle James Hill Steven Rizk Connie Weaver

### Unconfirmed

Rhona Applebaum Kari Ryan Mark Moorman University of Wisconsin, Madison McMaster University University of Massachusetts at Amherst University of Illinois at Urbana-Champaign Coca-Cola Company Egg Nutrition Center General Mills Inc.

### Mars, Incorporated

University of Alabama at Birmingham Cargill, Incorporated The University of Georgia University of Colorado Health and Wellness Center Mars, Incorporated Purdue University

Coca-Cola Company Kraft Foods Group, Inc. Kellogg Company



Amy Preston David Thomas Nelson Almeida Tom Boileau The Hershey Company Dr Pepper Snapple Group Kellogg Company Kraft Foods Group, Inc.

From:	Suzanne Harris	
Sent:	Tuesday, April 21, 2015 12:55 PM	
То:		'; 's.chang@griffith.edu.au';
	; Joanne Lupton;	
Cc:	1. 7	'carmel.james@griffith.edu.au';
	Chelsea L. Bishop; Betł	n-Ellen Berry; Shawn Sullivan; Beth
	Brueggemeyer	-
Subject:	Agenda, briefing documents and dial-in instru	ctions for the ILSI Financial Oversight
-	Committee conference call Tuesday, April 28	3, 2015
Attachments:	FOC 2015-04-28 agd.doc; FOC 2014-10-27 min	nutes BEB.docx; ILSI Financial Statement
	03312013.pui, itsi Performance.pui	

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The first conference call in 2015 for the ILSI Financial Oversight Committee is scheduled for **Tuesday, April 28, 2015, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour and the dial-in instructions are provided at the bottom of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the October 27, 2014 conference call

Agenda Item III. 2015 Year-to-date financial report; first quarter 2015 Raffa investment report

Please let me know if you have any questions. If you will not be able to join the conference call on April 28, you are welcome to send your comments and questions either to me to distribute to the committee or directly to the committee.

### **Dial-in Instructions**

If you are calling from:	Please dial:
Australia	1-800-064-762
Germany	0-800-723-5123
United Kingdom	0-800-169-0430
United States	1-888-585-9008

The conference room number for everyone is 476-399-389 #.

If you will be calling in from another country, please let me know which one so I can send you the appropriate toll-free number.



# March 2015 Portfolio Performance & Activity

ILSI - Board Designated Reserve 1156 15th Street, NW Washington, DC 20005

Description	March	YTD
Beginning Value	588,168.89	576,229.31
Net Contributions	0.00	0.00
Capital Appreciation	-1,580.06	9,988.60
Income	1,101.74	1,610.89
Management Fees	0.00	-138.23
Other Expenses	0.00	0.00
Ending Value	587,690.57	587,690.57
Total Investment Gain/Loss	-478.32	11,461.26
Time Weighted (gross)	-0.08	2.01
Time Weighted (net)	-0.08	1.99



# March 2015 Portfolio Performance & Activity

ILSI - Operating Reserve 1156 15th Street, NW Washingon, DC 20005

Description	March	YTD
Beginning Value	1,327,356.32	1,321,284.22
Net Contributions	-400,000.00	-400,000.00
Capital Appreciation	1,924.16	6,990.16
Income	1,174.74	2,497.79
Management Fees	0.00	-316.95
Other Expenses	0.00	0.00
Ending Value	930,455.22	930,455.22
Total Investment Gain/Loss	3,098.90	9,171.00
Time Weighted (gross)	0.28	0.76
Time Weighted (net)	0.28	0.74

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS		<u>3/31/2015</u>	_	12/31/2014	-	<u>12/31/2013</u>		<u>12/31/2012</u>		<u>12/31/2011</u>
Current Assets										
Cash	\$	441,355	\$	610,636	\$	229,748	\$	509,439	\$	773,367
Short-Term Investments		930,455		1,321,340		609,414		914,298		911,040
Accounts Receivable		1,639		96,518		104,586		169,244		119,954
		309,098		75,755		522,765		1/1,/82		109,126
Prepaid Annual Meeting Expenses		1,688		77,386		67,461		66,489		60,516
Prepaid Expenses and Other Current Assets	<u> </u>	4,529		61,934		27,900		16,979		24,342
lotal Current Assets		1,688,766		2,243,569		1,561,874		1,848,232		1,998,344
Other Assots										
Rent Receivable under Shared Shace Agreement		305 904		310 171		357 566		364 147		356 748
Board-Designated Reserve Fund		587 691		576 229		566 504		269 608		268 446
Total Other Assets		893 595		895 401		924 070		633 754		625 194
		000,000		000,101		02.,0.0		000,101		020,101
Fixed Assets										
Computer Software and Equipment		308,991		301,242		363,213		594,523		510,315
Office Furniture		114,075		114,075		114,075		114,075		114,075
Leasehold Improvements		723,761		723,761		723,761		723,761		703,909
Accumulated Depreciation		(776,992)		(776,992)		(759,231)		(672,454)		(508,231)
Total Net Fixed Asstes		369,834		362,085		441,818		759,904		820,068
Total Assets	\$	2,952,195	\$	3,501,055	\$	2,927,761	\$	3,241,890	\$	3,443,606
LIABILITES AND NET ASSETS										
<u>Current Liabilities</u>	¢	2 2 2 0	¢	00.000	¢	04 000	¢	00 070	¢	140.047
Accounts Payable	Ф	3,338	Ф	88,082 70,000	Ф	84,320 104 769	ф	82,373	Ф	140,847
Accided Liabilities		69,750		154 740		104,700		103,744		00,095
		16 151		260 603		14 315		8 513		8 513
Total Current Liabilities		89 239		573 715		333.608		354 950		368 557
		00,200		070,710		000,000		004,000		000,007
Long-Term Liabilities										
Deposits - ILSI Entities		246.000		246.000		246.000		246.000		246.000
Deferred Rent		634,716		648,885		758,189		833,414		891,432
Total Long-Term Liabilities		880,716		894,885		1,004,189		1,079,414		1,137,432
-										
Total Liabilities		969,955		1,468,600		1,337,796		1,434,364		1,505,989
Net Assets										
Beginning Balance		2,032,456		1,589,965		1,807,526		1,937,617		1,614,525
Current Year Change		(50,216)		442,491		(217,562)		(130,091)		323,092
Total Net Assets		1,982,240		2,032,456		1,589,965		1,807,526		1,937,617
Total Liabilities and Not Assets	¢	2 052 105	¢	3 501 055	¢	2 027 761	¢	2 241 900	¢	2 4 4 2 6 0 6
Total Liabilities and Net Assets	φ	2,952,195	φ	3,501,055	φ	2,927,701	φ	5,241,690	φ	3,443,000
	¢	530 340	¢	502 230	¢	510 782	¢	656 038	¢	550 847
Board-Designated Reserve Fund	φ	587 601	Ψ	576 220	Ψ	566 504	φ	260 602	φ	268 440
Restricted Programs (PIP GTE Africa Other)		520 461		600 828		363 907		133 252		151 425
International Branches (2012 and earlier included IFBiC)		334 740		263 168		148 771		748 628		957 905
Total Net Assets	\$	1.982.240	\$	2.032.456	\$	1.589.965	\$	1.807.526	\$	1.937.617
	<u> </u>	.,	Ŧ	_,,,,,	τ'	.,	*	.,,	٣	.,,
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1.599.527	\$	1.669.855	\$	1.228.266	\$	1,493,282	\$	1.629.787
Current Ratio <sup>(2)</sup>	Ŧ	18 02	Ŧ	2 01	Ŧ	.,0,00	Ŧ	5 21	Ŧ	5 42
		10.92		3.31		4.00		J.21		J.4Z

<sup>(1)</sup> The 2015 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2015 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

#### Internal Financial Statement

INTERNATIONAL LIFE SCIENCES INSTITUTE		ILSI GC		COMN	IUNICATIONS			ILSI PRESS		SUBTOTAL	ILSI UNRESTRIC	TED (1)
FUNCTIONAL ACTIVITY STATEMENT	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	`% YTD/
For the Three Months Ended March 31, 2015	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
· · · ·												
REVENIJE												
		749.000	0%			NI/A			NI/A		749.000	0.0/
BRANCH/INSTITUTE ASSESSMENT	-	746,000	0%	-		IN/A	-	-	IN/A	-	746,000	0%
CONFERENCE/ REGISTRATION FEES	51,969	30,000	173%	-		N/A	-		N/A	51,969	30,000	173%
CONTRIBUTIONS	30,000		N/A	-		N/A	-		N/A	30,000	-	N/A
FEE FOR SERVICES	-		N/A	-		N/A	-		N/A	-	-	N/A
SHARED SERVICES REIMBURSEMENT	-		N/A	-		N/A	-		N/A			N/A
INVESTMENT AND OTHER INCOME	21,031	26,000	81%	-		N/A	-		N/A	21,031	26,000	81%
PUBLICATIONS - NUTRITION REVIEWS	-		N/A	-		N/A	296,288	402,500	74%	296,288	402,500	74%
TOTAL REVENUE	103,000	804,000	13%	-	-	N/A	296,288	402,500	74%	399,288	1,206,500	33%
EXPENSES												
COMMUNICATIONS	5,861	10,370	57%	5,699	13,875	41%	53	1,910	3%	11,613	26,155	44%
FINANCIAL/PROFESSIONAL FEES	6,830	30,000	23%			N/A			N/A	6,830	30,000	23%
GENERAL & ADMINISTRATIVE												
Shared Services Overhead	29,214	133,700	22%			N/A			N/A	29,214	133,700	22%
Rent	12.841	48.600	26%			N/A			N/A	12.841	48,600	26%
Depreciation		39 071	0%			N/A			N/A	-	39 071	0%
Other	2 090	9 1 1 0	23%	2 573	6 300	41%	539	17 855	3%	5 202	33 265	16%
Indirect Reimbursement	(63,673)	(279 558)	23%	33 644	151 553	22%	24 911	116 957	21%	(5,119)	(11.048)	46%
maneot rembuloement	(00,010)	(210,000)	2070	00,011	101,000	2270	24,011	110,001	21/0	(0,110)	(11,040)	4070
STAFFING												
Salarias	40.560	182 400	22%	30 641	135 800	23%	22 697	104 800	220/	03 888	423.000	22%
Denefite	40,000	102,400	22 /0	6 744	133,000	2370	22,007	104,000	22 /0	33,000	423,000	22 /0
Denenits Outeide Centiese	20,939	43,770	40%	0,741	32,392	2 1 70 N/A	4,991	20,102	20%	32,071	101,520	JZ 70
Outside Services	2,914	2,725	107%			N/A			N/A	2,914	2,725	107%
			N1/A	40.000	40.000	050/		0.000	00/	40.000	45 000	0.40/
CONSULTANTS			N/A	10,609	42,000	25%		3,000	0%	10,609	45,000	24%
				15.000	~~~~~	500/				15 000	~~~~~	500/
II SUPPORT SERVICES			N/A	15,000	30,000	50%			N/A	15,000	30,000	50%
PUBLICATIONS	682	5,000	14%	16,665	15,000	111%	18,652	41,600	45%	35,999	61,600	58%
MEETINGS												
Travel - Board	26,903	63,000	43%			N/A			N/A	26,903	63,000	43%
Travel - Staff	2,501	5,000	50%	3,705	10,000	37%	1,557	8,840	18%	7,763	23,840	33%
Travel - Advisors/Speakers/Invitees	9,552	6,000	159%			N/A	1,689	4,000	42%	11,241	10,000	112%
Group Functions/Business Meals	62,520	74,535	84%		1,000	0%	-	1,400	0%	62,520	76,935	81%
Other Expenses (Audiovisual/Mgmt Fee)	50,114	40,500	124%	506	3,000	17%			N/A	50,619	43,500	116%
SUBTOTAL MEETINGS	151,590	189,035	80%	4,211	14,000	30%	3,246	14,240	23%	159,046	217,275	73%
OTHER PROGRAM EXPENSES												
Grants, Contributions, Research	30.000		N/A			N/A			N/A	30.000	-	N/A
Intracompany Transfers - (Revenue)/Expense	,		N/A			N/A			N/A			N/A
TOTAL EXPENSES	239 848	414 229	58%	125 781	441 120	29%	75.079	325 514	23%	395 630	855 349	46%
	200,040		0070	120,701		2070		020,014	2070			
	(100.040)	200 774		(105 704)	(444 400)		001.000	76.000		(44,404)		
CHANGE IN NET ASSETS	(136,848)	389,771		(125,781)	(441,120)		221,209	76,986		(41,421)	25,638	
NET ASSETS, BEGINNING OF PERIOD	2,181,508	2,181,508		(2,207,360)	(2,207,360)		1,194,312	1,194,312		1,168,460	1,168,460	
	2 044 660	2 571 200		(2 222 144)	(2 640 400)		1 415 500	1 071 000		1 107 000	1 104 007	
INE I ASSETS, END OF PERIOD	2,044,660	2,571,280		(2,333,141)	(2,048,480)		1,415,520	1,271,298		1,127,039	1,194,097	

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC. Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	REST	RICTED PROGRA	MS	INT'L	BRANCH ACTIVI	ТҮ	SH	ARED SERVICES			TOTAL	
FUNCTIONAL ACTIVITY STATEMENT	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/	2015	2015	% YTD/
For the Three Months Ended March 31, 2015	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENUE												
BRANCH/INSTITUTE ASSESSMENT	_		N/A	-		N/A	_		N/A	-	748 000	0%
CONFERENCE/ REGISTRATION FEES			N/A	-		N/A	_		N/A	51 969	30,000	173%
CONTRIBUTIONS	80,000	222 000	36%	-		N/A	-		N/A	110,000	222 000	50%
EEE FOR SERVICES		222,000	N/A	-		N/A	_		N/A		-	N/A
SHARED SERVICES REIMBURSEMENT			N/A	-		N/A	322 990	1 513 350	21%	322 990	1 513 350	21%
			N/A	-		N/A	022,000	1,010,000	N/A	21 031	26,000	81%
PUBLICATIONS - NUTRITION REVIEWS			N/A	-		N/A	_		N/A	296 288	402 500	74%
TOTAL REVENUE	80,000	222,000	36%	-	-	N/A	322,990	1,513,350	21%	802,278	2,941,850	27%
EXPENSES		1 005			4 000	00/	0.040	50.000	100/	10.010	70.400	000/
COMMUNICATIONS	17	1,005	2%	-	1,360	0%	6,612	50,600	13%	18,243	79,120	23%
FINANCIAL/PROFESSIONAL FEES			N/A			N/A	9,332	50,050	19%	16,162	80,050	20%
GENERAL & ADMINISTRATIVE												
Shared Services Overhead			N/A			N/A			N/A	29,214	133,700	22%
Rent			N/A			N/A	39,800	150,500	26%	52,641	199,100	26%
Depreciation			N/A			N/A		20,000	0%	-	59,071	0%
Other	327	500	65%			N/A	17,579	150,700	12%	23,108	184,465	13%
Indirect Reimbursement	3,794	5,803	65%	1,325	5,245	25%			N/A	-	-	N/A
STAFFING												
Salaries	3 455	5 200	66%	1 206	4 700	26%	100 032	868 000	23%	208 481	1 300 000	23%
Benefits	760	1 248	61%	1,200	1 1 2 8	20%	43 085	200,000	20%	77 682	303 806	26%
Outside Services	700	1,240	N/A	205	1,120	24 /0 N/A	43,903	200,000	22 /0 N/A	2 014	2 725	107%
Outside Services			11/1			19/75			19/4	2,514	2,725	107 /6
CONSULTANTS		41,750	0%	9,078	40,932	22%			N/A	19,687	127,682	15%
IT SUPPORT SERVICES			N/A			N/A	919	6.400	14%	15.919	36,400	44%
PUBLICATIONS			N/A			N/A			N/A	35,999	61,600	58%
MEETINGS												
Travel - Board			N/A			N/A			N/A	26 903	63 000	43%
Travel - Staff		5 000	0%	4 448	7 800	57%	4 541	10 000	45%	16 751	46 640	36%
Travel - Advisors/Speakers/Invitees	20 736	142 665	15%	1 268	7,000	N/A	4,041	10,000	N/A	33 245	152 665	22%
Group Functions/Business Meals	3 362	3 055	110%	6 902	6 000	115%	290	7 100	4%	73 074	93,090	78%
Other Expenses (Audiovisual/Mamt Fee)	2 475	3 400	73%	3 936	3 040	129%	200	7,100	N/A	57 030	49 940	114%
SUBTOTAL MEETINGS	26,573	154,120	17%	16,553	16,840	98%	4,831	17,100	28%	207,004	405,335	51%
OTHER PROGRAM EXPENSES												
Grants, Contributions, Research	25,441	15.000	170%		15.520	0%			N/A	55.441	30.520	182%
Intracompany Transfers - (Revenue)/Expense	100,000	100,000	100%	(100,000)	(100,000)	100%			N/A	-		N/A
TOTAL EXPENSES	160,368	324,626	49%	(71,572)	(14,275)	501%	322,989	1,513,350	21%	852,494	3,004,564	28%
CHANCE IN NET ASSETS	(90.200)	(102.626)		71 570	14.075					(50.246)	(62 74 4)	
	(00,368)	(102,026)		/1,5/2	14,275		0	-		(50,216)	(02,714)	
NET ASSETS, BEGINNING OF PERIOD	600,828	600,828		263,168	263,168		-	-		2,032,456	2,032,456	
NET ASSETS, END OF PERIOD	520,461	498,202		334,740	277,443		0	-		1,982,240	1,969,742	
	=======			======			=============			======		

# ILSI Board of Trustees Financial Oversight Committee

# **Conference Call**

# Tuesday, April 28, 2015 9:00 – 10:00 am Eastern Daylight Time

# PROPOSED AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the October 27, 2014 Conference Call
- III. Review of 2015 Year-to-date Financial Statement
- IV. Pursuing an ILSI Annual Meeting Held outside of the United States Financial Implications
- V. New Business
- VI. Next Steps
- VII. Adjournment

### ILSI Board of Trustees Financial Oversight Committee

# Conference Call Monday, October 27, 2014

### **DRAFT MINUTES**

### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair, ILSI Financial Oversight Committee, began the conference call at 9:02 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated in the conference call: Dr. Todd Abraham, Dr. Sushila Chang, Dr. Joanne Lupton, Ms. Beth-Ellen Berry, Dr. Suzie Harris, and Mr. Shawn Sullivan. Dr. Lewis Smith was not available for the call, but sent his comments on the various agenda items to the full committee prior to the conference call.

Mr. Mark Murphy, Raffa Wealth Management, joined the call for the discussion of Agenda Item IV. The agenda is attached.

### II. Approval of Minutes from the July 28, 2014 Conference Call

The minutes were approved as distributed.

### III. Review of 2014 Year-end Projections and 2015 Budget

Ms. Berry reviewed the two-page document containing the 2014 year-end projections and 2015 budget which was distributed to the committee prior to the conference call (attached). The 2014 year-to-date balance sheet and functional activity statement was also distributed, but not discussed.

For the unrestricted functions, Ms. Berry noted that the main sources of revenue are branch assessments (ILSI Governance and Coordination) and ILSI Press royalty. Focusing on the Subtotal for the Unrestricted functions, Ms. Berry noted that a \$19,000 loss in net assets is projected for year-end compared to the \$35,000 loss budgeted for 2014. Two major changes account for the better than expected performance. First, ILSI received \$100,000 as a bonus from Oxford University Press upon signing a new publishing agreement with them for *Nutrition Reviews*. The unrestricted ILSI functions also had \$80,000 in unbudgeted expenses (two One ILSI grants of \$40,000 each – one to ILSI HESI and the other to ILSI Southeast Asia Region). The remaining components of the unrestricted ILSI functions budget were on target.

The proposed 2015 budget includes a small increase in branch assessments due to new branches beginning to pay the branch assessments. There is no fee for service revenue in the 2015 ILSI GC budget because Dr. Harris will not be the ILSI Research Foundation Executive Director in 2015. ILSI Research Foundation has been reimbursing ILSI for a portion (40 percent) of her salary. In terms of expenses, Dr. Harris will continue to serve as the part-time ILSI Executive Director. The salary line for ILSI GC includes her salary at 60 percent time. No other big changes are included in the ILSI GC budget, other than no credit for annual meeting expenses is expected.

The communications 2015 budget includes funding for consultants to help re-fresh the ILSI website. For ILSI Press, the revenue is the guaranteed minimum in the new agreement with Oxford University Press, though this minimum is not finalized yet. They will provide a larger editorial stipend (\$100,000 vs \$80,000 in the past agreement with Wiley). Expense for copyediting are expected to decline in 2015 as Oxford University Press will take on some of this responsibility. The Press budget is expected to generate \$76,000 in profit. It is possible that this figure will decline once Oxford University Press fully understands the revenue stream likely to be generated by *Nutrition Reviews*.

In response to a question from Dr. Abraham about the risk and opportunity with the ILSI Press budget, Dr. Harris said that the signing bonus would be re-invested in the journal over a period of several years, through subscriptions for new citation tracking tools, support for face-to-face editorial board meetings, support for editor-in-chief search, and professional development for Ms. Allison Worden, ILSI Publications Manager.

In terms of the restricted functions, Ms. Berry noted that the revenue and expenses for these accounts varies more as unexpected contributions are received and expended. The Restricted Programs include the ILSI Platform for International Partnerships and the contributions from The Coca-Cola Company. The latter have been distributed as requested by the donor to specific activities, e.g., Malaspina International Scholars Travel Award, and food safety training in Asia and in Africa. The Branch Staff Travel grant fund is also included in the Restricted Programs. The International Brach Activity includes funding held for the ILSI Focal Point in China (operating funds as well as training funds) and Latin American branches coordination. A new, part-time Latin American branches coordinator position has been established with funding from The Coca-Cola Company. The third restricted function – Shared Services – covers expenses shared by the four corporations that share the Washington office. This function will end 2014 on budget and the 2015 budget includes a one percent increase.

Ms. Berry said that there would likely be minor modifications to both the 2014 year-end projections and the 2015 budget before the 2015 ILSI Board of Trustees meeting. Dr. Lewis email his support for the proposed budget prior to the conference call.

**Action:** Dr. Lupton moved that the 2015 budget be forwarded to the ILSI Board of Trustees for approval during the January 17, 2015 meeting. Dr. Abraham seconded the motion and it carried unanimously.

# IV. Discussion of Revised Investment Policy

Mr. Mark Murphy, Raffa Wealth Management, first reviewed the performance of the Board-designated Reserve Fund over the past quarter. This report along with a quarterly report for the Operating Reserve was distributed to the committee prior to the conference call. He noted that the market had a solid performance for 2014 until mid-September, when equities declined. That trend has reversed and the market has done well over the past few weeks. Page 3 of the report shows that the fixed income portfolio for the ILSI Board-designated Reserve Fund is allocated in line with the investment policy targets. Page 4 shows that the return has been flat for the last month, but has increased by 1.4 percent since the beginning of the year. Mr. Murphy described this as a solid performance for the portfolio. The latter pages of the report show the performance of the various asset classes along with the benchmarks.

At the committee's request, Raffa Wealth Management sent a risk survey out to the committee members and senior staff (Ms. Berry and Dr. Harris). Based on the survey results, Mr. Murphy had recommended to the committee in July that they approve a change in the investment policy to allow a

less conservative portfolio – 40 percent equities and 60 percent bonds. At the committee's request he shared a red-line version of the investment policy for the ILSI Board-designated Reserve Fund that would implement the shift to a less conservative portfolio. While still conservative the new allocation would be liquid but with growth potential. The investment policy goals were revised to state that cash flow is not the primary function and the time horizon is longer term – 5 years – as opposed to 1 year in the current policy.

The asset class allocation recommended includes all areas of equities, domestic and international with the latter having both developed and developing country equities. Benchmarks for the new asset classes were added to the policy as well. Rebalancing is triggered when there is a 20 percent variance to the policy target. This is the same trigger as the current policy and is designed to reduce unnecessary trades. The allocation is evaluated on a quarterly basis.

A performance history for such a portfolio was provided to the committee prior to the conference call. Mr. Murphy pointed out that the model portfolio would have lost 12.5 percent of its value in 2008, but would have been more stable over the past 14 years than the S&P 500 index. While no one can predict future earnings, the past earnings for such a portfolio ranged between 5 and 9 percent, compared to the fixed income portfolio earnings of 1.5-2.00 percent. Mr. Murphy said that a fixed income portfolio could earn as much as 3 percent, but it can also have negative earnings.

In response to a question, Ms. Berry said that she has not had to withdraw funds for operating expenses from the Board-designated Reserve Fund, though the fund has not been in existence for much more than one year.

Action: The committee members present were all in favor of accepting the new investment policy (attached). They asked that Dr. Harris inform the ILSI Board of Trustees Executive Committee of the Financial Oversight Committee's intention to implement the new policy and to ask if there are any objections.

Mr. Murphy commented that support for the new policy was a smart decision.

# V. New Business

None was offered.

# VI. Next Steps

- Dr. Harris will send a message to the ILSI Executive Committee providing details about the proposed investment policy change and ask if there are objections. DONE, no objections received.
- 2015 proposed budget will be distributed to the ILSI Board of Trustees for approval in January 2015.

# VII. Adjournment

As there was no further business, Dr. Westring ended the conference call at approximately 10:00 a.m. Eastern Daylight Time.

Signed:\_\_\_\_\_ Date:\_\_\_\_\_

# ILSI Board of Trustees Financial Oversight Committee

# **Conference Call**

# Monday, October 27, 2014 9:00 – 10:00 am Eastern Daylight Time

# AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the July 28, 2014 Conference Call
- III. Review of 2014 Year-end Projections and 2015 Budget
- IV. Discussion of Revised Investment Policy Raffa Wealth Management
- V. New Business
- VI. Next Steps
- VII. Adjournment

From: Sent: To: Subject: Delia Murphy Monday, April 20, 2015 3:09 PM Joanne Lupton FW: The Beacon Hotel: Your Reservation Confirmation

Hello Joanne,

Below is your hotel reservation for the Conflict of Interest & Scientific Integrity Working Group meeting next week.

Best, Delia

From: Beacon Hotel & Corporate Quarters [mailto:VIP@crm.SafeCRM.com]
Sent: Monday, April 20, 2015 3:55 PM
To: Delia Murphy
Subject: The Beacon Hotel: Your Reservation Confirmation

View in Browser





# **RESERVATION CONFIRMATION**

Dear Joanne Lupton,

Thank you for choosing the **Beacon Hotel & Corporate Quarters** for your upcoming visit to Washington DC. We are pleased to confirm your reservation and look forward to your arrival. If there are any special needs you may have, feel free to contact us prior to your arrival. You may do so by calling our reservations department toll free at 1-800-821-4367 or direct 1-202-296-2100.

	RES	ERVA	TION	DETAIL	5
--	-----	------	------	--------	---

Confirmation Number	57427976-1
Guest Name	Joanne Lupton
Arrival Date	Wednesday April 29, 2015
Departure Date	Friday May 1, 2015

 Nightly Rate
 \$243.00 April 29- 30

The above rate(s) may not reflect all possible fees, additional charges or taxes associated with this reservation. For clarification regarding these charges, please contact our reservations department.

	POLICIES
Deposit Policy	A valid and fully funded credit or debit card is required to guarantee all reservations. For third party payment arrangements with a credit card, please contact the hotel's reservations department
Cancellation Policy	Reservation must be cancelled 24 hours prior to the day of arrival to avoid a penalty of one night's stay plus applicable tax.

Check-In Time	3:00 PM
Check-Out Time	12:00 Noon
Room Tax	14.5% City Occupancy Tax
Daily Parking Fee	<ul> <li>Secure underground valet parking for \$39/night plus 18% city tax</li> <li>Parking includes in/out service.</li> <li>Garage height restriction is 6 feet maximum. (Restrictions may apply for some SUVs.)</li> </ul>

WE ARE A 100% SMOKE-FREE PROPERTY (rooms and public areas).

	CONTACT INFORMATION
Main Number	1-202-296-2100
Reservations Number	1-800-821-4367
Reservations Fax	1-202-331-0227
Hotel Website	www.beaconhotelwdc.com

It will be our pleasure to welcome you. Should you wish additional information on our hotel and/or facilities, feel free to visit our website <u>www.beaconhotelwdc.com</u>. Have a safe and enjoyable journey.

Hector Torres General Manager

1615 Rhode Island Avenue, NW - Washington, DC 20036 | 800.821.4367 | Reservations 202.296.2100

Hotel Marketing Provided By Digital Alchemy From: Sent: To: Cc: Subject:

Joanne Lupton Monday, April 20, 2015 2:00 PM Delia Murphy Katie Stuart RE: ILSI North America Conflict of Interest and Scientific Integrity Working Group Meeting 30 April

Delia, I have scheduled the flights, and I will come in the night before the meeting and leave the day after the meeting. Thus I need hotel accommodations for Wed April 29 and Thurs April 30. If you could send me the confirmation number and the name and address of the hotel that would be great. Joanne

From: Delia Murphy
Sent: Tuesday, April 14, 2015 12:41 PM
To: Joanne Lupton
Cc: Katie Stuart (kstuart1978@msn.com)
Subject: RE: ILSI North America Conflict of Interest and Scientific Integrity Working Group Meeting 30 April

Hello Joanne,

Not too worry! The meeting will begin at 8:30 am EDT on Thursday, 30 April so I would recommend you come in the evening before. We plan to wrap up the meeting at 5:00 pm EDT so you may need to stay the night as well. ILSI North America will cover both nights if you choose to stay.

Thanks, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org

Follow ILSI North America:

From: Joanne Lupton [mailto:Joanne.Lupton@agnet.tamu.edu]
Sent: Tuesday, April 14, 2015 12:18 PM
To: Delia Murphy
Cc: Katie Stuart
Subject: RE: ILSI North America Conflict of Interest and Scientific Integrity Working Group Meeting 30 April

Delia:

So sorry about this. Being retired is taking up too much time. Could you tell me when the meeting starts and ends so that I know if I can get out the same day or need to spend the night of the 30th? Thanks, Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow

From: Delia Murphy
Sent: Monday, April 06, 2015 12:01 PM
To: Joanne Lupton
Subject: ILSI North America Conflict of Interest and Scientific Integrity Working Group Meeting 30 April

Hello Joanne,

I wanted to get in touch with you regarding your travel to the upcoming 30 April in-person meeting of the ILSI North America Conflict of Interest and Scientific Integrity Working Group. I know that you are planning to attend the meeting in-person, and as a scientific advisor to the Working Group, ILSI North America will cover your travel to the meeting.

Please contact ILSI North America's travel agent Michael Kerr at to book your flight to Washington, DC. Once you have booked your flight, I will make your hotel reservation for you. ILSI North America will cover up to two nights hotel accommodation.

As the meeting is coming up in just a few short weeks, I encourage you to plan your travel as soon as possible if you have not already done so. If you have already booked your travel, ILSI North America will reimburse your for your costs. Please let me know if you have any questions.

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America: From: Sent: To: Cc: Subject: Joanne Lupton Tuesday, April 14, 2015 11:18 AM Delia Murphy Katie Stuart RE: ILSI North America Conflict of Interest and Scientific Integrity Working Group Meeting 30 April

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Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America: From: Sent: To: Cc: Subject: Beth Brueggemeyer Tuesday, April 14, 2015 10:12 AM Donald Clark; Katie Stuart Joanne Lupton RE: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

Hi Katie,

Thanks - the reimbursement form and receipts have arrived in good order.

All the best to you. Beth

-----Original Message-----From: Donald Clark [mailto: Sent: Tuesday, April 14, 2015 10:33 AM To: Beth Brueggemeyer Subject: Dr. Joanne Lupton's Reimbursement 2015 ILSI Annual Meeting

Hello Ms. Brueggemeyer!

Ok, I believe we have the files set up where you can view them now.

Thank you, and please feel free to contact me with any questions.

Katie Stuart
From: Sent: To: Cc: Subject: Beth Brueggemeyer Thursday, April 09, 2015 12:04 PM Katie Stuart Joanne Lupton LUPTON RE: Reimbursement for ILSI 2015 Annual Mtg

Hi Katie,

Thanks for sending the reimbursement paperwork but....

I am not able to open any of the files that you sent. Our IT manager says if you log on to MSN.com and send them from there, I may be able to open them. Or send them from gmail.

OR, if you want to put them I the mail to me - that will also work.

Thanks for your help with this!

Beth

-----Original Message-----From: Katie Stuart [ Sent: Tuesday, April 7, 2015 4:31 PM To: Beth Brueggemeyer Cc: jlupton@tamu.edu Subject: Reimbursement for ILSI 2015 Annual Mtg

Hello Ms. Brueggemeyer,

Please see the enclosed attachment for Dr. Joanne Lupton's reimbursement.

Pleas feel free to contact me with any questions.

Thank you,

Katie Stuart

From:	Beth Brueggemeyer
Sent:	Wednesday, April 01, 2015 4:32 PM
То:	Joanne Lupton
Subject:	Re: LUPTON ILSI Annual Meeting expenses

Trust me!! You are not even close to being a pain in the neck! LOL

Beth

Sent from my iPhone

On Apr 1, 2015, at 5:28 PM, "Joanne Lupton" <<u>Joanne.Lupton@agnet.tamu.edu</u>> wrote:

Thanks so much Beth, sorry for being such a pain in the neck, Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition

From: Beth Brueggemeyer Sent: Wednesday, April 01, 2015 4:26 PM To: Joanne Lupton Subject: Re: LUPTON -- ILSI Annual Meeting expenses

Hi Joanne

You were on the ILSI master list for room and tax charges at the hotel.

ILSI does not pay for incidentals. Food charged to your room can be submitted for reimbursement.

Am happy to answer any questions you may have

Regards Beth

Sent from my iPhone

On Apr 1, 2015, at 5:16 PM, "Joanne Lupton" <<u>Joanne.Lupton@agnet.tamu.edu</u>> wrote:

Beth:

Thank you for sending me this reminder. As you may know I retired last October, Chelsea took another position prior to that time and this is something which fell through the cracks. I will go back and look right now as to what the expenses were. Can you tell me if ILSI picked up my hotel bill, or was that part of the reimbursement. I'll look back and see what I can find and it will get it you within a few days. Again, thanks for letting me know. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow

From: Beth Brueggemeyer Sent: Wednesday, April 01, 2015 3:05 PM To: Joanne Lupton; Chelsea L. Bishop Subject: LUPTON -- ILSI Annual Meeting expenses Importance: High

Dear Joanne and Chelsea,

We are preparing to finalize and complete the 2015 ILSI Annual Meeting expenses in the near future.

I do not see that we have received a reimbursement form for any expenses you incurred related to the Annual Mtg.

For your convenience, I have attached the ILSI BOT Reimbursement Guidelines and a Reimbursement Form. If you would complete the reimbursement form and return with the necessary receipts, we shall process reimbursement as quickly as possible.

If you have already submitted the form, it was not received; could you please resubmit?

Sending you wishes for a Happy Easter,

Beth

### Beth Brueggemeyer

 International Life Sciences Institute ■ 1156 15<sup>th</sup> Street, NW, Suite 200 ■ Washington,

 DC 20005-1734 ■

 E:
 ■ T: 202 659 0074 X148 ■ F: 202 659 3859 ■ Follow

ILSI on: <image001.png> <image002.png>

From: Sent: To: Subject: Joanne Lupton Wednesday, April 01, 2015 4:28 PM Beth Brueggemeyer RE: LUPTON -- ILSI Annual Meeting expenses

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From:	Beth Brueggemeyer			
Sent:	Wednesday, April 01, 2015 3:05 PM			
То:	Joanne Lupton; Chelsea L. Bishop			
Subject:	LUPTON ILSI Annual Meeting expenses			
Attachments:	Tab 00-b 2015 Reimbursement Expense Form.doc; Tab 00-b	2015 ILSI		
	Reimbursement Guidelines.doc			

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International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

#### Reimbursement Guidelines for ILSI Board of Trustees and Invitees

2015 ILSI Annual Meeting 18-21 January 2015 Sheraton Wild Horse Pass Resort Chandler, Phoenix (Phoenix metropolitan area)

The International Life Sciences Institute ("ILSI") is a public, non-profit organization as described in Section 501(c)(3) of the U.S. Internal Revenue Code. It is, therefore, necessary that we keep a careful record of expenditures in compliance with IRS regulations. ILSI is prepared to reimburse you for costs associated with your travel to Phoenix, Arizona. Information about ILSI reimbursement policies is shown below:

**Travel:** ILSI will reimburse you for the cost of round-trip economy/coach airfare between your home and Phoenix, AZ, along with associated ground transportation costs to and from your local airport and to and from the Phoenix Airport and the meeting venue (Sheraton Wild Horse Pass Resort, 5594 W. Wild Pass Blvd., Chandler, AZ 85226). We will also reimburse the cost of checking one piece of luggage. If you combine this trip with other business or personal travel, ILSI will reimburse you for the portion related to the ILSI 2015 Annual Meeting.

If you wish to book your airline ticket through ILSI's travel agency, Corporate Traveler (and have the cost directbilled to ILSI), please contact Michael Kerr at 703-236-1220 or michael.kerr@corporatetraveler.us and identify yourself as someone for whom ILSI is covering travel costs for the 2015 Annual Meeting.

**Ground transportation:** The easiest and most cost effective way to get to the hotel is via taxi – once you have secured your bags, just head to the taxicab stand at the airport. A one way fare to the hotel will cost around \$45 USD plus tip. For your airport return, it is best to make a reservation with a taxi company at least 24 or 48 hours prior to your departure date, as taxis are not readily available and waiting at the resort. You may also ask the hotel concierge desk for assistance prior to your departure.

**Lodging and Meals:** ILSI will request that costs associated with up to 6 nights hotel lodging be placed on the ILSI master account at the Sheraton Wild Horse Pass Resort and we will reimburse you for the cost of any meals not provided during the meeting. There will be planned receptions/buffet dinners on the evenings of January 18 and January 20 for all attendees. Continental breakfast will be served at the scientific sessions each morning.

<u>Visa</u>: If your travel to the USA requires a visa, ILSI will reimburse you the cost of the visa application fee. A receipt for the visa application fee should be submitted with your Expense Reimbursement Form.

**Incidental Expenses:** You are responsible for any charges of a personal nature and these should not be claimed for reimbursement (i.e., telephone, laundry, movies, bar, gift shop, tours, minibar, etc).

**Spouse Travel**: ILSI cannot cover the cost of a spouse or guest accompanying you to the meeting; however, there is no additional charge for a second person sharing your sleeping room.

**Reimbursement Procedures:** Please use the expense reimbursement form to itemize your expenses and email them to Ms. Beth Brueggemeyer at <u>bbrueggemeyer@ilsi.org</u>, or by regular mail to the ILSI offices, 1156 Fifteenth Street, NW, Suite 200, Washington, DC, 20005. If **you** purchased your airline tickets, copies of the receipt and boarding passes will be required for reimbursement, along with receipts for any other expense items over \$25 USD. Fax and electronic copies can be used for reimbursement purposes.



International Life Sciences Institute 
 1156 Fifteenth Street, NW
 1.202.659.0074 voice

 Suite 200
 1.202.659.3859 fax

 Washington, DC 20005
 www.ilsi.org

# International Life Sciences Institute Expense Reimbursement Form

Name:					Travel Date(s):			
Purpose of travel:						Travel location(s):		
Itemized expenses								
Date	Breakfast	Lunch	Dinner	Lodging	Travel	Other	Daily Total	Description of other expenses and currency
TOTAL CLAIM								

Date submitted:	Signature of claimant:
Date approved:	Signture of ILSI RF authorising party:

PLEASE ATTACH RECEIPTS FOR ALL ITEMS OF \$25USD OR MORE (or equivalent)

(Mileage is reimbursed at the rate of 56¢ per mile – or prevailing US gov't rate in effect in January 2015)

#### COMPLETE AND APPEND TO YOUR REIMBURSEMENT FORM:

Please indicate if the reimbursement is to be provided by: \_\_\_\_Cheque \_\_\_\_Bank Draft

# Please note that some banks charge processing fees to receive bank drafts. These fees are the responsibility of the payee and will not be reimbursed by ILSI.

For reimbursement by CHEQUE, please provide the following:
Name:
Street Address:
City:
Province/State:
Country:
Postal/zip code:
Telephone number:
For reimbursement by WIRE TRANSFER, please provide the following:         Bank Name:
Account Number:
Account Holder's Name:
ABA Routing Number (US Accounts):
Sort/Swift Code (non-US Accounts):
IBAN Number (non-US Accounts):
Bank Identifier Code (non-US Accounts):
Preferred currency:

From: Sent: To:	Su Th ac	uzanne Harris < > nursday, March 19, 2015 3:59 PM ; s.chang@griffith.edu.au; scohen@unmc.edu; ; mdoyle@uga.edu; damdrew@u.washington.edu; marion@vt.edu;
		Joanne Lupton; ; john.c.peters@ucdenver.edu; ;
Cc: Subject:	kv Bu Be Da	vallace@d.umn.edu; weavercm@purdue.edu; ; Flavio Zambrone Maureen Clarke; carmel.james@griffith.edu.au; jbradford@unmc.edu; Usui-Etsuko(?? ??); Chelsea L. Bishop; ; urnand,Valerie, ; haan@purdue.edu; eth Brueggemeyer; Beth-Ellen Berry; Michael Shirreffs; Shawn Sullivan ate for the mid-year ILSI Board of Trustees conference call Thursday, July 9, 2015
TO:	ILSI Board of Truste	ees
FROM:	Suzie Harris	
Thank you to th that I sent in lat <b>Daylight Time.</b>	ose of you who respo e February. Based or The call will not run l	onded to the poll for a date for the mid-year ILSI Board of Trustees conference call n your responses the best day is <b>Thursday, July 9, beginning at 9:00 a.m. Eastern</b> onger than two hours. Please mark your calendars with this important date.

I will send an agenda, briefing documents and dial-in instructions to you about two weeks prior to the conference call.

Let me know if you have any questions now or as the time for the call approaches.

From: Sent: To: Subject:	om:Suzanne Harrisnt:Tuesday, March 03, 2015 8:25 AMo:Joanne Luptonbject:RE: Polling for date for the mid-year ILSI Board of Trustees conference call						
Thank you, Joanne. Suzie							
From: Joanne Lupton [mailt Sent: Monday, March 02, 20 To: Suzanne Harris Subject: RE: Polling for date Suzie: I can make any of those time	o:Joanne.Lupton@agnet.tamu.edu] 015 11:49 AM e for the mid-year ILSI Board of Trustees conferences es. Joanne	ce call					
From: Suzanne Harris Sent: Wednesday, February To: 's.chang@griffith.edu.au'; 'sc 'mdoyle@uga.edu'; adamdre	25, 2015 9:43 AM ohen@unmc.edu'; w@u.washington.edu; 'marion@vt.edu';	; Catherine Field					
'john.c.peters@ucdenver.edu '; 'weavercm@purdue.edu'; Cc: ; 'jbradford@unmc.edu'; Usui-Etsuko(笛吹 悦子) Subject: Polling for date for	Joanne Lupton; ' '; ' carmel.ja '; ); Chelsea L. Bishop; ; Burnand,Valerie,VEVEY,CT-RSA '; Flavio Zambrone; Beth Brueggemeyer the mid-year ILSI Board of Trustees conference ca	g'; /allace@d.umn.edu'; mes@griffith.edu.au'; ; ; ); 'haan@purdue.edu'; all					
TO: ILSI Board of	of Trustees						
FROM: Suzie Harris							

Greetings to each of you. 2015 is off and running. I hope you are keeping up with all the various ILSI activities through the ILSI website and ILSI News.

It is time to set the date for the Board's mid-year conference call – a two-hour call that will begin at 9:00 a.m. Eastern Daylight Time. Please use the attached calendar to indicate the days in July when you are available to participate. The days marked with "X" are days when there are conflicts for that time slot. The call will not be held on these days.

Once you have marked your availability on the calendar, please return it to me. I will then send out another email confirming the date.

Please let me know if you have any questions.

From: Sent: To:	Suzanne Harris Wednesday, February 25,	2015 9:43 AM	
10.	adamdrew@u.washingtor	's.chang@griffith.edu.au'; 'so .edu; 'marion@vt.edu';	cohen@unmc.edu'; '; 'mdoyle@uga.edu'; e'; Catherine
	Field	;	·, · · · ·
		'john.c.peters@ud	; Joanne Lupton; cdenver.edu';
	'kwallace@d.umn.edu'; 'w	eavercm@purdue.edu'; '	;
Cc:	'carmel.james@griffith.edu	u.au'; 'jbradford@unmc.edu';	
		; Usui-Etsuko(?? ??)	
	Chelsea L. Bishop; '	1. /	
	Burnand, Valerie, VEVEY, CT	-RSA	'haan@purdue.edu';
		; Flavio Zambrone;	Beth Brueggemeyer
Subject: Attachments:	ILSI BOT mid-yr poll .doc	d-year ILSI Board of Trustees	s conference call

TO: ILSI Board of Trustees

FROM: Suzie Harris

Greetings to each of you. 2015 is off and running. I hope you are keeping up with all the various ILSI activities through the ILSI website and ILSI News.

It is time to set the date for the Board's mid-year conference call – a two-hour call that will begin at 9:00 a.m. Eastern Daylight Time. Please use the attached calendar to indicate the days in July when you are available to participate. The days marked with "X" are days when there are conflicts for that time slot. The call will not be held on these days.

Once you have marked your availability on the calendar, please return it to me. I will then send out another email confirming the date.

Please let me know if you have any questions.

Name:\_\_\_



27	28	29	30	31

From: Sent: To:		Suzanne Harris Tuesday, February 24,	2015 9:51 AM		
Cc:			; Joanne Lupton;	m' ; carmel.james@griffity.edu.au; Berry: Shawn Sulliyan: Beth	
Subject:		Brueggemeyer Dates for the 2015 ILS	I Financial Oversight Committe	e conference calls	
то:	ILSI Board of Tru	stees Financial Oversig	ht Committee		
FROM:	Suzie Harris				
Thank you to the responses I rece	ose who responde vived, here are the	ed to my polls for dates best dates:	for the ILSI Financial Oversigh	t Committee calls. Based on the	
Tuesday, April 2	8				
Tuesday, July 28	3				
Tuesday, Octobe	er 20				
The calls will be	gin at 9:00 a.m. Ea	astern Daylight Savings	Time. Please mark these date	s and time in your calendars.	
I will send you a	will send you an agenda with briefing documents about one week prior to each call, along with dial-in instructions.				

Please let me know if you have any questions.

From: Sent: To:		Suzanne Harris Thursday, February 19, 2015 1:59 PM '; Joanne Lupton;			
Cc:'; Chelsea L. BishopSubject:FW: Polling for 2015 ILSI Financial Oversight Committee conference call datesAttachments:2015-FOC poll - calendar 20150203.doc					
I am pestering	you to respond to t	he request below.			
Thank you for	your help.				
Suzie					
From: Suzann Sent: Wednes To: 'jlupton@tamu Cc: Subject: Pollin	ie Harris day, February 04, 2 edu'; ng for 2015 ILSI Fin	015 8:59 AM 's.chang@griffith.edu.au'; ' 'clbishop@tamu.edu' ancial Oversight Committee conference call dates			
то:	ILSI Board of Tru	stees Financial Oversight Committee			
FROM:	Suzie Harris				

It was good to have each of you with us for the 2015 ILSI Annual Meeting in Arizona. I hope you had a safe and easy trip home.

I have attached calendars for the last two weeks in April, July, and October, for you to use in indicating which days you are available for a one hour conference call beginning at 9:00 a.m. Washington time. Please mark these calendars and return them to me by Tuesday, February 17.

If you are no longer interested in serving on the ILSI Financial Oversight Committee – which I hope is not the case -- please let me know this as well.

# ILSI FINANCIAL OVERSIGHT COMMITTEE 2015 Conference Call Poll

April - May 2015						
Monday	Tuesday	Wednesday	Thursday	Friday		
20	21	22	23	24		
27	28	29	30	May 1		

July 2015				
Monday	Tuesday	Tuesday Wednesday Thursday Frid		Friday
20	21	22 X	23	24
27	28	29	30	31

October 2015				
Monday	Tuesday	Tuesday Wednesday Thursday Friday		
19	20	21	22	23
26	27	28	29	30

# ILSI FINANCIAL OVERSIGHT COMMITTEE 2015 Conference Call Poll

From: Sent:	Suzanne Harris Wednesday, February 04, 2015 7:56 AM
To:	; 's.chang@griffith.edu.au';
	'; Joanne Lupton;
Cc:	'; ' '; Chelsea L. Bishop
Subject:	Polling for 2015 ILSI Financial Oversight Committee conference call dates
Attachments:	2015-FOC poll - calendar 20150203.doc
TO:	ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

It was good to have each of you with us for the 2015 ILSI Annual Meeting in Arizona. I hope you had a safe and easy trip home.

I have attached calendars for the last two weeks in April, July, and October, for you to use in indicating which days you are available for a one hour conference call beginning at 9:00 a.m. Washington time. Please mark these calendars and return them to me by Tuesday, February 17.

If you are no longer interested in serving on the ILSI Financial Oversight Committee – which I hope is not the case -- please let me know this as well.

# ILSI FINANCIAL OVERSIGHT COMMITTEE 2015 Conference Call Poll

April - May 2015				
Monday	Tuesday	Wednesday	Thursday	Friday
20	21	22	23	24
27	28	29	30	May 1

July 2015				
Monday	Tuesday	Tuesday Wednesday Thursday Frid		Friday
20	21	22 X	23 <b>X</b>	24
27	28	29	30	31

October 2015				
Monday	Tuesday	Tuesday Wednesday Thursday Friday		
19	20	21	22	23
26	27	28	29	30

# ILSI FINANCIAL OVERSIGHT COMMITTEE 2015 Conference Call Poll

From:	Chareese Cunningham
Sent:	Monday, February 02, 2015 11:50 AM
То:	Joanne Lupton
Subject:	2015 ILSI Annual Meeting

Thank you again for attending the **2015 ILSI Annual Meeting** held at the Sheraton Wild Horse Pass Resort in Chandler, Arizona.

As a reminder, we would like to hear from you! Please let us know what you thought about the quality of the scientific sessions and location - just complete our survey by clicking here: <u>2015 ILSI Annual Meeting</u> <u>Survey</u>. Your comments, suggestions and ideas are very valuable to us and will be included in ILSI leadership's consideration in planning future meetings. If you have already completed the survey, please disregard this email.

In the meantime, we look forward to seeing you next year! We hope you will put on your calendar and plan to attend the 2016 ILSI Annual Meeting scheduled for 22-26 January at the Renaissance Vinoy Resort in St. Petersburg, Florida, USA.

Sincerely, Chareese

Chareese Cunningham 2015 ILSI Annual Meeting Manager

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From:Chareese CunninghamSent:Tuesday, January 27, 2015 9:52 AMTo:Joanne LuptonSubject:2015 ILSI Annual Meeting

Thank you for attending the **2015 ILSI Annual Meeting** recently held at the Sheraton Wild Horse Pass in Chandler, Arizona. We hope your learning and networking experiences were productive.

To that end, we would like to hear from you. Please let us know what you think about the quality of the scientific sessions and location - just complete our survey by clicking here: <u>2015 ILSI Annual Meeting Survey</u>. Your comments, suggestions and ideas will be forwarded to ILSI's leadership for their consideration in planning future meetings.

In the meantime, we do hope you will put on your calendar and plan to attend the 2016 ILSI Annual Meeting scheduled for 22-26 January at the Renaissance Vinoy Resort in St. Petersburg, Florida, USA.

Sincerely, Chareese

Chareese Cunningham 2015 ILSI Annual Meeting Manager

Powered by www.EventRebels.com

From: Sent: To: Cc: Subject: Michael Shirreffs Saturday, January 24, 2015 6:49 AM Michael Shirreffs Suzanne Harris ILSI presentations from Tuesday's sessions

Hello everyone:

Presentations from the ILSI North America and ILSI Europe sessions (caffeine, hazard vs. risk, healthy aging) are now available online:

http://www.ilsi.org/Pages/2015-Annual-Meeting.aspx

Presentations from the ILSI branch meetings, the branch posters, and the Alex Malaspina International Scholars will be posted early next week.

Best wishes,

Michael

Michael Shirreffs Director, ILSI Communications From: Sent: To: Cc: Subject: Michael Shirreffs Tuesday, January 20, 2015 8:33 PM Michael Shirreffs Suzanne Harris Presentations have been posted to the website

Did you miss the keynote speakers on Sunday? Or one of the presentations at the ILSI North America scientific sessions on Monday?

Copies of the speakers' slides are posted on the ILSI website:

http://www.ilsi.org/Pages/2015-Annual-Meeting.aspx

(Presentations from Tuesday's sessions will be posted soon.)

Some of the sessions were recorded and we'll post videos online. Watch for an announcement to come.

Best wishes,

Michael

Michael Shirreffs Director, ILSI Communications

From: Sent: To:	Suzanne Harris Wednesday, January 1	4, 2015 2:59 PM 's.chang@griffith.ed '; 'mdoylee	u.au'; 'scohen@unmc.edu'; @uga.edu'; adamdrew@u.washingto	; n.edu;
	marion@vt.edu ;		0 '; Joann	е
	Lupton; '		'; 'john.c.peters@ucdenver.edu';	
	'weavercm@purdue.ec	; ' du';	; ; 'kwallace@d.umn.edu'; ;	
Cc:			'jbradford@unmc.	edu';
				;
	Burnand,Valerie,VEVEY Shawn Sullivan; Beth B Worden; '	',CT-RSA rueggemeyer; Beth-E	'haan@purdue.ec llen Berry; Michael Shirreffs; Allison	lu';
Subject: Attachments:	New ILSI bylaw amend Draft Bylaw amendme	lment proposal for nt 14 Jan 2015.docx	vote on Saturday, January 17, 2015	

TO: ILSI Board of Trustees

FROM: Suzie Harris

I learned today from our primary contact point at WHO that the renewal of ILSI's status as an organization in official relations with WHO may be in jeopardy because one member company in one branch is part of a conglomerate that includes tobacco business. ILSI's status will be decided during the WHO Executive Board meeting on January 26-February 3, in Geneva.

To hopefully avoid losing our "official relations" status, a bylaw amendment will be presented (text attached) for a vote during the ILSI Board of Trustees meeting on Saturday, January 17, 2015.

This issue has been around for a number of years and WHO is well aware that ILSI does not work on issues related to tobacco. We have long had an informal policy of not working with tobacco companies and their issues. The amendment also bars firearms companies, another group excluded by WHO. To my knowledge no ILSI branch has ever had such a company as a member.

Please review the proposed bylaw amendment and come to the ILSI Board of Trustees meeting ready to discuss this issue.

#### **ARTICLE II: MEMBERSHIP**

Formatted: Justified

SECTION 1. The members shall be those firms, corporations, or other entities that (i) are producers offood, beverages, pharmaceuticals, cosmetics, agricultural and other chemicals, personal care and household products, or containers thereof, forestry and paper products, communications products, transportation products, energy products, or producers of ingredients used therein or in connection therewith, or producers of exercise equipment for human health, or providers of scientific and technical services used in the safety testing or production of the foregoing products; and (ii) are members in good standing of any of the Branches of ILSI (as defined in Article VIII, Section 1 of these bylaws); provided, however, that no trade association and no firm whose business consists principally of providing professional consulting service or advice may be a member of ILSI. In addition, a company is ineligible for membership in ILSI if that company or an affiliate engages in the manufacture, production, marketing, sale, or distribution of tobacco products or firearms. For purposes of this provision, the term "affiliate" means any company that controls, is controlled by, or is under common control with another company.

From:	Chareese Cunningham
Sent:	Monday, January 12, 2015 12:51 PM
То:	Joanne Lupton
Subject:	2015 ILSI Annual Meeting Logistic

The <u>2015 ILSI Annual Meeting</u> in Chandler, Arizona is fast upon us! Here are a few reminders to help make sure your travel and educational experiences are positive.

**1. Ground Transportation**: The Sheraton Wild Horse Pass Resort is located about 15 miles (20 minutes) from Phoenix Sky Harbor International Airport. The most efficient way to get to the hotel is via cab or Uber.

ILSI has partnered with Uber for this year's conference. ILSI attendees will receive \$20.00 off of their first ride with Uber with our coupon code. <u>Click here</u> for more information.

**2. Registration and Information Desk Hours:** Registration will be located in the Thunder One Foyer at the Satellite Registration Desk. The Thunder One Foyer is located below the hotel main lobby.

15 Thursday	9:30 am - 5:30 pm
16 Friday	7:15 am - 5:30 pm
17 Saturday	7:15 am - 5:00 pm
18 Sunday	7:00 am - 7:00 pm
19 Monday	6:30 am - 6:00 pm
20 Tuesday	6:30 am - 2:30 pm

**3. Major Events and Scientific Sessions:** A phenomenal line-up of speakers, dynamic topics and great networking events are planned for you. Here are some of the highlights:

18 Sunday Evening	ILSI Poster Session and Opening Reception/Dinner
19 Monday Morning	ILSI NA Scientific Session: Global Challenges and Solutions for Food and Nutrition Sustainability
19 Monday Afternoon	ILSI NA Scientific Session: I am the Microbiome: It's the Microbio + Me
20 Tuesday Morning	ILSI NA Scientific Session: Caffeine: Friend or Foe?
20 Tuesday Afternoon	ILSI Scientific Session: Hazard and Risk: The Exposure Revolution
20 Tuesday Afternoon	ILSI Europe Scientific Session: The Aging Brain
20 Tuesday Evening	Closing Reception/Dinner

4. Weather

and Dress Code: Chandler's climate in January is typically very comfortable. Average temperature in January during the day is  $67^{\circ}F$  (19°C) Fahrenheit with weather getting cooler in the evening with an average low of  $41^{\circ}F$  (5°C).

The dress code for the 2015 ILSI Annual Meeting is business casual – with most of the meetings taking place in the air conditioned hotel, you may want to bring a light sweater.

**5. Opening and Closing Reception/Dinner:** If you are planning on having a guest attend one or both of the receptions/dinners – your guest must be registered, badges will be checked. To register your guest, please contact Emily Grossberg at

Visit the ILSI Annual Meeting website to learn more about the things to do in Arizona.

See you in Arizona,

Chareese

Chareese Cunningham 2015 ILSI Annual Meeting

Powered by <u>www.EventRebels.com</u>

From:	Suzanne Harris >
Sent:	Wednesday, January 07, 2015 4:25 PM
То:	Joanne Lupton
Cc:	Chelsea L. Bishop
Subject:	Agenda and briefing material for the ILSI Board of Trustees meeting January 17, 2015
Attachments:	Tab 01-a Agenda.doc; LUPTON 2015 ILSI BOT Schedule.doc

Dear Joanne,

The ILSI Board of Trustees meeting will take place on **Saturday, January 17, 2015 beginning at 8:00 a.m. in Akimel 1, Sheraton Wild Horse Pass Resort, Chandler, Arizona.** The meeting will end by noon and lunch will be available for all trustees at that time. Breakfast will be available in the meeting room at 7:30 a.m.

The proposed agenda for the meeting is attached along with your individualized schedule for the 2015 ILSI Annual Meeting. The briefing documents for the meeting are posted on the ILSI Board of Trustees portal – <a href="https://www.ilsiextra.org/ilsi/bot/SitePages/Upcoming%20Meetings.aspx">https://www.ilsiextra.org/ilsi/bot/SitePages/Upcoming%20Meetings.aspx</a>.

Your user name is the information in your email address that precedes the @ sign. For example, for me the user name is sharris.

The password is Password1, unless you have changed your password for this portal. The link to use to change your password is <u>https://www.ilsiextra.org/Pages/Change%20Password.aspx</u>

You will receive a Board book containing most of these documents when you check-in at the ILSI registration desk (different from the hotel registration desk). The resource documents (last four on the portal list) will not be in your Board book.

Please let me know if you have any questions. I look forward to seeing you in Arizona.

Best regards,

Suzie

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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2015 ILSI Annual Meeting Chandler, Arizona

# **ILSI Board of Trustee Schedule**

# Dr. Joanne R. Lupton

Date and Time		Meeting	Location		
Fri Jan 16					
Fri Jan 16	8:00 am – 4:45 pm	ILSI Branch Staff Meeting	Kave 3		
Fri Jan 16	12:00 pm – 1:30 pm	ILSI Branch Staff Lunch	Beehive Patio		
	Sat Jan 17				
Sat Jan 17	8:00 am – 12:00 pm	ILSI Board of Trustees Meeting	Akimel 1		
Sat Jan 17	12:00 pm – 1:00 pm	Board of Trustees Lunch	Akimel Patio		
Sat Jan 17	1:00 pm – 5:00pm	ILSI North America Board of Trustees	Akimel 1		
Sat Jan 17	1:00 pm – 5:30 pm	ILSI Asian Branches Meeting	Akimel 2		
Sat Jan 17	6:30 pm – 9:30 pm	ILSI North America Board of Trustees Dinner	TBD		
0 1 10	0.00 10.00	Sun Jan 18			
Sun Jan 18	8:00 am – 12:00 pm	ILSI North America Assembly of Members and FNSP	Akimel 3 & 4		
Sun Jan 18	2:00 pm – 5:00 pm	ILSI Assembly of Members	Akimel 3 & 4		
Sun Jan 18	5:00 pm – 6:00 pm	Biotech Forum AND What is CSAFF?	Roadrunner		
Sun Jan 18	6:00 pm –7:00 pm	Poster Reception	Akimel Foyer		
Sun Jan 18	7:00 pm – 9:00 pm	Opening Reception	Akimel Lawn		
		Mon Jap 10			
	7.00 0.00	Malaspina International Scholar Travel Awardees			
Mon Jan 19	7:00 am – 8:30 am	Breakfast Meeting	Bird/Roadrunner		
Mon Jan 19	8:30 am - 12:00 pm	ILSI North America Scientific Session: Global Challenges	Akimel 4		
	F	and Solutions for Sustainability			
Mon Jan 19	2.00 pm – 5.30 pm	Microbiome: It's the Mircrobio + Me	Akimel 4		
Mon Jan 19	5:30 pm – 7:30 pm	Carbohydrates Forum	Kave 1		
Mon Jon 10	Time to be determined	Malaspina International Scholar Travel Awardee Dinner	Officito		
WUIT Jah 19		(Invitation Only – by Coke)	OII-SILE		
		Tue Jan 20			
Tue Jan 20	7:00 am – 8:30 am	ILSI India and ILSI South Africa Breakfast Meeting	Akimel 1		
Tue Jan 20	8:30 am – 12:30 pm	Foe?	Akimel 4		
Tue Jan 20	12:00 pm – 2:00 pm	II SLL atin America Branches Meeting	Akimel 1		
Tuo Jon 20	2:00 pm 5:00 pm	Scientific Session: Hazards and Risks: the Exposure			
Tue Jan 20	2:00 pm – 5:00 pm	Revolution	AKIIIIEI 4		
Tue Jan 20	5:00 pm – 6:30 pm	Scientific Session: The Aging Brain	Akimel 3		
Tue Jan 20	7:00 pm – 10:00 pm	Closing Reception	Akimel Lawn (tentative)		
Wed Jan 21	8:00 am – 10:00 am	2016 Scientific Program Planning Meeting	Bird/Roadrunner		

If there are any other meetings you would like to attend that are listed in the schedule as "Committee Members and invited guests," please see Suzie Harris.

## ILSI Board of Trustees Meeting

Saturday, 17 January 2015 8:00 am –Noon Chandler, Arizona

## AGENDA

I.	Call to Order	Dr. Sam Cohen	
II.	Approval of Minutes from the July 14, 2014 ILSI Board of Trustees Conference Call (Tab 2)	Dr. Sam Cohen	
III.	President's Report	Dr. Jerry Hjelle	
IV.	<ul> <li>Progress with Implementation of the One ILSI Strategy (Tab 3)</li> <li>a. ILSI Board Science Advisory Group Dr. Peter van Bladeren/Dr. Alan Boobis</li> <li>b. ILSI Board Value/Stakeholder Group Dr. Todd Abraham/Dr. Sam Cohen/Mr. Geoff Smith</li> <li>c. Thematic area collaborations</li> <li>d. One ILSI accountability</li> </ul>		
V.	Impact of Communications (Tab 4)	Mr. Michael Shirreffs	
VI.	Report from the Publications Committee (Tab 5)	Dr. Connie Weaver	
VII.	Report of the Financial Oversight Committee (Tab 6)	Dr. Liz Westring	
	a. 2014 Year-end Projections and 2015 Budget		
VIII.	Adoption of the ILSI Budget for 2015	Dr. Sam Cohen	
	BREAK – PHOTO (30 minutes)		
IX.	Report from the ILSI Research Foundation (Tab 7)	Dr. Adam Drewnowski	
X.	Report from the ILSI Platform for International Partnerships (Tab 8)	Dr. Suzie Harris	
XI.	<ul><li>Report of the Nomination Review Committee (Tab 9)</li><li>a. Introduction of Nominees to the ILSI Board of Trustees</li><li>b. Election of Officers and Executive Committee Members</li><li>c. Election of Trustees to the ILSI Research Foundation Board</li></ul>	Dr. Takeshi Kimura rd	
XII.	Comments from the ILSI Board Chair	Dr. Alan Boobis	

Dr. Rhona Applebaum

Comments from the ILSI President

- XIII. Other Business (Tab 10)
  a. New Branch Proposal
  b. Proposal from ILSI Japan
  c. Plans for 2016 and 2017 Annual Meetings
- XIV. Adjournment

Dr. Sam Cohen Dr. Michael Knowles Mr. Takashi Togami Dr. Suzie Harris

From: Sent: To: Subject:

Wednesday, December 31, 2014 10:20 AM Joanne Lupton ILSI News, Volume 32, Number 3

Dear Colleague:

Happy New Year! We hope you enjoy the latest issue of *ILSI News*. It in you will read about our programs, recent publications, upcoming meetings, and more.

http://www.ilsi.org/Documents/ILSI News Q4.pdf

Michael Shirreffs ILSI Director of Communications International Life Sciences Institute 1156 15th Street, NW, 2nd Floor Washington, DC 20005 www.ilsi.org

This e-mail was sent from International Life Sciences Institute

to jlupton@tamu.edu.

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To unsubscribe, please click on this link and follow the instructions: Unsubscribe

International Life Sciences Institute,1156 15th Street, NW Suite 200 Washington DC 20005, Phone Number: (202) 659-0074, Fax Number: (202) 659-3859, Email Address: ilsi@ilsi.org, Website : http://www.ilsi.org
From:	John Faulkner
Sent:	Wednesday, December 17, 2014 11:03 AM
Subject:	Your ILSI North America Science Briefs for November
Attachments:	Nutrition Briefs November 2014.pdf; Food Safety Briefs November 2014.pdf

Season's Greetings!

Although our **Food Safety** and **Nutrition** Science Briefs are not holiday themed, I do hope this note finds you happy, healthy and enjoying this special time of year.

Our briefs are compiled each month after a review of articles published in the most recent issues of the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion are those we believe address areas of greatest interest to ILSI North America's technical and project committees.

The **November** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will add them to our distribution list.

Happy Holidays,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Food Safety Briefs**

# November 2014

#### E. coli

#### Behavior of Shiga Toxigenic *Escherichia coli* Relevant to Lettuce Washing Processes and Consideration of Factors for Evaluating Washing Process Surrogates

K. Deng, X. Wang, L-H. Yen, H. Ding, M.L. Tortorello Journal of Food Protection, Vol. 77; No. 11, pp. 1860–1867, 2014 DOI: 10.4315/0362-028X.JFP-14-220

Link to full text: Click here

**Significance:** A range of behaviors of STEC strains during lettuce washing were demonstrated and may be helpful in hazard characterization, identifying factors to consider for evaluating washing process efficacy, and identifying phenotypic traits to select surrogates to validate washing processes.

To understand cross-contamination risk during washing, a collection of Shiga toxigenic *Escherichia coli* (STEC), including O157:H7 and other non-O157 strains, were tested for certain traits during washing of fresh-cut lettuce. Cross-contamination was assessed by evaluating transfer of bacteria from inoculated to uninoculated leaves during washing. Without chlorine, similar transfer to wash water and uninoculated leaves was shown. In 1 ppm of chlorine, cross-contamination was not detected with most strains, except for the substantial transfer by a STEC O111 strain and EcN in some replicates. Strain O111 and *E. Coli* Nissle 1917 (EcN) showed less inactivation in 0.25 ppm of chlorine water compared with O157 (P < 0.05). Lactic acid bacterial species (LAB) showed similar transfer and similar chlorine inactivation to O157. Considering together the sublethal chlorine sensitivity and detachment/attachment traits, neither EcN nor LAB displayed optimal characteristics as washing process surrogates for the STEC strains.

#### Biofilm Formation and Sanitizer Resistance of *Escherichia coli* O157:H7 Strains Isolated from "High Event Period" Meat Contamination

R. Wang, N. Kalchayanand, D.A. King, B.E. Luedtke, J.M. Bosilevac, T.M. Arthur

Journal of Food Protection, Vol. 77; No. 11, pp. 1982–1987, 2014

DOI: 10.4315/0362-028X.JFP-14-253

Link to full text: Click here

**Significance:** Biofilm formation and sanitization resistance could have a role in high event period beef contamination by *E. coli* O157:H7.

The researchers hypothesized that the high event period (HEP) contamination (i.e., a time period during which commercial meat plants experience a higher than usual rate of *Escherichia coli* O157:H7 contamination) may be due to certain in-plant colonized *E. coli* O157:H7 strains that are better able to survive

# **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

#### Food Safety Briefs

sanitization through biofilm formation. To test the hypothesis, a collection of 45 *E. coli* O157:H7 strains isolated from HEP beef contamination incidents and a panel of 47 *E. coli* O157:H7 strains of diverse genetic backgrounds were compared for biofilm formation and sanitizer resistance. Biofilm cell survival and recovery growth after sanitization were compared between the two strain collections using common sanitizers, including quaternary ammonium chloride, chlorine, and sodium chlorite. No difference in "early stage" biofilms was observed between the two strain collections after incubation at 22 to 25°C for 1 or 2 days. However, the HEP strains demonstrated significantly higher potency of "mature" biofilm formation after incubation for 4 to 6 days. Biofilms of the HEP strains also exhibited significantly stronger resistance to sanitization.

#### Inactivation of *Escherichia coli* O157:H7 in Biofilm on Food-Contact Surfaces by Sequential Treatments of Aqueous Chlorine Dioxide and Drying

J. Bang, A. Hong, H. Kim, L.R. Beuchat, M.S. Rhee, Y. Kim, et al. International Journal of Food Microbiology, Vol. 191, 17 November 2014; pp. 129–134, 2014

DOI: 10.1016/j.ijfoodmicro.2014.09.014

Link to full text: Click here

**Significance:** Aqueous chlorine dioxide treatment of food-contact surfaces results in residual lethality to *E. coli* O157:H7 during the drying process.

This study investigated the efficacy of sequential treatments of aqueous chlorine and chlorine dioxide and drying in killing Escherichia coli O157:H7 in biofilms formed on stainless steel, glass, plastic, and wooden surfaces. Cells attached to and formed a biofilm on wooden surfaces at significantly higher levels compared with other surface types. The lethal activities of sodium hypochlorite (NaOCl) and aqueous chlorine dioxide (ClO2) against E. coli O157:H7 in a biofilm on various food-contact surfaces were compared. Chlorine dioxide generally showed greater lethal activity than NaOCl against E. coli O157:H7 in a biofilm on the same type of surface. The resistance of E. coli O157:H7 to both sanitizers increased in the order of wood > plastic > glass > stainless steel. When wooden surfaces harboring E. coli O157:H7 biofilm were treated with ClO2 (200 µg/ml, 10 min), rinsed with water, and subsequently dried at 43% relative humidity and 22 °C, the number of E. coli O157:H7 on the surface decreased by an additional 6.4 CFU/coupon within 6 h of drying. However, when the wooden surface was treated with water or NaOCl and dried under the same conditions, the pathogen decreased by only 0.4 or 1.0 log CFU/coupon, respectively, after 12 h of drying.

#### Salmonella

# Efficacy of Various Sanitizers against *Salmonella* during Simulated Commercial Packing of Tomatoes

H. Wang, E.T. Ryser Journal of Food Protection, Vol. 77; No. 11, pp. 1868–1875, 2014 DOI: 10.4315/0362-028X.JFP-14-213

Link to full text: Click here

**Significance:** Salmonella populations decreased to non-detectable levels after processing with sanitizers on the equipment surfaces.



This study assessed the ability of six commonly used sanitizers (40 ppm of peroxyacetic acid, 40 ppm of mixed peracid, 40 ppm of available chlorine alone or acidified to pH 6.0 with citric acid or T-128, and electrolyzed water containing 40 ppm of available chlorine at pH 6.7) to reduce Salmonella on tomatoes, in wash water, and on equipment surfaces using a pilot-scale processing line. Red round tomatoes were dip inoculated to contain Salmonella at ~6 log CFU/g, air dried for 2 h, treated for 2 min in a 3.3-m-long dump tank and then dried on a roller conveyor, with sanitizer-free water serving as the control. All samples were appropriately neutralized, diluted, and surface plated on Trypticase soy agar containing 0.6% yeast extract, 0.05% ferric ammonium citrate, and 0.03% sodium thiosulfate with or without membrane filtration to enumerate Salmonella. All six sanitizer treatments were more efficacious than the water control, with chlorine plus citric acid yielding the greatest Salmonella reduction on tomatoes (3.1 log CFU/g). After processing, all sanitizer wash solutions contained significantly lower levels of Salmonella than the water control (3.0 log CFU/ml). The four chlorine-based sanitizer treatments yielded significantly lower Salmonella populations ( $P \le 0.05$ ) in the wash solution compared with peroxyacetic acid and mixed peracid.

# Evaluation of Chlorine Dioxide Gas Treatment to Inactivate *Salmonella enterica* on Mungbean Sprouts

V. Prodduk, B.A. Annous, L. Liu, K.L. Yam Journal of Food Protection, Vol. 77; No. 11, pp. 1876–1881, 2014 DOI: 10.4315/0362-028X.JFP-13-407 Link to full text: Click here

**Significance:** Chlorine dioxide gas was capable of penetrating and inactivating cells that are attached to inaccessible sites and/or are within biofilms on the sprout surface as compared with an aqueous chlorine wash.

The effectiveness of chlorine dioxide gas treatment to reduce *Salmonella* on artificially inoculated mungbean sprouts was evaluated. The effectiveness of gaseous chlorine dioxide (0.5 mg/liter of air) with or without tumbling was compared with an aqueous chlorine (200 ppm) wash treatment. Tumbling the inoculated sprouts during the chlorine dioxide gas application for 15, 30, and 60 min reduced *Salmonella* populations by 3.0, 4.0, and 5.5 log CFU/g, respectively, as compared with 3.0, 3.0, and 4.0 log CFU/g reductions obtained without tumbling, respectively. A 2.0 log CFU/g reduction in *Salmonella* was achieved with an aqueous chlorine wash. The difference in microbial reduction between chlorine dioxide gas versus aqueous chlorine wash points to the important role of surface topography, pore structure, bacterial attachment, and/or biofilm formation on sprouts.

#### Evaluation of *Salmonella* Thermal Inactivation Model Validity for Slow Cooking of Whole-Muscle Meat Roasts in a Pilot-Scale Oven

T.J. Breslin, M.I. Tenorio-Bernal, B.P. Marks, A.M. Booren, E.T. Ryser, N.O. Hall

Journal of Food Protection, Vol. 77; No. 11, pp. 1897–1903, 2014

DOI: 10.4315/0362-028X.JFP-14-035

Link to full text: Click here

**Significance:** Slow-cooked roasts, processed to a computed lethality at or near that required by the regulatory performance standards, as calculated with a state-dependent model, may be underprocessed.



This research evaluated the accuracy of a traditional log-linear inactivation model, developed via prior laboratory-scale isothermal tests, and a novel path-dependent model accounting for sublethal injury, applied to pilot-scale slow cooking of whole-muscle roasts. Irradiated turkey breasts, beef rounds, and pork loins were inoculated with an eight-serovar *Salmonella* cocktail via vacuum tumble marination in a salt-phosphate marinade. The resulting initial *Salmonella* population in the geometric center (core) was 7.0, 6.3, and 6.3 log CFU/g for turkey, beef, and pork, respectively. Seven different cooking schedules representing industry practices were evaluated in a pilot-scale, moist-air convection oven. Core temperatures recorded during cooking were used to calculate lethality real-time via the log-linear model. The path-dependent model reduced the bias (mean residual) and root mean square error by 4.24 and 4.60 log CFU/g respectively, in turkey; however, the new model did not reduce the prediction error in beef or pork.

#### Bacteriophage P22 to Challenge Salmonella in Foods

P. Zinno, C. Devirgiliis, D. Ercolini, D. Ongeng, G. Mauriello International Journal of Food Microbiology, Vol. 191, 17 November 2014; pp. 69–74, 2014 DOI: 10.1016/j.ijfoodmicro.2014.08.037 Link to full text: Click here

Significance: Phages may be useful in the control of food-borne pathogens.

The influence of phage addition on the fate of *Salmonella enterica* serovar Typhimurium in different foods was considered. Phage P22 was applied to the following: liquid eggs, energy drinks, whole and skimmed milk, apple juice, chicken breast and chicken mince all spiked with its host, whose growth was monitored for 24 and 48 h at 4 °C. Appreciable host inactivation was achieved compared to phage-free controls in all food matrices when 104 UFC/g host inoculum was used. Wild food strains belonging to the serotypes Typhimurium, Enteritidis, Derby Give, Newport, Muenchen and Muenster were assayed towards phage P22. Only isolates of *Salmonella* Typhimurium as well as *Salmonella* Derby and *Salmonella* Enteritidis was inhibited by the presence of P22 phage. Additional experiments were carried out by spiking liquid-eggs, chicken breast and chicken mince with mixes of wild *Salmonella* Typhimurium (at concentration of about 104 UFC/g) strains along with their relative phage P22. The results showed a reduction of 2–3 log cycles after 48 h at 4 °C depending on both mix of strains and the specific food.

#### Listeria

#### Geographical and Meteorological Factors Associated with Isolation of *Listeria* Species in New York State Produce Production and Natural Environments

T.K. Chapin, K.K. Nightingale, R.W. Worobo, M. Wiedmann, L.K. Strawn Journal of Food Protection, Vol. 77; No. 11, pp. 1919–1928, 2014 DOI: 10.4315/0362-028X.JFP-14-132

Link to full text: Click here

**Significance:** *Listeria* spp. were prevalent in both agricultural and nonagricultural environments and that geographical and meteorological factors associated with isolation of *Listeria* spp. were considerably different between the two environments.



This study was conducted to determine the prevalence and diversity of Listeria species in produce production and natural environments and to identify geographical and/or meteorological factors that affect the isolation of *Listeria* spp. in these environments. These data were also used to evaluate *Listeria* spp. as index organisms for L. monocytogenes in produce production environments. Environmental samples collected from produce production (n=588) and natural (n=734) environments in New York State were microbiologically analyzed to detect and isolate Listeria spp. The prevalence of Listeria spp. was approximately 33 and 34% for samples obtained from natural environments and produce production, respectively. Coisolation of L. monocytogenes and at least one other species of Listeria in a given sample was recorded for 3 and 9% of samples from natural environments and produce production, respectively. Soil moisture and proximity to water and pastures were highly associated with isolation of *Listeria* spp. in produce production environments, while elevation, study site, and proximity to pastures were highly associated with isolation of *Listeria* spp. in natural environments.

#### **Foodborne Pathogens**

# Co-Occurrence of Free-Living Protozoa and Foodborne Pathogens on Dishcloths: Implications for Food Safety

N. Chavatte, J. Baré, E. Lambrecht, I. Van Damme, M. Vaerewijck, K. Sabbe, et al. International Journal of Food Microbiology, Vol. 191, 17 November 2014;

pp. 89–96, 2014

DOI: 10.1016/j.ijfoodmicro.2014.08.030

Link to full text: Click here

**Significance:** Free-living protozoa, including some opportunistic pathogens, are a common and diverse group on dishcloths.

The occurrence of free-living protozoa (FLP) and foodborne bacterial pathogens on dishcloths was investigated. First various protocols for recovering and quantifying FLP from dishcloths were assessed. Enrichment was used to assess FLP diversity on dishcloths (n=38). FLP were found on 89% of the examined dishcloths; 100% of these tested positive for amoebae, 71% for flagellates and 47% for ciliates. Diversity was dominated by amoebae: vahlkampfiids, vannellids, Acanthamoeba spp., Hyperamoeba sp. and Vermamoeba vermiformis were most common. The ciliate genus Colpoda was especially abundant on dishcloths while heterotrophic nanoflagellates mainly belonged to the genus Bodo, the glissomonads and cercomonads. The total number of FLP in used dishcloths ranged from 10 to 104 MPN/cm<sup>2</sup>. Flagellates were the most abundant group, and ciliates the least abundant. Detergent use was identified as a prime determinant of FLP concentrations on used dishcloths. Bacterial load on dishcloths was high, with a mean total of aerobic bacteria of 7.47 log10 cfu/cm<sup>2</sup>. Escherichia coli was detected in 68% (26/38) of the used dishcloths, with concentrations up to 4 log10 cfu/cm<sup>2</sup>. Foodborne pathogens including Staphylococcus aureus (19/38), Arcobacter butzleri (5/38) and Salmonella enterica subsp. enterica ser. Halle (1/38) were also present.

# Adhesion of Salmonella Enteritidis and Listeria monocytogenes on Stainless Steel Welds

L.S. Casarin, A. Brandelli, F. de Oliveira Casarin, P.A. Soave, C.H. Wanke, E.C. Tondo

International Journal of Food Microbiology, Vol. 191, 17 November 2014; pp. 103–108, 2014



#### DOI: 10.1016/j.ijfoodmicro.2014.09.003

Link to full text: Click here

**Significance:** There was no correlation between adhesion to welds and stainless steel and the hydrophobicity.

This study investigated the adhesion of *Salmonella Enteritidis* and *Listeria mono-cytogenes* on the surface of metal inert gas, and tungsten inert gas welding, as well as to evaluate the cell and surface hydrophobicities. Results demonstrated that both bacteria adhered to the surface of welds and stainless steel at same levels.

#### Ochratoxin A

#### Effect of Temperature, Water Activity, and pH on Growth and Production of Ochratoxin A by Aspergillus niger and Aspergillus carbonarius from Brazilian Grapes

F.R.F. Passamani, T. Hernandes, N.A. Lopes, S.C. Bastos, W.D. Santiago, M. das Graças Cardoso, et al.

Journal of Food Protection, Vol. 77; No. 11, pp. 1947–1952, 2014

DOI: 10.4315/0362-028X.JFP-13-495

Link to full text: Click here

**Significance:** The evaluated fungi are able to grow and produce ochratoxin A in a wide range of temperature, water activity, and pH.

This study evaluated the influence of temperature, water activity (aw), and pH on the development and production of ochratoxin A (OTA) in a semisynthetic grape culture medium by Aspergillus carbonarius and Aspergillus niger strains. To analyze the growth conditions and production of OTA, an experimental design was conducted using response surface methodology as a tool to assess the effects of these abiotic variables on fungal behavior. A. carbonarius showed the highest growth at temperatures from 20 to 33°C, aw between 0.95 and 0.98, and pH levels between 5 and 6.5. Similarly, for A. niger, temperatures between 24 and 37°C, aw greater than 0.95, and pH levels between 4 and 6.5 were optimal. The greatest toxin concentrations for A. carbonarius and A. niger (10  $\mu$ g/g and 7.0  $\mu$ g/g, respectively) were found at 15°C, aw 0.99, and pH 5.35. The lowest pH was found to contribute to greater OTA production.

#### Food Allergy

# Decreased Bone Mineral Density in Young Adult IgE-Mediated Cow's Milk-Allergic Patients

L. Nachshon, M.R. Goldberg, N. Schwartz, T. Sinai, R. Amitzur-Levy,

A. Elizur, et al.

Journal of Allergy and Clinical Immunology, Vol. 134, No. 5; pp. 1108–1113, 2014 DOI: 10.1016/j.jaci.2014.06.026

Link to full text: Click here

**Significance:** Patients with IgE-mediated cow's milk allergy have a significant risk of reduced bone mineral density and early osteoporosis, which appears to be reversible on milk desensitization.



This prospective observational study determined the effects of dairy restriction on bone mineral density (BMD) in young adult IgE-mediated cow's milk–allergic (IgE-CMA) patients. Densitometric measurements of postpubertal patients diagnosed with IgE-CMA (group I, n=33) were compared with those of volunteers matched for age and sex without IgE-CMA (control group II, n=24). In a second analysis, group I and II patients were compared with IgE-CMA patients who after desensitization consumed milk for 12 to 39 months before analysis (group III, n=12). Densitometric measurements (average T scores and Z scores) of the hip, femoral neck, and lumbar spine of IgE-CMA patients were significantly lower than of those in the control group (P<.0001). A T score below -2.5 SD, identifying a risk for osteoporosis, was found in 27% of IgE-CMA patients but in none of the controls (P=.0071). Calcium intake was severely reduced in allergic patients than in controls (P<.0001). BMD measurements in group III were significantly greater than in group I (P<.0001) and unchanged from the control group.

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1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org



# **Nutrition Briefs**

# November 2014

#### **Diabetes**

Fiber Intake and Plasminogen Activator Inhibitor-1 in Type 2 Diabetes: Look AHEAD (Action for Health in Diabetes) Trial Findings at Baseline and Year 1

L.M. Belalcazar, A.M. Anderson, W. Lang, D.C. Schwenke, S.M. Haffner, H. Yatsuya, et al. and the Look AHEAD (Action for Health in Diabetes) Research Group

Journal of the Academy of Nutrition and Dietetics, Vol. 114, No. 11; pp. 1800–1810, 2014

DOI: 10.1016/j.jand.2014.06.357

Link to full text: Click here

**Significance:** Increasing fiber intake in overweight/obese individuals with diabetes interested in weight loss is challenging.

The associations of fiber intake and its changes with plasminogen activator inhibitor 1 (PAI-1) were examined before and during an intensive lifestyle intervention (ILI) for weight loss in 1,701 Look AHEAD (Action for Health in Diabetes) participants with dietary, fitness, and PAI-1 data at baseline and 1 year. At baseline, median fiber intake was 17.9 g/day. Each 8.3 g/day higher fiber intake was associated with a 9.2% lower PAI-1 level (P=0.008); this association persisted after weight and fitness adjustments (P=0.03). Higher baseline intake of fruit (P=0.019) and high-fiber grain and cereal (P=0.029) were related to lower PAI-1 levels. Although successful in improving weight and physical fitness at 1 year, the ILI in Look AHEAD resulted in small increases in fiber intake (4.1 g/day, compared with -2.35 g/day with diabetes support and education) that were not related to PAI-1 change (P=0.34). Only 31.3% of ILI participants (39.8% of women, 19.1% of men) met daily fiber intake recommendations.

#### Glycemic Control and Excess Mortality in Type 1 Diabetes

M. Lind, A-M. Svensson, M. Kosiborod, S. Gudbjörnsdottir, A. Pivodic, H. Wedel, et al.

New England Journal of Medicine, Vol. 371, No. 21; pp. 1972–1982, 2014 DOI: 10.1056/NEJMoa1408214

Link to full text: Click here

**Significance:** Patients with type 1 diabetes and a glycated hemoglobin level of  $\leq$ 6.9% had a risk of death from any cause or from cardiovascular causes that was twice as high as the risk for matched controls.

This registry-based observational study determined the excess risk of death according to the level of glycemic control in patients with type 1 diabetes (T1DM). For each patient, five controls were randomly selected from the general population and matched according to age, sex, and county. Patients and controls

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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were followed until December 31, 2011. The mean follow-up in the diabetes and control groups was 8.0 and 8.3 years, respectively. Overall, 2701 of 33,915 patients with diabetes (8.0%) died, as compared with 4835 of 169,249 controls (2.9%) (adjusted hazard ratio (HR), 3.52; 95% CI, 3.06-4.04); the corresponding rates of death from cardiovascular causes were 2.7% and 0.9% (adjusted HR, 4.60; 95% CI, 3.47-6.10). The multivariable-adjusted HR for death from any cause according to the glycated hemoglobin level for patients with diabetes as compared with controls were 2.36 (95% CI, 1.97-2.83) for a glycated hemoglobin level of 7.0 to 7.8%, 3.11 (95% CI, 2.66-3.62) for a level of 7.9 to 8.7%, 3.65 (95% CI, 3.11-4.30) for a level of 8.8-9.6%, and 8.51 (95% CI, 7.24-10.01) for a level  $\geq$ 9.7%. Corresponding HRs for death from cardiovascular causes were 2.92 (95% CI, 2.07-4.13), 3.39 (95% CI, 2.49-4.61), 4.44 (95% CI, 3.32-5.96), 5.35 (95% CI, 3.94-7.26), and 10.46 (95% CI, 7.62-14.37).

#### **Food Allergy**

#### Decreased Bone Mineral Density in Young Adult IgE-Mediated Cow's Milk-Allergic Patients

L. Nachshon, M.R. Goldberg, N. Schwartz, T. Sinai, R. Amitzur-Levy, A. Elizur, et al. Journal of Allergy and Clinical Immunology, Vol. 134, No. 5; pp. 1108–1113, 2014 DOI: 10.1016/j.jaci.2014.06.026

Link to full text: Click here

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This prospective observational study determined the effects of dairy restriction on bone mineral density (BMD) in young adult IgE-mediated cow's milk–allergic (IgE-CMA) patients. Densitometric measurements of postpubertal patients diagnosed with IgE-CMA (group I, n=33) were compared with those of volunteers matched for age and sex without IgE-CMA (control group II, n=24). In a second analysis, group I and II patients were compared with IgE-CMA patients who after desensitization consumed milk for 12 to 39 months before analysis (group III, n=12). Densitometric measurements (average T scores and Z scores) of the hip, femoral neck, and lumbar spine of IgE-CMA patients were significantly lower than of those in the control group (P<.0001). A T score below -2.5 SD, identifying a risk for osteoporosis, was found in 27% of IgE-CMA patients but in none of the controls (P=.0071). Calcium intake was severely reduced in allergic patients than in controls (P<.0001). BMD measurements in group III were significantly greater than in group I (P<.0001) and unchanged from the control group.

#### **Metabolic Syndrome**

Substituting Water for Sugar-Sweetened Beverages Reduces Circulating Triglycerides and the Prevalence of Metabolic Syndrome in Obese but Not in Overweight Mexican Women in a Randomized Controlled Trial

S. Hernández-Cordero, S. Barquera, S. Rodríguez-Ramírez, M.A. Villanueva-Borbolla, T. González de Cossio, J.R. Dommarco, et al.

Journal of Nutrition, Vol. 144, No. 11; pp. 1742–1752, 2014 DOI: 10.3945/ jn.114.193490



Link to full text: Click here

**Significance:** Providing water and nutritional counseling was effective in increasing water intake and in partially decreasing sugar-sweetened beverage intake.

This study determined if replacing sugar-sweetened beverages (SSBs) with water affects plasma triglycerides (TGs), weight, and other cardiometabolic factors. Overweight/obese women reporting a SSB intake of at least 250 kcal/d were randomly allocated to the water and education provision (WEP) group (n=120)or the education provision (EP)-only group (n=120). The WEP group received biweekly water deliveries, and both groups received equal monthly nutrition counseling. The WEP group sessions included activities to encourage increased water intake, reduced SSB intake, and substitution of water for SSBs. The WEP group increased water intake and decreased SSB intake significantly over time, but there were no differences in plasma TG between groups at the end of the intervention (WEP at baseline:  $155 \pm 2.10 \text{ mg/dL}$ ; WEP at 9 mo:  $149 \pm 2.80 \text{ mg/}$ dL; EP at baseline:  $150 \pm 1.90 \text{ mg/dL}$ ; EP at 9 mo:  $161 \pm 2.70 \text{ mg/dL}$ ; P for mean comparisons at 9 mo = 0.10). Secondary analyses showed significant effects on plasma TGs (change from baseline to 9 mo: WEP,  $-28.9 \pm 7.7$  mg/dL; EP, 8.5  $\pm$  10.9 mg/dL; P = 0.03) and metabolic syndrome (MetS) prevalence at 9 mo (WEP: 18.1%; EP: 37.7%; P = 0.02) among obese participants.

#### Inflammation

#### Dairy Product Consumption Has No Impact on Biomarkers of Inflammation among Men and Women with Low-Grade Systemic Inflammation

M-È. Labonté, A. Cyr, M.M. Abdullah, M-C. Lépine, M-C. Vohl, P. Jones, et al. Journal of Nutrition, Vol. 144, No. 11; pp. 1760–1767, 2014 DOI: 10.3945/ jn.114.200576 Link to full text: Click here

**Significance:** Short-term consumption of a combination of low- and high-fat dairy products as part of a healthy diet has no adverse effects on inflammation.

This multicenter randomized crossover study investigated the impact of dairy food consumption on biomarkers of inflammation in 112 healthy men and women with high-sensitivity C-reactive protein (hs-CRP) values >1 mg/L. Subjects consumed 3 servings/d of dairy (375 mL low-fat milk, 175 g low-fat yogurt, and 30 g regular-fat cheddar cheese) or energy-matched control (fruit juice, vegetable juice, cashews, and 1 cookie) products as part of prudent 4-wk diets, each separated by a 4- to 8-wk washout period. Analysis of within-diet changes (post- vs. prediet values) showed a significant reduction in hs-CRP concentrations after the control diet (-11.7%, P=0.05) but no change after the dairy diet (-7.3%, P=0.47). As a result, changes in hs-CRP differed between the dairy and control diets (P=0.04). Both the control and dairy diets similarly reduced interleukin-6 concentrations compared with diet-specific baseline values (-17.6% and -19.9%, respectively; P<0.0001 for both, P=0.77 for between-diet comparison). No between- or within-diet difference was observed in adiponectin concentrations, and there was also no between-diet difference in the expression of inflammatory genes and transcription factors.



## **Infant Formula**

# Prebiotic Effect of an Infant Formula Supplemented with Galacto-Oligosaccharides: Randomized Multicenter Trial

M. Giovannini, E. Verduci, D. Gregori, S. Ballali, S. Soldi, D. Ghisleni et al. for the PLAGOS Trial Study Group

Journal of the American College of Nutrition, Vol. 33, No. 5; pp. 385–393, 2014 DOI: 10.1080/07315724.2013.878232

Link to full text: Click here

**Significance:** The prebiotic-supplemented formula mimicked the effect of human milk in promoting Bifidobacterium and Lactobacillus growth and in inhibiting Clostridium growth, resulting in a significantly lower presence of colic.

This randomized, double-blind, controlled, parallel-group clinical trial investigated the effects of a galacto-oligosaccharides (GOS)-supplemented formula on the intestinal microbiota in healthy term infants, with a specific consideration for gastrointestinal symptoms as colic, stool frequency and consistency, regurgitation. Three groups were considered: breastfed, formula-fed, and GOSsupplemented formula-fed infants. Formula-fed infants were randomized to receive either the control or the study formula and consume the assigned formula exclusively until the introduction of complementary feeding. The nutritional composition of the 2 formulas was identical, apart from the supplemented GOS (0.4 g/100 mL) in the study formula. Four different types of bacteria were evaluated in order to assess the efficacy of GOS-supplemented formula on infants: Bifidobacterium, Lactobacillus, and Clostridium, Escherichia coli. 199 breastfed and 163 formula-fed infants were recruited. GOS-supplemented formula presented normal and soft stools in the majority of episodes (89%). In the supplemented group the incidence of colic was lower with respect to the control group. A significantly lower count of Clostridium and a higher count of Bifidobacterium were found when comparing study formula and control formula in infants with colic. Moreover, the ratio between Clostridium count and Bifidobacterium and Lactobacillus count was in favor of the latter two when considering the GOSsupplemented formula group with respect to the control one.

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1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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From:	Beth Brueggemeyer
Sent:	Wednesday, December 03, 2014 6:48 AM
То:	Joanne Lupton
Subject:	RE: Lupton – Bio for review/updating

Thanks Joanne!

Beth BrueggemeyerInternational Life Sciences Institute1156 15<sup>th</sup> Street, NW, Suite 200Washington, DC 20005-1734E:T: 202 659 0074 X148F: 202 659 3859Follow ILSI on:

From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Tuesday, December 02, 2014 10:27 PM
To: Beth Brueggemeyer
Cc: Stella S. Taddeo
Subject: RE: Lupton – Bio for review/updating

Dear Beth: I have made a few changes and the edited bio is below. Thanks, Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Stella S. Taddeo Sent: Tuesday, December 02, 2014 10:45 AM To: Joanne Lupton Subject: FW: Lupton – Bio for review/updating Importance: High

From: Beth Brueggemeyer
Sent: Monday, December 01, 2014 10:44 PM
To: Joanne Lupton
Cc: Chelsea L. Bishop
Subject: Lupton – Bio for review/updating

Dear Joanne,

We are preparing the materials for the upcoming 2015 ILSI Annual Meeting and would appreciate your assistance in reviewing and updating your biographical information.

Below is your bio as listed in the document prepared prior to the 2014 ILSI Annual Meeting held January 2014 in Bermuda.

Would you take a few minutes and review/update the information below. Please return it to me with your approval or changes by **Thursday, December 11**.

#### Lupton, Joanne R., PhD

*Dr. Joanne R. Lupton* is a Distinguished Professor, Regent's Professor and University Faculty Fellow at Texas A&M University. She chaired the Macronutrients Panel for the Dietary Reference Intakes, Food and Nutrition Board, National Academy of Sciences, and also chaired the National Academy panel to determine the definition of dietary fiber. She spent one year at the Food and Drug Administration helping to develop levels of scientific evidence required for health claims and served on the 2005 Dietary Guidelines Committee. She is an elected member of the Institute of Medicine, and is currently on the Food and Nutrition Board. Her research is on the effect of diet on colon physiology and colon cancer with a particular focus on dietary fiber and n-3 fatty acids.

Dr. Lupton is equally committed to teaching and research and has received a number of teaching awards including the national USDA teaching award and the Association of Former Students at Texas A&M Teaching award. She has mentored more than 100 MS and PhD students while at Texas A&M. She received the Dannon mentoring award in 2004.

Dr. Lupton is Past President of the American Society for Nutrition (ASN) and she is currently serving on the Board of Trustees of ILSI Global. Her undergraduate degree is from Mt. Holyoke College and her Ph.D. in Nutrition is from the University of California at Davis.

Please let me know if you have any questions.

Thank you very much.

Warm regards,

Beth

Beth Brueggemeyer International Life Sciences Institute ■ 1156 15<sup>th</sup> Street, NW, Suite 200 ■ Washington, DC 20005-1734 ■ E: T: 202 659 0074 X148 ■ F: 202 659 3859 ■ Follow ILSI on: 🖬 ■

From: Sent: To:	elia Murphy lesday, December 02, 2014 7:45 AM		
	; james.hill@ucdenver.edu;	; james.hill@ucdenver.edu;	
	; Joanne Lupton; m; mdoyl ; weavercm@purdue.edu;	le@uga.edu;	
	; DAllison@uab.edu; Sharon Weiss;		
	; jwerdman@illinois.edu; fergc@foodsci.umass ; dblund@ ;	s.edu; @wisc.edu;	
	dwyerj1@od.nih.gov; OffuttS@gao.gov; ; ;		
Cc: Subject: Attachments:	Eric Hentges; Alison Kretser ILSI North America Conflict of Interest & Scientific Integrity Working Gro COI 2 Dec Call Agenda.doc; Materials 2 Dec Call.pdf	oup	

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Conference Call Agenda and Materials

Please find attached the agenda and materials for the 1 ½ hour conference call with the Working Group this morning, Tuesday, 2 December from 10:00-11:30 am EST.

Please use our conference call number to dial in: 1-888-585-9008 Access code: 327847914

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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A. Kretser

A. Kretser

# Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Thursday, 29 May, 2014, 10:00-11:30 am EDT

#### Purpose: To update the Working Group on the Public-Private Partnership (PPP) and recent activities.

#### I. Welcome and Introductions

a. Ms. Alison Kretser welcomed Working Group members to the call and led introductions. She noted that the group has not met for 5 months and tremendous progress of activities has been made since that time.

#### II. Communications/Publications on PPP

#### a. Mid America Food Processors Association Presentation, March 2014 A. Kretser

- i. The 3 Partners of A Partnership for Public Health: *Branded Food Products Database* gave a presentation on the PPP at the Mid America Food Processors Association (MAFPA) Annual Meeting in March 2014. MAFPA invited the Partnership to present after attending the 14 November 2013 listening session in Washington, DC. The Partnership connected with many small and mid-size companies and there was a lot of interest and support for the project. MAFPA has committed its membership to lead the small and mid-size companies in the submission of data.
- ii. Coming out of meeting, Red Gold, a mid-sized company that produces canned tomatoes, has agreed to be part of the beta test.

# b. "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," *Nutrition Today*, March 2014

- "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," is a recent publication by Sylvia Rowe and Nick Alexander that focuses on PPPs in nutrition. The publication was a separate project from ILSI North America but A Partnership for Public Health: *Branded Food Products Database* is cited in the article.
- ii. At this point, the article is not open access and we do not have the final version.



iii. Action Item: Post the final publication on the COI Extranet and let the Working Group know when it is complete.

E. Hentges

#### c. Experimental Biology Reception on PPPs

# i. Dr. Eric Hentges shared information about a reception on PPPs that was held during the Experimental Biology (EB) meeting in San Diego. The reception was organized by USDA and ASN as a continuation of the initiative that USDA ARS and NIH/NCI began which was spearheaded by Dr. Catherine Woteki and Dr. John Milner. A Partnership for Public Health: *Branded Food Products Database* was originally identified in this initiative as a PPP that should be developed.

- The reception included an update on the activities of the USDA ARS and NIH/NCI collaboration. They are looking moving forward with existing projects and looking for new PPPs to develop.
- iii. Dr. Hentges noted that there are opportunities for further collaborations, particularly in the Microbiome area. He suggested that one of ILSI North America's Committees that has been sunsetted could potentially come back and become a part of the collaboration.
- iv. Dr. Hentges and Ms. Kretser presented on the Partnership and shared an update on the progress. 80 individuals, including Dr. Hentges, Ms. Kretser, and several Working Group members, were present.

#### d. National Nutrient Databank Conference, May 2014 A. Kretser

- i. The 3 Partners presented at the National Nutrient Databank Conference (NNDC) in May. Ms. Kretser noted that the PPP was the showcase of the meeting and that NNDC was an ideal venue to present on the Partnership because it represents a core group of end users of the enhanced USDA National Nutrient Database. 110 attendees were present at NNDC.
- ii. The 3 Partners gave a 1 ½ hour presentation which provided the most up to date information on the progress on Partnership. The Partnership also sponsored a breakfast, featured a poster at the poster session, and held an informal listening session at lunch. The Partners sat at 4 tables with individuals who wanted to continue the discussion and learn more about how they can become engaged.



- iii. In preparation for the conference, a logo for the Partnership was developed that incorporated the logos of the 3 Partners. The Partners are continuing to refine the logo and the ATIP Foundation expressed interest in making further edits so the logo was not shared with the Working Group.
- iv. Ms. Kretser noted that there were several outcomes of the Partnership's presence at NNDC, including: furthering the credibility of the Partnership and giving the initiative high visibility.
- v. During the Q&A after the presentation, there was a strong desire from the nutrition research community that, as the Partnership moves forward and works through implementation and automation of imputing nutrient values, FNDDS codes, and food groups, this becomes an open source, transparent process. It was encouraging to hear this from the community of end users and it was clear that USDA heard that message.
- vi. The Partnership's presence at NNDC created an opportunity to connect with new universities, including the University of Utah and UNC Chapel Hill.
  - A doctoral student from the University of Utah presented on how to assign FNDDS codes and the Partnership connected with her academic advisor, Dr. John Hurdle in the computer science program.
  - 2. Ms. Emily Yoon from UNC Chapel Hill presented on the work of Dr. Barry Popkin's group. The Partners had the opportunity to establish a relationship with Ms. Yoon and her team. They confirmed that the success of the PPP will benefit their database.
  - 3. The Partnership plans to continue outreach with these universities.
- vii. The Partners met with several proprietary databases (Food Essentials, NuVal, ESHA, and the NYC Department of Health who manage MenuStat) that were present and were able to ask them if they were concerned about the PPP impacting their business model. It was confirmed that the proprietary databases present believe the publically available enhanced database will be a benefit to them because it would become the source of the data to pull from and they would no longer have to collect the data themselves. Currently, many proprietary databases spend considerable resources gathering data themselves by pulling the data from websites, or purchasing and



photographing products from the grocery store. By having the data in a publically available database with the assurance that the data is current, the proprietary databases can focus on the analysis of the data, marketing, etc.

- viii. The Partners met Interim Director of the Beltsville Nutrition Center, Dr. Jim Harnly, and briefed him on the Partnership's activities. A discussion on automating algorithms was had and Dr. Harnly noted that it would be a new paradigm to create or develop these algorithms. Further work is needed to develop the process for automation of algorithms and the Partnership will continue to explore this discussion.
  - ix. The Partnership plans to attend future NNDC meetings to provide an update on the progress of the initiative and continue to receive input from this important group of stakeholders.

#### e. Canadian Nutrition Society Food for Health Workshop, June 2014 E. Hentges

 Over the last 2 years, ILSI North America has looked to enhance its activities in Canada and has established a relationship with the Canadian Nutrition Society (CNS). ILSI North America and CNS will jointly the Food for Health Workshop -Principles and Philosophies for Development of Ongoing Public-Private Partnerships to Support Food-Health Research in June 2014, in conjunction with the CNS Annual Meeting. Dr. Hentges will present on A Partnership for Public Health: *Branded Food Product Database* as a case study for ILSI North America. Dairy Farmers of America will also present case study.

#### f. 17th IUFoST World Congress of Food Science and Technology, August 2014 E. Hentges

- Dr. Hentges shared that he will also present on the Partnership as part of a session at the 17<sup>th</sup> IUFoST World Congress of Food Science and Technology in Montreal in August.
- ii. Dr. Daryl Lund, chair of the Working Group, noted that he would be present at IUFoST and is the incoming chair of the scientific council.

#### g. John Milner Memorial Symposium, 12 June, 2014

#### A. Kretser

 USDA is hosting a symposium on June 12 in honor of Dr. John Milner. The symposium will have 6 presentations, including a presentation from Dr. Richard Black, PepsiCo Inc. on PPPs. Dr. Black will include information about A Partnership



for Public Health: *Branded Food Products Database* as he serves as the co-chair of the Steering Committee. This will be another good opportunity for the Partnership to gain visibility.

#### III. Proof of Concept: A Partnership for Public Health: Branded Food Products Database

# A. Kretser A. Kretser

#### a. Meeting with USDA Under Secretary on PPP Progress Report

- i. Ms. Kretser shared that the 3 Partners met with USDA Under Secretary Dr. Catherine Woteki on 7 Feb to discuss the Partnership Progress Report that she received on 18 January 2014. The 200 page Progress Report served to document and chronicle all of the activities of the PPP over the past year including the development of the groups. The report explains how the Partners have used the 12 principles to guide the establishment and operation of the initiative and the importance of transparency in how decisions were reached and the key players involved in the initiative.
- ii. Dr. Woteki was tremendously appreciative of all the work that has been completed in such a short period of time. She approved the Progress Report and requested a 90-day and a 12 month budget be developed. The Partnership responded to USDA with developed budgets for the 90-day period and the first 12 months on 27 February, 2014 and after some discussions, a final budget was sent to USDA on 8 April, 2014. Both budgets were approved on 21 May and funds from USDA will be allocated for the project.
- iii. Once the Specific Cooperative Agreement is put in place between USDA and the ATP Foundation and the funds for the 90-day beta test are transferred, the ATIP Foundation can proceed to sign the contract with FSEnet, the chosen GS1 certified data pool provider.

#### **b.** Implementation Phase

#### A. Kretser

- i. Budget
  - Ms. Kretser shared that the proposed Partnership budget from the ATIP Foundation and ILSI North America for the 90-day beta test and the remaining 9 months of the first year was approved by USDA. USDA and the



ATIP Foundation are working on a Specific Cooperative Agreement to transfer the funds.

#### ii. Beta Testing

- Once the contract with FSEnet, the GS1 certified data pool provider, is signed with the ATIP Foundation, there will be a 45 day period to set up and configure the portal to receive published data from manufacturers.
- 2. The beta test includes 5 beta test companies: Campbell Soup Company, Cargill, Incorporated, ConAgra Foods Inc., General Mills Inc. and Red Gold. Ms. Kretser shared that Red Gold, a medium sized canned tomato company, is not a current member of the GS1 community so they will test the non-GS1 portal. The Partners have agreed to bear the cost of having this portal so that those outside the GS1 community can participate in the initiative. FSEnet has already established this portal.
- 3. The Partners plan to hold a mapping exercise with the 5 beta test companies to finalize the attributes.

#### iii. Outreach Strategy

- In anticipation of the Partnership budget being approved by USDA, the Communications Group has developed several outreach documents at the request of the Steering Committee. A Value Proposition document and a document on the Features of the Enhanced USDA National Nutrient Database have been developed.
- 2. As part of the outreach strategy developed by the ATIP Foundation, 7 categories of stakeholders have been identified who have a vested interest in the success of the Branded Food Products Database. The ATIP Foundation will lead outreach to these 7 categories for data submission and financial support. ILSI North America will provide subject matter support to the ATIP Foundation but will not participate in the funding ask.
- 3. The Academy of Nutrition and Dietetics (AND) has already expressed interest in financially supporting this initiative and becoming an inaugural supporter. We also anticipate that proprietary databases may be another key



source of funding as they realize the positive impact of this initiative on their business models.

- ILSI North America has continued to stress to the Partners that the contribution of the food industry is the submission of the data and not funds. Data submission is a crucial role and without data, there will not be a database.
- ILSI North America plans to schedule a conference call with the ILSI North America official representatives to discuss a pledge letter for manufacturers to sign pledging that their company will submit data to the Branded Food Products Database.
- Dr. Daryl Lund noted that the Value Proposition covers all interested parties except the key value for consumers and suggested that this should be included.
  - a. Dr. Hentges noted that the Partnership has not identified a direct to consumer group yet to engage but have thought of philanthropic organizations for the ATIP Foundation to coordinate outreach to.
  - b. Dr. Jennifer Van de Ligt shared that she would like to discuss the outreach to consumers further with the ATIP Foundation. Consumers are a large group and if the Partnership could resonate on a consumer level and could bring in small monetary donations, the funds could become pretty substantial.
  - c. The idea will be taken back to the Communications Group.
- 7. It was noted that PPPs are extremely challenging and require dedication. If the government does not move forward, the Partnership is in a stand-still. For ILSI North America, as we look to get involved in PPPs in the future, serious thought needs to be put in beforehand. It was suggested that the Board discuss the Partnership at Mid-year and what it means for ILSI North America's reputation to be a part of public-private partnerships. There are huge benefits to participating in PPPs, but they can also have unintended challenges.



- Dr. Johanna Dwyer commented that the potential success of this Branded Food Products Database initiative will be an enormous plus for ILSI North America. This is a different level of collaboration than we have had before.
- 9. Ms. Kretser shared that the principles that have been developed are playing out. The Partners have had the opportunity to work together as a team and develop trust but it doesn't come easily and the Partners have to work at it every day but tremendous progress has been made.

#### IV. GMA's Consumer Information Transparency Initiative

#### **E.** Hentges

- a. Dr. Hentges noted that many ILSI North America member companies have seen this GMA Consumer Information Transparency Initiative (CITI) and have inquired how the initiative works with the *Branded Food Products Database*. ILSI North America has kept in close contact with GMA and FMI on this initiative and have continued to brief them on updates to the *Branded Food Products Database*. The two initiatives will be synergistic and will complement each other as both are using the GS1 system so manufacturers will only have to submit their data once and can send it to both initiatives.
- b. The CITI initiative will focus on the consumer and plans to set standards within GS1 for 3,000 new attributes. Defining these new attributes benefits the *Branded Food Products Database* as manufacturers can potentially submit these same attributes in the future if the Partnership agrees.

#### V. Support of Professional Societies of COI PPP Principles

# E. Hentges

- a. Dr. Hentges noted that this subject was brought up at Annual Meeting 2014 and the possibility of a summit or collection of major professional societies and federal agencies coming together in support of the PPP principles was discussed. At the conclusion of the summit, the professional societies would agree to a consensus statement on private funding for research and general acceptance of principles for PPPs, such as the Obesity Society Statement.
- b. The professional societies that ILSI North America has already spoken to, including the American Society for Nutrition (ASN), Institute of Food Technologists (IFT), and AND, and



all are supportive of the summit. Planning has begun to bring these societies together at the end of 2014.

c. Dr. Lund noted that it might be helpful for societies who publish journals to have their editors participate in summit.

#### VI. GRAS Assessment

#### E. Hentges

- a. Dr. Hentges shared that pulling together a meeting to develop best practices to reduce bias when putting GRAS assessment panels together had been brought up at Mid-Year 2013 and again at Annual Meeting 2014. However, ILSI North America has not had the staff resources to dedicate to this thus far.
- b. Dr. Hentges noted that ILSI North America is looking to develop this project as a Board Task Force which would use the board contingency fund.
- c. The Working Group felt that the Conflict of Interest Summit idea seems to overlap with the GRAS Assessment project and wondered if there was a way to combine the two projects.
  - i. Dr. Hentges noted that there is synergism between the two projects. FDA intends to develop a conflict of interest document in the fall of 2014 so it would be beneficial to have a manuscript to share with FDA on best practices for advisory committees. The conflict of interest summit development may take longer to get together. The manuscript from the GRAS Assessment could be shared at the summit.
- d. Dr. Lund brought up an earlier idea from the Working Group to speak with IFT about creating a tutorial that could be used as an education tool about GRAS assessment.
  - Dr. Hentges informed the Working Group that IFT is developing a project along a similar vein. ILSI North America does not have a real education channel so this project has not progressed. Dr. Hentges plans to discuss the topic with Will Fisher, IFT, further as IFT is the logical organization to carry out this project.

#### VII. Next Steps

#### D. Lund

- a. Dr. Lund outline the next steps for the ongoing projects, including:
  - i. Implementation and outreach of A Partnership for Public Health: Branded Food Products Database, including a successful beta test.



- ii. Scheduling time to discuss the pledge letter for data submission with ILSI North America official representatives.
- iii. Planning of the Conflict of Interest Summit of Professional Societies
  - 1. If Working Group members have suggestions of other professional societies to engage, please share.
- iv. GRAS Assessment
  - 1. ILSI North America will move forward with the development of a paper and will look into developing a tutorial on GRAS and GRAS process. Explore the possibility of integrating the GRAS and COI Summit projects by sharing the GRAS paper on the selection of GRAS panels at the Summit meeting.
- b. Dr. Ferg Clydesdale suggested looking at opportunities for collaboration with IOM and the Food Forum, particularly with the GRAS qualifications.

VIII. Adjournment

A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

#### Thursday, 29 May, 2014, 10:00-11:30 am EDT

#### **Attendees**

Daryl Lund, chair Fergus Clydesdale Johanna Dwyer John Erdman Rachel Goldstein Eric Hentges Alison Kretser Richard Lane Beate Lloyd Delia Murphy Juan Navia Joseph Ratliff Shawn Sullivan Jennifer van de Ligt Liz Westring

#### **Unable to Attend**

David Allison Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle James Hill Joanne Lupton Debra Miller Amy Preston Claudia Riedt Steven Rizk Kari Ryan David Thomas Wamwari Waichungo Sharon Weiss

University of Wisconsin, Madison University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign Mars, Incorporated ILSI North America ILSI North America PepsiCo Inc. Coca-Cola Company ILSI North America McNeil Nutritionals, LLC Dr Pepper Snapple Group ILSI North America Cargill, Incorporated General Mills Inc.

University of Alabama at Birmingham Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia University of Colorado Health and Wellness Center Texas A&M University The Hershey Company The Hershey Company Dr Pepper Snapple Group Mars, Incorporated Kraft Foods Group, Inc. Dr Pepper Snapple Group Coca-Cola Company **ILSI** North America

# Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm (Continental Breakfast Available Starting at 8:30am)

# Agenda

### Meeting Goals/ Objectives:

- 1. Agreement on purpose and goals
- 2. Agreement on statement of task
- 3. Agreement on a set of general principles for nutrition-related research public-private partnerships
- 4. Action items with deadlines delineated

#### Facilitator: Sylvia Rowe

Welcome and Introductions	Sylvia Rowe	9:00am
Purpose and Context	David Klurfeld; Eric Hentges	9:30
Importance of Public-Private Partnerships	Cathie Woteki	9:45
Review of Statement of Task	Sylvia Rowe	10:15
Discussion of General Principles	Sylvia Rowe	11:00
Lunch		12:00pm
Continued Discussion	Sylvia Rowe	1:00
Wrap-Up and Next Steps	Sylvia Rowe; David Klurfeld; Eric Hentges	3:30

#### **Additional Materials**

- 1. Roster
- 2. Principles from Rowe et al, 2013 Paper
- 3. Comments about the Principles (as of Nov. 19 noon)
- 4. Rowe et al, 2013 Paper
- 5. Statement of Task (SOT) with Timeline and Reference Links
- 6. Links to References for Context

#### Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm

#### **Meeting Attendee List**

Sonja Connor, MS, RDN, LD President, Academy of Nutrition and Dietetics Research Associate Professor Department of Medicine Oregon Health Sciences University Portland, OR connors@ohsu.edu

Rosa K. Hand, MS, RDN, LD Senior Manager, Dietetics Practice Based Research Network Academy of Nutrition and Dietetics Chicago, IL

Mary Beth Whalen Chief Operating Officer Academy of Nutrition and Dietetics Executive Director, Academy Foundation Chicago, IL

Michael H. Stolar, PhD Senior Vice President, American Gastroenterological Association Bethesda, MD

Dorothea K. Vafiadis, MS, FAHA Director, Healthy Living American Heart Association Washington, DC

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Wendy Johnson-Askew, PhD, MPH Chair, Food and Nutrition Section American Public Health Association Vice President for Corporate Affairs Nestle Florham Park, NJ John E. Courtney, PhD Executive Officer American Society for Nutrition Bethesda, MD

Robert M. Russell, MD Chair, American Society for Nutrition Foundation Board of Trustees Arlington, MA <u>rob.russell@tufts.edu</u>

Patrick J. Stover, PhD President-Elect, American Society for Nutrition Professor and Director Division of Nutritional Sciences Cornell University Ithaca, NY pjs13@cornell.edu

Barbara Bowman, PhD Director, Division for Heart Disease and Stroke Prevention National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention Atlanta, GA <u>Bbb8@cdc.gov</u>

Laura Pillsbury Food Technologist Office of Foods & Veterinary Medicine U.S. Food and Drug Administration Silver Spring, MD laura.pillsbury@fda.hhs.gov

Robert A. Burns, PhD Vice President, Health and Nutrition Policy Grocery Manufacturers Association Washington, DC Christie Tarantino, FASAE, CAE Executive Vice President Institute of Food Technologists Chicago, IL

Janet Collins, PhD, RD, CFS Past President, Institute of Food Technologists Senior Manager, Corporate Regulatory Affairs DuPont Washington, DC

Mary Ellen Camire, PhD President, Institute of Food Technologists Department of Food Science and Human Nutrition University of Maine Orono, ME mary.camire@umit.maine.edu

Donald L. Zink, PhD President, International Association for Food Protection Senior Science Advisor Center for Food Safety and Applied Nutrition US Food & Drug Administration College Park, MD donald.zink@fda.hhs.gov

David W. Tharp, CAE Executive Director International Association for Food Protection Des Moines, IA

Alison J. Kretser, MS, RD Director, Science Programs International Life Sciences Institute North America Washington, DC

Eric Hentges, PhD Co-chair, Working Group V. Collaborative Process Executive Director International Life Sciences Institute North America Washington, DC

Van S. Hubbard, MD, PhD Director, National Institutes of Health Division of Nutrition Research Coordination Rear Admiral, U.S. Public Health Service (*Ret.*) Bethesda, MD hubbardv@mail.nih.gov Nancy J. Emenaker, PhD, MEd, RD Health Sciences Administrator Division of Cancer Prevention National Cancer Institute National Institutes of Health Bethesda, MD emenaken@mail.nih.gov

Lisa Kaeser, JD Program Analyst Office of Legislation and Public Policy Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health Bethesda, MD kaeserl@mail.nih.gov

Charlotte Pratt, MS, PhD, RD Program Director, Clinical Applications and Prevention Branch Division of Prevention and Population Sciences Division of Cardiovascular Sciences National Heart, Lung, and Blood Institute National Institutes of Health Bethesda, MD prattc@nhlbi.nih.gov

Paul M. Coates, PhD Director, Office of Dietary Supplements National Institutes of Health Bethesda, MD coatesp@od.nih.gov

Catherine Woteki, PhD Under Secretary, Research, Education, and Economics Chief Scientist US Department of Agriculture <u>Catherine.Woteki@osec.usda.gov</u>

Pamela Starke-Reed, PhD Deputy Administrator, Nutrition, Food Safety and Quality Agricultural Research Service, US Department of Agriculture Beltsville, MD Pamela.Starke-Reed@ARS.USDA.GOV

David M. Klurfeld, PhD Co-chair, Working Group V. Collaborative Process National Program Leader, Human Nutrition Agricultural Research Service, US Department of Agriculture Beltsville, MD david.klurfeld@ars.usda.gov Dionne Toombs, PhD Director, Division of Nutrition Institute of Food Safety and Nutrition National Institute of Food and Agriculture US Department of Agriculture Washington, DC dtoombs@nifa.usda.gov

Robert Brackett, PhD Member, Working Group V. Collaborative Process Director and Vice President, National Center for Food Safety and Technology Illinois Institute of Technology Institute for Food Safety and Health Chicago, IL rbrackett@iit.edu

Ratna Mukherjea, PhD Member, Working Group V. Collaborative Process Global Nutrition Leader DuPont Nutrition & Health St Louis, MO

Sylvia Rowe, PhD President SR Strategy, LLC Washington, DC

Nick Alexander Science Writer

Linda Meyers, PhD Senior Science Advisor American Society for Nutrition Bethesda, MD

Delia Murphy Science Program Associate International Life Sciences Institute North America Washington, DC

# Statement of Task: Achieving a Transparent, Actionable Framework for Food and Nutrition Research-Related Public-Private Partnerships

### **Overview**

There is an urgent need for an expanded, rigorous, and focused research agenda in food and nutrition that is driven by increased awareness that food, nutrition, and human health are closely linked through complex interactions, and a recognition that associated costs contribute substantially to rising national health care expenditures. New research approaches are critically needed to capitalize on our current understanding of the role of food and food systems in chronic disease prevention and management and to translate this knowledge into the development of public health interventions, innovative products, and evidence-based policies that meet the public's expectations and support the health of the nation. However, government resources devoted to food and nutrition research are shrinking, stifling economic growth and innovation in the food and nutrition sector and delaying the opportunity to better harmonize the food system and human health.

Public-private partnerships (PPPs), collaborative relationships involving partners from government, industry, and academia, are increasingly appreciated as a novel approach to simultaneously advance public health and a 21<sup>st</sup> century food and nutrition research agenda, resulting in a food system that can support both consumer and commercial interests in the development of new products and markets. PPPs are the only mechanism known to bring together the best scientists from all sectors with distinct, yet complementary, expertise and perspectives. By bringing expertise from diverse disciplines and sectors together to address research questions where public health and other benefits are achievable, PPPs combine and maximize multidisciplinary resources in a time when financial and other resources devoted to food and nutrition research are limited. Risks can be largely shared and the comprehensive approach necessary to address today's complex scientific questions is best achieved through the involvement of multiple disciplines and partners.

PPPs are not always the best approach to investigate certain areas of food and nutrition research. A roadmap is necessary to help organizations understand when to use PPPs for food and nutrition research and how to use and operate PPPs most efficiently and effectively. While several groups have developed principles for the creation of food and nutrition partnerships (3<sup>rd</sup> World Conference on Research Integrity, 2013; Institute of Medicine, 2012; Canadian Institutes of Health Research, 2008), such principles have generally been developed in silos and may not be actively used by the various types of organizations to determine when and how to undertake a PPP. Rowe et al. (2013) sought to compile existing guidelines using a 3-step process which resulted in the articulation of 12 potential principles for establishing and managing successful research PPPs.

Thus, this activity aims to stimulate the expansion, accessibility, and acceptance of PPPs by unifying and moving existing principles for food and nutrition research PPPs forward, making them publicly available for all interested parties to reference and use. Numerous food and nutrition research professional/scientific societies, non-profit research foundations, and federal

agencies will be involved in the identification of these principles, and agreement and endorsement of the unified set of PPP principles will be gained from additional stakeholders, representing a collective effort to achieve the best research outcomes possible. With such widespread involvement and endorsement, it is hoped that this framework will be broadly used by the collaborating organizations and others to create PPPs that will ultimately improve public health.

This activity is part of the work of the government-wide Interagency Committee on Human Nutrition Research (ICHNR) to build food and nutrition partnerships that began in 2011. Four research areas with the greatest potential for both public health impact and implementation feasibility emerged: (1) Food Composition and Nutrition Monitoring; (2) Biomarkers; (3) The Microbiome, and (4) Consumer Behavior. Working groups with representation from government, academia and industry were created. A fifth working group on Collaborative Process was also created to identify characteristics of successful PPPs and potential barriers to success. This activity carries on the work of Working Group V. Collaborative Process, co-chaired by David Klurfeld, Ph.D., USDA/ Agricultural Research Service (ARS) National Program Leader in Human Nutrition, and Eric Hentges, Ph.D., Executive Director of the International Life Sciences Institute North America. Other members of Working Group V are Robert Brackett, Ph.D., Illinois Institute of Technology Vice President and Director of the Illinois Institute for Food Safety and Health, and Ratna Mukherjea, Ph.D., Global Nutrition Leader at DuPont Nutrition & Health.

Through a cooperative agreement with USDA/ ARS, the American Society for Nutrition (ASN) will convene representatives from: USDA, ASN, the Academy of Nutrition and Dietetics (AND), American Heart Association (AHA), American Gastroenterological Association (AGA), the Food and Nutrition Section of the American Public Health Association (APHA), the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Grocery Manufacturers Association (GMA), Institute of Food Technologists (IFT), International Association of Food Protection (IAFP), International Life Sciences Institute North America (ILSI North America), and the National Institutes for Health (NIH) to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

#### **Project Goals/ Objectives**

The main purpose of the face-to-face meeting is to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

- The framework will be developed in partnership by key food and nutrition-related federal agencies, non-profit research foundations, and professional societies. Sign on to the principles will be sought from all partners and other relevant organizations.
- The framework will be made publically available to be used as a model by interested public and private organizations. Commitment is needed from all involved to promote the principles, including publishing the framework in the relevant publications of each partner organization, as applicable.

• Commitment is needed from all involved to update the framework on a regular, as-needed basis, to enhance the value and sustainability of the framework.

#### **Process for Moving Forward**

The following timeline for action will facilitate the achievement of the expected goals and objectives. The timeline can be altered at any time for sufficient flexibility. However, a sense of urgency should be encouraged and maintained in order to achieve the optimal outcome.

- Initiate 1<sup>st</sup> outreach to secure commitment from all relevant professional/scientific societies, non-profit research foundations, and federal agencies (henceforth known as collaborators) for involvement on the proposed project.
- Hold preliminary conference call for collaborators on September 5, 2014.
- Collaborators agree to Statement of Task *by October 10, 2014*. In doing so, all collaborators agree to assist with achievement of goals/objectives as outlined in the statement of task.
- Begin discussions with publishers of relevant journals to secure agreement to publish framework and assure coordination of deadlines, etc. *in November 2014*.
- Hold meeting of collaborators in Washington, D.C. *on December 8, 2014* to develop a transparent, actionable framework for food and nutrition research-related PPPs.
- Identify date and location *by January 16, 2015* for a meeting to publicly unveil framework. This will be an invite-only stakeholder meeting, ideally hosted at the location of an independent public agency, such as the <u>Government University Industry Research</u> <u>Roundtable (GUIRR) of the National Academy of Sciences</u>.
- Secure sign on and promotional support for the framework from collaborators *by March 16*, *2015*. Securing such support may require gaining Board and membership approval(s), as applicable.
- Conduct outreach to relevant organizations that may wish to sign on to the framework *by March 16, 2015.*
- Publish framework and other relevant materials in applicable journals *Target*: April 2015.
- Create program including topics and speakers for public unveiling of the framework that will clearly articulate goals/objectives and framework *by April 1, 2015*.
- Develop and finalize invitation list for public unveiling of framework. Send joint invite from collaborators *by April 17, 2015*.

• Announce the framework at public unveiling meeting – *Target: May 12, 2015.* Engage all attendees in the dialogue and secure their commitment to share and implement the framework.

## Public-Private Partnership References

- <sup>3<sup>rd</sup></sup> World Conference on Research Integrity. "Montreal statement on research integrity in crossboundary research collaborations." Montreal, Canada. May 2013. <u>http://www.cehd.umn.edu/olpd/montrealstatement.pdf</u>
- Rowe S, Alexander N, Kretser A, Steele R, Kretsch M, Applebaum R, Clydesdale F, Cummins D, Hentges E, Navia J, et al. Principles for building public-private partnerships to benefit food safety, nutrition, and health research. *Nutr Rev* Oct 2013;71:682-91. http://www.ncbi.nlm.nih.gov/pmc/articles/pmc3886300/
- Institute of Medicine. 2012. Building public-private partnerships in food and nutrition: Workshop summary. Washington, DC: The National Academies Press. https://www.ncbi.nlm.nih.gov/books/nbk97331/
- Canadian Institutes of Health Research. 2008. "Building trust to address the obesity epidemic workshop report." King City, Ontario. The Building Trust Initiative. http://buildingtrustinitiative.files.wordpress.com/2011/05/building-trust-report-vol-1.pdf

#### A Partnership for Public Health



#### Features of the Enhanced USDA National Nutrient Database

The goal of the Public-Private Partnership is to expand the current nutrient data by obtaining compositional data directly from the food industry. An expanded database will contain much more information on individual food items allowing for a true assessment of the extent and fluidity of the food system.

Nutrition Facts Serving Size 2/3 cup (55g) Servings Per Container About 8	1.	<ul> <li>Parent Company (Manufacturer, Subsidiary, signature line) or Private</li> <li>Label (signature line)</li> <li>Enhanced database will allow for more specific data collection</li> </ul>		
Amount Per Serving		and analysis in NHANES; allowing for more specific assessment		
Calories 230 Calories from Fat 40		of foods eaten by the population.		
% Daily Value*	2.	2. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when		
Total Fat 8g 12%	-	available)		
Saturated Fat 1g 5%				
Trans Fat 0g		• Information available as packaged and as prepared, with		
Cholesterol Omg 0%		added ingredients		
Sodium 160mg 7%		• No longer will a nutritional value be based on an averaged or		
Dietory Eiber 4a		generic database value		
Sugars 10		Server e autorise variae.		
Protein 3g	-	If someone reports having eating		
Protein Sy	3.	Product name and generic descriptor		
Vitamin A 10%	4.	Weights and measures		
Vitamin C 8%	5.	Serving size and servings per package		
Calcium 20%		the actual brana item consumea.		
Iron 45%				
Your daily value may be higher or lower depending on your calorie needs. Calories: 2,000 2,500 Total Fat Less than 65g 80g Sat Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g	6. 7.	<ul> <li>Date Stamp associated with most current formulation (effective date of change/introduction)</li> <li>Historical data on food products will allow for tracking dietary trends.</li> <li>Ingredient list and sub-list (hierarchical and in descending order)</li> </ul>		
INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, HEDUCED Iron, Thiamin Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Foild John Greun Schurd Schurd And Dan Mai (Anth Tand		• This information has never been captured before in the National		
FOR FRESHNESS), CORN SYRUP SOLIDS, DEXTROSE, HIGH FRUCTOSE CORN SYRUP FRICTOSE, GIVERNIN, CONTAINS 2%, OR LESS OF CACAA		Nutrient Database. Having this information available will allow		
(PROCESSED WITH ALKALI), POLYDEXTROSE, MODIFIED CORN STARCH, SALT, DRIED CREAM, CALCIUM CARBONATE, CORNSTARCH, LEAVENING (BAKING		for analysis that has never been done.		
SODA, SODIUM ACID PYROPHOSPHATE, MONOCÁLCIUM PHOŠPHATE, Calcium Sulfate), distilled monoglycerides, hydrogenated Palm	8.	GTIN Number		
KENNEL DIL, SJOUM STEARDYL LACYTALE, GELNIK, COLOR ANDED, SDY LEGTIHL, DATEM, MATURAL AND ANTIFICIAL, FLAND, WAILLA ETRACT, CARNAUSA WAX, XANTHAN GUN, VITAMIN A PALMITATE, YELLOW & LAKE, RED 40 J. DAKE, CARANEL COLOR, NICHANNER, BLUK & V. LAKE, REDUCED IRON, YELLOW & LAKE, PRIDOXICA, HOROCILIORIC VITAMIN BJ, RIBO- FLANN VITAMIN BJ, THAMIN MTOROCILIORIC VITAMIN BJ, RIBO-	/	<ul> <li>Specific nutrient composition directly from the food product, correlated to this number, will be available.</li> </ul>		
5 901234 123457 >	s f E	Food composition databases are central to the conduct of nutrition research, as they tandardize how foods can be characterized in terms of nutrients, dietary guidance-based food groups and other relevant dietary constituents. A Partnership for Public Health: Branded Food Products Database will provide researchers the first-ever completely free and		
	р g	nublicly available database on the composition of foods by brand name. This will enable greater specificity in all types of nutrition studies of individual's diets and food		

environments."

- Dr. Susan Krebs-Smith, National Institutes of Health



# Agenda: **Best Practices Workshop for ILSI North America Members** For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Conference Call Dial-in information: 1-888-585-9008, Access code: 327847914

Purpose: The Best Practices Workshop is being held for ILSI North America member companies in preparation for full implementation of A Partnership for Public Health: Branded Food Products Database.

I.	Welcome and Introductions	A. Kretser
II.	GS1 Source	A. Fernandez/ S. Brown
III.	Overview of the Beta Test	R. Rosenbaum/ M. Hamilton
IV.	Perspectives from Beta Test Companies	Beta Test Companies
V.	Questions and Discussion	All
VI.	Data Submission to FSEnet Prior to Full Implementation	R. Rosenbaum
VII.	Pledge Letter and Press Release	A. Kretser
VIII.	Next Steps	A. Kretser
IX.	Adjournment	A. Kretser


# Attendance: Best Practices Workshop for ILSI North America Members For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Attendees Scott Brown Donna Courtney **Bill Ferguson** Angela Fernandez Merissa Hamilton Alison Kretser Kyle McKillop Timothy Morck Alanna Moshfegh Matt Muldoon Rachel Murphy Delia Murphy **Debbie** Nece Rob Rosenbaum Trish Zecca Attending via Conference Call Nick Alexander Jennifer Bauman Cathy Bone Chris Chatzidakis David Cockram Richard D'Aloisio Christine Downs Lori Fix Judy Gluvna Kristin Harris Paul Hoffman Katlyn Kutzlo Minh Le Shannon Lytle Michael Marino Debra Miller Gary Montgomery Sheila Ost Eric Park Claudia Riedt

GS1 The Hershey Company Kellogg Company GS1 FSEnet **ILSI** North America University of Maryland Nestle USA USDA ARS FSEnet **DSM Nutritional Products ILSI North America** Cargill, Incorporated **ATIP** Foundation Campbell Soup Company SR Strategy

Campbell Soup Company Monsanto Company ConAgra Food Inc. Abbott Nutrition Mondelez International Abbott Nutrition Unilever Abbott Nutrition Hillshire Brands Kraft Foods Group Inc. Red Gold, Inc. Herbalife International of America, Inc. Red Gold, Inc. Kellogg Company The Hershey Company Abbott Nutrition ConAgra Foods Inc. Monsanto Company Dr Pepper Snapple Group



Andrew Shao Lynette Shawd Jennifer Van de Ligt Casey Zanis

Unable to Attend Doug Balentine **Richard Black** Greg Buckley Philippe Caradec Joseph Carlos Stuart Craig Brent Flickinger Jennifer Garrett Llaine Groninger Leslie Henderson Becki Holmes Cassie Hoover Christina Khoo Dot Lagg Suzanne Lee Beate Llovd Mark Maier Michael McBurney Susan McKee Mark Moorman Phil Morreale Matthew Muldoon Gabriella Parisse Christine Pelkman Fred Shinnick Miro Smriga Steve Rizk Sylvia Rowe Juan Navia Brian Schaneberg Stephan Theis Cass Wade-Kudla David Walsh Liz Westring Paul Zanno

Herbalife International of America, Inc. General Mills Inc. Cargill, Incorporated Herbalife International of America, Inc.

Unilever PepsiCo Inc. PepsiCo Inc. Danone Waters of America, Inc. Abbott Nutrition DuPont Archer Daniels Midland Company McCain Foods USA The Hershey Company Mondelez International Red Bull GmbH Nestle USA Ocean Spray Cranberries, Inc. Mars Chocolate North America Nestle USA The Coca Cola Company Valspar Corporation **DSM** Nutritional Products Kraft Foods Group Inc. Kellogg Company Mondelez International FSEnet Tate & Lyle Ingredion Incorporated Senomyx, Inc. Ajinomoto North America, Inc. Mars, Incorporated SR Strategy McNeil Nutritionals, LLC Starbucks Corporation BENEO General Mills Inc. Herbalife International of America, Inc. General Mills Inc. Dr Pepper Snapple Group

# A Partnership for Public Health: Branded Food Products Database







# Pledge Letter

As a member of ILSI North America and a food/ingredient manufacturer, we are signing this voluntary pledge letter to submit nutrient composition and label data on behalf of A Partnership for Public Health: *Branded Food Products Database*. We commit to using GS1 standards through an ATIP Foundation contracted GS1 certified data pool provider for inclusion as part of an enhanced USDA National Nutrient Database. We are aware this data will become publically available once received by the USDA National Nutrient Database. The proposed addition of branded food compositional data to the USDA National Nutrient Database is an essential tool for developing research strategies to inform public policy regarding food and nutrition and will create a database more truly reflective of the breadth and depth of the nation's food supply. Various sectors of the research community and the food and health care industries will find this database valuable. For example, this will enhance the National Health and Nutrition Examination Survey (NHANES) by more accurately characterizing food selection and nutrient intakes for Americans; nutrition software developers can produce enhanced software so that dietitians will be able to better tailor diets to nutritional needs; medical researchers will be able to better link dietary intakes to measures of optimal health; authoritative scientific bodies will be able to develop better guidelines that will promote public health; and food manufacturers could use this to improve product formulations.

The enhancements brought about by this Public-Private Partnership will ensure that USDA ARS nutrient composition data will remain the "Gold Standard" for the next decade and beyond.

The following information (attributes) will be submitted. These attributes are currently on the food packaging label. However, by providing these attributes in the GS1 format, it is possible to have the most up-to-date version of this data available to the public through the USDA National Nutrient Database.

- 1. Parent Company (manufacturer, subsidiary, signature line) or Private Label (signature line)
- 2. Product Name and Generic Descriptor
- 3. Global Trade Item Number (GTIN)
- 4. Ingredient List and Sub-List (hierarchical and in descending order)
- 5. Weights and Measures (net weight/volume of package)
- 6. Serving Size and Servings per Package
- 7. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)
  - a. (as packaged and as prepared with added ingredients)
- 8. Date Stamp associated with most current formulation (effective date of change/introduction)

By signing this pledge letter, our company will be recognized as an inaugural participant of A Partnership for Public Health: *Branded Food Products Database*. Our company's name will be included in the list of inaugural participants that will be part of the Partnership press release on the initiative.

Signature:	Date:	
Company Name:		

# A Partnership for Public Health



Branded Food Products Database

# <u>A Partnership for Public Health: Branded Food Products Database</u> Value Proposition

# **Story of the Partnership**

Assessing the nutritional health of the American people depends on accurate and comprehensive data regarding the nutrient composition of commonly consumed foods. USDA's Agricultural Research Service (ARS) maintains a National Nutrient Database of the composition of such foods, and although the food industry has compositional data for their own products, very little of that data is publicly available through the database. As part of USDA's response to the Presidential Memorandum in October 2011, ARS approached ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information. Previous efforts by USDA on their own had seen limited success which is not unexpected given the volume and fluidity of branded food products in the U.S. marketplace.

Accordingly, the USDA, the International Life Sciences Institute (ILSI) North America and the ATIP Foundation (Agricultural Technology Innovation Partnership) have formed a Public-Private Partnership to enhance public health by augmenting the USDA National Nutrient Database with "nutrient composition of branded foods and private label" data provided by the food industry. This Partnership will ensure this information will be made publically available to those who utilize such data including the federal agencies, the research community, proprietary databases and end users, and the food industry.

The Partnership has established expert groups whose representation is made up of federal government agencies, academic nutrition researchers, a non-government organization (NGO), and ILSI North America member scientists. These expert groups, with additional input from two listening sessions, submitted recommendations for approval by the Steering Committee and, ultimately, these were approved by Dr. Catherine Woteki, USDA Under Secretary for Research, Education, and Economics (REE) and Chief Scientist. These recommendations included specific attributes that will be submitted to the enhanced USDA National Nutrient Database. More work remains to be done and supporters will have the opportunity to participate in these discussions.

Enhancement of the USDA National Nutrient Database through this Public-Private Partnership will be conducted in phases, with information from the Nutrition Facts Panel being obtained first and other, more detailed information being obtained at later stages. The database enhancement is also tied to changes in the infrastructure of the USDA National Nutrient Database that will allow the data to be accessed and utilized more efficiently. The changes brought about by this Public-Private Partnership will ensure that USDA nutrient composition data will remain the "Gold Standard" for the next decade and beyond.



A public-private partnership provides the framework to convene the expertise to compile nutrient data on branded and private label products, secure the private sector engagement in providing this information, as well as the broad-based constituent funding necessary to maximize content and provide timely information for nutrition, agricultural and diet-related health policy on the nutrient composition of the U.S. food supply.

# What are the Benefits to Participating in the Partnership?

Corporations and organizations can participate either as providers of branded or private label food product nutrition data, or as financial contributors to support the development and sustainability of the enhanced USDA National Nutrient Database. The ATIP Foundation will acknowledge participants on the Foundation website pages under the Partnership logo. The listing of participants verifies the commitment of professional societies, organizations, and corporations that support this important initiative who will become members of the Sustaining Stakeholder Council. The Sustaining Stakeholder Council will review progress and make recommendations to the Partnership.

# How will Success be Measured?

There are many indicators of success for this initiative. For example, the Partnership will have achieved success when thousands of branded and private label products are integrated in real time into the enhanced National Nutrient Database and timely updates are routine. Success will have been achieved when the database is viewed as the most comprehensive nutrient database. Success can be measured by the breadth of manufacturers- large, medium, and small- who are voluntarily participating. Other goals for measuring success will be met when information provided on an individual food product also includes imputed nutrient data and food groups, and the source of the nutrient values is transparent. USDA will issue comprehensive reports on the nutritional composition of the food supply. Success will also be measured by the presence of a vibrant group of sustaining members who support the long term viability of the enhanced USDA National Nutrient Database. Achievement will be measured by other countries adopting our system.

# Value of Initiative

- Historical data on branded and private label food products will become available. The nutrition research community will benefit enormously from having this information for tracking dietary trends.
- The value of this initiative in the Development Phase has been the governing structure that has established key groups to meet the challenges and achieve the goals set by the Partnership: the Steering Committee, the Operation and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.
  - The Criteria Group developed the set of attributes that were reaffirmed by the listening sessions.
  - The Criteria Group brought together expertise across a broad range of nutrition professionals who developed the data quality system sanctioned by the USDA.



- The IT infrastructure, capitalizing on the established GS1 network, has been designed to be nimble and to accommodate future needs for years to come.
- A Sustaining Stakeholder Council will be made up of supporters (both financial contributors and providers of data) of the initiative. This Council will review progress and make recommendations to the Partnership.
- In the Implementation Phase, the Technical Stakeholder Group will provide a formal process to gather technical, nutritional, analytical, and research information needs, that will facilitate the knowledge and utility that can be derived from the Branded Food Products Database.
- The 12 principles for establishing and operating a public-private partnership are clearly visible within the Partnership.

# Key Value for Government

An expanded database will contain much more information on individual food items allowing for research and policy to be based on a true assessment of the extent and fluidity of the food system.

"The composition of the food supply and consumer dietary choices are key inputs for agricultural and food policy decisions. Comprehensive data can inform these decisions, but the volume and fluidity of branded food products in the U.S. marketplace are key challenges. USDA has concluded that this is best pursued through a public-private partnership led by the ATIP Foundation and ILSI North America that is transparent and inclusive of all facets of the diverse food system in North America."

--- Dr. Catherine Woteki, Chief Scientist and USDA Under Secretary for Research, Education, and Economics

"The American diet is diverse. The addition of nutrition information from branded foods will be a tremendous asset to monitoring the American diet and achievements of industry to make healthier products."

--- Dr. Barbara Bowman, CDC

"Having data on branded food products to supplement the USDA National Nutrient Database will be extremely helpful to FDA in tracking the composition of the food supply and making food policy decisions to promote public health," said Jessica Leighton, PhD, senior nutrition science and policy advisor in FDA's Office of Foods and Veterinary Medicine. "The more accurate picture we have of the nutrient content of the food supply, the better informed our decisions on labeling requirements and encouraging food product reformulation will be."

--- Dr. Jessica Leighton, FDA

# Key Value for Nutrition Researchers

Additional data in the USDA National Nutrient Database will greatly benefit the NHANES survey by allowing for more specific assessment of foods eaten. For example, if a person reports



having eaten an item such as "vegetable soup", instead of the nutritional value being based on an averaged and generic database value, it would be based on the actual brand item consumed, and nutrient composition would be that supplied by the company.

"As a frequent user of the National Nutrient Database, it is with extreme pleasure to hear that the Public-Private Partnership is moving forward. The Harvard School of Public Health maintains a nutrient database for the analysis of semi-quantitative food frequency questionnaires. This database requires accurate and up to date brand data for cereals, margarines, oils, and fortified foods. The Public-Private Partnership would provide a more efficient means for us to maintain this accurate time specific brand data in our system."

--- Laura Sampson Kent, Harvard School of Public Health

# Key Value for Proprietary Database End Users

The enhanced USDA National Nutrient Database will increase the number of food products for end users who develop applications for consumers and health professionals. By expanding the data available for use in private applications, consumers seeking to eat more healthy diets and dieticians with the responsibility of developing specific diets are the beneficiaries of this information.

"A Partnership for Public Health: Branded Food Products Database will be a valuable resource to the University of Minnesota Nutrition Coordinating Center. It will allow us to improve the currency and completeness of our food and nutrient database, which will benefit nutrition researchers across the country who rely on it to carry out nutrition-related studies."

--- Lisa Harnack, University of Minnesota Nutrition Coordinating Center

# Key Value for Professional Societies

- The professional society members rely on the comprehensiveness of the USDA National Nutrient Database for their effort to tease out dietary patterns and nutrient inter-relationships with chronic disease/s.
- The enhanced database will provide more accurate information about what their clients are truly eating.

"The USDA's National Nutrient Database is the basis for the science and evidence-based practice of nutrition and dietetics. This important resource helps clinicians counsel patients, researchers plan projects, and food production experts create menus and products. This unique public-private partnership to expand the database and make it more comprehensively reflect the food supply available to consumers



Branded Food Products Database

is crucial. We believe that ultimately this database expansion will improve the public's health, aligning with our mission."

--- Sonja L. Connor, MS, RDN, LD, President-elect 2013-2014, Academy of Nutrition and Dietetics

# Key Value for Industry

- The enhanced USDA National Nutrient Database will become the single source of truth for nutrition data on branded and private label products.
  - Manufacturers will no longer have to respond to multiple requests from retailers and others and instead direct them to the Database.
- Recognizing that participation in this initiative will be resource-intensive for manufacturers, the Partnership has leveraged the existing GS1 community to ensure alignment with current industry practices.
  - Companies are already submitting product information into the GS1 network.
  - Trust has already been established that the system is secure and manufacturers can assure the accuracy of their shared data.
- Manufacturers recognize that more customers and consumers want virtual nutrition product information and the demand for this information will only intensify in the future.
  - Participation will ensure that your data is included in existing and newly developed nutrition apps that will draw from the augmented Database.
  - Participation will ensure improved customer service for the growing trend in online grocery sales and food delivery systems, such as Amazon, require virtual nutrition information.
- Manufacturers provide extensive recipes on their own websites and would benefit from having more accurate nutrient information on ingredients used in these recipes.

"General Mills is interested in continuing to work with the Public-Private Partnership to eventually provide our customers and consumers with a single source of accurate, up-to-date label information, available electronically through USDA"

--- Elizabeth Westring, General Mills Inc.

"This Partnership seeks to expand the USDA Standard Reference to include up-to-date branded manufacture data. It is critical that this data be available to researchers utilizing intake data, and others monitoring the food supply, in order to accurately represent the nutrition of our products in the marketplace and responsibly inform public policy."

--- Patricia Zecca, Campbell Soup Company

v.11.18.14

North American Branch of the International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743

202.659.0074 voice 202.659.3859 fax www.ilsina.org

# **ILSI North America**

# 2012 Membership Letter on Conflict of Interest Program

The topic of "conflict of interest" (COI) in conducting scientific activities is an issue of continuing concern and importance to the future of research related to nutrition, health, and food and ingredient safety. The purpose of this letter is to provide an analysis of the challenging environment in which we are operating and to gain your support for ILSI North America's (NA) program to address this issue.

ILSI was founded on the premise that there is great benefit to the development and application of science when academia, government, and industry work together to resolve issues of mutual interest. For over 30 years, the work of ILSI—and all its branches have documented this initial premise as a proven fact.

Clearly, it is in the interest of both the food industry and the general public to conduct the research necessary to meet legal requirements, and improve the safety of the food supply. It is equally important that the food industry help advance nutrition and health knowledge on the role of food—including both food ingredients and food components. Much of this research falls outside of the mission of traditional federal funding agencies and would not be done without food industry support and would be a detriment to consumers.

Despite a wealth of benefits industry sponsored research and science programs have provided, there continues to be significant public debate on the credibility of such support. While biases can come from many sources, much of the debate has focused on one area—industry funding. The end result has been the demand by some that all industry-funded research, whether conducted at contract research organizations or universities, be denied consideration in the formulation of public policy. Furthermore, scientists who have conducted industry-funded research have been barred from serving on public advisory committees.

ILSI-NA maintains that the scientific process requires open, transparent examination and honest interpretation of data, regardless of a researcher's affiliation or source of funding. In 2007 the ILSI-NA Board initiated a program to address COI issues. The program has been highly successful in developing "guiding principles" for industry funding of research (see enclosed publication), which have been endorsed by the leadership of three major professional societies. Results of this work have been published in six different peer-reviewed journals and presented at numerous scientific conferences. The next steps involve development of criteria for participation on scientific advisory panels and establishment of appropriate protocols for successful public/private partnerships to advance public health.

Issues related to COI will not be going away anytime soon. Continued engagement by ILSI-NA is required to ensure sound, evidence-based science prevails, and that credible scientists, regardless of affiliation, continue to have a voice in the debate. Our public-sector Trustees have volunteered both their time and expertise in the development of the current program. However—and this fact stunned me-only 20% of ILSI-NA's membership is providing financial support.

As important as this issue is to the food industry, we need all members to support initiatives related to COI. The current assessment for this activity is \$10,000 per company.

So here's my request. Review this letter—at least once more if not twice. I realize it's pretty long and I apologize for same. Post reading, if you have any questions or require further clarification on the current

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202.659.0074 voice 202.659.3859 fax www.ilsina.org

## **ILSI North America**

situation we face, please reach out either to me (W—4046762177; email <u>rapplebaum@na.ko.com</u>) or Eric Hentges (W-2026590074x196; email <u>ehentges@ilsi.org</u>). If additional explanation is needed, we can connect you to other members of the ILSI-NA Board, or to one of ILSI-NA's public-sector Trustees.

Now...if you haven't any questions, I encourage you to contact Eric and pledge your Company's support. It's what we need—it's what your Company needs—it's what the public needs to ensure scientific truth and evidence based deliberations, and decisions prevail.

Thank you for considering the request herein.

Sincerely yours,

Rhona Applebaum, PhD President, ILSI North America

# **Publications/Programs to date:**

• 2009 Guiding Principles

"Funding food science and nutrition research: financial conflicts and scientific integrity" Rowe S, Alexander N, Clydesdale FM, et al. Funding food science and nutrition research: financial conflicts and scientific integrity. Am J Clin Nutr 2009;89:1285–91.

- Simultaneous publication of the paper:
  - ♦ Nutrition Reviews
  - ♦ American Journal of Clinical Nutrition
  - ♦ Journal of the American Dietetic Association
  - $\diamond$  Journal of Nutrition
  - ♦ Journal of Food Science
  - *♦ Nutrition Today*
- Presentations at:
  - ♦ Experimental Biology (EB Conference) April 2009
  - ♦ Institute of Food Technologists (IFT) conference June 9
  - ♦ American Dietetic Association (ADA) conference October 18
- 2011 "Funding Source and Research Report Quality in Nutrition Practice-Related Research" Myers EF, Parrott JS, Cummins DS, Splett P (2011) Funding Source and Research Report Quality in Nutrition Practice-Related Research. PLoS ONE 6(12): e28437. doi:10.1371/journal.pone.0028437
- Rowe S, et al. "How experts are chosen to inform public policy: Can the process be improved?", Health Policy (2013), http://dx.doi.org/10.1016/j.healthpol.2013.01.012

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# **ILSI North America**

- Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research, Rowe, S. et.al *Nutrition Reviews* 2013; 71(10):682-691
- "Branded Food Products Database for Public Health" Public-Private Partnership between ILSI North America, the USDA/ARS, and the ATIP (Agricultural Technology Innovation Partnership) Foundation.
- "Principles and Philosophies for Development of Ongoing Partnerships to Support Food-Health Research", Canadian Nutrition Society and ILSI North America Food for Health Workshop 2014



# Agenda: Working Group on Conflict of Interest & Scientific Integrity **Conference Call**

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

Dial-in information: 1-888-585-9008, Access code: 327847914

Purpose: To update the Working Group on recent activities and discuss future plans.

I.	Welcome and Introductions	A. Kretser
II.	Approval of 29 May Meeting Minutes	D. Lund
III.	Support of Professional Societies of COI PPP Principles	E. Hentges
	a. 8 December Meeting	
	b. 12 May Unveiling	
IV.	A Partnership for Public Health: Branded Food Products Database	A. Kretser
	a. National Nutrient Databank Conference Proceedings	
	b. Beta Test	
	c. Best Practices Workshop	
	d. Pledge Letter	
	e. Outreach Strategy	
V.	GRAS Assessment	E. Hentges
VI.	New Projects	D. Lund
VII.	Next Steps	D. Lund
	a. 2015 In-Person Meeting	
VIII.	Adjournment	A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

#### **Attendees**

Daryl Lund, chair David Allison Fergus Clydesdale Johanna Dwyer John Erdman Eric Hentges Alison Kretser **Richard Lane** Beate Lloyd Joanne Lupton Debra Miller Delia Murphy Claudia Riedt Amy Preston David Thomas Jennifer van de Ligt Connie Weaver

## **Tentative**

Mark Moorman

#### **Unable to Attend**

Rhona Applebaum Stephanie Atkinson Kerr Dow Rachel Goldstein Joseph Ratliff Kari Ryan Shawn Sullivan Liz Westring

### **Unconfirmed**

Nelson Almeida Tom Boileau Michael Doyle James Hill Steven Rizk

University of Wisconsin, Madison University of Alabama at Birmingham University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign ILSI North America **ILSI** North America PepsiCo Inc. Coca-Cola Company Texas A&M University The Hershey Company **ILSI** North America Dr Pepper Snapple Group The Hershey Company Dr Pepper Snapple Group Cargill, Incorporated Purdue University

## Kellogg Company

Coca-Cola Company McMaster University Cargill, Incorporated Mars, Incorporated Dr Pepper Snapple Group Kraft Foods Group, Inc. ILSI North America General Mills Inc.

Kellogg Company Kraft Foods Group, Inc. The University of Georgia University of Colorado Health and Wellness Center Mars, Incorporated

From: Sent: To:	Delia Murphy Tuesday, December 0	2, 2014 7:45 AM	
		; Shawn Sullivan; james.hill@ucdenver.ec	
	Alison Kretser; s	; Joanne Lupton; ; weavercm@purdue.edu; ; DAllison@uab.edu; Sharon Weiss; ; Eric Hentges; ; jwerdman@illinois.edu; fergc@food ;	; mdoyle@uga.edu; dsci.umass.edu; ; dblund@wisc.edu;
	dwyerj1@od.nih.gov;	OffuttS@gao.gov;	
Cc:	Eric Hentges; Alison Kretser		
Subject:	ILSI North America Conflict of Interest & Scientific Integrity Working Group		
Attachments:	COI 2 Dec Call Agenda.doc; Materials 2 Dec Call.pdf		

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Conference Call Agenda and Materials

Please find attached the agenda and materials for the 1 ½ hour conference call with the Working Group this morning, Tuesday, 2 December from 10:00-11:30 am EST.

Please use our conference call number to dial in: 1-888-585-9008 Access code: 327847914

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

A. Kretser

A. Kretser

# Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Thursday, 29 May, 2014, 10:00-11:30 am EDT

# Purpose: To update the Working Group on the Public-Private Partnership (PPP) and recent activities.

### I. Welcome and Introductions

a. Ms. Alison Kretser welcomed Working Group members to the call and led introductions. She noted that the group has not met for 5 months and tremendous progress of activities has been made since that time.

## II. Communications/Publications on PPP

## a. Mid America Food Processors Association Presentation, March 2014 A. Kretser

- i. The 3 Partners of A Partnership for Public Health: *Branded Food Products Database* gave a presentation on the PPP at the Mid America Food Processors Association (MAFPA) Annual Meeting in March 2014. MAFPA invited the Partnership to present after attending the 14 November 2013 listening session in Washington, DC. The Partnership connected with many small and mid-size companies and there was a lot of interest and support for the project. MAFPA has committed its membership to lead the small and mid-size companies in the submission of data.
- ii. Coming out of meeting, Red Gold, a mid-sized company that produces canned tomatoes, has agreed to be part of the beta test.

# b. "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," *Nutrition Today*, March 2014

- "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," is a recent publication by Sylvia Rowe and Nick Alexander that focuses on PPPs in nutrition. The publication was a separate project from ILSI North America but A Partnership for Public Health: *Branded Food Products Database* is cited in the article.
- ii. At this point, the article is not open access and we do not have the final version.



iii. Action Item: Post the final publication on the COI Extranet and let the Working Group know when it is complete.

**E. Hentges** 

### c. Experimental Biology Reception on PPPs

# i. Dr. Eric Hentges shared information about a reception on PPPs that was held during the Experimental Biology (EB) meeting in San Diego. The reception was organized by USDA and ASN as a continuation of the initiative that USDA ARS and NIH/NCI began which was spearheaded by Dr. Catherine Woteki and Dr. John Milner. A Partnership for Public Health: *Branded Food Products Database* was originally identified in this initiative as a PPP that should be developed.

- The reception included an update on the activities of the USDA ARS and NIH/NCI collaboration. They are looking moving forward with existing projects and looking for new PPPs to develop.
- iii. Dr. Hentges noted that there are opportunities for further collaborations, particularly in the Microbiome area. He suggested that one of ILSI North America's Committees that has been sunsetted could potentially come back and become a part of the collaboration.
- iv. Dr. Hentges and Ms. Kretser presented on the Partnership and shared an update on the progress. 80 individuals, including Dr. Hentges, Ms. Kretser, and several Working Group members, were present.

## d. National Nutrient Databank Conference, May 2014 A. Kretser

- i. The 3 Partners presented at the National Nutrient Databank Conference (NNDC) in May. Ms. Kretser noted that the PPP was the showcase of the meeting and that NNDC was an ideal venue to present on the Partnership because it represents a core group of end users of the enhanced USDA National Nutrient Database. 110 attendees were present at NNDC.
- ii. The 3 Partners gave a 1 ½ hour presentation which provided the most up to date information on the progress on Partnership. The Partnership also sponsored a breakfast, featured a poster at the poster session, and held an informal listening session at lunch. The Partners sat at 4 tables with individuals who wanted to continue the discussion and learn more about how they can become engaged.



- iii. In preparation for the conference, a logo for the Partnership was developed that incorporated the logos of the 3 Partners. The Partners are continuing to refine the logo and the ATIP Foundation expressed interest in making further edits so the logo was not shared with the Working Group.
- iv. Ms. Kretser noted that there were several outcomes of the Partnership's presence at NNDC, including: furthering the credibility of the Partnership and giving the initiative high visibility.
- v. During the Q&A after the presentation, there was a strong desire from the nutrition research community that, as the Partnership moves forward and works through implementation and automation of imputing nutrient values, FNDDS codes, and food groups, this becomes an open source, transparent process. It was encouraging to hear this from the community of end users and it was clear that USDA heard that message.
- vi. The Partnership's presence at NNDC created an opportunity to connect with new universities, including the University of Utah and UNC Chapel Hill.
  - A doctoral student from the University of Utah presented on how to assign FNDDS codes and the Partnership connected with her academic advisor, Dr. John Hurdle in the computer science program.
  - 2. Ms. Emily Yoon from UNC Chapel Hill presented on the work of Dr. Barry Popkin's group. The Partners had the opportunity to establish a relationship with Ms. Yoon and her team. They confirmed that the success of the PPP will benefit their database.
  - 3. The Partnership plans to continue outreach with these universities.
- vii. The Partners met with several proprietary databases (Food Essentials, NuVal, ESHA, and the NYC Department of Health who manage MenuStat) that were present and were able to ask them if they were concerned about the PPP impacting their business model. It was confirmed that the proprietary databases present believe the publically available enhanced database will be a benefit to them because it would become the source of the data to pull from and they would no longer have to collect the data themselves. Currently, many proprietary databases spend considerable resources gathering data themselves by pulling the data from websites, or purchasing and



photographing products from the grocery store. By having the data in a publically available database with the assurance that the data is current, the proprietary databases can focus on the analysis of the data, marketing, etc.

- viii. The Partners met Interim Director of the Beltsville Nutrition Center, Dr. Jim Harnly, and briefed him on the Partnership's activities. A discussion on automating algorithms was had and Dr. Harnly noted that it would be a new paradigm to create or develop these algorithms. Further work is needed to develop the process for automation of algorithms and the Partnership will continue to explore this discussion.
  - ix. The Partnership plans to attend future NNDC meetings to provide an update on the progress of the initiative and continue to receive input from this important group of stakeholders.

## e. Canadian Nutrition Society Food for Health Workshop, June 2014 E. Hentges

 Over the last 2 years, ILSI North America has looked to enhance its activities in Canada and has established a relationship with the Canadian Nutrition Society (CNS). ILSI North America and CNS will jointly the Food for Health Workshop -Principles and Philosophies for Development of Ongoing Public-Private Partnerships to Support Food-Health Research in June 2014, in conjunction with the CNS Annual Meeting. Dr. Hentges will present on A Partnership for Public Health: *Branded Food Product Database* as a case study for ILSI North America. Dairy Farmers of America will also present case study.

## f. 17th IUFoST World Congress of Food Science and Technology, August 2014 E. Hentges

- Dr. Hentges shared that he will also present on the Partnership as part of a session at the 17<sup>th</sup> IUFoST World Congress of Food Science and Technology in Montreal in August.
- ii. Dr. Daryl Lund, chair of the Working Group, noted that he would be present at IUFoST and is the incoming chair of the scientific council.

#### g. John Milner Memorial Symposium, 12 June, 2014

#### A. Kretser

 USDA is hosting a symposium on June 12 in honor of Dr. John Milner. The symposium will have 6 presentations, including a presentation from Dr. Richard Black, PepsiCo Inc. on PPPs. Dr. Black will include information about A Partnership



for Public Health: *Branded Food Products Database* as he serves as the co-chair of the Steering Committee. This will be another good opportunity for the Partnership to gain visibility.

## III. Proof of Concept: A Partnership for Public Health: Branded Food Products Database

# A. Kretser A. Kretser

### a. Meeting with USDA Under Secretary on PPP Progress Report

- i. Ms. Kretser shared that the 3 Partners met with USDA Under Secretary Dr. Catherine Woteki on 7 Feb to discuss the Partnership Progress Report that she received on 18 January 2014. The 200 page Progress Report served to document and chronicle all of the activities of the PPP over the past year including the development of the groups. The report explains how the Partners have used the 12 principles to guide the establishment and operation of the initiative and the importance of transparency in how decisions were reached and the key players involved in the initiative.
- ii. Dr. Woteki was tremendously appreciative of all the work that has been completed in such a short period of time. She approved the Progress Report and requested a 90-day and a 12 month budget be developed. The Partnership responded to USDA with developed budgets for the 90-day period and the first 12 months on 27 February, 2014 and after some discussions, a final budget was sent to USDA on 8 April, 2014. Both budgets were approved on 21 May and funds from USDA will be allocated for the project.
- iii. Once the Specific Cooperative Agreement is put in place between USDA and the ATP Foundation and the funds for the 90-day beta test are transferred, the ATIP Foundation can proceed to sign the contract with FSEnet, the chosen GS1 certified data pool provider.

#### **b.** Implementation Phase

#### A. Kretser

- i. Budget
  - Ms. Kretser shared that the proposed Partnership budget from the ATIP Foundation and ILSI North America for the 90-day beta test and the remaining 9 months of the first year was approved by USDA. USDA and the



ATIP Foundation are working on a Specific Cooperative Agreement to transfer the funds.

## ii. Beta Testing

- Once the contract with FSEnet, the GS1 certified data pool provider, is signed with the ATIP Foundation, there will be a 45 day period to set up and configure the portal to receive published data from manufacturers.
- 2. The beta test includes 5 beta test companies: Campbell Soup Company, Cargill, Incorporated, ConAgra Foods Inc., General Mills Inc. and Red Gold. Ms. Kretser shared that Red Gold, a medium sized canned tomato company, is not a current member of the GS1 community so they will test the non-GS1 portal. The Partners have agreed to bear the cost of having this portal so that those outside the GS1 community can participate in the initiative. FSEnet has already established this portal.
- 3. The Partners plan to hold a mapping exercise with the 5 beta test companies to finalize the attributes.

## iii. Outreach Strategy

- In anticipation of the Partnership budget being approved by USDA, the Communications Group has developed several outreach documents at the request of the Steering Committee. A Value Proposition document and a document on the Features of the Enhanced USDA National Nutrient Database have been developed.
- 2. As part of the outreach strategy developed by the ATIP Foundation, 7 categories of stakeholders have been identified who have a vested interest in the success of the Branded Food Products Database. The ATIP Foundation will lead outreach to these 7 categories for data submission and financial support. ILSI North America will provide subject matter support to the ATIP Foundation but will not participate in the funding ask.
- 3. The Academy of Nutrition and Dietetics (AND) has already expressed interest in financially supporting this initiative and becoming an inaugural supporter. We also anticipate that proprietary databases may be another key



source of funding as they realize the positive impact of this initiative on their business models.

- ILSI North America has continued to stress to the Partners that the contribution of the food industry is the submission of the data and not funds. Data submission is a crucial role and without data, there will not be a database.
- ILSI North America plans to schedule a conference call with the ILSI North America official representatives to discuss a pledge letter for manufacturers to sign pledging that their company will submit data to the Branded Food Products Database.
- Dr. Daryl Lund noted that the Value Proposition covers all interested parties except the key value for consumers and suggested that this should be included.
  - a. Dr. Hentges noted that the Partnership has not identified a direct to consumer group yet to engage but have thought of philanthropic organizations for the ATIP Foundation to coordinate outreach to.
  - b. Dr. Jennifer Van de Ligt shared that she would like to discuss the outreach to consumers further with the ATIP Foundation. Consumers are a large group and if the Partnership could resonate on a consumer level and could bring in small monetary donations, the funds could become pretty substantial.
  - c. The idea will be taken back to the Communications Group.
- 7. It was noted that PPPs are extremely challenging and require dedication. If the government does not move forward, the Partnership is in a stand-still. For ILSI North America, as we look to get involved in PPPs in the future, serious thought needs to be put in beforehand. It was suggested that the Board discuss the Partnership at Mid-year and what it means for ILSI North America's reputation to be a part of public-private partnerships. There are huge benefits to participating in PPPs, but they can also have unintended challenges.



- Dr. Johanna Dwyer commented that the potential success of this Branded Food Products Database initiative will be an enormous plus for ILSI North America. This is a different level of collaboration than we have had before.
- 9. Ms. Kretser shared that the principles that have been developed are playing out. The Partners have had the opportunity to work together as a team and develop trust but it doesn't come easily and the Partners have to work at it every day but tremendous progress has been made.

### IV. GMA's Consumer Information Transparency Initiative

#### **E.** Hentges

- a. Dr. Hentges noted that many ILSI North America member companies have seen this GMA Consumer Information Transparency Initiative (CITI) and have inquired how the initiative works with the *Branded Food Products Database*. ILSI North America has kept in close contact with GMA and FMI on this initiative and have continued to brief them on updates to the *Branded Food Products Database*. The two initiatives will be synergistic and will complement each other as both are using the GS1 system so manufacturers will only have to submit their data once and can send it to both initiatives.
- b. The CITI initiative will focus on the consumer and plans to set standards within GS1 for 3,000 new attributes. Defining these new attributes benefits the *Branded Food Products Database* as manufacturers can potentially submit these same attributes in the future if the Partnership agrees.

## V. Support of Professional Societies of COI PPP Principles

# E. Hentges

- a. Dr. Hentges noted that this subject was brought up at Annual Meeting 2014 and the possibility of a summit or collection of major professional societies and federal agencies coming together in support of the PPP principles was discussed. At the conclusion of the summit, the professional societies would agree to a consensus statement on private funding for research and general acceptance of principles for PPPs, such as the Obesity Society Statement.
- b. The professional societies that ILSI North America has already spoken to, including the American Society for Nutrition (ASN), Institute of Food Technologists (IFT), and AND, and



all are supportive of the summit. Planning has begun to bring these societies together at the end of 2014.

c. Dr. Lund noted that it might be helpful for societies who publish journals to have their editors participate in summit.

## VI. GRAS Assessment

#### E. Hentges

- a. Dr. Hentges shared that pulling together a meeting to develop best practices to reduce bias when putting GRAS assessment panels together had been brought up at Mid-Year 2013 and again at Annual Meeting 2014. However, ILSI North America has not had the staff resources to dedicate to this thus far.
- b. Dr. Hentges noted that ILSI North America is looking to develop this project as a Board Task Force which would use the board contingency fund.
- c. The Working Group felt that the Conflict of Interest Summit idea seems to overlap with the GRAS Assessment project and wondered if there was a way to combine the two projects.
  - i. Dr. Hentges noted that there is synergism between the two projects. FDA intends to develop a conflict of interest document in the fall of 2014 so it would be beneficial to have a manuscript to share with FDA on best practices for advisory committees. The conflict of interest summit development may take longer to get together. The manuscript from the GRAS Assessment could be shared at the summit.
- d. Dr. Lund brought up an earlier idea from the Working Group to speak with IFT about creating a tutorial that could be used as an education tool about GRAS assessment.
  - Dr. Hentges informed the Working Group that IFT is developing a project along a similar vein. ILSI North America does not have a real education channel so this project has not progressed. Dr. Hentges plans to discuss the topic with Will Fisher, IFT, further as IFT is the logical organization to carry out this project.

## VII. Next Steps

#### D. Lund

- a. Dr. Lund outline the next steps for the ongoing projects, including:
  - i. Implementation and outreach of A Partnership for Public Health: Branded Food Products Database, including a successful beta test.



- ii. Scheduling time to discuss the pledge letter for data submission with ILSI North America official representatives.
- iii. Planning of the Conflict of Interest Summit of Professional Societies
  - 1. If Working Group members have suggestions of other professional societies to engage, please share.
- iv. GRAS Assessment
  - ILSI North America will move forward with the development of a paper and will look into developing a tutorial on GRAS and GRAS process. Explore the possibility of integrating the GRAS and COI Summit projects by sharing the GRAS paper on the selection of GRAS panels at the Summit meeting.
- b. Dr. Ferg Clydesdale suggested looking at opportunities for collaboration with IOM and the Food Forum, particularly with the GRAS qualifications.

VIII. Adjournment

A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

## Thursday, 29 May, 2014, 10:00-11:30 am EDT

### **Attendees**

Daryl Lund, chair Fergus Clydesdale Johanna Dwyer John Erdman Rachel Goldstein Eric Hentges Alison Kretser Richard Lane Beate Lloyd Delia Murphy Juan Navia Joseph Ratliff Shawn Sullivan Jennifer van de Ligt Liz Westring

## **Unable to Attend**

David Allison Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle James Hill Joanne Lupton Debra Miller Amy Preston Claudia Riedt Steven Rizk Kari Ryan David Thomas Wamwari Waichungo Sharon Weiss

University of Wisconsin, Madison University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign Mars, Incorporated ILSI North America ILSI North America PepsiCo Inc. Coca-Cola Company ILSI North America McNeil Nutritionals, LLC Dr Pepper Snapple Group ILSI North America Cargill, Incorporated General Mills Inc.

University of Alabama at Birmingham Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia University of Colorado Health and Wellness Center Texas A&M University The Hershey Company The Hershey Company Dr Pepper Snapple Group Mars, Incorporated Kraft Foods Group, Inc. Dr Pepper Snapple Group Coca-Cola Company **ILSI** North America

# Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm (Continental Breakfast Available Starting at 8:30am)

# Agenda

# Meeting Goals/ Objectives:

- 1. Agreement on purpose and goals
- 2. Agreement on statement of task
- 3. Agreement on a set of general principles for nutrition-related research public-private partnerships
- 4. Action items with deadlines delineated

# Facilitator: Sylvia Rowe

Welcome and Introductions	Sylvia Rowe	9:00am
Purpose and Context	David Klurfeld; Eric Hentges	9:30
Importance of Public-Private Partnerships	Cathie Woteki	9:45
Review of Statement of Task	Sylvia Rowe	10:15
Discussion of General Principles	Sylvia Rowe	11:00
Lunch		12:00pm
Continued Discussion	Sylvia Rowe	1:00
Wrap-Up and Next Steps	Sylvia Rowe; David Klurfeld; Eric Hentges	3:30

# **Additional Materials**

- 1. Roster
- 2. Principles from Rowe et al, 2013 Paper
- 3. Comments about the Principles (as of Nov. 19 noon)
- 4. Rowe et al, 2013 Paper
- 5. Statement of Task (SOT) with Timeline and Reference Links
- 6. Links to References for Context

# Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm

## **Meeting Attendee List**

Sonja Connor, MS, RDN, LD President, Academy of Nutrition and Dietetics Research Associate Professor Department of Medicine Oregon Health Sciences University Portland, OR connors@ohsu.edu

Rosa K. Hand, MS, RDN, LD Senior Manager, Dietetics Practice Based Research Network Academy of Nutrition and Dietetics Chicago, IL

Mary Beth Whalen Chief Operating Officer Academy of Nutrition and Dietetics Executive Director, Academy Foundation Chicago, IL

Michael H. Stolar, PhD Senior Vice President, American Gastroenterological Association Bethesda, MD

Dorothea K. Vafiadis, MS, FAHA Director, Healthy Living American Heart Association Washington, DC d

Wendy Johnson-Askew, PhD, MPH Chair, Food and Nutrition Section American Public Health Association Vice President for Corporate Affairs Nestle Florham Park, NJ John E. Courtney, PhD Executive Officer American Society for Nutrition Bethesda, MD

Robert M. Russell, MD Chair, American Society for Nutrition Foundation Board of Trustees Arlington, MA <u>rob.russell@tufts.edu</u>

Patrick J. Stover, PhD President-Elect, American Society for Nutrition Professor and Director Division of Nutritional Sciences Cornell University Ithaca, NY pjs13@cornell.edu

Barbara Bowman, PhD Director, Division for Heart Disease and Stroke Prevention National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention Atlanta, GA <u>Bbb8@cdc.gov</u>

Laura Pillsbury Food Technologist Office of Foods & Veterinary Medicine U.S. Food and Drug Administration Silver Spring, MD laura.pillsbury@fda.hhs.gov

Robert A. Burns, PhD Vice President, Health and Nutrition Policy Grocery Manufacturers Association Washington, DC Christie Tarantino, FASAE, CAE Executive Vice President Institute of Food Technologists Chicago, IL

Janet Collins, PhD, RD, CFS Past President, Institute of Food Technologists Senior Manager, Corporate Regulatory Affairs DuPont Washington, DC

Mary Ellen Camire, PhD President, Institute of Food Technologists Department of Food Science and Human Nutrition University of Maine Orono, ME mary.camire@umit.maine.edu

Donald L. Zink, PhD President, International Association for Food Protection Senior Science Advisor Center for Food Safety and Applied Nutrition US Food & Drug Administration College Park, MD donald.zink@fda.hhs.gov

David W. Tharp, CAE Executive Director International Association for Food Protection Des Moines, IA

Alison J. Kretser, MS, RD Director, Science Programs International Life Sciences Institute North America Washington, DC

Eric Hentges, PhD Co-chair, Working Group V. Collaborative Process Executive Director International Life Sciences Institute North America Washington, DC

Van S. Hubbard, MD, PhD Director, National Institutes of Health Division of Nutrition Research Coordination Rear Admiral, U.S. Public Health Service (*Ret.*) Bethesda, MD hubbardv@mail.nih.gov Nancy J. Emenaker, PhD, MEd, RD Health Sciences Administrator Division of Cancer Prevention National Cancer Institute National Institutes of Health Bethesda, MD emenaken@mail.nih.gov

Lisa Kaeser, JD Program Analyst Office of Legislation and Public Policy Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health Bethesda, MD kaeserl@mail.nih.gov

Charlotte Pratt, MS, PhD, RD Program Director, Clinical Applications and Prevention Branch Division of Prevention and Population Sciences Division of Cardiovascular Sciences National Heart, Lung, and Blood Institute National Institutes of Health Bethesda, MD prattc@nhlbi.nih.gov

Paul M. Coates, PhD Director, Office of Dietary Supplements National Institutes of Health Bethesda, MD coatesp@od.nih.gov

Catherine Woteki, PhD Under Secretary, Research, Education, and Economics Chief Scientist US Department of Agriculture <u>Catherine.Woteki@osec.usda.gov</u>

Pamela Starke-Reed, PhD Deputy Administrator, Nutrition, Food Safety and Quality Agricultural Research Service, US Department of Agriculture Beltsville, MD Pamela.Starke-Reed@ARS.USDA.GOV

David M. Klurfeld, PhD Co-chair, Working Group V. Collaborative Process National Program Leader, Human Nutrition Agricultural Research Service, US Department of Agriculture Beltsville, MD david.klurfeld@ars.usda.gov Dionne Toombs, PhD Director, Division of Nutrition Institute of Food Safety and Nutrition National Institute of Food and Agriculture US Department of Agriculture Washington, DC <u>dtoombs@nifa.usda.gov</u>

Robert Brackett, PhD Member, Working Group V. Collaborative Process Director and Vice President, National Center for Food Safety and Technology Illinois Institute of Technology Institute for Food Safety and Health Chicago, IL rbrackett@iit.edu

Ratna Mukherjea, PhD Member, Working Group V. Collaborative Process Global Nutrition Leader DuPont Nutrition & Health St Louis, MO

Sylvia Rowe, PhD President SR Strategy, LLC Washington, DC rowe@srstrategy.com

Nick Alexander Science Writer

Linda Meyers, PhD Senior Science Advisor American Society for Nutrition Bethesda, MD

Delia Murphy Science Program Associate International Life Sciences Institute North America Washington, DC

# Statement of Task: Achieving a Transparent, Actionable Framework for Food and Nutrition Research-Related Public-Private Partnerships

# **Overview**

There is an urgent need for an expanded, rigorous, and focused research agenda in food and nutrition that is driven by increased awareness that food, nutrition, and human health are closely linked through complex interactions, and a recognition that associated costs contribute substantially to rising national health care expenditures. New research approaches are critically needed to capitalize on our current understanding of the role of food and food systems in chronic disease prevention and management and to translate this knowledge into the development of public health interventions, innovative products, and evidence-based policies that meet the public's expectations and support the health of the nation. However, government resources devoted to food and nutrition research are shrinking, stifling economic growth and innovation in the food and nutrition sector and delaying the opportunity to better harmonize the food system and human health.

Public-private partnerships (PPPs), collaborative relationships involving partners from government, industry, and academia, are increasingly appreciated as a novel approach to simultaneously advance public health and a 21<sup>st</sup> century food and nutrition research agenda, resulting in a food system that can support both consumer and commercial interests in the development of new products and markets. PPPs are the only mechanism known to bring together the best scientists from all sectors with distinct, yet complementary, expertise and perspectives. By bringing expertise from diverse disciplines and sectors together to address research questions where public health and other benefits are achievable, PPPs combine and maximize multidisciplinary resources in a time when financial and other resources devoted to food and nutrition research are limited. Risks can be largely shared and the comprehensive approach necessary to address today's complex scientific questions is best achieved through the involvement of multiple disciplines and partners.

PPPs are not always the best approach to investigate certain areas of food and nutrition research. A roadmap is necessary to help organizations understand when to use PPPs for food and nutrition research and how to use and operate PPPs most efficiently and effectively. While several groups have developed principles for the creation of food and nutrition partnerships (3<sup>rd</sup> World Conference on Research Integrity, 2013; Institute of Medicine, 2012; Canadian Institutes of Health Research, 2008), such principles have generally been developed in silos and may not be actively used by the various types of organizations to determine when and how to undertake a PPP. Rowe et al. (2013) sought to compile existing guidelines using a 3-step process which resulted in the articulation of 12 potential principles for establishing and managing successful research PPPs.

Thus, this activity aims to stimulate the expansion, accessibility, and acceptance of PPPs by unifying and moving existing principles for food and nutrition research PPPs forward, making them publicly available for all interested parties to reference and use. Numerous food and nutrition research professional/scientific societies, non-profit research foundations, and federal

agencies will be involved in the identification of these principles, and agreement and endorsement of the unified set of PPP principles will be gained from additional stakeholders, representing a collective effort to achieve the best research outcomes possible. With such widespread involvement and endorsement, it is hoped that this framework will be broadly used by the collaborating organizations and others to create PPPs that will ultimately improve public health.

This activity is part of the work of the government-wide Interagency Committee on Human Nutrition Research (ICHNR) to build food and nutrition partnerships that began in 2011. Four research areas with the greatest potential for both public health impact and implementation feasibility emerged: (1) Food Composition and Nutrition Monitoring; (2) Biomarkers; (3) The Microbiome, and (4) Consumer Behavior. Working groups with representation from government, academia and industry were created. A fifth working group on Collaborative Process was also created to identify characteristics of successful PPPs and potential barriers to success. This activity carries on the work of Working Group V. Collaborative Process, co-chaired by David Klurfeld, Ph.D., USDA/ Agricultural Research Service (ARS) National Program Leader in Human Nutrition, and Eric Hentges, Ph.D., Executive Director of the International Life Sciences Institute North America. Other members of Working Group V are Robert Brackett, Ph.D., Illinois Institute of Technology Vice President and Director of the Illinois Institute for Food Safety and Health, and Ratna Mukherjea, Ph.D., Global Nutrition Leader at DuPont Nutrition & Health.

Through a cooperative agreement with USDA/ ARS, the American Society for Nutrition (ASN) will convene representatives from: USDA, ASN, the Academy of Nutrition and Dietetics (AND), American Heart Association (AHA), American Gastroenterological Association (AGA), the Food and Nutrition Section of the American Public Health Association (APHA), the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Grocery Manufacturers Association (GMA), Institute of Food Technologists (IFT), International Association of Food Protection (IAFP), International Life Sciences Institute North America (ILSI North America), and the National Institutes for Health (NIH) to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

# **Project Goals/ Objectives**

The main purpose of the face-to-face meeting is to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

- The framework will be developed in partnership by key food and nutrition-related federal agencies, non-profit research foundations, and professional societies. Sign on to the principles will be sought from all partners and other relevant organizations.
- The framework will be made publically available to be used as a model by interested public and private organizations. Commitment is needed from all involved to promote the principles, including publishing the framework in the relevant publications of each partner organization, as applicable.

• Commitment is needed from all involved to update the framework on a regular, as-needed basis, to enhance the value and sustainability of the framework.

# **Process for Moving Forward**

The following timeline for action will facilitate the achievement of the expected goals and objectives. The timeline can be altered at any time for sufficient flexibility. However, a sense of urgency should be encouraged and maintained in order to achieve the optimal outcome.

- Initiate 1<sup>st</sup> outreach to secure commitment from all relevant professional/scientific societies, non-profit research foundations, and federal agencies (henceforth known as collaborators) for involvement on the proposed project.
- Hold preliminary conference call for collaborators on September 5, 2014.
- Collaborators agree to Statement of Task *by October 10, 2014*. In doing so, all collaborators agree to assist with achievement of goals/objectives as outlined in the statement of task.
- Begin discussions with publishers of relevant journals to secure agreement to publish framework and assure coordination of deadlines, etc. *in November 2014*.
- Hold meeting of collaborators in Washington, D.C. *on December 8, 2014* to develop a transparent, actionable framework for food and nutrition research-related PPPs.
- Identify date and location *by January 16, 2015* for a meeting to publicly unveil framework. This will be an invite-only stakeholder meeting, ideally hosted at the location of an independent public agency, such as the <u>Government University Industry Research</u> <u>Roundtable (GUIRR) of the National Academy of Sciences</u>.
- Secure sign on and promotional support for the framework from collaborators *by March 16*, *2015*. Securing such support may require gaining Board and membership approval(s), as applicable.
- Conduct outreach to relevant organizations that may wish to sign on to the framework *by March 16, 2015.*
- Publish framework and other relevant materials in applicable journals *Target*: April 2015.
- Create program including topics and speakers for public unveiling of the framework that will clearly articulate goals/objectives and framework *by April 1, 2015*.
- Develop and finalize invitation list for public unveiling of framework. Send joint invite from collaborators *by April 17, 2015*.

• Announce the framework at public unveiling meeting – *Target: May 12, 2015.* Engage all attendees in the dialogue and secure their commitment to share and implement the framework.

# Public-Private Partnership References

- <sup>3<sup>rd</sup></sup> World Conference on Research Integrity. "Montreal statement on research integrity in crossboundary research collaborations." Montreal, Canada. May 2013. <u>http://www.cehd.umn.edu/olpd/montrealstatement.pdf</u>
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- Institute of Medicine. 2012. Building public-private partnerships in food and nutrition: Workshop summary. Washington, DC: The National Academies Press. https://www.ncbi.nlm.nih.gov/books/nbk97331/
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## A Partnership for Public Health



## Features of the Enhanced USDA National Nutrient Database

The goal of the Public-Private Partnership is to expand the current nutrient data by obtaining compositional data directly from the food industry. An expanded database will contain much more information on individual food items allowing for a true assessment of the extent and fluidity of the food system.

Nutrition Facts Serving Size 2/3 cup (55g) Servings Per Container About 8	1.	<ul> <li>Parent Company (Manufacturer, Subsidiary, signature line) or Private</li> <li>Label (signature line)</li> <li>Enhanced database will allow for more specific data collection</li> </ul>
Amount Per Serving		and analysis in NHANES; allowing for more specific assessment
Calories 230 Calories from Fat 40		of foods eaten by the population.
% Daily Value*	2.	Nutrition Facts Panel (NFP) and Expanded Facts Panel (when
Total Fat 8g 12%	-	available)
Saturated Fat 1g 5%		• Information might be "as proclassed" and "as propagod" with
Trans Fat 0g		• Information available as packaged and as prepared, with
Cholesterol Omg 0%		added ingredients
Sodium 160mg 7%		• No longer will a nutritional value be based on an averaged or
Dietory Eiber 4a		generic database value
Sugars 10		Server e autorise variae.
Protein 3g	-	If someone reports having eating
Protein Sy	3.	Product name and generic descriptor
Vitamin A 10%	4.	Weights and measures
Vitamin C 8%	5.	Serving size and servings per package
Calcium 20%		the actual brana item consumea.
Iron 45%		
Your daily value may be higher or lower depending on your calorie needs. Calories: 2,000 2,500 Total Fat Less than 65g 80g Sat Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g	6. 7.	<ul> <li>Date Stamp associated with most current formulation (effective date of change/introduction)</li> <li>Historical data on food products will allow for tracking dietary trends.</li> <li>Ingredient list and sub-list (hierarchical and in descending order)</li> </ul>
INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, HEDUCED Iron, Thiamin Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Foild John Greun Schub Corden and Dan Mai (Antu Taub		• This information has never been captured before in the National
FOR FRESHNESS), CORN SYRUP SOLIDS, DEXTROSE, HIGH FRUCTOSE CORN SYRUP FRICTOSE, GIVERNIN, CONTAINS 2%, OR LESS OF CACAA		Nutrient Database. Having this information available will allow
(PROCESSED WITH ALKALI), POLYDEXTROSE, MODIFIED CORN STARCH, SALT, DRIED CREAM, CALCIUM CARBONATE, CORNSTARCH, LEAVENING (BAKING		for analysis that has never been done.
SODA, SODIUM ACID PYROPHOSPHATE, MONOCÁLCIUM PHOŠPHATE, Calcium Sulfate), distilled monoglycerides, hydrogenated Palm	8.	GTIN Number
KENNEL DIL, SJOUM STEARDYL LACYTALE, GELNIK, COLOR ANDED, SDY LEGTIHL, DATEM, MATURAL AND ANTIFICIAL, FLAND, WAILLA ETRACT, CARNAUSA WAX, XANTHAN GUN, VITAMIN A PALMITATE, YELLOW & LAKE, RED 40 J. DAKE, CARANEL COLOR, NICHANNER, BLUK & V. LAKE, REDUCED IRON, YELLOW & LAKE, PRIDOXICA, HOROCILIORIC VITAMIN BJ, RIBO- FLANN VITAMIN BJ, THAMIN MTOROCILIORIC VITAMIN BJ, RIBO-	/	<ul> <li>Specific nutrient composition directly from the food product, correlated to this number, will be available.</li> </ul>
5 901234 123457 >	s f E	Food composition databases are central to the conduct of nutrition research, as they tandardize how foods can be characterized in terms of nutrients, dietary guidance-based food groups and other relevant dietary constituents. A Partnership for Public Health: Branded Food Products Database will provide researchers the first-ever completely free and
	р g	nublicly available database on the composition of foods by brand name. This will enable greater specificity in all types of nutrition studies of individual's diets and food

environments."

- Dr. Susan Krebs-Smith, National Institutes of Health



# Agenda: **Best Practices Workshop for ILSI North America Members** For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Conference Call Dial-in information: 1-888-585-9008, Access code: 327847914

Purpose: The Best Practices Workshop is being held for ILSI North America member companies in preparation for full implementation of A Partnership for Public Health: Branded Food Products Database.

I.	Welcome and Introductions	A. Kretser
II.	GS1 Source	A. Fernandez/ S. Brown
III.	Overview of the Beta Test	R. Rosenbaum/ M. Hamilton
IV.	Perspectives from Beta Test Companies	Beta Test Companies
V.	Questions and Discussion	All
VI.	Data Submission to FSEnet Prior to Full Implementation	R. Rosenbaum
VII.	Pledge Letter and Press Release	A. Kretser
VIII.	Next Steps	A. Kretser
IX.	Adjournment	A. Kretser



# Attendance: Best Practices Workshop for ILSI North America Members For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Attendees Scott Brown Donna Courtney **Bill Ferguson** Angela Fernandez Merissa Hamilton Alison Kretser Kyle McKillop Timothy Morck Alanna Moshfegh Matt Muldoon Rachel Murphy Delia Murphy Debbie Nece Rob Rosenbaum Trish Zecca Attending via Conference Call Nick Alexander Jennifer Bauman Cathy Bone Chris Chatzidakis David Cockram Richard D'Aloisio Christine Downs Lori Fix Judy Gluvna Kristin Harris Paul Hoffman Katlyn Kutzlo Minh Le Shannon Lytle Michael Marino Debra Miller Gary Montgomery Sheila Ost Eric Park Claudia Riedt

GS1 The Hershey Company Kellogg Company GS1 FSEnet **ILSI** North America University of Maryland Nestle USA USDA ARS FSEnet **DSM Nutritional Products ILSI North America** Cargill, Incorporated **ATIP** Foundation Campbell Soup Company SR Strategy

Campbell Soup Company Monsanto Company ConAgra Food Inc. Abbott Nutrition Mondelez International Abbott Nutrition Unilever Abbott Nutrition Hillshire Brands Kraft Foods Group Inc. Red Gold, Inc. Herbalife International of America, Inc. Red Gold, Inc. Kellogg Company The Hershey Company Abbott Nutrition ConAgra Foods Inc. Monsanto Company Dr Pepper Snapple Group


Andrew Shao Lynette Shawd Jennifer Van de Ligt Casey Zanis

Unable to Attend Doug Balentine **Richard Black** Greg Buckley Philippe Caradec Joseph Carlos Stuart Craig Brent Flickinger Jennifer Garrett Llaine Groninger Leslie Henderson Becki Holmes Cassie Hoover Christina Khoo Dot Lagg Suzanne Lee Beate Llovd Mark Maier Michael McBurney Susan McKee Mark Moorman Phil Morreale Matthew Muldoon Gabriella Parisse Christine Pelkman Fred Shinnick Miro Smriga Steve Rizk Sylvia Rowe Juan Navia Brian Schaneberg Stephan Theis Cass Wade-Kudla David Walsh Liz Westring Paul Zanno

Herbalife International of America, Inc. General Mills Inc. Cargill, Incorporated Herbalife International of America, Inc.

Unilever PepsiCo Inc. PepsiCo Inc. Danone Waters of America, Inc. Abbott Nutrition DuPont Archer Daniels Midland Company McCain Foods USA The Hershey Company Mondelez International Red Bull GmbH Nestle USA Ocean Spray Cranberries, Inc. Mars Chocolate North America Nestle USA The Coca Cola Company Valspar Corporation **DSM** Nutritional Products Kraft Foods Group Inc. Kellogg Company Mondelez International FSEnet Tate & Lyle Ingredion Incorporated Senomyx, Inc. Ajinomoto North America, Inc. Mars, Incorporated SR Strategy McNeil Nutritionals, LLC Starbucks Corporation BENEO General Mills Inc. Herbalife International of America, Inc. General Mills Inc. Dr Pepper Snapple Group

# A Partnership for Public Health: Branded Food Products Database







# Pledge Letter

As a member of ILSI North America and a food/ingredient manufacturer, we are signing this voluntary pledge letter to submit nutrient composition and label data on behalf of A Partnership for Public Health: *Branded Food Products Database*. We commit to using GS1 standards through an ATIP Foundation contracted GS1 certified data pool provider for inclusion as part of an enhanced USDA National Nutrient Database. We are aware this data will become publically available once received by the USDA National Nutrient Database. The proposed addition of branded food compositional data to the USDA National Nutrient Database is an essential tool for developing research strategies to inform public policy regarding food and nutrition and will create a database more truly reflective of the breadth and depth of the nation's food supply. Various sectors of the research community and the food and health care industries will find this database valuable. For example, this will enhance the National Health and Nutrition Examination Survey (NHANES) by more accurately characterizing food selection and nutrient intakes for Americans; nutrition software developers can produce enhanced software so that dietitians will be able to better tailor diets to nutritional needs; medical researchers will be able to better link dietary intakes to measures of optimal health; authoritative scientific bodies will be able to develop better guidelines that will promote public health; and food manufacturers could use this to improve product formulations.

The enhancements brought about by this Public-Private Partnership will ensure that USDA ARS nutrient composition data will remain the "Gold Standard" for the next decade and beyond.

The following information (attributes) will be submitted. These attributes are currently on the food packaging label. However, by providing these attributes in the GS1 format, it is possible to have the most up-to-date version of this data available to the public through the USDA National Nutrient Database.

- 1. Parent Company (manufacturer, subsidiary, signature line) or Private Label (signature line)
- 2. Product Name and Generic Descriptor
- 3. Global Trade Item Number (GTIN)
- 4. Ingredient List and Sub-List (hierarchical and in descending order)
- 5. Weights and Measures (net weight/volume of package)
- 6. Serving Size and Servings per Package
- 7. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)
  - a. (as packaged and as prepared with added ingredients)
- 8. Date Stamp associated with most current formulation (effective date of change/introduction)

By signing this pledge letter, our company will be recognized as an inaugural participant of A Partnership for Public Health: *Branded Food Products Database*. Our company's name will be included in the list of inaugural participants that will be part of the Partnership press release on the initiative.

Signature:	Date:	
Company Name:		

# A Partnership for Public Health



Branded Food Products Database

# <u>A Partnership for Public Health: Branded Food Products Database</u> Value Proposition

# **Story of the Partnership**

Assessing the nutritional health of the American people depends on accurate and comprehensive data regarding the nutrient composition of commonly consumed foods. USDA's Agricultural Research Service (ARS) maintains a National Nutrient Database of the composition of such foods, and although the food industry has compositional data for their own products, very little of that data is publicly available through the database. As part of USDA's response to the Presidential Memorandum in October 2011, ARS approached ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information. Previous efforts by USDA on their own had seen limited success which is not unexpected given the volume and fluidity of branded food products in the U.S. marketplace.

Accordingly, the USDA, the International Life Sciences Institute (ILSI) North America and the ATIP Foundation (Agricultural Technology Innovation Partnership) have formed a Public-Private Partnership to enhance public health by augmenting the USDA National Nutrient Database with "nutrient composition of branded foods and private label" data provided by the food industry. This Partnership will ensure this information will be made publically available to those who utilize such data including the federal agencies, the research community, proprietary databases and end users, and the food industry.

The Partnership has established expert groups whose representation is made up of federal government agencies, academic nutrition researchers, a non-government organization (NGO), and ILSI North America member scientists. These expert groups, with additional input from two listening sessions, submitted recommendations for approval by the Steering Committee and, ultimately, these were approved by Dr. Catherine Woteki, USDA Under Secretary for Research, Education, and Economics (REE) and Chief Scientist. These recommendations included specific attributes that will be submitted to the enhanced USDA National Nutrient Database. More work remains to be done and supporters will have the opportunity to participate in these discussions.

Enhancement of the USDA National Nutrient Database through this Public-Private Partnership will be conducted in phases, with information from the Nutrition Facts Panel being obtained first and other, more detailed information being obtained at later stages. The database enhancement is also tied to changes in the infrastructure of the USDA National Nutrient Database that will allow the data to be accessed and utilized more efficiently. The changes brought about by this Public-Private Partnership will ensure that USDA nutrient composition data will remain the "Gold Standard" for the next decade and beyond.



A public-private partnership provides the framework to convene the expertise to compile nutrient data on branded and private label products, secure the private sector engagement in providing this information, as well as the broad-based constituent funding necessary to maximize content and provide timely information for nutrition, agricultural and diet-related health policy on the nutrient composition of the U.S. food supply.

# What are the Benefits to Participating in the Partnership?

Corporations and organizations can participate either as providers of branded or private label food product nutrition data, or as financial contributors to support the development and sustainability of the enhanced USDA National Nutrient Database. The ATIP Foundation will acknowledge participants on the Foundation website pages under the Partnership logo. The listing of participants verifies the commitment of professional societies, organizations, and corporations that support this important initiative who will become members of the Sustaining Stakeholder Council. The Sustaining Stakeholder Council will review progress and make recommendations to the Partnership.

# How will Success be Measured?

There are many indicators of success for this initiative. For example, the Partnership will have achieved success when thousands of branded and private label products are integrated in real time into the enhanced National Nutrient Database and timely updates are routine. Success will have been achieved when the database is viewed as the most comprehensive nutrient database. Success can be measured by the breadth of manufacturers- large, medium, and small- who are voluntarily participating. Other goals for measuring success will be met when information provided on an individual food product also includes imputed nutrient data and food groups, and the source of the nutrient values is transparent. USDA will issue comprehensive reports on the nutritional composition of the food supply. Success will also be measured by the presence of a vibrant group of sustaining members who support the long term viability of the enhanced USDA National Nutrient Database. Achievement will be measured by other countries adopting our system.

# Value of Initiative

- Historical data on branded and private label food products will become available. The nutrition research community will benefit enormously from having this information for tracking dietary trends.
- The value of this initiative in the Development Phase has been the governing structure that has established key groups to meet the challenges and achieve the goals set by the Partnership: the Steering Committee, the Operation and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.
  - The Criteria Group developed the set of attributes that were reaffirmed by the listening sessions.
  - The Criteria Group brought together expertise across a broad range of nutrition professionals who developed the data quality system sanctioned by the USDA.



- The IT infrastructure, capitalizing on the established GS1 network, has been designed to be nimble and to accommodate future needs for years to come.
- A Sustaining Stakeholder Council will be made up of supporters (both financial contributors and providers of data) of the initiative. This Council will review progress and make recommendations to the Partnership.
- In the Implementation Phase, the Technical Stakeholder Group will provide a formal process to gather technical, nutritional, analytical, and research information needs, that will facilitate the knowledge and utility that can be derived from the Branded Food Products Database.
- The 12 principles for establishing and operating a public-private partnership are clearly visible within the Partnership.

# Key Value for Government

An expanded database will contain much more information on individual food items allowing for research and policy to be based on a true assessment of the extent and fluidity of the food system.

"The composition of the food supply and consumer dietary choices are key inputs for agricultural and food policy decisions. Comprehensive data can inform these decisions, but the volume and fluidity of branded food products in the U.S. marketplace are key challenges. USDA has concluded that this is best pursued through a public-private partnership led by the ATIP Foundation and ILSI North America that is transparent and inclusive of all facets of the diverse food system in North America."

--- Dr. Catherine Woteki, Chief Scientist and USDA Under Secretary for Research, Education, and Economics

"The American diet is diverse. The addition of nutrition information from branded foods will be a tremendous asset to monitoring the American diet and achievements of industry to make healthier products."

--- Dr. Barbara Bowman, CDC

"Having data on branded food products to supplement the USDA National Nutrient Database will be extremely helpful to FDA in tracking the composition of the food supply and making food policy decisions to promote public health," said Jessica Leighton, PhD, senior nutrition science and policy advisor in FDA's Office of Foods and Veterinary Medicine. "The more accurate picture we have of the nutrient content of the food supply, the better informed our decisions on labeling requirements and encouraging food product reformulation will be."

--- Dr. Jessica Leighton, FDA

# Key Value for Nutrition Researchers

Additional data in the USDA National Nutrient Database will greatly benefit the NHANES survey by allowing for more specific assessment of foods eaten. For example, if a person reports



having eaten an item such as "vegetable soup", instead of the nutritional value being based on an averaged and generic database value, it would be based on the actual brand item consumed, and nutrient composition would be that supplied by the company.

"As a frequent user of the National Nutrient Database, it is with extreme pleasure to hear that the Public-Private Partnership is moving forward. The Harvard School of Public Health maintains a nutrient database for the analysis of semi-quantitative food frequency questionnaires. This database requires accurate and up to date brand data for cereals, margarines, oils, and fortified foods. The Public-Private Partnership would provide a more efficient means for us to maintain this accurate time specific brand data in our system."

--- Laura Sampson Kent, Harvard School of Public Health

# Key Value for Proprietary Database End Users

The enhanced USDA National Nutrient Database will increase the number of food products for end users who develop applications for consumers and health professionals. By expanding the data available for use in private applications, consumers seeking to eat more healthy diets and dieticians with the responsibility of developing specific diets are the beneficiaries of this information.

"A Partnership for Public Health: Branded Food Products Database will be a valuable resource to the University of Minnesota Nutrition Coordinating Center. It will allow us to improve the currency and completeness of our food and nutrient database, which will benefit nutrition researchers across the country who rely on it to carry out nutrition-related studies."

--- Lisa Harnack, University of Minnesota Nutrition Coordinating Center

# Key Value for Professional Societies

- The professional society members rely on the comprehensiveness of the USDA National Nutrient Database for their effort to tease out dietary patterns and nutrient inter-relationships with chronic disease/s.
- The enhanced database will provide more accurate information about what their clients are truly eating.

"The USDA's National Nutrient Database is the basis for the science and evidence-based practice of nutrition and dietetics. This important resource helps clinicians counsel patients, researchers plan projects, and food production experts create menus and products. This unique public-private partnership to expand the database and make it more comprehensively reflect the food supply available to consumers



Branded Food Products Database

is crucial. We believe that ultimately this database expansion will improve the public's health, aligning with our mission."

--- Sonja L. Connor, MS, RDN, LD, President-elect 2013-2014, Academy of Nutrition and Dietetics

# Key Value for Industry

- The enhanced USDA National Nutrient Database will become the single source of truth for nutrition data on branded and private label products.
  - Manufacturers will no longer have to respond to multiple requests from retailers and others and instead direct them to the Database.
- Recognizing that participation in this initiative will be resource-intensive for manufacturers, the Partnership has leveraged the existing GS1 community to ensure alignment with current industry practices.
  - Companies are already submitting product information into the GS1 network.
  - Trust has already been established that the system is secure and manufacturers can assure the accuracy of their shared data.
- Manufacturers recognize that more customers and consumers want virtual nutrition product information and the demand for this information will only intensify in the future.
  - Participation will ensure that your data is included in existing and newly developed nutrition apps that will draw from the augmented Database.
  - Participation will ensure improved customer service for the growing trend in online grocery sales and food delivery systems, such as Amazon, require virtual nutrition information.
- Manufacturers provide extensive recipes on their own websites and would benefit from having more accurate nutrient information on ingredients used in these recipes.

"General Mills is interested in continuing to work with the Public-Private Partnership to eventually provide our customers and consumers with a single source of accurate, up-to-date label information, available electronically through USDA"

--- Elizabeth Westring, General Mills Inc.

"This Partnership seeks to expand the USDA Standard Reference to include up-to-date branded manufacture data. It is critical that this data be available to researchers utilizing intake data, and others monitoring the food supply, in order to accurately represent the nutrition of our products in the marketplace and responsibly inform public policy."

--- Patricia Zecca, Campbell Soup Company

v.11.18.14

North American Branch of the International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743

202.659.0074 voice 202.659.3859 fax www.ilsina.org

# **ILSI North America**

# 2012 Membership Letter on Conflict of Interest Program

The topic of "conflict of interest" (COI) in conducting scientific activities is an issue of continuing concern and importance to the future of research related to nutrition, health, and food and ingredient safety. The purpose of this letter is to provide an analysis of the challenging environment in which we are operating and to gain your support for ILSI North America's (NA) program to address this issue.

ILSI was founded on the premise that there is great benefit to the development and application of science when academia, government, and industry work together to resolve issues of mutual interest. For over 30 years, the work of ILSI—and all its branches have documented this initial premise as a proven fact.

Clearly, it is in the interest of both the food industry and the general public to conduct the research necessary to meet legal requirements, and improve the safety of the food supply. It is equally important that the food industry help advance nutrition and health knowledge on the role of food—including both food ingredients and food components. Much of this research falls outside of the mission of traditional federal funding agencies and would not be done without food industry support and would be a detriment to consumers.

Despite a wealth of benefits industry sponsored research and science programs have provided, there continues to be significant public debate on the credibility of such support. While biases can come from many sources, much of the debate has focused on one area—industry funding. The end result has been the demand by some that all industry-funded research, whether conducted at contract research organizations or universities, be denied consideration in the formulation of public policy. Furthermore, scientists who have conducted industry-funded research have been barred from serving on public advisory committees.

ILSI-NA maintains that the scientific process requires open, transparent examination and honest interpretation of data, regardless of a researcher's affiliation or source of funding. In 2007 the ILSI-NA Board initiated a program to address COI issues. The program has been highly successful in developing "guiding principles" for industry funding of research (see enclosed publication), which have been endorsed by the leadership of three major professional societies. Results of this work have been published in six different peer-reviewed journals and presented at numerous scientific conferences. The next steps involve development of criteria for participation on scientific advisory panels and establishment of appropriate protocols for successful public/private partnerships to advance public health.

Issues related to COI will not be going away anytime soon. Continued engagement by ILSI-NA is required to ensure sound, evidence-based science prevails, and that credible scientists, regardless of affiliation, continue to have a voice in the debate. Our public-sector Trustees have volunteered both their time and expertise in the development of the current program. However—and this fact stunned me-only 20% of ILSI-NA's membership is providing financial support.

As important as this issue is to the food industry, we need all members to support initiatives related to COI. The current assessment for this activity is \$10,000 per company.

So here's my request. Review this letter—at least once more if not twice. I realize it's pretty long and I apologize for same. Post reading, if you have any questions or require further clarification on the current

1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743

202.659.0074 voice 202.659.3859 fax www.ilsina.org

# **ILSI North America**

situation we face, please reach out either to me (W—4046762177; email ) or Eric ) hentges (W-2026590074x196; email ). If additional explanation is needed, we can connect you to other members of the ILSI-NA Board, or to one of ILSI-NA's public-sector Trustees.

Now...if you haven't any questions, I encourage you to contact Eric and pledge your Company's support. It's what we need—it's what your Company needs—it's what the public needs to ensure scientific truth and evidence based deliberations, and decisions prevail.

Thank you for considering the request herein.

Sincerely yours,

Rhona Applebaum, PhD President, ILSI North America

# **Publications/Programs to date:**

• 2009 Guiding Principles

"Funding food science and nutrition research: financial conflicts and scientific integrity" Rowe S, Alexander N, Clydesdale FM, et al. Funding food science and nutrition research: financial conflicts and scientific integrity. Am J Clin Nutr 2009;89:1285–91.

- Simultaneous publication of the paper:
  - ♦ Nutrition Reviews
  - ♦ American Journal of Clinical Nutrition
  - ♦ Journal of the American Dietetic Association
  - $\diamond$  Journal of Nutrition
  - ♦ Journal of Food Science
  - ♦ Nutrition Today
- Presentations at:
  - ♦ Experimental Biology (EB Conference) April 2009
  - ♦ Institute of Food Technologists (IFT) conference June 9
  - ♦ American Dietetic Association (ADA) conference October 18
- 2011 "Funding Source and Research Report Quality in Nutrition Practice-Related Research" Myers EF, Parrott JS, Cummins DS, Splett P (2011) Funding Source and Research Report Quality in Nutrition Practice-Related Research. PLoS ONE 6(12): e28437. doi:10.1371/journal.pone.0028437
- Rowe S, et al. "How experts are chosen to inform public policy: Can the process be improved?", Health Policy (2013), http://dx.doi.org/10.1016/j.healthpol.2013.01.012

North American Branch of the International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743 202.659.0074 voice 202.659.3859 fax www.ilsina.org

# **ILSI North America**

- Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research, Rowe, S. et.al *Nutrition Reviews* 2013; 71(10):682-691
- "Branded Food Products Database for Public Health" Public-Private Partnership between ILSI North America, the USDA/ARS, and the ATIP (Agricultural Technology Innovation Partnership) Foundation.
- "Principles and Philosophies for Development of Ongoing Partnerships to Support Food-Health Research", Canadian Nutrition Society and ILSI North America Food for Health Workshop 2014



# Agenda: Working Group on Conflict of Interest & Scientific Integrity **Conference Call**

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

Dial-in information: 1-888-585-9008, Access code: 327847914

Purpose: To update the Working Group on recent activities and discuss future plans.

I.	Welcome and Introductions	A. Kretser
II.	Approval of 29 May Meeting Minutes	D. Lund
III.	Support of Professional Societies of COI PPP Principles	E. Hentges
	a. 8 December Meeting	
	b. 12 May Unveiling	
IV.	A Partnership for Public Health: Branded Food Products Database	A. Kretser
	a. National Nutrient Databank Conference Proceedings	
	b. Beta Test	
	c. Best Practices Workshop	
	d. Pledge Letter	
	e. Outreach Strategy	
V.	GRAS Assessment	E. Hentges
VI.	New Projects	D. Lund
VII.	Next Steps	D. Lund
	a. 2015 In-Person Meeting	
VIII.	Adjournment	A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 2 December, 2014, 10:00-11:30 am EDT

#### **Attendees**

Daryl Lund, chair David Allison Fergus Clydesdale Johanna Dwyer John Erdman Eric Hentges Alison Kretser **Richard Lane** Beate Lloyd Joanne Lupton Debra Miller Delia Murphy Claudia Riedt Amy Preston David Thomas Jennifer van de Ligt Connie Weaver

# **Tentative**

Mark Moorman

#### **Unable to Attend**

Rhona Applebaum Stephanie Atkinson Kerr Dow Rachel Goldstein Joseph Ratliff Kari Ryan Shawn Sullivan Liz Westring

# **Unconfirmed**

Nelson Almeida Tom Boileau Michael Doyle James Hill Steven Rizk

University of Wisconsin, Madison University of Alabama at Birmingham University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign ILSI North America **ILSI** North America PepsiCo Inc. Coca-Cola Company Texas A&M University The Hershey Company **ILSI** North America Dr Pepper Snapple Group The Hershey Company Dr Pepper Snapple Group Cargill, Incorporated Purdue University

# Kellogg Company

Coca-Cola Company McMaster University Cargill, Incorporated Mars, Incorporated Dr Pepper Snapple Group Kraft Foods Group, Inc. ILSI North America General Mills Inc.

Kellogg Company Kraft Foods Group, Inc. The University of Georgia University of Colorado Health and Wellness Center Mars, Incorporated

From: Sent: To:	Delia Murphy Friday, November 21, 2014 1:43 PM		
	; Shawn Sullivan; james.hill@ucdenver.edu;		
	; Joanne Lupton; ; mdoyle@uga.edu;		
	weavercm@purdue.edu;		
	DAllison@uab.edu; Sharon Weiss;		
	Eric Hentges; ;		
	; jwerdman@illinois.edu; fergc@foodsci.umass.edu; dblund@wisc.edu;		
	;		
Cc:	Eric Hentges; Alison Kretser		
Subject:	ILSI North America Conflict of Interest & Scientific Integrity Working Group Agenda and Materials for 2 December Call		
Attachments:	Agenda and Materials 2 Dec Call.pdf		

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Agenda and Materials for 2 December Call

Please find attached a PDF that contains the agenda and materials for the 2 December conference call with the Conflict of Interest & Scientific Integrity Working Group from 10:00 to 11:30 am EST. Please review the materials in advance of the conference call. On the left hand side of the PDF is a bookmarks tab (which looks like a ribbon) that allows you to navigate the individual documents within the PDF.

Please use our conference call number to dial in: 1-888-585-9008 Access code: 327847914

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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# **Tentative**

Kerr Dow Claudia Riedt

# **Unable to Attend**

Rhona Applebaum Joseph Ratliff Kari Ryan Shawn Sullivan

# **Unconfirmed**

Nelson Almeida Fergus Clydesdale Michael Doyle Rachel Goldstein Johanna Dwyer James Hill Beate Lloyd Steven Rizk University of Wisconsin, Madison University of Alabama at Birmingham McMaster University University of Illinois at Urbana-Champaign ILSI North America ILSI North America PepsiCo Inc. Texas A&M University The Hershey Company ILSI North America The Hershey Company Dr Pepper Snapple Group Cargill, Incorporated General Mills Inc.

Cargill, Incorporated Dr Pepper Snapple Group

Coca-Cola Company Dr Pepper Snapple Group Kraft Foods Group, Inc. ILSI North America

Kellogg Company University of Massachusetts at Amherst The University of Georgia Mars, Incorporated NIH/Tufts University Medical Center University of Colorado Health and Wellness Center Coca-Cola Company Mars, Incorporated



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

A. Kretser

A. Kretser

# Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Thursday, 29 May, 2014, 10:00-11:30 am EDT

# Purpose: To update the Working Group on the Public-Private Partnership (PPP) and recent activities.

#### I. Welcome and Introductions

a. Ms. Alison Kretser welcomed Working Group members to the call and led introductions. She noted that the group has not met for 5 months and tremendous progress of activities has been made since that time.

# II. Communications/Publications on PPP

# a. Mid America Food Processors Association Presentation, March 2014 A. Kretser

- i. The 3 Partners of A Partnership for Public Health: *Branded Food Products Database* gave a presentation on the PPP at the Mid America Food Processors Association (MAFPA) Annual Meeting in March 2014. MAFPA invited the Partnership to present after attending the 14 November 2013 listening session in Washington, DC. The Partnership connected with many small and mid-size companies and there was a lot of interest and support for the project. MAFPA has committed its membership to lead the small and mid-size companies in the submission of data.
- ii. Coming out of meeting, Red Gold, a mid-sized company that produces canned tomatoes, has agreed to be part of the beta test.

# b. "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," *Nutrition Today*, March 2014

- "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communication Challenge," is a recent publication by Sylvia Rowe and Nick Alexander that focuses on PPPs in nutrition. The publication was a separate project from ILSI North America but A Partnership for Public Health: *Branded Food Products Database* is cited in the article.
- ii. At this point, the article is not open access and we do not have the final version.



iii. Action Item: Post the final publication on the COI Extranet and let the Working Group know when it is complete.

**E. Hentges** 

#### c. Experimental Biology Reception on PPPs

# i. Dr. Eric Hentges shared information about a reception on PPPs that was held during the Experimental Biology (EB) meeting in San Diego. The reception was organized by USDA and ASN as a continuation of the initiative that USDA ARS and NIH/NCI began which was spearheaded by Dr. Catherine Woteki and Dr. John Milner. A Partnership for Public Health: *Branded Food Products Database* was originally identified in this initiative as a PPP that should be developed.

- The reception included an update on the activities of the USDA ARS and NIH/NCI collaboration. They are looking moving forward with existing projects and looking for new PPPs to develop.
- iii. Dr. Hentges noted that there are opportunities for further collaborations, particularly in the Microbiome area. He suggested that one of ILSI North America's Committees that has been sunsetted could potentially come back and become a part of the collaboration.
- iv. Dr. Hentges and Ms. Kretser presented on the Partnership and shared an update on the progress. 80 individuals, including Dr. Hentges, Ms. Kretser, and several Working Group members, were present.

# d. National Nutrient Databank Conference, May 2014 A. Kretser

- i. The 3 Partners presented at the National Nutrient Databank Conference (NNDC) in May. Ms. Kretser noted that the PPP was the showcase of the meeting and that NNDC was an ideal venue to present on the Partnership because it represents a core group of end users of the enhanced USDA National Nutrient Database. 110 attendees were present at NNDC.
- ii. The 3 Partners gave a 1 ½ hour presentation which provided the most up to date information on the progress on Partnership. The Partnership also sponsored a breakfast, featured a poster at the poster session, and held an informal listening session at lunch. The Partners sat at 4 tables with individuals who wanted to continue the discussion and learn more about how they can become engaged.



- iii. In preparation for the conference, a logo for the Partnership was developed that incorporated the logos of the 3 Partners. The Partners are continuing to refine the logo and the ATIP Foundation expressed interest in making further edits so the logo was not shared with the Working Group.
- iv. Ms. Kretser noted that there were several outcomes of the Partnership's presence at NNDC, including: furthering the credibility of the Partnership and giving the initiative high visibility.
- v. During the Q&A after the presentation, there was a strong desire from the nutrition research community that, as the Partnership moves forward and works through implementation and automation of imputing nutrient values, FNDDS codes, and food groups, this becomes an open source, transparent process. It was encouraging to hear this from the community of end users and it was clear that USDA heard that message.
- vi. The Partnership's presence at NNDC created an opportunity to connect with new universities, including the University of Utah and UNC Chapel Hill.
  - A doctoral student from the University of Utah presented on how to assign FNDDS codes and the Partnership connected with her academic advisor, Dr. John Hurdle in the computer science program.
  - 2. Ms. Emily Yoon from UNC Chapel Hill presented on the work of Dr. Barry Popkin's group. The Partners had the opportunity to establish a relationship with Ms. Yoon and her team. They confirmed that the success of the PPP will benefit their database.
  - 3. The Partnership plans to continue outreach with these universities.
- vii. The Partners met with several proprietary databases (Food Essentials, NuVal, ESHA, and the NYC Department of Health who manage MenuStat) that were present and were able to ask them if they were concerned about the PPP impacting their business model. It was confirmed that the proprietary databases present believe the publically available enhanced database will be a benefit to them because it would become the source of the data to pull from and they would no longer have to collect the data themselves. Currently, many proprietary databases spend considerable resources gathering data themselves by pulling the data from websites, or purchasing and



photographing products from the grocery store. By having the data in a publically available database with the assurance that the data is current, the proprietary databases can focus on the analysis of the data, marketing, etc.

- viii. The Partners met Interim Director of the Beltsville Nutrition Center, Dr. Jim Harnly, and briefed him on the Partnership's activities. A discussion on automating algorithms was had and Dr. Harnly noted that it would be a new paradigm to create or develop these algorithms. Further work is needed to develop the process for automation of algorithms and the Partnership will continue to explore this discussion.
  - ix. The Partnership plans to attend future NNDC meetings to provide an update on the progress of the initiative and continue to receive input from this important group of stakeholders.

# e. Canadian Nutrition Society Food for Health Workshop, June 2014 E. Hentges

 Over the last 2 years, ILSI North America has looked to enhance its activities in Canada and has established a relationship with the Canadian Nutrition Society (CNS). ILSI North America and CNS will jointly the Food for Health Workshop -Principles and Philosophies for Development of Ongoing Public-Private Partnerships to Support Food-Health Research in June 2014, in conjunction with the CNS Annual Meeting. Dr. Hentges will present on A Partnership for Public Health: *Branded Food Product Database* as a case study for ILSI North America. Dairy Farmers of America will also present case study.

# f. 17th IUFoST World Congress of Food Science and Technology, August 2014 E. Hentges

- Dr. Hentges shared that he will also present on the Partnership as part of a session at the 17<sup>th</sup> IUFoST World Congress of Food Science and Technology in Montreal in August.
- ii. Dr. Daryl Lund, chair of the Working Group, noted that he would be present at IUFoST and is the incoming chair of the scientific council.

#### g. John Milner Memorial Symposium, 12 June, 2014

#### A. Kretser

 USDA is hosting a symposium on June 12 in honor of Dr. John Milner. The symposium will have 6 presentations, including a presentation from Dr. Richard Black, PepsiCo Inc. on PPPs. Dr. Black will include information about A Partnership



for Public Health: *Branded Food Products Database* as he serves as the co-chair of the Steering Committee. This will be another good opportunity for the Partnership to gain visibility.

# III. Proof of Concept: A Partnership for Public Health: Branded Food Products Database

# A. Kretser A. Kretser

#### a. Meeting with USDA Under Secretary on PPP Progress Report

- i. Ms. Kretser shared that the 3 Partners met with USDA Under Secretary Dr. Catherine Woteki on 7 Feb to discuss the Partnership Progress Report that she received on 18 January 2014. The 200 page Progress Report served to document and chronicle all of the activities of the PPP over the past year including the development of the groups. The report explains how the Partners have used the 12 principles to guide the establishment and operation of the initiative and the importance of transparency in how decisions were reached and the key players involved in the initiative.
- ii. Dr. Woteki was tremendously appreciative of all the work that has been completed in such a short period of time. She approved the Progress Report and requested a 90-day and a 12 month budget be developed. The Partnership responded to USDA with developed budgets for the 90-day period and the first 12 months on 27 February, 2014 and after some discussions, a final budget was sent to USDA on 8 April, 2014. Both budgets were approved on 21 May and funds from USDA will be allocated for the project.
- iii. Once the Specific Cooperative Agreement is put in place between USDA and the ATP Foundation and the funds for the 90-day beta test are transferred, the ATIP Foundation can proceed to sign the contract with FSEnet, the chosen GS1 certified data pool provider.

#### **b.** Implementation Phase

#### A. Kretser

- i. Budget
  - Ms. Kretser shared that the proposed Partnership budget from the ATIP Foundation and ILSI North America for the 90-day beta test and the remaining 9 months of the first year was approved by USDA. USDA and the



ATIP Foundation are working on a Specific Cooperative Agreement to transfer the funds.

# ii. Beta Testing

- Once the contract with FSEnet, the GS1 certified data pool provider, is signed with the ATIP Foundation, there will be a 45 day period to set up and configure the portal to receive published data from manufacturers.
- 2. The beta test includes 5 beta test companies: Campbell Soup Company, Cargill, Incorporated, ConAgra Foods Inc., General Mills Inc. and Red Gold. Ms. Kretser shared that Red Gold, a medium sized canned tomato company, is not a current member of the GS1 community so they will test the non-GS1 portal. The Partners have agreed to bear the cost of having this portal so that those outside the GS1 community can participate in the initiative. FSEnet has already established this portal.
- 3. The Partners plan to hold a mapping exercise with the 5 beta test companies to finalize the attributes.

# iii. Outreach Strategy

- In anticipation of the Partnership budget being approved by USDA, the Communications Group has developed several outreach documents at the request of the Steering Committee. A Value Proposition document and a document on the Features of the Enhanced USDA National Nutrient Database have been developed.
- 2. As part of the outreach strategy developed by the ATIP Foundation, 7 categories of stakeholders have been identified who have a vested interest in the success of the Branded Food Products Database. The ATIP Foundation will lead outreach to these 7 categories for data submission and financial support. ILSI North America will provide subject matter support to the ATIP Foundation but will not participate in the funding ask.
- 3. The Academy of Nutrition and Dietetics (AND) has already expressed interest in financially supporting this initiative and becoming an inaugural supporter. We also anticipate that proprietary databases may be another key



source of funding as they realize the positive impact of this initiative on their business models.

- ILSI North America has continued to stress to the Partners that the contribution of the food industry is the submission of the data and not funds. Data submission is a crucial role and without data, there will not be a database.
- ILSI North America plans to schedule a conference call with the ILSI North America official representatives to discuss a pledge letter for manufacturers to sign pledging that their company will submit data to the Branded Food Products Database.
- Dr. Daryl Lund noted that the Value Proposition covers all interested parties except the key value for consumers and suggested that this should be included.
  - a. Dr. Hentges noted that the Partnership has not identified a direct to consumer group yet to engage but have thought of philanthropic organizations for the ATIP Foundation to coordinate outreach to.
  - b. Dr. Jennifer Van de Ligt shared that she would like to discuss the outreach to consumers further with the ATIP Foundation. Consumers are a large group and if the Partnership could resonate on a consumer level and could bring in small monetary donations, the funds could become pretty substantial.
  - c. The idea will be taken back to the Communications Group.
- 7. It was noted that PPPs are extremely challenging and require dedication. If the government does not move forward, the Partnership is in a stand-still. For ILSI North America, as we look to get involved in PPPs in the future, serious thought needs to be put in beforehand. It was suggested that the Board discuss the Partnership at Mid-year and what it means for ILSI North America's reputation to be a part of public-private partnerships. There are huge benefits to participating in PPPs, but they can also have unintended challenges.



- Dr. Johanna Dwyer commented that the potential success of this Branded Food Products Database initiative will be an enormous plus for ILSI North America. This is a different level of collaboration than we have had before.
- 9. Ms. Kretser shared that the principles that have been developed are playing out. The Partners have had the opportunity to work together as a team and develop trust but it doesn't come easily and the Partners have to work at it every day but tremendous progress has been made.

#### IV. GMA's Consumer Information Transparency Initiative

#### **E.** Hentges

- a. Dr. Hentges noted that many ILSI North America member companies have seen this GMA Consumer Information Transparency Initiative (CITI) and have inquired how the initiative works with the *Branded Food Products Database*. ILSI North America has kept in close contact with GMA and FMI on this initiative and have continued to brief them on updates to the *Branded Food Products Database*. The two initiatives will be synergistic and will complement each other as both are using the GS1 system so manufacturers will only have to submit their data once and can send it to both initiatives.
- b. The CITI initiative will focus on the consumer and plans to set standards within GS1 for 3,000 new attributes. Defining these new attributes benefits the *Branded Food Products Database* as manufacturers can potentially submit these same attributes in the future if the Partnership agrees.

# V. Support of Professional Societies of COI PPP Principles

# E. Hentges

- a. Dr. Hentges noted that this subject was brought up at Annual Meeting 2014 and the possibility of a summit or collection of major professional societies and federal agencies coming together in support of the PPP principles was discussed. At the conclusion of the summit, the professional societies would agree to a consensus statement on private funding for research and general acceptance of principles for PPPs, such as the Obesity Society Statement.
- b. The professional societies that ILSI North America has already spoken to, including the American Society for Nutrition (ASN), Institute of Food Technologists (IFT), and AND, and



all are supportive of the summit. Planning has begun to bring these societies together at the end of 2014.

c. Dr. Lund noted that it might be helpful for societies who publish journals to have their editors participate in summit.

# VI. GRAS Assessment

#### E. Hentges

- a. Dr. Hentges shared that pulling together a meeting to develop best practices to reduce bias when putting GRAS assessment panels together had been brought up at Mid-Year 2013 and again at Annual Meeting 2014. However, ILSI North America has not had the staff resources to dedicate to this thus far.
- b. Dr. Hentges noted that ILSI North America is looking to develop this project as a Board Task Force which would use the board contingency fund.
- c. The Working Group felt that the Conflict of Interest Summit idea seems to overlap with the GRAS Assessment project and wondered if there was a way to combine the two projects.
  - i. Dr. Hentges noted that there is synergism between the two projects. FDA intends to develop a conflict of interest document in the fall of 2014 so it would be beneficial to have a manuscript to share with FDA on best practices for advisory committees. The conflict of interest summit development may take longer to get together. The manuscript from the GRAS Assessment could be shared at the summit.
- d. Dr. Lund brought up an earlier idea from the Working Group to speak with IFT about creating a tutorial that could be used as an education tool about GRAS assessment.
  - Dr. Hentges informed the Working Group that IFT is developing a project along a similar vein. ILSI North America does not have a real education channel so this project has not progressed. Dr. Hentges plans to discuss the topic with Will Fisher, IFT, further as IFT is the logical organization to carry out this project.

# VII. Next Steps

#### D. Lund

- a. Dr. Lund outline the next steps for the ongoing projects, including:
  - i. Implementation and outreach of A Partnership for Public Health: Branded Food Products Database, including a successful beta test.



- ii. Scheduling time to discuss the pledge letter for data submission with ILSI North America official representatives.
- iii. Planning of the Conflict of Interest Summit of Professional Societies
  - 1. If Working Group members have suggestions of other professional societies to engage, please share.
- iv. GRAS Assessment
  - 1. ILSI North America will move forward with the development of a paper and will look into developing a tutorial on GRAS and GRAS process. Explore the possibility of integrating the GRAS and COI Summit projects by sharing the GRAS paper on the selection of GRAS panels at the Summit meeting.
- b. Dr. Ferg Clydesdale suggested looking at opportunities for collaboration with IOM and the Food Forum, particularly with the GRAS qualifications.

VIII. Adjournment

A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

# Thursday, 29 May, 2014, 10:00-11:30 am EDT

#### **Attendees**

Daryl Lund, chair Fergus Clydesdale Johanna Dwyer John Erdman Rachel Goldstein Eric Hentges Alison Kretser Richard Lane Beate Lloyd Delia Murphy Juan Navia Joseph Ratliff Shawn Sullivan Jennifer van de Ligt Liz Westring

# **Unable to Attend**

David Allison Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle James Hill Joanne Lupton Debra Miller Amy Preston Claudia Riedt Steven Rizk Kari Ryan David Thomas Wamwari Waichungo Sharon Weiss

University of Wisconsin, Madison University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign Mars, Incorporated ILSI North America ILSI North America PepsiCo Inc. Coca-Cola Company ILSI North America McNeil Nutritionals, LLC Dr Pepper Snapple Group ILSI North America Cargill, Incorporated General Mills Inc.

University of Alabama at Birmingham Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia University of Colorado Health and Wellness Center Texas A&M University The Hershey Company The Hershey Company Dr Pepper Snapple Group Mars, Incorporated Kraft Foods Group, Inc. Dr Pepper Snapple Group Coca-Cola Company **ILSI** North America

# Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm (Continental Breakfast Available Starting at 8:30am)

# Agenda

# Meeting Goals/ Objectives:

- 1. Agreement on purpose and goals
- 2. Agreement on statement of task
- 3. Agreement on a set of general principles for nutrition-related research public-private partnerships
- 4. Action items with deadlines delineated

# Facilitator: Sylvia Rowe

Welcome and Introductions	Sylvia Rowe	9:00am
Purpose and Context	David Klurfeld; Eric Hentges	9:30
Importance of Public-Private Partnerships	Cathie Woteki	9:45
Review of Statement of Task	Sylvia Rowe	10:15
Discussion of General Principles	Sylvia Rowe	11:00
Lunch		12:00pm
Continued Discussion	Sylvia Rowe	1:00
Wrap-Up and Next Steps	Sylvia Rowe; David Klurfeld; Eric Hentges	3:30

# **Additional Materials**

- 1. Roster
- 2. Principles from Rowe et al, 2013 Paper
- 3. Comments about the Principles (as of Nov. 19 noon)
- 4. Rowe et al, 2013 Paper
- 5. Statement of Task (SOT) with Timeline and Reference Links
- 6. Links to References for Context

# Achieving a Transparent, Actionable Framework for Public-Private Partnerships A Working Meeting

ILSI North America; 1156 15th Street, NW, Suite 200, Washington, DC 20005 Monday, December 8, 2014 9:00am - 4:00pm

# **Meeting Attendee List**

Sonja Connor, MS, RDN, LD President, Academy of Nutrition and Dietetics Research Associate Professor Department of Medicine Oregon Health Sciences University Portland, OR connors@ohsu.edu

Rosa K. Hand, MS, RDN, LD Senior Manager, Dietetics Practice Based Research Network Academy of Nutrition and Dietetics Chicago, IL

Mary Beth Whalen Chief Operating Officer Academy of Nutrition and Dietetics Executive Director, Academy Foundation Chicago, IL

Michael H. Stolar, PhD Senior Vice President, American Gastroenterological Association Bethesda, MD

Dorothea K. Vafiadis, MS, FAHA Director, Healthy Living American Heart Association Washington, DC

Wendy Johnson-Askew, PhD, MPH Chair, Food and Nutrition Section American Public Health Association Vice President for Corporate Affairs Nestle Florham Park, NJ John E. Courtney, PhD Executive Officer American Society for Nutrition Bethesda, MD

Robert M. Russell, MD Chair, American Society for Nutrition Foundation Board of Trustees Arlington, MA <u>rob.russell@tufts.edu</u>

Patrick J. Stover, PhD President-Elect, American Society for Nutrition Professor and Director Division of Nutritional Sciences Cornell University Ithaca, NY pjs13@cornell.edu

Barbara Bowman, PhD Director, Division for Heart Disease and Stroke Prevention National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention Atlanta, GA <u>Bbb8@cdc.gov</u>

Laura Pillsbury Food Technologist Office of Foods & Veterinary Medicine U.S. Food and Drug Administration Silver Spring, MD laura.pillsbury@fda.hhs.gov

Robert A. Burns, PhD Vice President, Health and Nutrition Policy Grocery Manufacturers Association Washington, DC Christie Tarantino, FASAE, CAE Executive Vice President Institute of Food Technologists Chicago, IL

Janet Collins, PhD, RD, CFS Past President, Institute of Food Technologists Senior Manager, Corporate Regulatory Affairs DuPont Washington, DC

Mary Ellen Camire, PhD President, Institute of Food Technologists Department of Food Science and Human Nutrition University of Maine Orono, ME mary.camire@umit.maine.edu

Donald L. Zink, PhD President, International Association for Food Protection Senior Science Advisor Center for Food Safety and Applied Nutrition US Food & Drug Administration College Park, MD donald.zink@fda.hhs.gov

David W. Tharp, CAE Executive Director International Association for Food Protection Des Moines, IA

Alison J. Kretser, MS, RD Director, Science Programs International Life Sciences Institute North America Washington, DC

Eric Hentges, PhD Co-chair, Working Group V. Collaborative Process Executive Director International Life Sciences Institute North America Washington, DC

Van S. Hubbard, MD, PhD Director, National Institutes of Health Division of Nutrition Research Coordination Rear Admiral, U.S. Public Health Service (*Ret.*) Bethesda, MD hubbardv@mail.nih.gov Nancy J. Emenaker, PhD, MEd, RD Health Sciences Administrator Division of Cancer Prevention National Cancer Institute National Institutes of Health Bethesda, MD emenaken@mail.nih.gov

Lisa Kaeser, JD Program Analyst Office of Legislation and Public Policy Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health Bethesda, MD kaeserl@mail.nih.gov

Charlotte Pratt, MS, PhD, RD Program Director, Clinical Applications and Prevention Branch Division of Prevention and Population Sciences Division of Cardiovascular Sciences National Heart, Lung, and Blood Institute National Institutes of Health Bethesda, MD prattc@nhlbi.nih.gov

Paul M. Coates, PhD Director, Office of Dietary Supplements National Institutes of Health Bethesda, MD coatesp@od.nih.gov

Catherine Woteki, PhD Under Secretary, Research, Education, and Economics Chief Scientist US Department of Agriculture <u>Catherine.Woteki@osec.usda.gov</u>

Pamela Starke-Reed, PhD Deputy Administrator, Nutrition, Food Safety and Quality Agricultural Research Service, US Department of Agriculture Beltsville, MD Pamela.Starke-Reed@ARS.USDA.GOV

David M. Klurfeld, PhD Co-chair, Working Group V. Collaborative Process National Program Leader, Human Nutrition Agricultural Research Service, US Department of Agriculture Beltsville, MD david.klurfeld@ars.usda.gov Dionne Toombs, PhD Director, Division of Nutrition Institute of Food Safety and Nutrition National Institute of Food and Agriculture US Department of Agriculture Washington, DC dtoombs@nifa.usda.gov

Robert Brackett, PhD Member, Working Group V. Collaborative Process Director and Vice President, National Center for Food Safety and Technology Illinois Institute of Technology Institute for Food Safety and Health Chicago, IL rbrackett@iit.edu

Ratna Mukherjea, PhD Member, Working Group V. Collaborative Process Global Nutrition Leader DuPont Nutrition & Health St Louis, MO

Sylvia Rowe, PhD President SR Strategy, LLC Washington, DC

Nick Alexander Science Writer

Linda Meyers, PhD Senior Science Advisor American Society for Nutrition Bethesda, MD

Delia Murphy Science Program Associate International Life Sciences Institute North America Washington, DC

# Statement of Task: Achieving a Transparent, Actionable Framework for Food and Nutrition Research-Related Public-Private Partnerships

# **Overview**

There is an urgent need for an expanded, rigorous, and focused research agenda in food and nutrition that is driven by increased awareness that food, nutrition, and human health are closely linked through complex interactions, and a recognition that associated costs contribute substantially to rising national health care expenditures. New research approaches are critically needed to capitalize on our current understanding of the role of food and food systems in chronic disease prevention and management and to translate this knowledge into the development of public health interventions, innovative products, and evidence-based policies that meet the public's expectations and support the health of the nation. However, government resources devoted to food and nutrition research are shrinking, stifling economic growth and innovation in the food and nutrition sector and delaying the opportunity to better harmonize the food system and human health.

Public-private partnerships (PPPs), collaborative relationships involving partners from government, industry, and academia, are increasingly appreciated as a novel approach to simultaneously advance public health and a 21<sup>st</sup> century food and nutrition research agenda, resulting in a food system that can support both consumer and commercial interests in the development of new products and markets. PPPs are the only mechanism known to bring together the best scientists from all sectors with distinct, yet complementary, expertise and perspectives. By bringing expertise from diverse disciplines and sectors together to address research questions where public health and other benefits are achievable, PPPs combine and maximize multidisciplinary resources in a time when financial and other resources devoted to food and nutrition research are limited. Risks can be largely shared and the comprehensive approach necessary to address today's complex scientific questions is best achieved through the involvement of multiple disciplines and partners.

PPPs are not always the best approach to investigate certain areas of food and nutrition research. A roadmap is necessary to help organizations understand when to use PPPs for food and nutrition research and how to use and operate PPPs most efficiently and effectively. While several groups have developed principles for the creation of food and nutrition partnerships (3<sup>rd</sup> World Conference on Research Integrity, 2013; Institute of Medicine, 2012; Canadian Institutes of Health Research, 2008), such principles have generally been developed in silos and may not be actively used by the various types of organizations to determine when and how to undertake a PPP. Rowe et al. (2013) sought to compile existing guidelines using a 3-step process which resulted in the articulation of 12 potential principles for establishing and managing successful research PPPs.

Thus, this activity aims to stimulate the expansion, accessibility, and acceptance of PPPs by unifying and moving existing principles for food and nutrition research PPPs forward, making them publicly available for all interested parties to reference and use. Numerous food and nutrition research professional/scientific societies, non-profit research foundations, and federal

agencies will be involved in the identification of these principles, and agreement and endorsement of the unified set of PPP principles will be gained from additional stakeholders, representing a collective effort to achieve the best research outcomes possible. With such widespread involvement and endorsement, it is hoped that this framework will be broadly used by the collaborating organizations and others to create PPPs that will ultimately improve public health.

This activity is part of the work of the government-wide Interagency Committee on Human Nutrition Research (ICHNR) to build food and nutrition partnerships that began in 2011. Four research areas with the greatest potential for both public health impact and implementation feasibility emerged: (1) Food Composition and Nutrition Monitoring; (2) Biomarkers; (3) The Microbiome, and (4) Consumer Behavior. Working groups with representation from government, academia and industry were created. A fifth working group on Collaborative Process was also created to identify characteristics of successful PPPs and potential barriers to success. This activity carries on the work of Working Group V. Collaborative Process, co-chaired by David Klurfeld, Ph.D., USDA/ Agricultural Research Service (ARS) National Program Leader in Human Nutrition, and Eric Hentges, Ph.D., Executive Director of the International Life Sciences Institute North America. Other members of Working Group V are Robert Brackett, Ph.D., Illinois Institute of Technology Vice President and Director of the Illinois Institute for Food Safety and Health, and Ratna Mukherjea, Ph.D., Global Nutrition Leader at DuPont Nutrition & Health.

Through a cooperative agreement with USDA/ ARS, the American Society for Nutrition (ASN) will convene representatives from: USDA, ASN, the Academy of Nutrition and Dietetics (AND), American Heart Association (AHA), American Gastroenterological Association (AGA), the Food and Nutrition Section of the American Public Health Association (APHA), the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Grocery Manufacturers Association (GMA), Institute of Food Technologists (IFT), International Association of Food Protection (IAFP), International Life Sciences Institute North America (ILSI North America), and the National Institutes for Health (NIH) to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

# **Project Goals/ Objectives**

The main purpose of the face-to-face meeting is to develop a transparent and actionable framework for establishment and operation of PPPs to achieve the best food and nutrition-related research outcomes.

- The framework will be developed in partnership by key food and nutrition-related federal agencies, non-profit research foundations, and professional societies. Sign on to the principles will be sought from all partners and other relevant organizations.
- The framework will be made publically available to be used as a model by interested public and private organizations. Commitment is needed from all involved to promote the principles, including publishing the framework in the relevant publications of each partner organization, as applicable.

• Commitment is needed from all involved to update the framework on a regular, as-needed basis, to enhance the value and sustainability of the framework.

# **Process for Moving Forward**

The following timeline for action will facilitate the achievement of the expected goals and objectives. The timeline can be altered at any time for sufficient flexibility. However, a sense of urgency should be encouraged and maintained in order to achieve the optimal outcome.

- Initiate 1<sup>st</sup> outreach to secure commitment from all relevant professional/scientific societies, non-profit research foundations, and federal agencies (henceforth known as collaborators) for involvement on the proposed project.
- Hold preliminary conference call for collaborators on September 5, 2014.
- Collaborators agree to Statement of Task *by October 10, 2014*. In doing so, all collaborators agree to assist with achievement of goals/objectives as outlined in the statement of task.
- Begin discussions with publishers of relevant journals to secure agreement to publish framework and assure coordination of deadlines, etc. *in November 2014*.
- Hold meeting of collaborators in Washington, D.C. *on December 8, 2014* to develop a transparent, actionable framework for food and nutrition research-related PPPs.
- Identify date and location *by January 16, 2015* for a meeting to publicly unveil framework. This will be an invite-only stakeholder meeting, ideally hosted at the location of an independent public agency, such as the <u>Government University Industry Research</u> <u>Roundtable (GUIRR) of the National Academy of Sciences</u>.
- Secure sign on and promotional support for the framework from collaborators *by March 16*, *2015*. Securing such support may require gaining Board and membership approval(s), as applicable.
- Conduct outreach to relevant organizations that may wish to sign on to the framework *by March 16, 2015.*
- Publish framework and other relevant materials in applicable journals *Target*: April 2015.
- Create program including topics and speakers for public unveiling of the framework that will clearly articulate goals/objectives and framework *by April 1, 2015*.
- Develop and finalize invitation list for public unveiling of framework. Send joint invite from collaborators *by April 17, 2015*.

• Announce the framework at public unveiling meeting – *Target: May 12, 2015.* Engage all attendees in the dialogue and secure their commitment to share and implement the framework.

# Public-Private Partnership References

- <sup>3<sup>rd</sup></sup> World Conference on Research Integrity. "Montreal statement on research integrity in crossboundary research collaborations." Montreal, Canada. May 2013. <u>http://www.cehd.umn.edu/olpd/montrealstatement.pdf</u>
- Rowe S, Alexander N, Kretser A, Steele R, Kretsch M, Applebaum R, Clydesdale F, Cummins D, Hentges E, Navia J, et al. Principles for building public-private partnerships to benefit food safety, nutrition, and health research. *Nutr Rev* Oct 2013;71:682-91. http://www.ncbi.nlm.nih.gov/pmc/articles/pmc3886300/
- Institute of Medicine. 2012. Building public-private partnerships in food and nutrition: Workshop summary. Washington, DC: The National Academies Press. https://www.ncbi.nlm.nih.gov/books/nbk97331/
- Canadian Institutes of Health Research. 2008. "Building trust to address the obesity epidemic workshop report." King City, Ontario. The Building Trust Initiative. http://buildingtrustinitiative.files.wordpress.com/2011/05/building-trust-report-vol-1.pdf

# A Partnership for Public Health



# Features of the Enhanced USDA National Nutrient Database

The goal of the Public-Private Partnership is to expand the current nutrient data by obtaining compositional data directly from the food industry. An expanded database will contain much more information on individual food items allowing for a true assessment of the extent and fluidity of the food system.

Nutrition Facts Serving Size 2/3 cup (55g) Servings Per Container About 8	1.	<ul> <li>Parent Company (Manufacturer, Subsidiary, signature line) or Private</li> <li>Label (signature line)</li> <li>Enhanced database will allow for more specific data collection</li> </ul>	
Amount Per Serving		and analysis in NHANES; allowing for more specific assessment	
Calories 230 Calories from Fat 40		of foods eaten by the population.	
% Daily Value*	2.	Nutrition Facts Panel (NFP) and Expanded Facts Panel (when	
Total Fat 8g 12%	-	available)	
Saturated Fat 1g 5%		$\frac{1}{1}$	
Trans Fat 0g		• Information available as packaged and as prepared, with	
Cholesterol Omg 0%		added ingredients	
Sodium 160mg 7%		• No longer will a nutritional value be based on an averaged or	
Dietory Eiber 4a		generic database value	
Sugars 10		Server e autorise variae.	
Protein 3g	-	If someone reports having eating	
Protein Sy	3.	Product name and generic descriptor	
Vitamin A 10%	4.	Weights and measures	
Vitamin C 8%	5.	Serving size and servings per package	
Calcium 20%		the actual brana item consumea.	
Iron 45%			
Your daily value may be higher or lower depending on your calorie needs. Calories: 2,000 2,500 Total Fat Less than 65g 80g Sat Fat Less than 20g 25g Cholesterol Less than 300mg 300mg Sodium Less than 2,400mg 2,400mg Total Carbohydrate 300g 375g Dietary Fiber 25g 30g	6. 7.	<ul> <li>Date Stamp associated with most current formulation (effective date of change/introduction)</li> <li>Historical data on food products will allow for tracking dietary trends.</li> <li>Ingredient list and sub-list (hierarchical and in descending order)</li> </ul>	
INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, HEDUCED Iron, Thiamin Mononitrate (Vitamin B1), Riboflavin (Vitamin B2), Foild John Greun Schub Corden and Dan Mai (Antu Taub		• This information has never been captured before in the National	
FOR FRESHNESS), CORN SYRUP SOLIDS, DEXTROSE, HIGH FRUCTOSE CORN SYRUP FRICTOSE, GIVERNIN, CONTAINS 2%, OR LESS OF CACAA		Nutrient Database. Having this information available will allow	
(PROCESSED WITH ALKALI), POLYDEXTROSE, MODIFIED CORN STARCH, SALT, DRIED CREAM, CALCIUM CARBONATE, CORNSTARCH, LEAVENING (BAKING		for analysis that has never been done.	
SODA, SODIUM ACID PYROPHOSPHATE, MONOCÁLCIUM PHOŠPHATE, Calcium Sulfate), distilled monoglycerides, hydrogenated Palm	8.	GTIN Number	
KENNEL DIL, SJOUM STEARDYL LACYTALE, GELNIK, COLOR ANDED, SDY LEGTIHL, DATEM, MATURAL AND ANTIFICIAL, FLAND, WAILLA ETRACT, CARNAUSA WAX, XANTHAN GUN, VITAMIN A PALMITATE, YELLOW & LAKE, RED 440 LAKE, CARANEL COLOR, NICHANNER, BLUK Z LAKE, REDUCED IRON, YELLOW & LAKE, PRIDOXICA HOROCHLORIDC VITAMIN BJ, RIBO- FLANN VITAMIN BJ, THRAIM MTOROCHLORIDC VITAMIN BJ, RIBO- FLANN VITAMIN BJ, THRAIM MTOROCHLORIDC VITAMIN BJ, RIBO- FLAND VITAMIN BJ, THRAIM MTOROCHLORIDC VITAMIN BJ, RIBO-	/	<ul> <li>Specific nutrient composition directly from the food product, correlated to this number, will be available.</li> </ul>	
5 901234 123457 >	s f E	Food composition databases are central to the conduct of nutrition research, as they tandardize how foods can be characterized in terms of nutrients, dietary guidance-based food groups and other relevant dietary constituents. A Partnership for Public Health: Branded Food Products Database will provide researchers the first-ever completely free and	
	р g	nublicly available database on the composition of foods by brand name. This will enable greater specificity in all types of nutrition studies of individual's diets and food	

environments."

- Dr. Susan Krebs-Smith, National Institutes of Health



# Agenda: **Best Practices Workshop for ILSI North America Members** For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Conference Call Dial-in information: 1-888-585-9008, Access code: 327847914

Purpose: The Best Practices Workshop is being held for ILSI North America member companies in preparation for full implementation of A Partnership for Public Health: Branded Food Products Database.

I.	Welcome and Introductions	A. Kretser
II.	GS1 Source	A. Fernandez/ S. Brown
III.	Overview of the Beta Test	R. Rosenbaum/ M. Hamilton
IV.	Perspectives from Beta Test Companies	Beta Test Companies
V.	Questions and Discussion	All
VI.	Data Submission to FSEnet Prior to Full Implementation	R. Rosenbaum
VII.	Pledge Letter and Press Release	A. Kretser
VIII.	Next Steps	A. Kretser
IX.	Adjournment	A. Kretser


# Attendance: Best Practices Workshop for ILSI North America Members For A Partnership for Public Health: Branded Food Products Database

Wednesday, 19 November, 2014, 10:00 am-3:00 pm EST

Attendees Scott Brown Donna Courtney **Bill Ferguson** Angela Fernandez Merissa Hamilton Alison Kretser Kyle McKillop Timothy Morck Alanna Moshfegh Matt Muldoon Rachel Murphy Delia Murphy Debbie Nece Rob Rosenbaum Trish Zecca Attending via Conference Call Nick Alexander Jennifer Bauman Cathy Bone Chris Chatzidakis David Cockram Richard D'Aloisio Christine Downs Lori Fix Judy Gluvna Kristin Harris Paul Hoffman Katlyn Kutzlo Minh Le Shannon Lytle Michael Marino Debra Miller Gary Montgomery Sheila Ost Eric Park Claudia Riedt

GS1 The Hershey Company Kellogg Company GS1 FSEnet **ILSI** North America University of Maryland Nestle USA USDA ARS FSEnet **DSM Nutritional Products ILSI North America** Cargill, Incorporated **ATIP** Foundation Campbell Soup Company SR Strategy

Campbell Soup Company Monsanto Company ConAgra Food Inc. Abbott Nutrition Mondelez International Abbott Nutrition Unilever Abbott Nutrition Hillshire Brands Kraft Foods Group Inc. Red Gold, Inc. Herbalife International of America, Inc. Red Gold, Inc. Kellogg Company The Hershey Company Abbott Nutrition ConAgra Foods Inc. Monsanto Company Dr Pepper Snapple Group



Andrew Shao Lynette Shawd Jennifer Van de Ligt Casey Zanis

Unable to Attend Doug Balentine **Richard Black** Greg Buckley Philippe Caradec Joseph Carlos Stuart Craig Brent Flickinger Jennifer Garrett Llaine Groninger Leslie Henderson Becki Holmes Cassie Hoover Christina Khoo Dot Lagg Suzanne Lee Beate Llovd Mark Maier Michael McBurney Susan McKee Mark Moorman Phil Morreale Matthew Muldoon Gabriella Parisse Christine Pelkman Fred Shinnick Miro Smriga Steve Rizk Sylvia Rowe Juan Navia Brian Schaneberg Stephan Theis Cass Wade-Kudla David Walsh Liz Westring Paul Zanno

Herbalife International of America, Inc. General Mills Inc. Cargill, Incorporated Herbalife International of America, Inc.

Unilever PepsiCo Inc. PepsiCo Inc. Danone Waters of America, Inc. Abbott Nutrition DuPont Archer Daniels Midland Company McCain Foods USA The Hershey Company Mondelez International Red Bull GmbH Nestle USA Ocean Spray Cranberries, Inc. Mars Chocolate North America Nestle USA The Coca Cola Company Valspar Corporation **DSM** Nutritional Products Kraft Foods Group Inc. Kellogg Company Mondelez International FSEnet Tate & Lyle Ingredion Incorporated Senomyx, Inc. Ajinomoto North America, Inc. Mars, Incorporated SR Strategy McNeil Nutritionals, LLC Starbucks Corporation BENEO General Mills Inc. Herbalife International of America, Inc. General Mills Inc. Dr Pepper Snapple Group

# A Partnership for Public Health: Branded Food Products Database







#### Pledge Letter

As a member of ILSI North America and a food/ingredient manufacturer, we are signing this voluntary pledge letter to submit nutrient composition and label data on behalf of A Partnership for Public Health: *Branded Food Products Database*. We commit to using GS1 standards through an ATIP Foundation contracted GS1 certified data pool provider for inclusion as part of an enhanced USDA National Nutrient Database. We are aware this data will become publically available once received by the USDA National Nutrient Database. The proposed addition of branded food compositional data to the USDA National Nutrient Database is an essential tool for developing research strategies to inform public policy regarding food and nutrition and will create a database more truly reflective of the breadth and depth of the nation's food supply. Various sectors of the research community and the food and health care industries will find this database valuable. For example, this will enhance the National Health and Nutrition Examination Survey (NHANES) by more accurately characterizing food selection and nutrient intakes for Americans; nutrition software developers can produce enhanced software so that dietitians will be able to better tailor diets to nutritional needs; medical researchers will be able to better link dietary intakes to measures of optimal health; authoritative scientific bodies will be able to develop better guidelines that will promote public health; and food manufacturers could use this to improve product formulations.

The enhancements brought about by this Public-Private Partnership will ensure that USDA ARS nutrient composition data will remain the "Gold Standard" for the next decade and beyond.

The following information (attributes) will be submitted. These attributes are currently on the food packaging label. However, by providing these attributes in the GS1 format, it is possible to have the most up-to-date version of this data available to the public through the USDA National Nutrient Database.

- 1. Parent Company (manufacturer, subsidiary, signature line) or Private Label (signature line)
- 2. Product Name and Generic Descriptor
- 3. Global Trade Item Number (GTIN)
- 4. Ingredient List and Sub-List (hierarchical and in descending order)
- 5. Weights and Measures (net weight/volume of package)
- 6. Serving Size and Servings per Package
- 7. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)
  - a. (as packaged and as prepared with added ingredients)
- 8. Date Stamp associated with most current formulation (effective date of change/introduction)

By signing this pledge letter, our company will be recognized as an inaugural participant of A Partnership for Public Health: *Branded Food Products Database*. Our company's name will be included in the list of inaugural participants that will be part of the Partnership press release on the initiative.

Signature:	Date:	
Company Name:		

# A Partnership for Public Health



Branded Food Products Database

# <u>A Partnership for Public Health: Branded Food Products Database</u> Value Proposition

#### **Story of the Partnership**

Assessing the nutritional health of the American people depends on accurate and comprehensive data regarding the nutrient composition of commonly consumed foods. USDA's Agricultural Research Service (ARS) maintains a National Nutrient Database of the composition of such foods, and although the food industry has compositional data for their own products, very little of that data is publicly available through the database. As part of USDA's response to the Presidential Memorandum in October 2011, ARS approached ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information. Previous efforts by USDA on their own had seen limited success which is not unexpected given the volume and fluidity of branded food products in the U.S. marketplace.

Accordingly, the USDA, the International Life Sciences Institute (ILSI) North America and the ATIP Foundation (Agricultural Technology Innovation Partnership) have formed a Public-Private Partnership to enhance public health by augmenting the USDA National Nutrient Database with "nutrient composition of branded foods and private label" data provided by the food industry. This Partnership will ensure this information will be made publically available to those who utilize such data including the federal agencies, the research community, proprietary databases and end users, and the food industry.

The Partnership has established expert groups whose representation is made up of federal government agencies, academic nutrition researchers, a non-government organization (NGO), and ILSI North America member scientists. These expert groups, with additional input from two listening sessions, submitted recommendations for approval by the Steering Committee and, ultimately, these were approved by Dr. Catherine Woteki, USDA Under Secretary for Research, Education, and Economics (REE) and Chief Scientist. These recommendations included specific attributes that will be submitted to the enhanced USDA National Nutrient Database. More work remains to be done and supporters will have the opportunity to participate in these discussions.

Enhancement of the USDA National Nutrient Database through this Public-Private Partnership will be conducted in phases, with information from the Nutrition Facts Panel being obtained first and other, more detailed information being obtained at later stages. The database enhancement is also tied to changes in the infrastructure of the USDA National Nutrient Database that will allow the data to be accessed and utilized more efficiently. The changes brought about by this Public-Private Partnership will ensure that USDA nutrient composition data will remain the "Gold Standard" for the next decade and beyond.



A public-private partnership provides the framework to convene the expertise to compile nutrient data on branded and private label products, secure the private sector engagement in providing this information, as well as the broad-based constituent funding necessary to maximize content and provide timely information for nutrition, agricultural and diet-related health policy on the nutrient composition of the U.S. food supply.

#### What are the Benefits to Participating in the Partnership?

Corporations and organizations can participate either as providers of branded or private label food product nutrition data, or as financial contributors to support the development and sustainability of the enhanced USDA National Nutrient Database. The ATIP Foundation will acknowledge participants on the Foundation website pages under the Partnership logo. The listing of participants verifies the commitment of professional societies, organizations, and corporations that support this important initiative who will become members of the Sustaining Stakeholder Council. The Sustaining Stakeholder Council will review progress and make recommendations to the Partnership.

#### How will Success be Measured?

There are many indicators of success for this initiative. For example, the Partnership will have achieved success when thousands of branded and private label products are integrated in real time into the enhanced National Nutrient Database and timely updates are routine. Success will have been achieved when the database is viewed as the most comprehensive nutrient database. Success can be measured by the breadth of manufacturers- large, medium, and small- who are voluntarily participating. Other goals for measuring success will be met when information provided on an individual food product also includes imputed nutrient data and food groups, and the source of the nutrient values is transparent. USDA will issue comprehensive reports on the nutritional composition of the food supply. Success will also be measured by the presence of a vibrant group of sustaining members who support the long term viability of the enhanced USDA National Nutrient Database. Achievement will be measured by other countries adopting our system.

#### Value of Initiative

- Historical data on branded and private label food products will become available. The nutrition research community will benefit enormously from having this information for tracking dietary trends.
- The value of this initiative in the Development Phase has been the governing structure that has established key groups to meet the challenges and achieve the goals set by the Partnership: the Steering Committee, the Operation and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.
  - The Criteria Group developed the set of attributes that were reaffirmed by the listening sessions.
  - The Criteria Group brought together expertise across a broad range of nutrition professionals who developed the data quality system sanctioned by the USDA.



- The IT infrastructure, capitalizing on the established GS1 network, has been designed to be nimble and to accommodate future needs for years to come.
- A Sustaining Stakeholder Council will be made up of supporters (both financial contributors and providers of data) of the initiative. This Council will review progress and make recommendations to the Partnership.
- In the Implementation Phase, the Technical Stakeholder Group will provide a formal process to gather technical, nutritional, analytical, and research information needs, that will facilitate the knowledge and utility that can be derived from the Branded Food Products Database.
- The 12 principles for establishing and operating a public-private partnership are clearly visible within the Partnership.

#### Key Value for Government

An expanded database will contain much more information on individual food items allowing for research and policy to be based on a true assessment of the extent and fluidity of the food system.

"The composition of the food supply and consumer dietary choices are key inputs for agricultural and food policy decisions. Comprehensive data can inform these decisions, but the volume and fluidity of branded food products in the U.S. marketplace are key challenges. USDA has concluded that this is best pursued through a public-private partnership led by the ATIP Foundation and ILSI North America that is transparent and inclusive of all facets of the diverse food system in North America."

--- Dr. Catherine Woteki, Chief Scientist and USDA Under Secretary for Research, Education, and Economics

"The American diet is diverse. The addition of nutrition information from branded foods will be a tremendous asset to monitoring the American diet and achievements of industry to make healthier products."

--- Dr. Barbara Bowman, CDC

"Having data on branded food products to supplement the USDA National Nutrient Database will be extremely helpful to FDA in tracking the composition of the food supply and making food policy decisions to promote public health," said Jessica Leighton, PhD, senior nutrition science and policy advisor in FDA's Office of Foods and Veterinary Medicine. "The more accurate picture we have of the nutrient content of the food supply, the better informed our decisions on labeling requirements and encouraging food product reformulation will be."

--- Dr. Jessica Leighton, FDA

#### Key Value for Nutrition Researchers

Additional data in the USDA National Nutrient Database will greatly benefit the NHANES survey by allowing for more specific assessment of foods eaten. For example, if a person reports



having eaten an item such as "vegetable soup", instead of the nutritional value being based on an averaged and generic database value, it would be based on the actual brand item consumed, and nutrient composition would be that supplied by the company.

"As a frequent user of the National Nutrient Database, it is with extreme pleasure to hear that the Public-Private Partnership is moving forward. The Harvard School of Public Health maintains a nutrient database for the analysis of semi-quantitative food frequency questionnaires. This database requires accurate and up to date brand data for cereals, margarines, oils, and fortified foods. The Public-Private Partnership would provide a more efficient means for us to maintain this accurate time specific brand data in our system."

--- Laura Sampson Kent, Harvard School of Public Health

#### Key Value for Proprietary Database End Users

The enhanced USDA National Nutrient Database will increase the number of food products for end users who develop applications for consumers and health professionals. By expanding the data available for use in private applications, consumers seeking to eat more healthy diets and dieticians with the responsibility of developing specific diets are the beneficiaries of this information.

"A Partnership for Public Health: Branded Food Products Database will be a valuable resource to the University of Minnesota Nutrition Coordinating Center. It will allow us to improve the currency and completeness of our food and nutrient database, which will benefit nutrition researchers across the country who rely on it to carry out nutrition-related studies."

--- Lisa Harnack, University of Minnesota Nutrition Coordinating Center

#### Key Value for Professional Societies

- The professional society members rely on the comprehensiveness of the USDA National Nutrient Database for their effort to tease out dietary patterns and nutrient inter-relationships with chronic disease/s.
- The enhanced database will provide more accurate information about what their clients are truly eating.

"The USDA's National Nutrient Database is the basis for the science and evidence-based practice of nutrition and dietetics. This important resource helps clinicians counsel patients, researchers plan projects, and food production experts create menus and products. This unique public-private partnership to expand the database and make it more comprehensively reflect the food supply available to consumers



Branded Food Products Database

is crucial. We believe that ultimately this database expansion will improve the public's health, aligning with our mission."

--- Sonja L. Connor, MS, RDN, LD, President-elect 2013-2014, Academy of Nutrition and Dietetics

#### Key Value for Industry

- The enhanced USDA National Nutrient Database will become the single source of truth for nutrition data on branded and private label products.
  - Manufacturers will no longer have to respond to multiple requests from retailers and others and instead direct them to the Database.
- Recognizing that participation in this initiative will be resource-intensive for manufacturers, the Partnership has leveraged the existing GS1 community to ensure alignment with current industry practices.
  - Companies are already submitting product information into the GS1 network.
  - Trust has already been established that the system is secure and manufacturers can assure the accuracy of their shared data.
- Manufacturers recognize that more customers and consumers want virtual nutrition product information and the demand for this information will only intensify in the future.
  - Participation will ensure that your data is included in existing and newly developed nutrition apps that will draw from the augmented Database.
  - Participation will ensure improved customer service for the growing trend in online grocery sales and food delivery systems, such as Amazon, require virtual nutrition information.
- Manufacturers provide extensive recipes on their own websites and would benefit from having more accurate nutrient information on ingredients used in these recipes.

"General Mills is interested in continuing to work with the Public-Private Partnership to eventually provide our customers and consumers with a single source of accurate, up-to-date label information, available electronically through USDA"

--- Elizabeth Westring, General Mills Inc.

"This Partnership seeks to expand the USDA Standard Reference to include up-to-date branded manufacture data. It is critical that this data be available to researchers utilizing intake data, and others monitoring the food supply, in order to accurately represent the nutrition of our products in the marketplace and responsibly inform public policy."

--- Patricia Zecca, Campbell Soup Company

v.11.18.14

North American Branch of the International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743

202.659.0074 voice 202.659.3859 fax www.ilsina.org

#### **ILSI North America**

#### 2012 Membership Letter on Conflict of Interest Program

The topic of "conflict of interest" (COI) in conducting scientific activities is an issue of continuing concern and importance to the future of research related to nutrition, health, and food and ingredient safety. The purpose of this letter is to provide an analysis of the challenging environment in which we are operating and to gain your support for ILSI North America's (NA) program to address this issue.

ILSI was founded on the premise that there is great benefit to the development and application of science when academia, government, and industry work together to resolve issues of mutual interest. For over 30 years, the work of ILSI—and all its branches have documented this initial premise as a proven fact.

Clearly, it is in the interest of both the food industry and the general public to conduct the research necessary to meet legal requirements, and improve the safety of the food supply. It is equally important that the food industry help advance nutrition and health knowledge on the role of food—including both food ingredients and food components. Much of this research falls outside of the mission of traditional federal funding agencies and would not be done without food industry support and would be a detriment to consumers.

Despite a wealth of benefits industry sponsored research and science programs have provided, there continues to be significant public debate on the credibility of such support. While biases can come from many sources, much of the debate has focused on one area—industry funding. The end result has been the demand by some that all industry-funded research, whether conducted at contract research organizations or universities, be denied consideration in the formulation of public policy. Furthermore, scientists who have conducted industry-funded research have been barred from serving on public advisory committees.

ILSI-NA maintains that the scientific process requires open, transparent examination and honest interpretation of data, regardless of a researcher's affiliation or source of funding. In 2007 the ILSI-NA Board initiated a program to address COI issues. The program has been highly successful in developing "guiding principles" for industry funding of research (see enclosed publication), which have been endorsed by the leadership of three major professional societies. Results of this work have been published in six different peer-reviewed journals and presented at numerous scientific conferences. The next steps involve development of criteria for participation on scientific advisory panels and establishment of appropriate protocols for successful public/private partnerships to advance public health.

Issues related to COI will not be going away anytime soon. Continued engagement by ILSI-NA is required to ensure sound, evidence-based science prevails, and that credible scientists, regardless of affiliation, continue to have a voice in the debate. Our public-sector Trustees have volunteered both their time and expertise in the development of the current program. However—and this fact stunned me-only 20% of ILSI-NA's membership is providing financial support.

As important as this issue is to the food industry, we need all members to support initiatives related to COI. The current assessment for this activity is \$10,000 per company.

So here's my request. Review this letter—at least once more if not twice. I realize it's pretty long and I apologize for same. Post reading, if you have any questions or require further clarification on the current

1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743

202.659.0074 voice 202.659.3859 fax www.ilsina.org

#### **ILSI North America**

situation we face, please reach out either to me (W—4046762177; email ) or Eric ) hentges (W-2026590074x196; email If additional explanation is needed, we can connect you to other members of the ILSI-NA Board, or to one of ILSI-NA's public-sector Trustees.

Now...if you haven't any questions, I encourage you to contact Eric and pledge your Company's support. It's what we need—it's what your Company needs—it's what the public needs to ensure scientific truth and evidence based deliberations, and decisions prevail.

Thank you for considering the request herein.

Sincerely yours,

Rhona Applebaum, PhD President, ILSI North America

#### **Publications/Programs to date:**

• 2009 Guiding Principles

"Funding food science and nutrition research: financial conflicts and scientific integrity" Rowe S, Alexander N, Clydesdale FM, et al. Funding food science and nutrition research: financial conflicts and scientific integrity. Am J Clin Nutr 2009;89:1285–91.

- Simultaneous publication of the paper:
  - ♦ Nutrition Reviews
  - ♦ American Journal of Clinical Nutrition
  - ♦ Journal of the American Dietetic Association
  - $\diamond$  Journal of Nutrition
  - ♦ Journal of Food Science
  - ♦ Nutrition Today
- Presentations at:
  - ♦ Experimental Biology (EB Conference) April 2009
  - ♦ Institute of Food Technologists (IFT) conference June 9
  - ♦ American Dietetic Association (ADA) conference October 18
- 2011 "Funding Source and Research Report Quality in Nutrition Practice-Related Research" Myers EF, Parrott JS, Cummins DS, Splett P (2011) Funding Source and Research Report Quality in Nutrition Practice-Related Research. PLoS ONE 6(12): e28437. doi:10.1371/journal.pone.0028437
- Rowe S, et al. "How experts are chosen to inform public policy: Can the process be improved?", Health Policy (2013), http://dx.doi.org/10.1016/j.healthpol.2013.01.012

North American Branch of the International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005-1743 202.659.0074 voice 202.659.3859 fax www.ilsina.org

#### **ILSI North America**

- Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research, Rowe, S. et.al *Nutrition Reviews* 2013; 71(10):682-691
- "Branded Food Products Database for Public Health" Public-Private Partnership between ILSI North America, the USDA/ARS, and the ATIP (Agricultural Technology Innovation Partnership) Foundation.
- "Principles and Philosophies for Development of Ongoing Partnerships to Support Food-Health Research", Canadian Nutrition Society and ILSI North America Food for Health Workshop 2014

From: Sent: To: Subject:

Monday, November 17, 2014 10:06 AM Joanne Lupton ILSI News, Volume 32, Number 3

Dear Colleague:

We hope you enjoy the latest issue of *ILSI News*. It in you will read about our programs, recent publications, upcoming meetings, and more. Highlights include:

- Information on the Annual Meeting scientific program
- Science communication in Taiwan
- New videos from ILSI North America on food safety

http://www.ilsi.org/Documents/Q3 2014 v2.pdf

Michael Shirreffs ILSI Director of Communications International Life Sciences Institute 1156 15th Street, NW, 2nd Floor Washington, DC 20005 www.ilsi.org

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to jlupton@tamu.edu.

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International Life Sciences Institute,1156 15th Street, NW Suite 200 Washington DC 20005, Phone Number: (202) 659-0074, Fax Number: (202) 659-3859, Email Address: ilsi@ilsi.org, Website : http://www.ilsi.org

From: Sent: To:	Beth Brueggemeyer Monday, October 27, 201 ; 'r 's.ch	> .4 12:16 PM '; hang@griffith.edu.au'; scohen@unr ; mdoyle@uga.edu; adamd	; nc.edu; lrew@u.washington.edu;
	marion@vt.edu; eisenbra	@rhrk.uni-kl.de;	
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		; E	Burnand, Valerie, VEVEY, CT-
	RSA	; 'haan@purdue.edu';	
		; Beth-Ellen Berry; Shawn	Sullivan
Subject: Attachments:	ATTACHED DOCUMENT ILSI 2013 Form 990 BOAF	- ILSI draft IRS Form 990 for 2013 RD REVIEW.PDF	

#### Apologies – this time WITH the attached draft 990.

To the ILSI Board of Trustees:

Attached is ILSI's draft IRS Form 990 for 2013. This form is the U.S. Internal Revenue Service's primary tax compliance tool for tax-exempt organizations. It is also a public document that is made available by the IRS and other organizations such as GuideStar to the public. The form gives exempt organizations the opportunity to "tell their story" and provide narrative information to supplement the schedules.

The form includes a section on governance practices. One question on the form in particular asks if a copy of the Form 990 was provided to the organization's governing body before it was filed. We believe it is in the best interest of the organization to answer yes to this question and provide you with a copy of ILSI's Form 990. This will give you an opportunity to exercise your fiduciary duty to make sure that the organization is following all laws and best practices.

Please note that descriptions or other narratives that exceed the space allotted on the forms are continued on Schedule O. The Schedules are in alphabetical order. Also, only those contributions in 2013 that exceeded the greater of \$5,000 or 2% of the amount on Form 990, Part VIII, line 1h are included on Schedule B. Because the Form 990 is for calendar year 2013, it is the 2013 trustees and officers whose names appear. Names of trustees who were elected for the first time in January 2014 are not included.

It is not necessary for you to reply to this email or indicate that you approve of the Form 990 and its related schedules. The return has been sent to you for information purposes. However, <u>if you do have any serious concerns or</u> <u>questions about information contained in the form, we would appreciate it if you would let us know by October 31,</u> <u>2014.</u>

#### Thank you,

Beth-Ellen Berry, CPA Chief Financial Officer International Life Sciences Institute 1156 15th Street, NW, 2nd Floor Washington, DC 20005 Phone: 202-659-0074 Fax: 202-659-3617 www.ilsi.org

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Form <b>990</b>
Department of the Treasury

Internal Revenue Service

# Return of Organization Exempt From Income Tax Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except private foundations)

▶ Do not enter Social Security numbers on this form as it may be made public.

▶ Information about Form 990 and its instructions is at www.irs.gov/form990



AF	or th	e 2013 calendar year, or tax year beginning and	ending	-			
B c	heck if pplicab	e: C Name of organization		D Employer identific	ation number		
	Addre						
	Name Doing Business As ILSI 52-113						
	Initial returr	Number and street (or P.O. box if mail is not delivered to street address)	Room/suite	E Telephone number			
	 ated	□ 1156 15TH STREET, NW	200	(202)	659-0074		
	Amer	City or town, state or province, country, and ZIP or foreign postal code		<b>G</b> Gross receipts \$	3,692,732.		
		WASHINGTON, DC 20005		H(a) Is this a group ret	turn		
	penu	F Name and address of principal officer: SUZANNE S. HARRIS	for subordinates? Yes X No				
		SAME AS C ABOVE		H(b) Are all subordinates inc	No Yes		
11	ax-ex	tempt status: $\boxed{X}$ 501(c)(3) $\boxed{501(c)}$ ( ) ( insert no.) $\boxed{4947(a)(1)}$	or 527	If "No," attach a l	ist. (see instructions)		
<u>J</u> /	Vebsi	te: ► WWW.ILSI.ORG		H(c) Group exemption	number 🕨		
KF	orm o	f organization: 🔟 Corporation 🔄 Trust 🔄 Association 🔛 Other 🕨	L Year	of formation: 1978 M	State of legal domicile: DC		
Pa	art I	Summary	~~				
e	1	Briefly describe the organization's mission or most significant activities: SEE	SCHEDU	LE O			
ane							
'ern	2	Check this box 🕨 📖 if the organization discontinued its operations or dispo	sed of more	than 25% of its net ass	sets.		
õ	3	Number of voting members of the governing body (Part VI, line 1a)			31		
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	4	Number of independent voting members of the governing body (Part VI, line 1b)			) 		
ties	5	Total number of individuals employed in calendar year 2013 (Part V, line 2a)			10		
tič	6	Total number of volunteers (estimate if necessary)			/ 5		
Ac	7a	Total unrelated business revenue from Part VIII, column (C), line 12			0.		
	b	Net unrelated business taxable income from Form 990-1, line 34			0.		
				Prior Year	1 006 /0/		
IUe	8	Contributions and grants (Part VIII, line In)	······ —	1, 4, 1, 540	1,330,434		
ven	9	Program service revenue (Part VIII, line 2g)	······	32 640	13 / 9/		
Å	11	Other revenue (Part VIII, column (A), lines 5, 4, and 70)		15 979	5 512		
	12	Total revenue, add lines 9 through 11 (must equal Dart )(III, column (A), line 12)		3 118 753	3 692 732.		
	12	Grante and similar amounts paid (Part IX, column (A), lines 1.3)		133,575.	754,276.		
	14	Benefits naid to or for members (Part IX column (A) line 4)		0.	0.		
s	15	Salaries other compensation employee benefits (Part IX column (A) lines 5-10)		1,640,679.	1,740,717.		
Ise	16a	Professional fundraising fees (Part IX column (A), line 11e)		0.	0.		
per	b	Total fundraising expenses (Part IX column (D) line 25)	0.	-			
ш	17	Other expenses (Part IX, column (A), lines 11a-11d, 11f-24e)		1,447,342.	1,395,580.		
	18	Total expenses, Add lines 13-17 (must equal Part IX, column (A), line 25)		3,221,596.	3,890,573.		
	19	Revenue less expenses. Subtract line 18 from line 12		-102,843.	-197,841.		
or Ses			Be	ginning of Current Year	End of Year		
sets	20	Total assets (Part X, line 16)		3,175,401.	2,860,299.		
t As d B	21	Total liabilities (Part X, line 26)		1,367,874.	1,270,336.		
Fun	22	Net assets or fund balances. Subtract line 21 from line 20		1,807,527.	1,589,963.		
Pa	art II	Signature Block					
Und	er pen	alties of perjury, I declare that I have examined this return, including accompanying schedule	es and statem	ents, and to the best of my	knowledge and belief, it is		

true, correct, and complete. Declaration of preparer (other than officer) is based on all information of which preparer has any knowledge.

Sign Here	Signature of officer SUZANNE S. HARRIS, EXE Type or print name and title	CUTIVE DIRECTOR	Date
Paid	Print/Type preparer's name JOHN HUSKINS	Preparer's signature Date	Check PTIN if self-employed <b>P01081531</b>
Preparer	Firm's name JOHNSON LAMBERT	LLP	Firm's EIN 52-1446779
Use Only	Firm's address 700 SPRING FORES	ST RD., STE. 115 09	Phone no.919-719-6400
May the II	RS discuss this return with the preparer shown ab	ove? (see instructions)	X Yes No
220001 10 0	12 I UA For Department Reduction Act Nati	as any the congrete instructions	Earm 990 (2012)

332001 10-29-13 LHA For Paperwork Reduction Act Notice, see the separate instructions.

Form	n 990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131788	Page <b>2</b>
Pa	Int III Statement of Program Service Accomplishments	
	Check if Schedule O contains a response or note to any line in this Part III	X
1	Briefly describe the organization's mission:	
	THE INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI) IS A NONPROFIT,	
	WORLDWIDE FOUNDATION THAT SEEKS TO IMPROVE THE WELL-BEING OF THE	
	GENERAL PUBLIC THROUGH THE ADVANCEMENT OF SCIENCE. ITS GOAL IS TO	
	FURTHER THE UNDERSTANDING OF SCIENTIFIC ISSUES RELATING TO NUTRITIO	N,
2	Did the organization undertake any significant program services during the year which were not listed on	37
	the prior Form 990 or 990-EZ?	LA No
_	If "Yes," describe these new services on Schedule O.	V
3	Did the organization cease conducting, or make significant changes in how it conducts, any program services?	LA No
	If "Yes," describe these changes on Schedule O.	
4	Describe the organization's program service accomplishments for each of its three largest program services, as measured by expenses	3.
	Section 501(c)(3) and 501(c)(4) organizations are required to report the amount of grants and allocations to others, the total expenses,	and
4-	revenue, if any, for each program service reported.	<u> </u>
4a	(Code:) (Expenses \$I, 302, 023 • including grants of \$I (Revenue \$) (Revenue \$	<u> </u>
	ORGANIZATION BY THE FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED	
	NATIONS (FAO) AND THE WORLD HEALTH ORGANIZATION (WHO) THE TIST	
	PLATFORM FOR INTERNATIONAL PARTNERSHIPS (PIP) MANAGES THE WORK PLAN	g
	AGREED TO WITH FAO AND WHO. THESE WORK PLANS INCLUDE ACTIVITIES	<u> </u>
	RELATED TO CHEMICAL AND MICROBIAL RISK ASSESSMENT AS WELL AS FOOD	
	SAFETY CAPACITY BUILDING IN DEVELOPING COUNTRIES. ILSI INITIATED A	N
	EFFORT TO EXPAND ITS PRESENCE IN AFRICA IN 2013 THROUGH FOOD SAFETY	
	CAPACITY BUILDING ACTIVITIES. THE ILSI INTERNATIONAL FOOD	
	BIOTECHNOLOGY COMMITTEE (IFBIC) COMPLETED ITS WORK IN 2013 AND	
	TRANSFERRED ITS REMAINING RESOURCES, INCLUDING THE ILSI CROP	
	COMPOSITION DATABASE (ILSI-CCDB) TO THE ILSI RESEARCH FOUNDATION TO	
4b	(Code:) (Expenses \$ 1,196,602. including grants of \$ ) (Revenue \$ 1,196,	<b>602.</b> )
	ILSI SHARED SERVICES - ILSI PROVIDES THE STAFF AND SERVICES TO SUPP	ORT
	THE OPERATIONAL ACTIVITIES SUCH AS HUMAN RESOURCES, ACCOUNTING, LEG	AL,
	INFORMATION TECHNOLOGY AND GENERAL BUSINESS SERVICES OF THE US-BASE	D
	ILSI AFFILIATED ORGANIZATIONS INCLUDING ILSI NORTH AMERICA, ILSI	
	RESEARCH FOUNDATION, AND THE ILSI HEALTH AND ENVIRONMENTAL SCIENCES	
	INSTITUTE. THE COSTS OF THESE SERVICES ARE REIMBURSED TO ILSI BY TH	£
	AFFILIATED ORGANIZATIONS.	
4c	(Code: ) (Expenses \$ 845,127, including grants of \$ 46,825, ) (Bevenue \$ 42,	046.)
	GLOBAL BRANCH MANAGEMENT - ILSI PROVIDES THE GOVERNANCE AND	/
	COORDINATION FOR THE INTERNATIONAL NETWORK OF BRANCHES THAT SEEK TO	
	IMPROVE THE WELL-BEING OF THE GENERAL PUBLIC THROUGH THE ADVANCEMEN	T OF
	SCIENCE. BRANCHES CURRENTLY OPERATE WITHIN ARGENTINA, BRAZIL, EUROP	Е,
	INDIA, JAPAN, KOREA, MEXICO, NORTH AFRICA & GULF REGION, NORTH AMER	ICA,
	NORTH ANDEAN, SOUTH AFRICA, SOUTH ANDEAN, SOUTHEAST ASIA REGION, AS	
	WELL AS A FOCAL POINT IN CHINA AND A GLOBAL BRANCH, THE HEALTH AND	
	ENVIRONMENTAL SCIENCES INSTITUTE. IN 2013, A NEW BRANCH WAS ESTABLI	SHED
	IN TAIWAN. ILSI MAINTAINS A WEBSITE FOR THE BRANCHES; CONDUCTS AN	
	ANNUAL MEETING; PROVIDES ADMINISTRATIVE SUPPORT FOR THE ILSI FOCAL	
	POINT IN CHINA/COCA COLA JOINT TRAINING PROGRAMS ON FOOD SAFETY RIS	K
	ANALYSIS AND PHYSICAL ACTIVITY; AND PROVIDES COMMUNICATIONS AND OTH	ER
4d	Other program services (Describe in Schedule O.)	
<u> </u>	(Expenses 433,000 • including grants of \$) (Revenue \$ 444,096 •)	
4e	I otal program service expenses ► 3, / 10, / 04.	
33200 10-29-	SEE SCHEDULE O FOR CONTINUATION(S)	<b>30</b> (2013)

- orm	990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131	.788	F
Pa	t IV Checklist of Required Schedules		
			Yes
1	Is the organization described in section 501(c)(3) or 4947(a)(1) (other than a private foundation)?		
_	It "Yes," complete Schedule A	1	
2	Is the organization required to complete Schedule B, Schedule of Contributors?	2	
3	Did the organization engage in direct or indirect political campaign activities on behalf of or in opposition to candidates for		
4	Public office? If Yes, complete Schedule C, Part I	3	
4	during the tax year? If "Yes," complete Schedule C. Part II.	4	
5	Is the organization a section $501(c)(4)$ , $501(c)(5)$ , or $501(c)(6)$ organization that receives membership dues, assessments, or	-	
Ŭ	similar amounts as defined in Revenue Procedure 98-19? If "Yes." complete Schedule C. Part III	5	
6	Did the organization maintain any donor advised funds or any similar funds or accounts for which donors have the right to		
	provide advice on the distribution or investment of amounts in such funds or accounts? If "Yes," complete Schedule D, Part I	6	
7	Did the organization receive or hold a conservation easement, including easements to preserve open space,		
	the environment, historic land areas, or historic structures? If "Yes," complete Schedule D, Part II	7	
8	Did the organization maintain collections of works of art, historical treasures, or other similar assets? If "Yes," complete		
	Schedule D, Part III	8	
9	Did the organization report an amount in Part X, line 21, for escrow or custodial account liability; serve as a custodian for		
	amounts not listed in Part X; or provide credit counseling, debt management, credit repair, or debt negotiation services?		
	If "Yes," complete Schedule D, Part IV	9	
10	Did the organization, directly or through a related organization, hold assets in temporarily restricted endowments, permanent		
	endowments, or quasi-endowments? If "Yes," complete Schedule D, Part V	10	
1	If the organization's answer to any of the following questions is "Yes," then complete Schedule D, Parts VI, VII, VIII, IX, or X		
	as applicable.		
а	Did the organization report an amount for land, buildings, and equipment in Part X, line 10? If res, complete Schedule D,	110	x
h	Did the organization report an amount for investments, other securities in Part X. line 12 that is 5% or more of its total	11a	- 23
5	assets reported in Part X. line 162 If "Yes." complete Schedule D. Part VII	11h	
с	Did the organization report an amount for investments - program related in Part X (line 13 that is 5% or more of its total	110	
-	assets reported in Part X, line 16? If "Yes," complete Schedule D, Part VIII	11c	
d	Did the organization report an amount for other assets in Part X, line 15 that is 5% or more of its total assets reported in		
	Part X, line 16? If "Yes," complete Schedule D, Part IX	11d	X
е	Did the organization report an amount for other liabilities in Part X, line 25? If "Yes," complete Schedule D, Part X	11e	X
f	Did the organization's separate or consolidated financial statements for the tax year include a footnote that addresses		
	the organization's liability for uncertain tax positions under FIN 48 (ASC 740)? If "Yes," complete Schedule D, Part X	11f	X
12a	Did the organization obtain separate, independent audited financial statements for the tax year? If "Yes," complete		
	Schedule D, Parts XI and XII	12a	
b	Was the organization included in consolidated, independent audited financial statements for the tax year?		
	If "Yes," and if the organization answered "No" to line 12a, then completing Schedule D, Parts XI and XII is optional	12b	X
13	Is the organization a school described in section 170(b)(1)(A)(ii)? If "Yes," complete Schedule E	13	
14a	Did the organization maintain an office, employees, or agents outside of the United States?	<u>14a</u>	
D	bid the organization have aggregate revenues or expenses of more than \$10,000 from grantmaking, fundraising, business,		
	or more 2 If "Yes," complete Schedule F. Parts Land IV	14h	x
15	Did the organization report on Part IX column (A) line 3 more than \$5,000 of grants or other assistance to or for any	140	
15	foreign organization? If "Yes " complete Schedule F. Parts II and IV	15	x
16	Did the organization report on Part IX, column (A). line 3, more than \$5,000 of addredate drants or other assistance to	<u> </u>	†
	or for foreign individuals? If "Yes," complete Schedule F, Parts III and IV	16	x
17	Did the organization report a total of more than \$15,000 of expenses for professional fundraising services on Part IX.		1
	column (A), lines 6 and 11e? If "Yes," complete Schedule G, Part I	17	
18	Did the organization report more than \$15,000 total of fundraising event gross income and contributions on Part VIII, lines		
	1c and 8a? If "Yes," complete Schedule G, Part II	18	
			1

Page 3

19 Did the organization report more than \$15,000 of gross income from gaming activities on Part VIII, line 9a? If "Yes," Х complete Schedule G, Part III 19 20a Did the organization operate one or more hospital facilities? *If* "Yes," *complete Schedule H* 20a **b** If "Yes" to line 20a, did the organization attach a copy of its audited financial statements to this return? 20b

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No

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Form	990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1132	1788	F
1 a	Checklist of Required Schedules (continued)		Ves
21	Did the organization report more than \$5.000 of grants or other assistance to any domestic organization or		103
	government on Part IX, column (A), line 1? If "Yes," complete Schedule I, Parts I and II	21	x
22	Did the organization report more than \$5,000 of grants or other assistance to individuals in the United States on Part IX, column (A), line 2? If "Yes," complete Schedule I, Parts I and III	22	x
23	Did the organization answer "Yes" to Part VII, Section A, line 3, 4, or 5 about compensation of the organization's current		
	and former officers, directors, trustees, key employees, and highest compensated employees? If "Yes," complete Schedule J	23	x
24a	Did the organization have a tax-exempt bond issue with an outstanding principal amount of more than \$100,000 as of the last day of the year, that was issued after December 31, 2002? <i>If</i> "Yes," <i>answer lines 24b through 24d and complete Schedule K. If</i> "No", <i>ao to line 25a</i>	24a	
b	Did the organization invest any proceeds of tax-exempt bonds beyond a temporary period exception?	24b	
с	Did the organization maintain an escrow account other than a refunding escrow at any time during the year to defease any tax-exempt bonds?	24c	
d	Did the organization act as an "on behalf of" issuer for bonds outstanding at any time during the year?	24d	
25a	Section 501(c)(3) and 501(c)(4) organizations. Did the organization engage in an excess benefit transaction with a disqualified person during the year? If "Yes," complete Schedule L, Part I	25a	
b	Is the organization aware that it engaged in an excess benefit transaction with a disqualified person in a prior year, and that the transaction has not been reported on any of the organization's prior Forms 990 or 990-EZ? If "Yes," complete Schedule L, Part I	25b	
26	Did the organization report any amount on Part X, line 5, 6, or 22 for receivables from or payables to any current or former officers, directors, trustees, key employees, highest compensated employees, or disqualified persons? If so, complete Schedule L, Part II	26	
27	Did the organization provide a grant or other assistance to an officer, director, trustee, key employee, substantial contributor or employee thereof, a grant selection committee member, or to a 35% controlled entity or family member of any of these persons? <i>If</i> "Yes," <i>complete Schedule L, Part III</i>	27	
28	Was the organization a party to a business transaction with one of the following parties (see Schedule L, Part IV instructions for applicable filing thresholds, conditions, and exceptions):		
а	A current or former officer, director, trustee, or key employee? If "Yes," complete Schedule L, Part IV	28a	
b	A family member of a current or former officer, director, trustee, or key employee? If "Yes," complete Schedule L, Part IV	28b	
C	director, trustee, or direct or indirect owner? If "Yes," complete Schedule L, Part IV	28c	
29	Did the organization receive more than \$25,000 in non-cash contributions? If "Yes," complete Schedule M	29	
30	Did the organization receive contributions of art, historical treasures, or other similar assets, or qualified conservation contributions? <i>If</i> "Yes," <i>complete Schedule M</i>	30	
31	Did the organization liquidate, terminate, or dissolve and cease operations? If "Yes," complete Schedule N, Part I	31	
32	Did the organization sell, exchange, dispose of, or transfer more than 25% of its net assets? <i>If "Yes," complete Schedule N, Part II</i>	32	
33	Did the organization own 100% of an entity disregarded as separate from the organization under Regulations sections 301.7701-2 and 301.7701-3? If "Yes," complete Schedule R, Part I	33	
34	Was the organization related to any tax-exempt or taxable entity? If "Yes," complete Schedule R, Part II, III, or IV, and		

Part V, line 1

within the meaning of section 512(b)(13)? If "Yes," complete Schedule R, Part V, line 2

Section 501(c)(3) organizations. Did the organization make any transfers to an exempt non-charitable related organization?

If "Yes," complete Schedule R, Part V, line 2

and that is treated as a partnership for federal income tax purposes? If "Yes," complete Schedule R, Part VI

35a Did the organization have a controlled entity within the meaning of section 512(b)(13)?

b If "Yes" to line 35a, did the organization receive any payment from or engage in any transaction with a controlled entity

Did the organization conduct more than 5% of its activities through an entity that is not a related organization

Note. All Form 990 filers are required to complete Schedule O

Did the organization complete Schedule O and provide explanations in Schedule O for Part VI, lines 11b and 19?

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No

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Х Form **990** (2013)

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orm	990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE	52-	1131
Par	t V Statements Regarding Other IRS Filings and Tax Compliance		
	Check if Schedule O contains a response or note to any line in this Part V		<u></u>
		I. I	16
1a	Enter the number reported in Box 3 of Form 1096. Enter -0- if not applicable	1a	0
b	Enter the number of Forms W-2G included in line 1a. Enter -0- if not applicable		0
С	Did the organization comply with backup withholding rules for reportable payments to vendors and r	eportable gaming	
•	(gambling) winnings to prize winners?		
za	Enter the number of employees reported on Form W-3, Transmittal of Wage and Tax Statements,		15
h	fied for the calendar year ending with or within the year covered by this return	[2a]	
D	Nate of the sum of lines 1e and 2e is greater than 250, you may be required to 6-file (eee instruction	ns: 	
2-	Note. If the sum of lines have uprelated business greater than 250, you may be required to e-me (see instructions	5)	
Ja	If "Ves " has it filed a Farm 000 T for this year? If "No " to line 2h, provide an explanation in Schedula	······	
D 40	If Yes, has it filed a Form 990-1 for this year? If No, to life 50, provide an explanation in Schedule		
4a	At any time during the calendar year, did the organization have an interest in, or a signature or other	authority over, a	
<b>L</b>	Inancial account in a foreign country (such as a bank account, securities account, or other infancial	account)?	
D	The Yes," enter the name of the foreign country: ►	A	
Ea	See instructions for himg requirements for Form TD F 90-22. I, Report of Foreign Bank and Financial	Accounts.	
5a L	Was the organization a party to a promoted tax sheller transaction at any time during the tax year?		
0	If "Vee " to line 5e or 5h, did the organization file Form 2006 T2		
62	Does the organization have appual gross receipts that are permally greater than \$100,000, and did the	ha arganization cal	
0a	any contributions that were not tax deductible as charitable contributions?	ne organization soi	ICIL
h	If "Ves." did the organization include with every collectation an every statement that such contributions :	tions or difts	
D	were not tax deductible?	tions of gints	
7	Organizations that may receive deductible contributions under section 170(c)		
' ``	Did the organization receive a payment in excess of \$75 made partly as a contribution and partly for goods and set	rvices provided to the	a navor?
a h	If "Ves." did the organization potify the donor of the value of the goods or services provided?		puyor.
č	Did the organization sell, exchange, or otherwise dispose of tangible personal property for which it w	uas required	
Ŭ	to file Form 82822	astequied	
Ь	If "Yes " indicate the number of Forms 8282 filed during the year	7 d	
e	Did the organization receive any funds, directly or indirectly, to pay premiums on a personal benefit of	contract?	
f	Did the organization, during the year, pay premiums, directly or indirectly on a personal benefit contr	ract?	
a	If the organization received a contribution of gualified intellectual property, did the organization file Fi	orm 8899 as requir	red?
9 h	If the organization received a contribution of cars, boats, airplanes, or other vehicles, did the organization	ation file a Form 10	)98-C?
8	Sponsoring organizations maintaining donor advised funds and section 509(a)(3) supporting organizations. D	id the supporting	
	organization, or a donor advised fund maintained by a sponsoring organization, have excess business holdings at	any time during the y	/ear?
9	Sponsoring organizations maintaining donor advised funds.	, ,	
а	Did the organization make any taxable distributions under section 4966?		
b	Did the organization make a distribution to a donor, donor advisor, or related person?		
0	Section 501(c)(7) organizations. Enter:		
а	Initiation fees and capital contributions included on Part VIII, line 12	10a	
b	Gross receipts, included on Form 990, Part VIII, line 12, for public use of club facilities	10b	
1	Section 501(c)(12) organizations. Enter:		
а	Gross income from members or shareholders	11a	
b	Gross income from other sources (Do not net amounts due or paid to other sources against		
	amounts due or received from them.)	11b	
2a	Section 4947(a)(1) non-exempt charitable trusts. Is the organization filing Form 990 in lieu of Form	1041?	
b	If "Yes," enter the amount of tax-exempt interest received or accrued during the year	12b	
3	Section 501(c)(29) qualified nonprofit health insurance issuers.		
а	Is the organization licensed to issue qualified health plans in more than one state?		
	Note. See the instructions for additional information the organization must report on Schedule O.		
b	Enter the amount of reserves the organization is required to maintain by the states in which the		
		1 I	

c Enter the amount of reserves on hand \_\_\_\_\_\_ 13c

**b** If "Yes," has it filed a Form 720 to report these payments? If "No," provide an explanation in Schedule O

14a Did the organization receive any payments for indoor tanning services during the tax year?

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Yes

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No

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VI	Governance, Management, and Disclosure For each "Yes" response to lines 2 through 7b below, and for a "No" response
	to line 8a, 8b, or 10b below, describe the circumstances, processes, or changes in Schedule O. See instructions.

# Check if Schedule O contains a response or note to any line in this Part VI

$ \mathbf{v} $	

Sec	tion A Governing Body and Management					
000	tion A. doverning body and management				Voc	No
10	Enter the number of voting members of the governing body at the end of the tax year	1a	3	1	103	
ia	If there are material differences in voting rights among members of the governing body at the end of the tax year			7		
	hody delegated broad authority to an executive committee or similar committee explain in Schedule 0					
h	Enter the number of voting members included in line 1a, above, who are independent	11	3	1		
2	Did any officer director trustee or key employee have a family relationship or a business relationsh	nin witl	n any other	=		
-	officer director trustee or key employee?			2		x
3	Did the organization delegate control over management duties customarily performed by or under t	he dire	ect supervision	-		
5	of officers directors or trustees or key employees to a management company or other person?			3		x
А	Did the organization make any significant changes to its governing documents since the prior Form	990 v	/as filed?	4		x
5	Did the organization have any significant changes to its governing documents since the prior rom	secte?	as med:	5		x
6	Did the organization become aware daming the year of a significant aversion of the organization of an			6	x	
7a	Did the organization have members stockholders or other persons who had the power to elect or a	annoir	it one or	Ť		
74	more members of the governing body?	appon		7a	x	
b	Are any governance decisions of the organization reserved to (or subject to approval by) members	stock	holders or	- Tu		
	persons other than the governing hody?	01001		7h		x
8	Did the organization contemporaneously document the meetings held or written actions undertaken during the v	ear by t	he following.	10		
a	The governing body?	our by i	ine reneting.	8a	x	
h	Each committee with authority to act on behalf of the governing body?			8h	x	
9	Is there any officer director trustee or key employee listed in Part VII. Section A who cannot be re	acheo	l at the			
Ū	organization's mailing address? If "Yes," provide the names and addresses in Schedule O			9		x
Sec	tion B. Policies (This Section B requests information about policies not required by the Internal I	Reveni	Je Code.)			
			,		Yes	No
10a	Did the organization have local chapters, branches, or affiliates?			10a	Х	
b	If "Yes," did the organization have written policies and procedures governing the activities of such	chapte	ers, affiliates,			
	and branches to ensure their operations are consistent with the organization's exempt purposes?	•		10b	X	
11a	Has the organization provided a complete copy of this Form 990 to all members of its governing bo	dy bef	ore filing the form?	11a	Х	
b	Describe in Schedule O the process, if any, used by the organization to review this Form 990.					
12a	Did the organization have a written conflict of interest policy? If "No," go to line 13			12a	X	
b	Were officers, directors, or trustees, and key employees required to disclose annually interests that could give ris	se to co	nflicts?	12b	Х	
с	Did the organization regularly and consistently monitor and enforce compliance with the policy? If "	Yes," d	describe			
	in Schedule O how this was done			12c	X	
13	Did the organization have a written whistleblower policy?			13	Х	
14	Did the organization have a written document retention and destruction policy?			14	Х	
15	Did the process for determining compensation of the following persons include a review and appro-	val by	independent			
	persons, comparability data, and contemporaneous substantiation of the deliberation and decision	?				
а	The organization's CEO, Executive Director, or top management official			15a	Х	
b	Other officers or key employees of the organization			15b		X
	If "Yes" to line 15a or 15b, describe the process in Schedule O (see instructions).					
16a	Did the organization invest in, contribute assets to, or participate in a joint venture or similar arrange	ement	with a			
	taxable entity during the year?			16a		Х
b	If "Yes," did the organization follow a written policy or procedure requiring the organization to evalu	ate its	participation			
	in joint venture arrangements under applicable federal tax law, and take steps to safeguard the org	anizati	on's			
	exempt status with respect to such arrangements?			16b		
Sec	tion C. Disclosure					
17	List the states with which a copy of this Form 990 is required to be filed $\blacktriangleright$ SEE SCHEDULE	0				
18	Section 6104 requires an organization to make its Forms 1023 (or 1024 if applicable), 990, and 990	-T (Seo	ction 501(c)(3)s only	availat	ble	
	for public inspection. Indicate how you made these available. Check all that apply.					
	Upon request	in in So	chedule O)			
19	19 Describe in Schedule O whether (and if so, how), the organization made its governing documents, conflict of interest policy, and			nd fina	ncial	
	statements available to the public during the tax year.					
20	State the name, physical address, and telephone number of the person who possesses the books	and re	cords of the organiz	ation:	►	
	DETR-EDDEN BERRI - $(202)009-00/4$ 1156 15mm gropper NW NO 200 WAGUINGRON DO 20	005				

#### Part VII Compensation of Officers, Directors, Trustees, Key Employees, Highest Compensated **Employees, and Independent Contractors**

Check if Schedule O contains a response or note to any line in this Part VII

Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees Section A. 1a Complete this table for all persons required to be listed. Report compensation for the calendar year ending with or within the organization's tax year.

List all of the organization's current officers, directors, trustees (whether individuals or organizations), regardless of amount of compensation.

Enter -0- in columns (D), (E), and (F) if no compensation was paid.

• List all of the organization's current key employees, if any. See instructions for definition of "key employee."

• List the organization's five current highest compensated employees (other than an officer, director, trustee, or key employee) who received reportable compensation (Box 5 of Form W-2 and/or Box 7 of Form 1099-MISC) of more than \$100,000 from the organization and any related organizations.

• List all of the organization's former officers, key employees, and highest compensated employees who received more than \$100,000 of reportable compensation from the organization and any related organizations.

• List all of the organization's former directors or trustees that received, in the capacity as a former director or trustee of the organization, more than \$10,000 of reportable compensation from the organization and any related organizations.

List persons in the following order: individual trustees or directors; institutional trustees; officers; key employees; highest compensated employees; and former such persons.

Check this box if neither the organization nor any related organization compensated any current officer, director, or trustee. 

(A)	(B)			(0	C)			(D)	(E)	(F)
Name and Title	Average	(do	not c	Pos heck	itior more	) than	one	Reportable	Reportable	Estimated
	hours per	box	, unle	ss pe	rson irecto	is bot	h an	compensation	compensation	amount of
	week	5				17 4 44	1	from	from related	other
	(list any	lirecto						organization	(W-2/1000-MISC)	from the
	related	e or c	stee			Isatec		(W-2/1099-MISC)	(1033-10100)	organization
	organizations	truste	al tru:		yee	mpe		(		and related
	below	idual	tution	er	emplo	est co loyee	Jer			organizations
	line)	Indiv	Insti	Offic	Key	High emp	Form			
(1) DR. SAMUEL M. COHEN	2.00									
CHAIR		Х		Х				0.	0.	0.
(2) DR. JOHN MILNER	2.00									
VICE CHAIR		Х		Х				0.	0.	0.
(3) DR. JERRY HJELLE	2.00									
PRESIDENT		X		Х				0.	0.	0.
(4) DR. RHONA S. APPLEBAUM	2.00									
VICE PRESIDENT		Х		X				0.	0.	0.
(5) DR. SARA VALDES MARTINEZ	2.00									
SECRETARY		X		Х	р. <sup>2</sup>			0.	0.	0.
(6) DR. ELIZABETH WESTRING	2.00									
TREASURER		X		Х				0.	0.	0.
(7) DR. MARION EHRICH	2.00									
MEMBER AT LARGE		Х		Х				0.	0.	0.
(8) DR. TAMOTSU KUWATA	2.00									
MEMBER AT LARGE		Х		Х				0.	0.	0.
(9) PROF. GERT MEIJER	2.00									
MEMBER AT LARGE		Х		Х				0.	0.	0.
(10) MR. GEOFFRY SMITH	2.00									
MEMBER AT LARGE		Х		Х				0.	0.	0.
(11) DR. TODD ABRAHAM	2.00									
TRUSTEE		X						0.	0.	0.
(12) DR. SCOTT E. BELANGER	2.00									
TRUSTEE		Х						0.	0.	0.
(13) DR. ALAN BOOBIS	2.00									
TRUSTEE		Х						0.	0.	0.
(14) DR. SUSHILA CHANG	2.00									
TRUSTEE		Х						0.	0.	0.
(15) DR. DENNIS J. DEVLIN	2.00									
TRUSTEE		Х						0.	0.	0.
(16) DR. ADAM DREWNOWSKI	2.00									
TRUSTEE		X						0.	0.	0.
(17) PROF. GERHARD EISENBRAND	2.00									
TRUSTEE		X						0.	0.	0.

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Part VII Section A. Officers, Directors, Trus	tees, Key Em	ploy	vees,	an	d Hi	ighe	st C	Compensated Employe	es (continued)				
(A)	(B)			(0	C)			(D)	(E)			(F)	
Name and title	Average	(do	not ch	Pos	ition	ן than	one	Reportable	Reportable		E۶	timate	əd
	hours per	box	, unles	ss pe	rson	is bot	h an	compensation	compensation		an	nount	of
	week	Offic	cer an	dad	recto	or/trus	tee)	from	from related			other	
	(list any	ector						the	organizations		com	pensa	ation
	hours for	ordir	e,			ated		organization	(W-2/1099-MISC	)	fr	om th	е
	organizations	ustee	truste		a	bens		(W-2/1099-MISC)			org	anızat	lion
	below	ual tru	onal		ploye	t com					an	a relat	ea
	line)	divid	stitut	fficer	iy em	ghes	ormer				orga	anizati	0115
(18) DR JAY I GOODMAN	2 00	드	-	ò	\ <u>₹</u>	ты	цщ.						
TOTIONER	2.00	v						0		<u>م</u>			Δ
	2 00							0.		<u>··</u>			
(19) DR. TAKESHI KIMORA	2.00	v						0		^			Δ
	2 00							0.		<u>.</u>			<u> </u>
(20) DR. JANET KING	2.00	v						0		^			Δ
TRUSTEE (TO MAY 13)	2 00	^						0.		<u> </u>			<u> </u>
(21) DR. MICHAEL E. KNOWLES	2.00							0		^			0
TRUSTEE		Ă						0.		0.			0.
(22) DR. IK-BOO KWON	2.00												•
TRUSTEE		X						0.		0.			0.
(23) DR. JOANNE R. LUPTON	2.00									~			•
TRUSTEE		X						0.		0.			0.
(24) DR. JOHN PETERS	2.00									_			•
TRUSTEE		Х						0.		0.			0.
(25) PROF. GERHARD RECHKEMMER	2.00												
TRUSTEE		X						0.		0.			0.
(26) MR. FELIPE RODRIGUEZ PALACIOS	2.00					ľ							-
TRUSTEE		Х						0.		0.			0.
1b Sub-total								0.		0.			0.
c Total from continuation sheets to Part V	I, Section A							673,213.		0.	12	1,0	<u>29.</u>
d Total (add lines 1b and 1c)								673,213.		0.	12	1,0	29.
2 Total number of individuals (including but n	ot limited to th	iose	liste	d al	bove	e) wł	וס r	eceived more than \$100	,000 of reportable				
compensation from the organization													4
										_		Yes	No
3 Did the organization list any former officer,	director, or tru	iste	e, ke	y er	nplo	oyee	, or	highest compensated e	mployee on				
line 1a? If "Yes," complete Schedule J for s	uch individual	<b>)</b>						-			3		Х
4 For any individual listed on line 1a, is the su	um of reportab	le co	ompe	ensa	atior	n and	d ot	her compensation from	the organization				
and related organizations greater than \$15	0,000? <i>If</i> "Yes,	" со	mple	ete S	Sche	edule	ə J i	for such individual	-		4	Х	
5 Did any person listed on line 1a receive or a	accrue comper	nsat	ion f	rom	any	y unr	elat	ted organization or indivi	dual for services				
rendered to the organization? If "Yes," com	plete Schedul	e J f	or su	ich	pers	son		-			5		Х
Section B. Independent Contractors	· · · · · · · · · · · · · · · · · · ·												
1 Complete this table for your five highest co	mpensated ind	depe	ende	nt c	onti	racto	ors 1	that received more than	\$100,000 of comp	ens	ation	rom	
the organization. Report compensation for	the calendar y	ear	endiı	ng v	vith	or w	ithi	n the organization's tax	/ear.				
(A)	•							(B)			((	)	
Name and business	address							Description of s	ervices	С	ompe	nsatio	n
RETRIEVAL SYSTEMS CORPORA	ATION												
2071 CHAIN BRIDGE RD, VII	ENNA, VA	A 2	221	.82	2			IT SERVICES			12	2,0	50.
												-	
2 Total number of independent contractors (i	ncluding but n	ot lii	miteo	d to	tho	se li: 1	steo	d above) who received m	ore than				
5 IUU UUU of compensation from the organi	zation 🖿					<b>-</b>							

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Section A. Officers, Directors,	Irustees, Key E	mplo	byee	s, a	nd F	ligh	est	Compensated Employ	rees (continued)	( <b>-</b> )
(A)	(B)			(0	))			(D)	(E)	(F)
Name and title	Average		heck	Pos	ition that	) ann		Reportable	Reportable	Estimated
	list any related	ustee or director	trustee		8	npensated employee		from the organization (W-2/1099-MISC)	from related organizations (W-2/1099-MISC)	other compensation from the organization and related
	below line)	Individual tr	Institutional	Officer	Key employ	Highest con	Former			organizations
(27) DR. P. K. SETH	2.00	<b>.</b> ,						0	0	0
TRUSTEE		<u>⊢</u> ▲			┣		<u> </u>	0.	0.	0.
(28) DR. LEWIS L. SMITH	2.00								0	0
TRUSTEE								0.	υ.	0.
(29) DR. GEOFF THOMPSON	2.00								0	0
TRUSTEE								0.	0.	0.
(30) DR. PETER VAN BLADEREN	2.00								0	0
TRUSTEE								0.	υ.	0.
(31) DR. CONNIE WEAVER TRUSTEE	2.00	x						0.	0.	0.
(32) DR. FLAVIO A.D. ZAMBRONE	2.00									
TRUSTEE		X						0.	0.	0.
(33) DR. SUZANNE S. HARRIS	24.00									
EXECUTIVE DIRECTOR	16.00	]		Х				246,513.	0.	37,622.
(34) MS. BETH-ELLEN BERRY	10.00							150.000	0	
CHIEF FINANCIAL OFFICER	10.00	$\vdash$		х				152,996.	0.	30,657.
(35) MR. SHAWN SULLIVAN GENERAL COUNSEL	10.00	1				x		147,225.	0.	34,075.
(36) MR. MICHAEL SHIRREFFS	40.00	$\square$					hÎ			
COMMUNICATIONS DIRECTOR		1				X		126,479.	0.	18,675.
		K								
		-								
		-								
		╞								
		$\left  \right $								
		$\left  \right $								
Total to Part VII. Section A line 1c		<u> </u>	<u> </u>		<u> </u>	<u> </u>	<u> </u>	673.213.		121,029.
								· · · · · · · · · · · · · · · · · · ·		,:=>•

Form 990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE						52-1131	788 Page 9
Pa	t VII	II Statement of Revenue					Ŭ
		Check if Schedule O contains a response of	or note to any lir	e in this Part VIII			
				<b>(A)</b> Total revenue	<b>(B)</b> Related or exempt function revenue	<b>(C)</b> Unrelated business revenue	(D) Revenue excluded from tax under sections 512 - 514
ts s	1 a	Federated campaigns 1a					
un	b	Membership dues					
ĞĔ	- C	Fundraising events					
i k	b b	Belated organizations 1d	140,000.				
اغنی Difi	۵ ۵	Government grants (contributions)					
ŝ	f	All other contributions diffs grants and					
her	•	similar amounts not included above	856.494.				
Ē		Noncesh contributions included in lines 12-1f: $\$$	000,1010				
and	9 h	Total Add lines 12-1f		1.996.494.			
			Business Code				
0	2 a	FEES FROM AFFILIATES	900099	1,287,953.	1,287,953.		
Ś	- u h	SCIENTIFIC PUBLICATION	900099	347,233.	347,233.		
Sei	~ c	MEETING REGISTRATIONS	900099	42,046.	42,046.		
an Se	b b			,	,		
2 2 2 2 2 2	۵ ۵						
Pres	f	All other program service revenue					
	a	<b>Total.</b> Add lines 2a-2f		1,677,232.			
	3	Investment income (including dividends, intere	st, and				
		other similar amounts)	, •	13,494.			13,494.
	4	Income from investment of tax-exempt bond p	roceeds				
	5	Royalties	►	5,512.	5,512.		
		(i) Real	(ii) Personal				
	6 a	Gross rents					
	b	Less: rental expenses					
	с	Rental income or (loss)					
	d	Net rental income or (loss)	<b>&gt;</b>				
	7 a	Gross amount from sales of (i) Securities	(ii) Other				
		assets other than inventory					
	b	Less: cost or other basis					
		and sales expenses					
	С	Gain or (loss)					
	d	Net gain or (loss)					
e	8 a	Gross income from fundraising events (not					
le le		including \$ of					
Be		contributions reported on line 1c). See					
Jer		Part IV, line 18 a					
₹	b	b Less: direct expenses b	<b>k</b>				
	c	Net income or (loss) from fundraising events	····· ►				
	9 a	Gross income from gaming activities. See					
	h	Part IV, III e 19 a					
	u o	Det income or (loco) from coming activities					
	10 2	Gross sales of inventory loss returns	·····				
	iu a	and allowances					
	h	and anowances a					
	0	Net income or (loss) from sales of inventory					
	U						
	11 2						
	a						
	с 0						
	с b	All other revenue					
	e	Total. Add lines 11a-11d					
	12	Total revenue. See instructions.	<b>•</b>	3,692.732.	1,682,744.	0.	13,494.

Form 990 (	2013)	TNLERN	ATTONAL
Part IX	Statement of	f Functional	Expenses

Section 501(c)(3) and 501(c)(4) organizations must complete all columns. All other organizations must complete column (A).

	Check if Schedule O contains a respor	nse or note to any line in	this Part IX		
Do r 7b,	not include amounts reported on lines 6b, 8b, 9b, and 10b of Part VIII.	<b>(A)</b> Total expenses	<b>(B)</b> Program service expenses	<b>(C)</b> Management and general expenses	<b>(D)</b> Fundraising expenses
1	Grants and other assistance to governments and				
	organizations in the United States. See Part IV, line 21	681,936.	681,936.		
2	Grants and other assistance to individuals in				
	the United States. See Part IV, line 22	6,542.	6,542.		
3	Grants and other assistance to governments,				
	organizations, and individuals outside the				
	United States. See Part IV, lines 15 and 16 $\dots$	65,798.	65,798.		
4	Benefits paid to or for members				
5	Compensation of current officers, directors,				
	trustees, and key employees	467,788.	254,705.	213,083.	
6	Compensation not included above, to disqualified				
	persons (as defined under section 4958(f)(1)) and				
	persons described in section 4958(c)(3)(B)				
7	Other salaries and wages	1,019,694.	1,002,556.	17,138.	
8	Pension plan accruals and contributions (include				
	section 401(k) and 403(b) employer contributions)	54,611.		54,611.	
9	Other employee benefits	107,710.		107,710.	
10	Payroll taxes	90,914.		90,914.	
11	Fees for services (non-employees):				
а	Management			10.001	
b	Legal	15,243.	5,209.	10,034.	
С	Accounting	14,869.		14,869.	
d	Lobbying				
е	Professional fundraising services. See Part IV, line 17	1 750		1 750	
f	Investment management fees	1,759.		1,/59.	
g	Other. (If line 11g amount exceeds 10% of line 25,	125 050		20 001	
	column (A) amount, list line 11g expenses on Sch O.)	135,958.	115,86/.	20,091.	
12	Advertising and promotion	170 274	165 660	12 714	
13	Office expenses	1/9, 3/4.	105,000.	13,/14.	
14	Information technology	04,001.	02,001.		
15	Royalties	144 155	121 277	10 070	
16	Occupancy	144,100.	131,277.	10 125	
17	Travel	201,001.	200,752.	19,135.	
18	Payments of travel or entertainment expenses	2 070	2 070		
	for any federal, state, or local public officials	192 790	179 863	12 027	
19	Conterences, conventions, and meetings	192,190.	179,005.	12,927•	
2U 01	Daymonts to affiliatos	15 888	15 888		
21	Payments to anniates	136 695.	31 573.	105 122.	
22		56.834.	56,834,	105,122.	
23	Other expenses Itemize expenses not covered	50,0510	50,0510		
24	above. (List miscellaneous expenses in line 24e. If line				
	24e amount exceeds 10% of line 25, column (A) amount list line 24e expenses on Schedule 0.)				
а	PUBLICATIONS	129,189.	129,189.		
h	OVERHEAD ALLOCATION	0.	486,743.	-486,743.	
c c	SHARED SERVICES ALLOCAT	0.	-197,796.	197,796.	
d d	BENEFITS ALLOCATION	0.	233,229.	-233,229.	
e	All other expenses		,==	· · , ·	
25	Total functional expenses. Add lines 1 through 24e	3,890,573.	3,718,764.	171,809.	0.
26	Joint costs. Complete this line only if the organization	. ,			
-	reported in column (B) joint costs from a combined				
	educational campaign and fundraising solicitation.				
	Check here if following SOP 98-2 (ASC 958-720)				
332010	) 10-29-13				Form <b>990</b> (2013)

33

34

Total net assets or fund balances

Total liabilities and net assets/fund balances

				F 0	1121700 44
Form Par	<u>1990 (</u> rt X	2013) INTERNATIONAL LIFE SCIENCES J	INSTITUTE	52-	1131/88 Page 11
		Check if Schedule O contains a response or note to any line in this Part X			
			(A) Beginning of year		(B) End of year
	1	Cash - non-interest-bearing	500.	1	500.
	2	Savings and temporary cash investments	569,753.	2	286,868.
	3	Pledges and grants receivable, net		3	
	4	Accounts receivable net	169,244.	4	104,586.
	5	Loans and other receivables from current and former officers, directors,	··· · · ·		,
		trustees, key employees, and highest compensated employees. Complete Part II of Schedule L		5	
	6	Loans and other receivables from other disqualified persons (as defined unde	r		
		section 4958(f)(1)), persons described in section 4958(c)(3)(B), and contributir employers and sponsoring organizations of section 501(c)(9) voluntary	ng		
ts		employees' beneficiary organizations (see instr). Complete Part II of Sch L		6	
sse	7	Notes and loans receivable, net		7	
Ä	8	Inventories for sale or use		8	
	9	Prepaid expenses and deferred charges	16,977.	9	27,898.
	10a	Land, buildings, and equipment: cost or other			
		basis. Complete Part VI of Schedule D 10a 1, 201, 049			444 040
	b	Less: accumulated depreciation 10b 759,23	1 102 905.	10c	441,818.
	11	Investments - publicly traded securities	1,123,092.	11	1,118,298.
	12	Investments - other securities. See Part IV, line 11		12	
	13	Investments - program-related. See Part IV, line 11		13	
	14	Intangible assets		14	000 221
	15	Other assets. See Part IV, line 11		15	880,331.
	16	Total assets. Add lines 1 through 15 (must equal line 34)	<u> </u>	16	2,000,299.
	17	Accounts payable and accrued expenses		17	109,000.
	18	Grants payable	102 344	18	77 050
	19	Deterred revenue		19	11,039.
	20			20	
	21	Escrow or custodial account liability. Complete Part to of Schedule D		21	
ties	22	Loans and other payables to current and former officers, directors, trustees,			
bili		Complete Dart II of Schedule I		20	
Lia	22	Socured metagages and notes payable to unrelated third partices		22	
	24	Unsecured notes and loans payable to unrelated third parties		20	
	25	Other liabilities (including federal income tax, payables to related third			
		parties, and other liabilities not included on lines 17-24). Complete Part X of			
		Schedule D	1,079,414.	25	1,004,189.
	26	Total liabilities. Add lines 17 through 25	1,367,874.	26	1,270,336.
		Organizations that follow SFAS 117 (ASC 958), check here			
S		complete lines 27 through 29, and lines 33 and 34.			
nce	27	Unrestricted net assets	1,469,101.	27	1,062,999.
3ala	28	Temporarily restricted net assets	338,426.	28	526,964.
Эрг	29	Permanently restricted net assets		29	
Fur		Organizations that do not follow SFAS 117 (ASC 958), check here			
ç		and complete lines 30 through 34.			
ets	30	Capital stock or trust principal, or current funds		30	
Ass	31	Paid-in or capital surplus, or land, building, or equipment fund		31	
let /	32	Retained earnings, endowment, accumulated income, or other funds		32	
Z	1 22	Total not aparts or fund balances	1 1 807 527	22	1 1 589 967

33

34

1,589,963. 2,860,299.

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1,807,527. 3,175,401.

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Petrt XI       Reconciliation of Net Assets	Form	1990 (2013) INTERNATIONAL LIFE SCIENCES INSTITUTE	52	<u>-113</u>	1788	Pa	<sub>ge</sub> 12
Check if Schedule O contains a response or note to any line in this Part XI         1       Total revenue (must equal Part VII, column (A), line 25)         2       Total expenses (must equal Part X, column (A), line 25)         3       Revenue less expenses. Subtract line 2 from line 1         4       1, 8007, 52         5       Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))         6       1, 8007, 52         7       Prior period adjustments         9       Other changes in net assets or fund balances (explain in Schedule O)         9       Other changes in net assets or fund balances (explain in Schedule O)         1       1, 589, 960         Part XII       Financial Statements and Reporting         Check if Schedule O contains a response or note to any line in this Part XI       1         1       Accounting method used to prepare the Form 990:       Cash         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other         1       Yes       If 'wes', check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       Separate basis       Consolidated basis       B both consolidated and separate basis, consolidated basis, or both:       Separate basis       Consolidated basis       B both consol	Pa	rt XI Reconciliation of Net Assets					
1       Total revenue (must equal Part XII, column (A), line 12)       1       3, 692, 73         2       Total expenses (must equal Part IX, column (A), line 25)       2       3, 890, 57         3       Revenue less expenses. Subtract line 2 from line 1       3       -197, 584         4       Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))       4       1, 807, 55         5       Net unrealized gains (losses) on investments       6       -19, 72         6       Donated services and use of facilities       6       -19, 72         7       Investment expenses       7       -         8       9       Other changes in net assets or fund balances (explain in Schedule O)       9         9       Other changes in net assets or nucl balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       1, 589, 96         Part XII       Financial Statements and Reporting       -       -         1       Accounting method used to prepare the Form 990:       Cash       Accrual       Other         1       Accounting the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule 0.       -       2a         1       Accounting the organization changed its tatements compiled or reviewed by an independent accountant?       -       2a		Check if Schedule O contains a response or note to any line in this Part XI	<u></u>	<u></u>			
1       Total expenses (must equal Part IX, column (A), line 12)       1       3, 692, 73         2       Total expenses (must equal Part IX, column (A), line 25)       2       3, 890, 55         3       1 = 0, 72, 84         4       Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))       4       1, 807, 52         5       Net unrealized gains (losses) on investments       5       -19, 72         6       0 ther changes in net assets or fund balances (explain in Schedule O)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       9         10       Net assets or fund balances (explain in Schedule O)       9       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       1       1, 589, 96         11       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other       1       1, 589, 96         2a       Were the organization changed its method of accounting from a prio year or checked "Other, "explain in Schedule O.       2a       2a       1       Yes         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other (must equal Part X)       2a       2a       1 <td< td=""><td></td><td></td><td></td><td>1</td><td></td><td></td><td></td></td<>				1			
2       Total expenses (must equal Part IX, column (A), line 25)       2       3, 890, 57         3       Revenue less expenses. Subtract line 2 from line 1       -1.97, 84         4       1, 807, 52         5       Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))       4       1, 807, 52         5       Net unrealized gains (losses) on investments       5       -1.97, 72         6       Donated services and use of facilities       7         7       Investment expenses       7         8       9       Other changes in net assets or fund balances (explain in Schedule 0)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       10       1, 589, 96         Part XIII       Financial Statements and Reporting       10       1, 589, 96         Check if Schedule O contains a response or note to any line in this Part XII       10       1, 589, 96         9       Were the organization's financial statements compiled or reviewed by an independent accounfant?       12       2a         1       Accounting method used to prepare the Form 900:       Cash IX Accrual       Other       1         1       Accounting method used to brepare the Form 900:       Cash IX Accrual       Other       2a       2a<	1	Total revenue (must equal Part VIII, column (A), line 12)	1		3,69	2,7	32.
3       Revenue less expenses. Subtract line 2 from line 1       3       -197, 84         4       Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))       3       4       1, 8007, 52         5       Net unrealized gains (losses) on investments       5       -19, 72         6       Donated services and use of facilities       7       6         7       investment expenses       8       9         9       Other changes in net assets or fund balances (explain in Schedule O)       9       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (6))       1, 589, 966         Perior preido adjustments       8       9       1, 589, 966         Perior preido adjustments       9       10       1, 589, 966         Perior preido adjustments       901       1, 589, 966       1, 589, 966         Perior preido adjustments       10       1, 589, 966       2a       1       1, 589, 966         Perior preido adjustments       10       1, 589, 966       2a       2a       2a       2a         11       Accounting method used to prepare the Form 990:       Cash       X Accound Chare       2a       2a       2a       2a       2a       2a       2	2	Total expenses (must equal Part IX, column (A), line 25)	2		<u>3,89</u>	0,5	73.
4 Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))       4       1,807,52         5 Net unrealized gains (losses) on investments       6         7 Investment expenses       7         8 Prior period adjustments       9         9 Other changes in net assets or fund balances (explain in Schedule O)       9         10 Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       9         10 Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       1, 589, 96         Part XII       Financial Statements and Reporting       1         Check if Schedule O contains a response or note to any line in this Part XII       1         1 Accounting method used to prepare the Form 990:       Cash       X Accrual       Other         If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a       Vere the organization's financial statements compiled or reviewed by an independent accountant?       2a       2a         If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, or both:       Separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were addited on a separate basis, consolidated basis, or both:       2b       X <td>3</td> <td>Revenue less expenses. Subtract line 2 from line 1</td> <td>3</td> <td></td> <td>-19</td> <td><u>7,8</u></td> <td>41.</td>	3	Revenue less expenses. Subtract line 2 from line 1	3		-19	<u>7,8</u>	41.
5       Net unrealized gains (losses) on investments       5       -19,72         6       Donated services and use of facilities       6       7         7       Investment expenses       7       8         9       Other changes in net assets or fund balances (explain in Schedule O)       9       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (8))       1, 589,966         Pert XIII       Financial Statements and Reporting       1       1, 589,966         Part XIII       Financial Statements are response or note to any line in this Part XII       1         1       Accounting method used to prepare the Form 990:       Cash       X       Accrual       Other         1       Accounting method used to prepare the Form 990:       Cash       X       Accrual       Other       2a         1       Accounting method used to prepare the form 990:       Cash       X       Accrual       Other       2a       2a       1a       1a       2a       1a       2a <td< td=""><td>4</td><td>Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))</td><td>4</td><td></td><td>1,80</td><td><u>7,5</u></td><td>27.</td></td<>	4	Net assets or fund balances at beginning of year (must equal Part X, line 33, column (A))	4		1,80	<u>7,5</u>	27.
6       Donated services and use of facilities       6         7       Investment expenses       7         8       Prior priod adjustments       8         9       Other changes in net assets or fund balances (explain in Schedule O)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, columm (B)       10       1,589,96         Part XII       Financial Statements and Reporting       10       1,589,96         Part XIII       Financial Statements and Reporting       10       1,589,96         Check if Schedule O contains a response or note to any line in this Part XII       1       Yes         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other, "explain in Schedule O.         2a       Were the organization's financial statements compiled or reviewed by an independent accountant?       2a       2a         If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis       2b       X         b       Were the organization's financial statements audited by an independent accountant?       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were compiled or a separate basis.       2b       X         b       Were the organizat	5	Net unrealized gains (losses) on investments	5		-1	<u>9,7</u>	23.
7       Investment expenses       7         8       Prior period adjustments       9         9       Other changes in net assets or fund balances (explain in Schedule O)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       10       1, 589, 96         Part XII       Financial Statements and Reporting       10       1, 589, 96         Check if Schedule O contains a response or note to any line in this Part XII       Yes         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other         If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       Yes       Yes         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other       Yes         1       the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a       Yes       Yes         2       Were the organization is financial statements audited by an independent accountant?       Za       Za         1       M'Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       Separate basis       Consolidated basis       Both consolidated and separate basis       Zb </td <td>6</td> <td>Donated services and use of facilities</td> <td>6</td> <td></td> <td></td> <td></td> <td></td>	6	Donated services and use of facilities	6				
8       Prior period adjustments       8         9       Other changes in net assets or fund balances (explain in Schedule O)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       1       1,589,96         Part XII       Financial Statements and Reporting       1       1,589,96         Part XII       Financial Statements and Reporting       1       1         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other         1       the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a       2a         2       Were the organization's financial statements compiled or reviewed by an independent accountant?       2a       2a         1       f"Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       2a       2b       X         1       f"Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       2b       X         1       f"Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection process or selection process during the tax year, explai	7	Investment expenses	7				
9       Other changes in net assets or fund balances (explain in Schedule O)       9         10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       10       1,589,96         Part XII       Financial Statements and Reporting       10       1,589,96         Check if Schedule O contains a response or note to any line in this Part XII       10       1,589,96         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other       10         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other       1         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other       1         2a       Were the organization's financial statements compiled or reviewed by an independent accountant?       2a       1       1         1       Yes, check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis       Both consolidated and separate basis, consolidated basis       2b       X         1       Yes, check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis       Both consolidated and separate basis, consolidated basis, or both:       2b       X         1       Yes, ''check a	8	Prior period adjustments	8				
10       Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33, column (B))       10       1,589,96         Part XII       Financial Statements and Reporting       Image: Check if Schedule O contains a response or note to any line in this Part XII       Image: Check if Schedule O contains a response or note to any line in this Part XII         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other, "explain in Schedule O.         2a       Were the organization's financial statements compiled or reviewed by an independent accountant?       Image: Consolidated basis, or both:       2a         Image: Schedk a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       2b       X         Image: Schedk a box below to indicate whether the financial statements for the year were addited on a separate basis, consolidated basis, or both:       2b       X         Image: Schedk a box below to indicate whether the financial statements for the year were addited on a separate basis, consolidated basis, or both:       2b       X         Image: Schedk a box below to indicate whether the financial statements for the year were addited on a separate basis, consolidated basis, or both:       2b       X         Image: Schedk a box below to indicate whether the financial statements for the year were addited on a separate basis       2b       X         If "Yees," check a box below to indicate whether	9	Other changes in net assets or fund balances (explain in Schedule O)	9				0.
column (B)       10       1,589,96         Part XII       Financial Statements and Reporting       Image: Check if Schedule O contains a response or note to any line in this Part XII       Image: Check if Schedule O contains a response or note to any line in this Part XII         1       Accounting method used to prepare the Form 990:       Cash       Image: Check if Schedule O.         2       Were the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a         2       Were the organization is financial statements compiled or reviewed by an independent accountant?       2a         1       Mere the organization's financial statements and its by an independent accountant?       2a         1       Mere the organization's financial statements audited by an independent accountant?       2b       X         1       Mere the organization's financial statements audited by an independent accountant?       2b       X         1       Mere the organization's financial statements audited by an independent accountant?       2b       X         1       Mere the organization is financial statements and selection of an independent accountant?       2b       X         1       Mere the organization have a committee that assumes reponsibility for oversight of the audit, review, or compilation changed either its oversight process or selection process during the tax year, explain in Schedule O.       3a       As a result of a fed	10	Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 33,		1			
Part XII       Financial Statements and Reporting         Check if Schedule O contains a response or note to any line in this Part XII       Yes         1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other		column (B))	10		1,58	<u>9,9</u>	63.
Check if Schedule O contains a response or note to any line in this Part XII       Yes         1       Accounting method used to prepare the Form 990: Cash X Accrual Other       Other         If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a         2a       If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, or solidated basis, or both:       2a         Separate basis       Consolidated basis       Both consolidated and separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis       Consolidated basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?       2c       X         If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.       3a A a resuit of a federal award, was the organization required oudit or a	Pa	rt XII Financial Statements and Reporting					
1       Accounting method used to prepare the Form 990:       Cash       X Accrual       Other		Check if Schedule O contains a response or note to any line in this Part XII		<u></u>			
1       Accounting method used to prepare the Form 990:       Cash       X       Accrual       Other         If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a         2a       If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       2a       2a         3       Separate basis       Consolidated basis       Both consolidated and separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a basis       Image: Consolidated basis       Both consolidated and separate basis       2b       X         If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements						Yes	No
If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule O.       2a         2a       Were the organization's financial statements compiled or reviewed by an independent accountant?       2a         If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, or both:       2a         Separate basis       Consolidated basis       Both consolidated and separate basis       2b         b       Were the organization's financial statements audited by an independent accountant?       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         Separate basis       IX       Consolidated basis       Both consolidated and separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X       2c       X         If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection process during the tax year, explain in Schedule O.       3a As a result of a federal award,	1	Accounting method used to prepare the Form 990: Cash X Accrual Other					
2a       Were the organization's financial statements compiled or reviewed by an independent accountant?       2a         If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       2b       X         Separate basis       Consolidated basis       Both consolidated and separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?       2c       X         If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.       3a       3a         3a       5       If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits       3b       Form 990 (2		If the organization changed its method of accounting from a prior year or checked "Other," explain in Schedule	Ο.				
If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both:       Image: Consolidated basis       Both consolidated and separate basis         b       Were the organization's financial statements audited by an independent accountant?       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         If "Yes," the line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?       2c       X         If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.       3a       3a         3a       3a       3a       3a       3a       3a         b       If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits       3b       To separate basis	2a	Were the organization's financial statements compiled or reviewed by an independent accountant?			. 2a		X
separate basis, consolidated basis, or both:       Image: Consolidated basis       Both consolidated and separate basis       2b       X         b       Were the organization's financial statements audited by an independent accountant?       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         Separate basis       Image: Consolidated basis       Both consolidated and separate basis       1mage: Consolidated basis       2mage: Consolidated basis </td <td></td> <td>If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed</td> <td>d on a</td> <td></td> <td></td> <td></td> <td></td>		If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed	d on a				
<ul> <li>Separate basis</li> <li>Consolidated basis</li> <li>Both consolidated and separate basis</li> <li>Were the organization's financial statements audited by an independent accountant?</li> <li>If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:</li> <li>Separate basis</li> <li>Consolidated basis</li> <li>Both consolidated and separate basis</li> <li>If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?</li> <li>If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.</li> <li>As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit Act and OMB Circular A-133?</li> <li>If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits</li> </ul>		separate basis, consolidated basis, or both:					
b       Were the organization's financial statements audited by an independent accountant?       2b       X         If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       2b       X         Separate basis       X       Consolidated basis       Both consolidated and separate basis       2c       X         c       If "Yes," to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?       2c       X         If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.       3a       3a         a As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit Act and OMB Circular A-133?       3a       3a         b       If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits       3b       Form 990 (2		Separate basis Consolidated basis Both consolidated and separate basis					
If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both:       Image: Consolidated basis       Image:	b	Were the organization's financial statements audited by an independent accountant?			. 2b	Х	
consolidated basis, or both:       Separate basis		If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separat	e basi	s,			
<ul> <li>Separate basis X Consolidated basis Both consolidated and separate basis</li> <li>If "Yes" to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?</li> <li>If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.</li> <li>3a As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit Act and OMB Circular A-133?</li> <li>If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits</li> </ul>		consolidated basis, or both:					
c       If "Yes" to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?       2c       X         If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O.       2c       X         3a As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit Act and OMB Circular A-133?       3a       3a         b       If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits       3b       Form 990 (2)		Separate basis X Consolidated basis Both consolidated and separate basis					
review, or compilation of its financial statements and selection of an independent accountant?	с	If "Yes" to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the	e audi	t,			
If the organization changed either its oversight process or selection process during the tax year, explain in Schedule O. 3a As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit Act and OMB Circular A-133?  b If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits Form 990 (2)		review, or compilation of its financial statements and selection of an independent accountant?			_ <b>2</b> c	X	
3a As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Single Audit       3a         Act and OMB Circular A-133?       3a         b If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits       3b         Form 990 (2		If the organization changed either its oversight process or selection process during the tax year, explain in Sch	edule	0.			
Act and OMB Circular A-133? 3a b If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits Section 990 (2 Form 990 (2)	3a	As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Si	ngle A	Jdit			
<ul> <li>b If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why in Schedule O and describe any steps taken to undergo such audits</li> <li>3b</li> <li>Form 990 (2)</li> </ul>		Act and OMB Circular A-133?			. <b>3</b> a		X
or audits, explain why in Schedule O and describe any steps taken to undergo such audits	b	If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the requ	ired au	Jdit			
Form <b>990</b> (2		or audits, explain why in Schedule O and describe any steps taken to undergo such audits	<u></u>	<u></u>	. 3b		
					Form	990	(2013)

Total

Internal Rever	nue Service	Information abo	out Schedule A (Form 990	or 990-EZ)	and its inst	tructions is	at www.irs	any/form	990	Insp	ection	
Name of t	the organizati	on	X					Ei	mployer	identificat	ion nu	mber
		INTERNA	TIONAL LIFE	SCIEN	CES I	NSTIT	UTE		5	2-1131	788	
Part I	Reason	for Public Char	<b>ity Status</b> (All organiz	ations mu	st complet	te this par	t.) See inst	ructions.				
The organ	ization is not a	a private foundation	because it is: (For lines 1	1 through <sup>-</sup>	11. check	only one b	ox.)					
1	A church, co	nvention of churches	s, or association of chur	ches desc	ribed in <b>se</b>	ection 170	(b)(1)(A)(i)	_				
2	A school des	cribed in section 17	0(b)(1)(A)(ii), (Attach Sc	hedule F )			(~/(·//·//·//·/	•				
3	A hospital or	a cooperative hospi	tal service organization	described	in section	170(b)(1)	(A)(iii).					
4	A medical res	search organization	operated in conjunction	with a hos	pital desc	ribed in <b>se</b>	ction 170	(b)(1)(A)(ii	i). Enter	the hospita	l's nam	ne.
	city, and stat	e:						·- // ·// ·// ·/	,			,
5	5 An organization operated for the benefit of a college or university owned or operated by a governmental unit described in											
•	section 170(b)(1)(A)(iv). (Complete Part II.)											
6	A federal sta	ite or local governm	ent or governmental unit	t describe	d in sectio	on 170(b)( <sup>.</sup>	1)(A)(v).					
7 X	An organizati	ion that normally rec	eives a substantial part	of its supp	ort from a	aovernme	ental unit o	r from the	general	public des	cribed i	in
· —	section 170(	<b>b)(1)(A)(vi)</b> , (Comple	te Part II.)			9010111			general			
8	A community	trust described in s	ection 170(b)(1)(A)(vi).	(Complete	Part II )							
9	An organizati	ion that normally rec	eives: (1) more than 33 1	1/3% of its	support f	rom contri	butions, m	embershi	o fees, a	nd aross re	ceipts	from
	activities rela	ted to its exempt fur	nctions - subject to certa	in excepti	ons, and (	2) no more	than 33 1	/3% of its	support	from gross	sinvest	tment
	income and u	inrelated business ta	axable income (less sect	tion 511 ta	x) from bu	isinesses a	acquired b	v the orga	nization	after June	30, 197	75.
	See section	509(a)(2). (Complete	Part III.)					,			,	
10	An organizati	ion organized and or	perated exclusively to te	st for publ	ic safety. S	See sectio	on 509(a)(4	ю.				
11	An organizati	ion organized and or	perated exclusively for th	ne benefit (	of, to perfe	orm the fu	nctions of.	or to carry	v out the	purposes	of one	or
	more publicly	/ supported organiza	ations described in section	on 509(a)(	1) or sectio	on 509(a)(2	2). See <b>sec</b>	tion 509(a	a)(3). Ch	eck the box	k that	
	describes the	e type of supporting	organization and comple	ete lines 1	, 1e throuai	11h.	,	•	~ /			
		и <b>b</b> П Ту	/pell <b>c</b> .	pe III - Fu	nctionally	integrated	d	I 🛄 Тур	e III - No	n-functiona	lly inter	grated
е 🗌	By checking	this box, I certify tha	t the organization is not	controlled	directly o	r indirectly	/ by one oi	more disc	qualified	persons ot	her tha	in
	foundation m	anagers and other t	han one or more publicly	y supporte	d organiza	ations des	cribed in s	ection 509	9(a)(1) or	section 50	9(a)(2).	
f	If the organiz	ation received a writ	ten determination from t	the IRS tha	at it is a Ty	vpe I, Type	II, or Type	e				
	supporting of	rganization, check th	nis box									
g	Since August	t 17, 2006, has the o	organization accepted an	ny gift or co	ontributior	n from any	of the follo	owing pers	sons?			
	(i) A perso	n who directly or ind	irectly controls, either al	one or tog	ether with	persons o	described i	n (ii) and (i	iii) below	,	Yes	No
	the gove	erning body of the su	upported organization?							11g(i)		
	(ii) A family	member of a persor	described in (i) above?							11g(ii)		
	(iii) A 35% d	controlled entity of a	person described in (i) o	or (ii) above	ə?					11g(iii	)	
h	Provide the f	ollowing information	about the supported or	ganization	(s).							
(i) Name	of supported	(ii) EIN	(iii) Type of organization	(iv) Is the o	organization	(v) Did you	u notify the	(vi) Is	the	(vii) Amoun	t of mo	netary
orga	anization		(described on lines 1-9	in col. (i) lis	sted in your	organizat	ion in col.	(i) organiz	ed in the	su	oport	
			(see instructions)	governing			Support	0.8	. r			
			(,)	Yes	No	Yes	No	Yes	No			

# Public Charity Status and Public Support complete if the organization is a section 501(c)(3) organization or a section 4947(a)(1) nonexempt charitable trust.

Open to Public

•			<b>U</b> IIG	····
Con	nplete	if the	e organ	izatio

Department of the Treasury h .

		Informa
Name of the organizati	on	

Attach to Form 990 or Form 990-EZ.

SCHEDULE A
------------

(Form	990	or	990-EZ	)
•				

# OMB No. 1545-0047 3

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Insp	pect	tion

Schedule A (For

rm 990 or 990-EZ) 2013

### Schedule A (Form 990 or 990 EZ) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131788 Page 2

Part II

Support Schedule for Organizations Described in Sections 170(b)(1)(A)(iv) and 170(b)(1)(A)(vi) (Complete only if you checked the box on line 5, 7, or 8 of Part I or if the organization failed to qualify under Part III. If the organization fails to qualify under the tests listed below, please complete Part III.)

Sec	ction A. Public Support						
Cale	ndar year (or fiscal year beginning in) 🕨	(a) 2009	<b>(b)</b> 2010	(c) 2011	(d) 2012	(e) 2013	(f) Total
1	Gifts, grants, contributions, and						
	membership fees received. (Do not						
	include any "unusual grants.")	1,241,979.	1,598,638.	1,629,035.	1,471,346.	1,996,494.	7,937,492.
2	Tax revenues levied for the organ-						
	ization's benefit and either paid to						
	or expended on its behalf						
3	The value of services or facilities						
	furnished by a governmental unit to						
	the organization without charge						
4	Total. Add lines 1 through 3	1,241,979.	1,598,638.	1,629,035.	1,471,346.	1,996,494.	7,937,492.
5	The portion of total contributions						
	by each person (other than a						
	governmental unit or publicly						
	supported organization) included						
	on line 1 that exceeds 2% of the						
	amount shown on line 11,						
	column (f)						2,499,820.
6	Public support. Subtract line 5 from line 4.						5,437,672.
Sec	ction B. Total Support						
Cale	ndar year (or fiscal year beginning in) 🕨	(a) 2009	<b>(b)</b> 2010	(c) 2011	(d) 2012	<b>(e)</b> 2013	(f) Total
7	Amounts from line 4	1,241,979.	1,598,638.	1,629,035.	1,471,346.	1,996,494.	7,937,492.
8	Gross income from interest,						
	dividends, payments received on						
	securities loans, rents, royalties						
	and income from similar sources $\dots$	8,758.	8,693.	39,976.	37,713.	19,006.	114,146.
9	Net income from unrelated business						
	activities, whether or not the						
	business is regularly carried on						
10	Other income. Do not include gain						
	or loss from the sale of capital						
	assets (Explain in Part IV.)	8,019.					8,019.
11	Total support. Add lines 7 through 10						8,059,657.
12	Gross receipts from related activities,	, etc. (see instruction	ons)			12 8	<u>,316,369.</u>
13	First five years. If the Form 990 is for	r the organization's	s first, second, thir	d, fourth, or fifth ta	x year as a sectio	n 501(c)(3)	
0	organization, check this box and stor	here					<u></u>
<u>Sec</u>	ction C. Computation of Publ	ic Support Pe	rcentage				
14	Public support percentage for 2013 (	line 6, column (f) di	ivided by line 11, c	olumn (f))		14	<u>67.47 %</u>
15	Public support percentage from 2012	2 Schedule A, Part	II, line 14			15	12.00 %
16a	6a 33 1/3% support test - 2013. If the organization did not check the box on line 13, and line 14 is 33 1/3% or more, check this box and						
	stop here. The organization qualifies	as a publicly supp	orted organization				
b	<b>33 1/3% support test - 2012.</b> If the c	organization did no	ot check a box on l	ine 13 or 16a, and	line 15 is 33 1/3%	or more, check th	iis box
	and <b>stop here.</b> The organization qual	ifies as a publicly s	supported organiza	ation			▶∟
17a	7a 10% -facts-and-circumstances test - 2013. If the organization did not check a box on line 13, 16a, or 16b, and line 14 is 10% or more,					or more,	
	and if the organization meets the "fac	ts-and-circumstan	ces" test, check th	his box and <b>stop h</b> e	e <b>re.</b> Explain in Par	t IV how the organ	ization
	meets the "facts-and-circumstances"	test. The organiza	tion qualifies as a	publicly supported	organization		►∟
b	10% -facts-and-circumstances tes	t - 2012. If the org	anization did not c	heck a box on line	13, 16a, 16b, or 1	7a, and line 15 is	10% or
	more, and if the organization meets the "facts-and-circumstances" test, check this box and stop here. Explain in Part IV how the						
	organization meets the "facts-and-cire	cumstances" test.	The organization o	ualifies as a public	ly supported orga	nization	
18	Private foundation. If the organization	n did not check a	box on line 13, 16	a, 16b, 17a, or 17b	, check this box a	nd see instruction	s

Schedule A (Form 990 or 990-EZ) 2013

#### Part III Support Schedule for Organizations Described in Section 509(a)(2)

(Complete only if you checked the box on line 9 of Part I or if the organization failed to qualify under Part II. If the organization fails to qualify under the tests listed below, please complete Part II.)

Section A. Public Support							
Calendar year (or fiscal year beginning in) 🕨	<b>(a)</b> 2009	<b>(b)</b> 2010	(c) 2011	(d) 2012	(e)	2013	<b>(f)</b> Total
1 Gifts, grants, contributions, and							
membership fees received. (Do not							
include any "unusual grants.")							
2 Gross receipts from admissions, merchandise sold or services per- formed, or facilities furnished in any activity that is related to the organization's tax-exempt purpose							
<b>3</b> Gross receipts from activities that are not an unrelated trade or bus-							
iness under section 513							
4 I ax revenues levied for the organ- ization's benefit and either paid to or expended on its behalf							
5 The value of services or facilities							
furnished by a governmental unit to the organization without charge				$\wedge$			
6 Total. Add lines 1 through 5							
<b>7a</b> Amounts included on lines 1, 2, and							
b Amounts included on lines 2 and 3 received from other than disqualified persons that exceed the greater of \$5,000 or 1% of the amount on line 13 for the year		4					
c Add lines 7a and 7b		~					
8 Public support (Subtratiling 76 from line 6.)							
Section B. Total Support							
Calendar vear (or fiscal vear beginning in)	(a) 2009	<b>(b)</b> 2010	(c) 2011	(d) 2012	(e)	2013	(f) Total
9 Amounts from line 6	(,	() = 0.10	(0) = 0 + 1	(0, 2012	(-)		(.)
10a Gross income from interest, dividends, payments received on securities loans, rents, royalties and income from similar sources							
<b>b</b> Unrelated business taxable income							
(less section 511 taxes) from businesses							
acquired after June 30, 1975							
<ul> <li>c Add lines 10a and 10b</li> <li>11 Net income from unrelated business activities not included in line 10b,</li> </ul>							
whether or not the business is regularly carried on							
12 Other income. Do not include gain or loss from the sale of capital assets (Explain in Part IV.)							
13 Total support. (Add lines 9, 10c, 11, and 12.)							
14 First five years. If the Form 990 is for t	the organization's	s first, second, thir	d, fourth, or fifth ta	ax year as a sectio	n 501(c)	(3) organiz	ation,
check this box and stop here	<u></u>					<u></u>	▶∟
Section C. Computation of Public	c Support Pe	rcentage					
15 Public support percentage for 2013 (lir	ne 8, column (f) d	ivided by line 13, o	column (f))		15		%
16 Public support percentage from 2012	Schedule A, Part	III, line 15			16		%
Section D. Computation of Invest	tment Incom	e Percentage					
17 Investment income percentage for 201	<b>3</b> (line 10c, colur	nn (f) divided by lir	ne 13, column (f))		17		%
18 Investment income percentage from 2	012 Schedule A,	Part III, line 17			18		%
19a 33 1/3% support tests - 2013. If the c	organization did n	not check the box	on line 14, and line	e 15 is more than 3	33 1/3%	, and line 1	7 is not
more than 33 1/3%, check this box an	d <b>stop here.</b> The	organization qual	ifies as a publicly s	supported organiz	ation		
b 33 1/3% support tests - 2012. If the c	organization did n	ot check a box or	n line 14 or line 19a	a, and line 16 is mo	ore than	33 1/3%, a	and
line 18 is not more than 33 1/3%, chec	k this box and <b>s</b> f	top here. The orga	anization qualifies	as a publicly supp	orted or	ganization	
20 Private foundation. If the organization	did not check a	box on line 14, 19	a, or 19b, check th	his box and see ins	struction	s	

Schedule A	(Form 990 or 990-EZ) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131788 Page 4
Part IV	Supplemental Information. Provide the explanations required by Part II, line 10; Part II, line 17a or 17b; and Part III, line 12.
	Also complete this part for any additional information. (See instructions).

Schedule B (Form 990, 990-EZ, or 990-PF)
Department of the Treasury
Internal Revenue Service

# **Schedule of Contributors**

 Attach to Form 990, Form 990-EZ, or Form 990-PF.
 Information about Schedule B (Form 990, 990-EZ, or 990-PF) and its instructions is at www.irs.gov/form990 . OMB No. 1545-0047

2013

Employer identification number

	INTERNATIONAL LIFE SCIENCES INSTITUTE	52-1131788		
Organization type (che	eck one):			
Filers of:	Section:			
Form 990 or 990-EZ	X 501(c)( 3 ) (enter number) organization			
	4947(a)(1) nonexempt charitable trust <b>not</b> treated as a private foundation			
	527 political organization			
Form 990-PF	501(c)(3) exempt private foundation			
	501(c)(3) taxable private foundation			
Check if your organization is covered by the <b>General Rule</b> or a <b>Special Rule.</b> <b>Note.</b> Only a section 501(c)(7), (8), or (10) organization can check boxes for both the General Rule and a Special Rule. See instructions.				

#### **General Rule**

For an organization filing Form 990, 990-EZ, or 990-PF that received, during the year, \$5,000 or more (in money or property) from any one contributor. Complete Parts I and II.

#### **Special Rules**

**X** For a section 501(c)(3) organization filing Form 990 or 990-EZ that met the 33 1/3% support test of the regulations under sections 509(a)(1) and 170(b)(1)(A)(vi) and received from any one contributor, during the year, a contribution of the greater of (1) \$5,000 or (2) 2% of the amount on (i) Form 990, Part VIII, line 1h, or (ii) Form 990-EZ, line 1. Complete Parts I and II.

For a section 501(c)(7), (8), or (10) organization filing Form 990 or 990-EZ that received from any one contributor, during the year, total contributions of more than \$1,000 for use *exclusively* for religious, charitable, scientific, literary, or educational purposes, or the prevention of cruelty to children or animals. Complete Parts I, II, and III.

□ For a section 501(c)(7), (8), or (10) organization filing Form 990 or 990-EZ that received from any one contributor, during the year, contributions for use *exclusively* for religious, charitable, etc., purposes, but these contributions did not total to more than \$1,000. If this box is checked, enter here the total contributions that were received during the year for an *exclusively* religious, charitable, etc., purpose. Do not complete any of the parts unless the **General Rule** applies to this organization because it received *nonexclusively* religious, charitable, etc., etc., contributions of \$5,000 or more during the year

**Caution.** An organization that is not covered by the General Rule and/or the Special Rules does not file Schedule B (Form 990, 990-EZ, or 990-PF), but it **must** answer "No" on Part IV, line 2, of its Form 990; or check the box on line H of its Form 990-EZ or on its Form 990-PF, Part I, line 2, to certify that it does not meet the filing requirements of Schedule B (Form 990, 990-EZ, or 990-PF).

LHA For Paperwork Reduction Act Notice, see the Instructions for Form 990, 990-EZ, or 990-PF. Schedule B (Form 990, 990-EZ, or 990-PF) (2013)

Name of organization

Employer identification number

52-1131788

#### INTERNATIONAL LIFE SCIENCES INSTITUTE

Part I Contributors (see instructions). Use duplicate copies of Part I if additional space is needed. (a) (b) (c) (d) No. Name, address, and ZIP + 4 **Total contributions** Type of contribution 1 COCA-COLA COMPANY X Person Payroll P.O. BOX DRAWER 1734 337,000. Noncash \$ (Complete Part II for ATLANTA, GA 30301 noncash contributions.) (a) (b) (c) (d) No. Name, address, and ZIP + 4 **Total contributions** Type of contribution ILSI HEALTH & ENVIRONMENTAL SCIENCES 2 INSTITUTE X Person Payroll 1156 15TH STREET, 2ND FLOOR, N.W. 150,000. Noncash \$ (Complete Part II for WASHINGTON, DC 20005 noncash contributions.) (a) (b) (c) (d) **Total contributions** Type of contribution No. Name, address, and ZIP + 4 3 X ILSI NORTH AMERICA Person Payroll 2ND FLOOR, N.W. 150,000. Noncash 1156 15TH STREET, (Complete Part II for WASHINGTON, DC 20005 noncash contributions.) (a) (b) (c) (d) No. Name, address, and ZIP + 4 **Total contributions** Type of contribution 4 ILSI EUROPE Х Person Payroll 83 AVENUE E. MOUNIER BOX 6 B-1200 148,929. Noncash (Complete Part II for BRUSSELS, BELGIUM noncash contributions.) (a) (b) (c) (d) No. Name, address, and ZIP + 4 **Total contributions** Type of contribution 5 MONSANTO COMPANY X Person Payroll 5200 OLD ORCHARD ROAD 141,000. Noncash \$ (Complete Part II for SKOKIE, IL 60077 noncash contributions.) (c) (d) (a) (b) **Total contributions** No. Name, address, and ZIP + 4 Type of contribution 6 ILSI RESEARCH FOUNDATION X Person Payroll 140,000. 1156 15TH STREET, 2ND FLOOR, N.W. Noncash \$ (Complete Part II for WASHINGTON, DC 20005 noncash contributions.)

Schedule B (Form 990, 990-EZ, or 990-PF) (2013)

Employer identification number

52-1131788

#### INTERNATIONAL LIFE SCIENCES INSTITUTE

Part I	<b>Contributors</b> (see instructions). Use duplicate copies of Part I if additiona	l space is needed.	
(a) No	(b) Name address and <b>ZI</b> D + 4	(c) Total contributions	(d) Type of contribution
<u>7</u>	SYNGENTA INC. PO BOX 18300 GREENSBORO, NC 27419	\$ <u>112,000.</u>	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
8	DOW AGROSCIENCES 9330 ZIONSVILLE ROAD INDIANAPOLIS, IN 46268	\$106,000.	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
9	PIONEER HI-BRED INT'L, INC PO BOX 552, 7250 NW 62ND AVE JOHNSON, IA 50131	\$ <u>106,000.</u>	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
10	BAYER CROPSCIENCE USA LP 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709	\$100,000.	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
	BASF CORPORATION-USA 100 CAMPUS DRIVE FLORHAM PARK, NJ 07392	\$ <u>100,000.</u>	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
	MARS, INC 6885 ELM ST MCLEAN, VA 22101	\$ 65,000.	Person X Payroll Noncash (Complete Part II for noncash contributions.)

Schedule B (Form 990, 990-EZ, or 990-PF) (2013)

#### INTERNATIONAL LIFE SCIENCES INSTITUTE

Employer identification number

52-1131788

Part I	Contributors (see instructions). Use duplicate copies of Part I if additiona	l space is needed.	
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
13	ILSI SOUTHEAST ASIA GOLDHILL PLAZA POD BLOCK 03-45, 1 NEWTON ROAD 30899, SINGAPORE	\$45,428.	Person X Payroll Noncash (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
14	KELLOGG COMPANY		Person X
	ONE KELLOGG SQUARE BATTLE CREEK, MI 49016	\$ 40,000.	(Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
		\$	Person Payroll On Noncash October (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
		\$	Person Payroll On Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
		\$	Person Payroll On Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
		\$	Person Payroll Noncash (Complete Part II for noncash contributions.)

Schedule B (Form 990, 990-EZ, or 990-PF) (2013)	Page <b>3</b>
Name of organization	Employer identification number
INTERNATIONAL LIFE SCIENCES INSTITUTE	52-1131788

Part II	Noncash Property (see instructions). Use duplicate copies of Part II if a	dditional space is needed.	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received
		\$	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received
		\$	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received
		\$	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received
		\$	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received
		\$	
(a) No. from Part I	(b) Description of noncash property given	(c) FMV (or estimate) (see instructions)	(d) Date received

\$
lame of org	anization		Employer identification number
INTERN	NATIONAL LIFE SCIENCES	INSTITUTE	52-1131788
Part III	Exclusively religious, charitable, etc., ind year. Complete columns (a) through (e) and the total of exclusively religious, charitable, e Use duplicate copies of Part III if addition	ividual contributions to section 501( the following line entry. For organizat tc., contributions of <b>\$1,000 or less</b> fo nal space is needed.	(c)(7), (8), or (10) organizations that total more than \$1,000 for the second s
(a) No. from Part I	(b) Purpose of gift	(c) Use of gift	(d) Description of how gift is held
Γ		(e) Transfer of gi	jift
-	Transferee's name, address, a	Ind ZIP + 4	Relationship of transferor to transferee
(a) No. from Part I	(b) Purpose of gift	(c) Use of gift	(d) Description of how gift is held
		(e) Transfer of gi	yift
F	Transferee's name, address, a	Ind ZIP + 4	Relationship of transferor to transferee
(a) No. from Part I	(b) Purpose of gift	(c) Use of gift	(d) Description of how gift is held
	Transferee's name, address, a	(e) Transfer of gi	jift Relationship of transferor to transferee
	i		`
(a) No. from Part I	(b) Purpose of gift	(c) Use of gift	(d) Description of how gift is held
╞		(e) Transfer of gi	
+	Transferee's name, address, a	nd ZIP + 4	Relationship of transferor to transferee
1	-	[	

SCHEDULE	D
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#### (Form 990)

## **Supplemental Financial Statements**

Complete if the organization answered "Yes," to Form 990, Part IV, line 6, 7, 8, 9, 10, 11a, 11b, 11c, 11d, 11e, 11f, 12a, or 12b. Attach to Form 990.

Department of the Treasury	Attach to Form 990.
Internal Revenue Service	Information about Schedule D (Form 990) and its instructions is at www.irs.gov/form990.

Name of the organization

INTERNATIONAL LIFE SCIENCES INSTITUTE

Employer identification number 52-1131788

OMB No. 1545-0047

**Open to Public** 

Inspection

3

Pa	t I Organizations Maintaining Donor Advise	ed Funds or Other Similar Funds or	Accounts. Complete if the
	organization answered "Yes" to Form 990, Part IV, lin	e 6.	
		(a) Donor advised funds	(b) Funds and other accounts
1	Total number at end of year		
2	Aggregate contributions to (during year)		
3	Aggregate grants from (during year)		
4	Aggregate value at end of year		
5	Did the organization inform all donors and donor advisors in	writing that the assets held in donor advised for	unds
	are the organization's property, subject to the organization's	exclusive legal control?	Yes 🗌 No
6	Did the organization inform all grantees, donors, and donor a	advisors in writing that grant funds can be used	d only
	for charitable purposes and not for the benefit of the donor of	or donor advisor, or for any other purpose cont	ferring
	impermissible private benefit?		
Pa	t II Conservation Easements. Complete if the org	ganization answered "Yes" to Form 990, Part I	V, line 7.
1	Purpose(s) of conservation easements held by the organizat	ion (check all that apply).	
	Preservation of land for public use (e.g., recreation or e	education) Preservation of an historic	ally important land area
	Protection of natural habitat	Preservation of a certified	historic structure
	Preservation of open space		
2	Complete lines 2a through 2d if the organization held a quali	fied conservation contribution in the form of a	conservation easement on the last
	day of the tax year.		
			Held at the End of the Tax Year
а	Total number of conservation easements		_ 2a
b	Total acreage restricted by conservation easements		2b
С	Number of conservation easements on a certified historic str	ructure included in (a)	2c
d	Number of conservation easements included in (c) acquired	after 8/17/06, and not on a historic structure	
	listed in the National Register		2d
3	Number of conservation easements modified, transferred, re	leased, extinguished, or terminated by the org	anization during the tax
	year		
4	Number of states where property subject to conservation ea	sement is located	
5	Does the organization have a written policy regarding the pe	riodic monitoring, inspection, handling of	
	violations, and enforcement of the conservation easements i	it holds?	Yes II No
6	Staff and volunteer hours devoted to monitoring, inspecting,	and enforcing conservation easements during	g the year
7	Amount of expenses incurred in monitoring, inspecting, and	enforcing conservation easements during the	year ▶ \$
8	Does each conservation easement reported on line 2(d) above	ve satisfy the requirements of section 170(h)(4	)(B)(i)
	and section 170(h)(4)(B)(ii)?		Yes 🗆 No
9	In Part XIII, describe how the organization reports conservat	ion easements in its revenue and expense stat	tement, and balance sheet, and
	include, if applicable, the text of the footnote to the organiza	tion's financial statements that describes the	organization's accounting for
Da	conservation easements.	f Art Historical Trassuras or Otho	r Similar Assats
Fa	Complete if the organization answered "Ves" to Form	990 Part IV line 8	i Sinilai Assets.
	If the experimentation elected as permitted under SEAS 116 (AS		and balance about works of art
Id	historical trassures, or other similar assets hold for public ov	bibition aducation or research in furtherance	of public sonvice, provide, in Part XIII
	the text of the feetnets to its financial statements that deper	ibos those items	of public service, provide, in Part All,
h	If the organization elected as normitted under SEAS 116 (AS	IDES (TIESE ILETTS).	halance sheet works of art historical
U	trassures, or other similar assots hold for public exhibition	ducation, or research in furtherance of public	sorvice, provide the following amounts
	relating to these itoms:	ducation, or research in furtherance of publics	service, provide the following amounts
	(i) Boyonuos included in Form 990 Part VIII line 1		► ¢
	(ii) Assets included in Form 000 Part V		····· 🖌 🇳
2	If the organization received or held works of art historical tro	asures or other similar assets for financial asi	► Ψ n. provide
2	the following amounts required to be reported under SEAS 1	16 (ASC 958) relating to these items.	n, provide
9	Revenues included in Form 990. Part VIII line 1		▶ \$
a h	Assets included in Form 990 Part X		···· ► ♥
			💌 🤟

Sche	dule D (Form 990) 2013 INTERNA	TIONAL LIFE	SCIENCES	INSTIT	TUTE	52-1	13178	8 Page <b>2</b>
Pa	t III   Organizations Maintaining C	collections of Art,	Historical Tr	easures, o	or Other	Similar As	sets(contir	nued)
3	Using the organization's acquisition, accessi	on, and other records,	check any of the	following that	t are a signi	ificant use of	its collectio	n items
	(check all that apply):							
а	Public exhibition	d	Loan or exc	hange progra	ms			
b	Scholarly research	e	Other					
С	Preservation for future generations							
4	Provide a description of the organization's co	ollections and explain h	ow they further t	he organizatio	on's exemp	t purpose in F	Part XIII.	
5	During the year, did the organization solicit of	or receive donations of a	art, historical trea	sures, or othe	er similar as	sets		
Des	to be sold to raise funds rather than to be m	aintained as part of the	organization's co	ollection?			Yes	└── No
Pai	<b>TIV</b> Escrow and Custodial Arran	gements. Complete	if the organizatio	on answered "	Yes" to For	rm 990, Part I	V, line 9, or	
та	Is the organization an agent, trustee, custod	ian or other intermediar	y for contribution	ns or other as	sets not inc	luded	No.	
	on Form 990, Part X?					l	Yes	∟ NO
D	It "Yes," explain the arrangement in Part XIII	and complete the follow	wing table:				A	
	Designing belonce					10	Amoun	<u> </u>
с d	Additional during the year					10		
u	Distributions during the year					10		
f	Ending balance					16 1f		
2a	Did the organization include an amount on F	orm 990 Part X line 21	?	·····			Yes	No
b	If "Yes." explain the arrangement in Part XIII.	Check here if the expla	anation has been	provided in F	Part XIII	••••••		
Pa	t V Endowment Funds. Complete i	f the organization answ	rered "Yes" to Fo	orm 990, Part I	IV, line 10.			
	· · · ·	(a) Current year	(b) Prior year	(c) Two year	s back (d)	Three years ba	ck (e) Four	years back
1a	Beginning of year balance							-
b	Contributions							
с	Net investment earnings, gains, and losses							
d	Grants or scholarships							
е	Other expenditures for facilities							
	and programs							
f	Administrative expenses							
g	End of year balance							
2	Provide the estimated percentage of the cur	rent year end balance (	line 1g, column (a	a)) held as:				
а	Board designated or quasi-endowment	9	6					
b	Permanent endowment	%						
С	Temporarily restricted endowment	%						
	The percentages in lines 2a, 2b, and 2c show	uld equal 100%.						
3a	Are there endowment funds not in the posse	ession of the organization	on that are held a	administer	red for the	organization	г	
	by:							Yes No
	(i) unrelated organizations						3a(i)	
	(ii) related organizations						3a(ii)	
b	If "Yes" to 3a(ii), are the related organization	s listed as required on S	Schedule R?				3b	
4	t VI L and Ruildings and Equipm	e organization's endowr	nent funds.					
Fai	Complete if the organization onewers	d "Voo" to Form 000 D	art IV/ line 11a S	oo Eorm 000	Dort V line	10		
		(a) Cost or othe		or other				a value
	Description of property	basis (investmer	nt) basis	(other)	depred	ciation	(u) 600	value
19	Land		,		3.612.04			
h	Buildings							
c c	Leasehold improvements		72	3,761.	36	4,951.	35	8,810.
d	Equipment		47	7,288.	39	4,280.	8	3,008.
e	Other			-	-	-	-	-
Tota	. Add lines 1a through 1e. (Column (d) must e	qual Form 990, Part X,	column (B), line 1	10(c).)			44	1,818.
						0.1		000) 0040

Schedule D (Form 990) 2013

Schedule D (Form 990) 2013 INTERNATION	AL LIFE SCI	ENCES INSTITUTE 5	2-1131788 Page 3
Part VII Investments - Other Securities.			
Complete if the organization answered "Yes"	to Form 990, Part IV, li	ne 11b. See Form 990, Part X, line 12.	
(a) Description of security or category (including name of security)	<b>(b)</b> Book value	(c) Method of valuation: Cost or e	end-of-year market value
(1) Financial derivatives			
(2) Closely-held equity interests			
(3) Other			
(A)			
(B)			
(C)			
(D)			
(E)			
(F)			
(G)			
(H)			
Total. (Col. (b) must equal Form 990, Part X, col. (B) line 12.)			
Part VIII Investments - Program Related.			
Complete if the organization answered "Yes"	to Form 990, Part IV, li	ne 11c. See Form 990, Part X, line 13.	
(a) Description of investment	(b) Book value	(c) Method of valuation: Cost or e	end-of-year market value
(1)			
(2)			
(3)			
(4)			
(5)			
(6)			
(7)			
(8)			
(9)	·		
Total. (Col. (b) must equal Form 990, Part X, col. (B) line 13.) ►			
Part IX Other Assets.			
Complete if the organization answered "Yes"	to Form 990, Part IV, li	ne 11d. See Form 990, Part X, line 15.	
	Description		
(1) RENT RECEIVABLE, SHARED S	ERVICES AGR	EEMENT	357,566.
(2) DUE FROM AFFILIATES			522,765.
(3)			
(4)			
(5)			
(6)	-		
(7)			
(8)			
(9)			000 221
Total. (Column (b) must equal Form 990, Part X, col. (B) line	e 15.)		880,331.
Part X Other Liabilities.			
Complete if the organization answered "Yes"	to Form 990, Part IV, II	ne 11e or 11f. See Form 990, Part X, line :	25.
		(D) DUUK VAILLE	
(1) Federal income taxes		759 190	
(2) DEFEKKED KENT		/ 30 , 109 .	
(3) DEFOSTIS		240,000.	
(4)			
(5)			
(6)			
(7)			

(9)	
Total. (Column (b) must equal Form 990, Part X, col. (B) line 25.)	1,004,189.

2. Liability for uncertain tax positions. In Part XIII, provide the text of the footnote to the organization's financial statements that reports the organization's liability for uncertain tax positions under FIN 48 (ASC 740). Check here if the text of the footnote has been provided in Part XIII 🚺

(8)

Pa	rt XI Reconciliation of Revenue per Audited Financial Statemer	nts With Revenue per	Retur	n.
	Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.			-
1	Total revenue, gains, and other support per audited financial statements		. 1	
2	Amounts included on line 1 but not on Form 990, Part VIII, line 12:			
а	Net unrealized gains on investments	2a		
b	Donated services and use of facilities	2b		
с	Recoveries of prior year grants	2c		
d	Other (Describe in Part XIII.)	2d		
е	Add lines 2a through 2d		. 2e	
3	Subtract line 2e from line 1		. 3	
4	Amounts included on Form 990, Part VIII, line 12, but not on line 1:			
а	Investment expenses not included on Form 990, Part VIII, line 7b	4a		
b	Other (Describe in Part XIII.)	4b		
С	Add lines 4a and 4b		. 4c	
5	Total revenue. Add lines <b>3</b> and <b>4c.</b> (This must equal Form 990, Part I, line 12.)		5	
Pa	rt XII Reconciliation of Expenses per Audited Financial Stateme	ents With Expenses pe	er Retu	ırn.
Pa	rt XII Reconciliation of Expenses per Audited Financial Stateme Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.	ents With Expenses pe	er Retu	irn.
<b>Pa</b>	Reconciliation of Expenses per Audited Financial Stateme           Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.           Total expenses and losses per audited financial statements	ents With Expenses pe	er Retu	urn.
Pa 1 2	Reconciliation of Expenses per Audited Financial Stateme           Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.           Total expenses and losses per audited financial statements           Amounts included on line 1 but not on Form 990, Part IX, line 25:	ents With Expenses pe		Jrn.
Pa 1 2 a	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities	ents With Expenses pe		urn.
Pa 1 2 a b	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments	ents With Expenses pe		irn.
Pa 1 2 a b c	Reconciliation of Expenses per Audited Financial Statemer         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses	2a 2b 2c		Jrn.
Pa 1 2 a b c d	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)	2a 2b 2c 2d		Jrn.
Pa 1 2 a b c d e	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)         Add lines 2a through 2d	2a 2b 2c 2d		Jrn.
Pa 1 2 b c d 3	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)         Add lines 2a through 2d         Subtract line 2e from line 1	ents With Expenses per 2a 2b 2c 2d	2e 3	Jrn.
Pa 1 2 3 4	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other losses         Other losses         Subtract line 2e from line 1         Amounts included on Form 990, Part IX, line 25, but not on line 1:	2a 2b 2c 2d		irn.
Pa 1 2 b c d e 3 4 a	Reconciliation of Expenses per Audited Financial Statemer         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)         Add lines 2a through 2d         Subtract line 2e from line 1         Amounts included on Form 990, Part IX, line 25, but not on line 1:         Investment expenses not included on Form 990, Part VIII, line 7b	2a 2b 2c 2d 4a	1	Jrn.
Pa 1 2 a b c d e 3 4 a b	Reconciliation of Expenses per Audited Financial Statemer         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)         Add lines 2a through 2d         Subtract line 2e from line 1         Amounts included on Form 990, Part IX, line 25, but not on line 1:         Investment expenses not included on Form 990, Part VIII, line 7b         Other (Describe in Part XIII.)	2a 2b 2c 2d 4a 4b	2e 3	Jrn.
Pa 1 2 4 3 4 5 5 6 6 7 6 7 7 1 7 7 8 7 7 8 7 8 7 7 8 7 7 8 7 8 7	Reconciliation of Expenses per Audited Financial Stateme         Complete if the organization answered "Yes" to Form 990, Part IV, line 12a.         Total expenses and losses per audited financial statements         Amounts included on line 1 but not on Form 990, Part IX, line 25:         Donated services and use of facilities         Prior year adjustments         Other losses         Other (Describe in Part XIII.)         Add lines 2a through 2d         Subtract line 2e from line 1         Amounts included on Form 990, Part IX, line 25, but not on line 1:         Investment expenses not included on Form 990, Part VIII, line 7b         Other (Describe in Part XIII.)	2a 2b 2c 2d 4a 4b	2e 3	Jrn.

INTERNATIONAL LIFE SCIENCES INSTITUTE

#### Part XIII Supplemental Information.

Provide the descriptions required for Part II, lines 3, 5, and 9; Part III, lines 1a and 4; Part IV, lines 1b and 2b; Part V, line 4; Part X, line 2; Part XI, lines 2d and 4b; and Part XII, lines 2d and 4b. Also complete this part to provide any additional information.

PART X, LINE 2:

Schedule D (Form 990) 2013

EXPLANATION: ILSI BELIEVES THAT IT HAS APPROPRIATE SUPPORT FOR ANY TAX

POSITIONS TAKEN, AND AS SUCH, DOES NOT HAVE ANY UNCERTAIN TAX POSITIONS

THAT ARE MATERIAL TO THE CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER

<u>31, 2013</u>.

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SC (Fo	HEDULE F			nt of Act	ivities Outside the Ur			OMB No. 1	<sup>545-0047</sup>
Dena	tment of the Treasury	P	- Oompiete in	Attach to F	orm 990. See separate instruction	ons.	I, OF TO.	Open to	
Intern	al Revenue Service		Information abo	out Schedule F	(Form 990) and its instructions is at	www.irs.gov/f	orm990.	Inspect	ion
Nam	e of the organization	n					Employer ic	lentification	n number
IN	TERNATIONA	LL	IFE SCIE	NCES INS	TITUTE		52-113	1788	
Pa	rt I General	Infor	mation on A	ctivities Ou	tside the United States. Complete	ete if the orgar	ization answe	red "Yes" or	n
	Form 990, I	Part IV	, line 14b. the ergenization	maintain racar	de to substantiste the amount of its ar	onto and other	accietance		
•	the grantees' eligit	bility fo	or the grants or a	assistance, and	the selection criteria used to award the	e grants or ass	istance?	X Yes	🗌 No
2	For grantmakers. United States.	. Descr	ibe in Part V the	e organization's	procedures for monitoring the use of it	s grants and o	ther assistanc	e outside th	e
3	Activities per Regi	ion. (Th	ne following Part	I, line 3 table ca	an be duplicated if additional space is	needed.)			
	(a) Region		(b) Number of offices in the region	(c) Number of employees, agents, and independent contractors in region	(d) Activities conducted in region (by type) (e.g., fundraising, program services, investments, grants to recipients located in the region)	(e) If acti is a pro describe of servi	vity listed in (d gram service, e specific type ce(s) in region	i) (f expe fo inve in	) Total enditures or and estments region
EAS	T ASIA & THE								
PAC	IFIC		0	0	GRANTMAKING				25,000.
EUR	OPE		0	0	GRANTMAKING				8 622.
SOU	TH AMERICA		0	0	GRANTMAKING				21,525.
SOU	TH ASIA		0	0	GRANTMAKING				7,687.
SUB	-SAHARAN AFRICA		0	O	GRANTMAKING; PROGRAM SERVICE	INTERNATIO	JAL PROGRAM	s	13,578.
3 a	Sub-total		0	0					76,412.
b	Total from continu sheets to Part I	lation	0	0					0.
c	Totals (add lines 3 and 3b)	3a	0	0					76,412.

LHA For Paperwork Reduction Act Notice, see the Instructions for Form 990.

Schedule F (Form 990) 2013

#### Part II Grants and Other Assistance to Organizations or Entities Outside the United States. Complete if the organization answered "Yes" on Form 990, Part IV, line 15, for any recipient who received more than \$5,000. Part II can be duplicated if additional space is needed.

1 (a) Name of organization	<b>(b)</b> IRS code section and EIN (if applicable)	(c) Region	<b>(d)</b> Purpose of grant	(e) Amount of cash grant	(f) Manner of cash disbursement	(g) Amount of non-cash assistance	<b>(h)</b> Description of non-cash assistance	(i) Method of valuation (book, FMV, appraisal, other)
		EAST ASIA AND THE	SUPPORT FOR WORKSHOP					
		PACIFIC -	ON "STRENGTHENING					
		AUSTRALIA,	ASEAN RISK ASSESSMENT					
		BRUNEI, BURMA,	CAPACITIES: FOOD	25,000.	WIRE	٥.		
		EUROPE (INCLUDING	SUPPORT BRANCH TRAVEL					
		ICELAND &	EXPENSE TO ATTEND					
		GREENLAND) -	ILSI ANNUAL MEETING					
		ALBANIA, ANDORRA,	AND VIBRIO WORKSHOP	13,525.	WIRE	0.		
<ol> <li>Enter total number of the IRS, or for which t</li> <li>Enter total number of</li> </ol>	recipient organizatio he grantee or couns	ns listed above that are el has provided a section or entities	recognized as charities by the n 501(c)(3) equivalency letter	foreign country	, recognized as tax-e	xempt by		2

**3** Enter total number of other organizations or entities

# 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE

Part III Grants and Other Assistance to Individuals Outside the United States. Complete if the organization answered "Yes" on Form 990, Part IV, line 16.

(a) Type of grant or assistance	(b) Region	(c) Number of recipients	(d) Amount of cash grant	<b>(e)</b> Manner of cash disbursement	(f) Amount of non-cash assistance	(g) Description of non-cash assistance	<b>(h)</b> Method of valuation (book, FMV, appraisal, other)
INTERNSHIP WITH THE WORLD HEALTH ORGANIZATION IN	EUROPE (INCLUDING ICELAND & GREENLAND) -						
GENEVA, SWITZERLAND	ALBANIA, ANDORRA,	1	8,622.	WIRE	0.		
INTERNSHIP WITH THE WORLD HEALTH ORGANIZATION IN GENEVA SWITZERLAND	SOUTH AMERICA	1	8 000	WIRE	0		
SUPPORT FOR FOOD SAFETY RISK							
ANALYSIS TRAINING	SOUTH ASIA	1	7,687.	WIRE	0.		
			<sup>•</sup> C				

Schedule F (Form 990) 2013

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52-1131788

Schedule F (Form 990) 2013

# Schedule F (Form 990) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131 Part IV Foreign Forms

52-1151/00 Page 4
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		Schedule F (For	m 990) 2013
6	Did the organization have any operations in or related to any boycotting countries during the tax year? If "Yes," the organization may be required to file Form 5713, International Boycott Report. (see Instructions for Form 5713)	Yes	X No
5	Did the organization have an ownership interest in a foreign partnership during the tax year? If "Yes," the organization may be required to file Form 8865, Return of U.S. Persons With Respect To Certain Foreign Partnerships. (see Instructions for Form 8865)	🗆 Yes	X No
4	Was the organization a direct or indirect shareholder of a passive foreign investment company or a qualified electing fund during the tax year? If "Yes," the organization may be required to file Form 8621, Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund. (see Instructions for Form 8621)	🗆 Yes	X No
3	Did the organization have an ownership interest in a foreign corporation during the tax year? If "Yes," the organization may be required to file Form 5471, Information Return of U.S. Persons With Respect To Certain Foreign Corporations. (see Instructions for Form 5471)	Yes	X No
2	Did the organization have an interest in a foreign trust during the tax year? If "Yes," the organization may be required to file Form 3520, Annual Return to Report Transactions with Foreign Trusts and Receipt of Certain Foreign Gifts, and/or Form 3520-A, Annual Information Return of Foreign Trust With a U.S. Owner (see Instructions for Forms 3520 and 3520-A)	🗆 Yes	X No
1	Was the organization a U.S. transferor of property to a foreign corporation during the tax year? If "Yes," the organization may be required to file Form 926, Return by a U.S. Transferor of Property to a Foreign Corporation (see Instructions for Form 926)	Yes	X No

Schedule F (Form 990) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131788 Page 5
Provide the information required by Part I, line 2 (monitoring of funds); Part I, line 3, column (f) (accounting method; amounts of
investments vs. expenditures per region); Part II, line 1 (accounting method); Part III (accounting method); and Part III, column (c) (estimated number of recipients), as applicable. Also complete this part to provide any additional information.
PART I, LINE 2:
EXPLANATION: DEPENDING ON THE NATURE OF THE GRANT AND THE TYPE OF
RECIPIENT, ILSI WILL GENERALLY HAVE SIGNED AGREEMENTS THAT SPECIFY
REQUIRED REPORTS OR OTHER COMMUNICATIONS. STAFF MONITOR PROJECTS AS
REQUIRED TO ENSURE FUNDS ARE USED FOR THE INTENDED PURPOSE.
PART II, COLUMN (D):
REGION: EAST ASIA AND THE PACIFIC - AUSTRALIA, BRUNEI, BURMA, CAMBODIA,
(D) PURPOSE OF GRANT: SUPPORT FOR WORKSHOP ON "STRENGTHENING ASEAN RISK
ASSESSMENT CAPACITIES: FOOD CONSUMPTION DATA"

SCHEDULE I (Form 990) Department of the Treasury Internal Revenue Service	Comp ► Informat	Grants and Oth overnments, ar lete if the organizatio	ner Assistan nd Individua on answered "Yes ▶ Attach to For (Form 990) and its	<b>ce to Orgar</b> <b>Is in the Un</b> " to Form 990, Pa m 990. s instructions is a	nizations, ited States rt IV, line 21 or 22.	00	OMB No. 1545-0047 <b>2013</b> Open to Public Inspection
Name of the organization	NTONAL LIP	COTENCES I	NOMTHINE		Ū		Employer identification number
Part I General Information on Gran	I I UNAL LIFE	P 2CIENCE2 I	INSTITUTE				52-1151700
<ol> <li>Does the organization maintain recorr criteria used to award the grants or a</li> <li>Describe in Part IV the organization's</li> </ol>	ds to substantiate th ssistance? procedures for mon	e amount of the grants	s or assistance, the	e grantees' eligibili d States.	ty for the grants or ass	sistance, and the selec	tion X Yes No
Part II Grants and Other Assistance	to Governments an	d Organizations in th	e United States.	Complete if the org	anization answered	res" to Form 990, Part	IV, line 21, for any
recipient that received more the <b>1 (a)</b> Name and address of organizatio or government	n <b>(b)</b> EIN	(c) IRC section if applicable	(d) Amount of cash grant	ded. (e) Amount of non-cash assistance	(f) Method of valuation (book, FMV, appraisal, other)	(g) Description of non-cash assistance	(h) Purpose of grant or assistance
ILSI RESEARCH FOUNDATION 1156 15TH STREET N.W. 2ND FL WASHINGTON, DC 20005	52-1323610	501(C)3	204,997.	299,412.	FMV	SOFTWARE	SUPPORT FOR FUNDING THE CENTER FOR SAFETY ASSESSMENT OF FOOD AND FEED
ILSI HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE - 1156 15TH STREET N.W. 2ND FL - WASHINGTON, DC 20005	52-2337019	501(C)3	118,702.	0.			SUPPORT ILSI HESI PROTEIN ALLERGENICITY COMMITTEE AND SUPPORT FOR WORKSHOP
UNIVERSITY OF SOUTH CAROLINA RESEARCH FOUNDATION CHARLOTTE, NC 28275	57-0967350	501(C)3	34,825.	0.			SUPPORT FOR ILSI FOCAL POINT IN CHINA/COCA COLA FELLOWSHIP PROGRAM
UMCP FOUNDATION, UNIVERSITY OF MARYLAND, JIFSAN - 2134 PATAPSCC BLDG - COLLEGE PARK, MD 20742	52-2197311	501(C)3	24,000.	0.			SUPPORT FOR FOOD SAFETY RISK ANALYSIS TRAINING
<ul> <li>2 Enter total number of section 501(c)(</li> <li>3 Enter total number of other organization</li> </ul>	3) and government o ions listed in the line	 rganizations listed in th 1 table	l ne line 1 table	<u> </u>	I	1	↓4.

LHA For Paperwork Reduction Act Notice, see the Instructions for Form 990.

Schedule I (Form 990) (2013)

#### INTERNATIONAL LIFE SCIENCES INSTITUTE

52-1131788

Grants and Other Assistance to Individuals in the United States. Complete if the organization answered "Yes" to Form 990, Part IV, line 22. Part III can be duplicated if additional space is needed.

(a) Type of grant or assistance	(b) Number of recipients	(c) Amount of cash grant	(d) Amount of non- cash assistance	(e) Method of valuation (book, FMV, appraisal, other)	(f) Description of non-cash assistance
INTERNSHIP WITH THE WORLD HEALTH ORGANIZATION IN					
GENEVA, SWITZERLAND	1	6,542.	0.		
		•			

Part IV Supplemental Information. Provide the information required in Part I, line 2, Part III, column (b), and any other additional information.

PART I, LINE 2:

EXPLANATION: DEPENDING ON THE NATURE OF THE GRANT AND THE TYPE OF

RECIPIENT, ILSI WILL GENERALLY HAVE SIGNED AGREEMENTS THAT SPECIFY REQUIRED

REPORTS OR OTHER COMMUNICATIONS. STAFF MONITOR PROJECTS AS REQUIRED TO

ENSURE FUNDS ARE USED FOR THE INTENDED PURPOSE.

Page 2

SCHEDULE	OMB No.	1545-00	47
(Form 990) Eor certain Officers Directors Trustees Key Employees and Highest		0040	
Compensated Employees	20	2013	
Complete if the organization answered "Yes" on Form 990, Part IV, line 23.	Open t	Dubl	ic
Department of the Treasury Attach to Form 990. See separate instructions.	Inspe	ection	
Name of the organization	ver identificati	on nu	mber
INTERNATIONAL LIFE SCIENCES INSTITUTE 52	-113178	8	
Part I Questions Regarding Compensation		-	
		Yes	No
<b>1a</b> Check the appropriate box(es) if the organization provided any of the following to or for a person listed in Form 990.		100	
Part VII. Section A line 1a Complete Part III to provide any relevant information regarding these items			
First-class or charter travel			
Travel for companions			1
Tax indemnification and gross-up payments Health or social club dues or initiation fees			1
Discretionary spending account			1
<b>b</b> If any of the boxes on line 1a are checked, did the organization follow a written policy regarding payment or			
reimbursement or provision of all of the expenses described above? If "No." complete Part III to explain	1b		
2 Did the organization require substantiation prior to reimbursing or allowing expenses incurred by all directors.			
trustees, and officers, including the CEO/Executive Director, regarding the items checked in line 1a?	2		
3 Indicate which, if any, of the following the filing organization used to establish the compensation of the organization's			1
CEO/Executive Director. Check all that apply. Do not check any boxes for methods used by a related organization to			1
establish compensation of the CEO/Executive Director, but explain in Part III.			1
X Compensation committee Written employment contract			
Independent compensation consultant			1
X Form 990 of other organizations X Approval by the board or compensation committe	e		1
			1
4 During the year, did any person listed in Form 990, Part VII, Section A, line 1a, with respect to the filing			1
organization or a related organization:			
a Receive a severance payment or change-of-control payment?	4a		X
b Participate in, or receive payment from, a supplemental nonqualified retirement plan?	4b		X
c Participate in, or receive payment from, an equity-based compensation arrangement?	4c		X
If "Yes" to any of lines 4a-c, list the persons and provide the applicable amounts for each item in Part III.			1
Only section 501(c)(3) and 501(c)(4) organizations must complete lines 5-9.			
5 For persons listed in Form 990, Part VII, Section A, line 1a, did the organization pay or accrue any compensation			
contingent on the revenues of:			
a The organization?	5a		X
<b>b</b> Any related organization?	5b		X
If "Yes" to line 5a or 5b, describe in Part III.			1
6 For persons listed in Form 990, Part VII, Section A, line 1a, did the organization pay or accrue any compensation			1
contingent on the net earnings of:			37
a The organization?	<u>6a</u>		Ă V
b Any related organization?	6b		~
It "Yes" to line 6a or 6b, describe in Part III.			
I For persons listed in Form 990, Part VII, Section A, line 1a, did the organization provide any non-fixed payments	_		v
not described in lines 5 and 6? If "Yes," describe in Part III	7		~
were any amounts reported in Form 990, Part VII, paid or accrued pursuant to a contract that was subject to the			v
initial contract exception described in Regulations section 53.4958-4(a)(3)? If "Yes," describe in Part III	8		^
<ul> <li>IT "Yes" to line 8, did the organization also follow the rebuttable presumption procedure described in</li> </ul>			
Heguiations Section 53.4958-b(c)?			2010

#### INTERNATIONAL LIFE SCIENCES INSTITUTE 52-1131788

#### Part II Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees. Use duplicate copies if additional space is needed.

For each individual whose compensation must be reported in Schedule J, report compensation from the organization on row (i) and from related organizations, described in the instructions, on row (ii). Do not list any individuals that are not listed on Form 990, Part VII.

Note. The sum of columns (B)(i)-(iii) for each listed individual must equal the total amount of Form 990, Part VII, Section A, line 1a, applicable column (D) and (E) amounts for that individual.

		(B) Breakdown of W-2 and/or 1099-MISC compensat		SC compensation	(C) Retirement and	(D) Nontaxable	(E) Total of columns	(F) Compensation	
(A) Name and Title		(i) Base compensation	(ii) Bonus & incentive compensation	(iii) Other reportable compensation	compensation	Denents	(B)(()-(D)	in prior Form 990	
(1) DR. SUZANNE S. HARRIS	(i)	243,993.	0.	2,520.	17,414.	20,208.	284,135.	0.	
EXECUTIVE DIRECTOR	(ii)	0.	0.	0.	0.	0.	0.	0.	
(2) MS. BETH-ELLEN BERRY	(i)	152,029.	0.	967.	10,964.	19,693.	183,653.	0.	
CHIEF FINANCIAL OFFICER	(ii)	0.	0.	0.	0.	0.	0.	0.	
(3) MR. SHAWN SULLIVAN	(i)	146,317.	0.	908.	10,626.	23,449.	181,300.	0.	
GENERAL COUNSEL	(ii)	0.	0.	0.	0.	0.	0.	0.	
	(i)								
	(ii)								
	(i)								
	(ii)								
	(i)								
	(ii)								
	(i)		(						
	(ii)								
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	(ii)								
	(i)								
	(ii)								

332113
09-13-13

Schedule J (Form 990) 2013	INTERNATIONAL	LIFE	SCIENCES	INSTITUTE
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#### Part III Supplemental Information

Provide the information, explanation, or descriptions required for Part I, lines 1a, 1b, 3, 4a, 4b, 4c, 5a, 5b, 6a, 6b, 7, and 8, and for Part II. Also complete this part for any additional information.

52-1131788

Page 3

Schedule J (Form 990) 2013

SCHEDULE O (Form 990 or 990-EZ) Department of the Treasury Internal Revenue Service Information about Schedule O (Form 990 or 990-EZ) and its instructions is at www.irs.cov/f	-EZ OMB No. 1545-0047 <b>2013</b> Open to Public Inspection			
Name of the organization INTERNATIONAL LIFE SCIENCES INSTITUTE	Employer identification number 52-1131788			
FORM 990, PART I, LINE 1, DESCRIPTION OF ORGANIZATION MIS	SION:			
THE INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI) IS A NON	PROFIT,			
WORLDWIDE FOUNDATION THAT SEEKS TO IMPROVE THE WELL-BEING	OF THE			
GENERAL PUBLIC THROUGH THE ADVANCEMENT OF SCIENCE. ITS GO	AL IS TO			
FURTHER THE UNDERSTANDING OF SCIENTIFIC ISSUES RELATING TO	O NUTRITION,			
FOOD SAFETY, TOXICOLOGY, RISK ASSESSMENT, AND THE ENVIRON	MENT BY			
BRINGING TOGETHER SCIENTISTS FROM ACADEMIA, GOVERNMENT AND	D INDUSTRY.			
FORM 990, PART III, LINE 1, DESCRIPTION OF ORGANIZATION M	ISSION:			
FOOD SAFETY, TOXICOLOGY, RISK ASSESSMENT, AND THE ENVIRON	MENT BY			
BRINGING TOGETHER SCIENTISTS FROM ACADEMIA, GOVERNMENT AND	D INDUSTRY.			
FORM 990, PART III, LINE 4A, PROGRAM SERVICE ACCOMPLISHME	NTS:			
ESTABLISH THE CENTER FOR SAFETY ASSESSMENT OF FOOD AND FE	ED. IFBIC			
MADE MAJOR CONTRIBUTIONS OVER THE COURSE OF ITS 16 YEARS	TO KNOWLEDGE			
TRANSFER RELATED TO THE SAFETY OF FOODS AND FEED DERIVED	THROUGH THE			
USE OF MODERN BIOTECHNOLOGY TOOLS.				
FORM 990, PART III, LINE 4C, PROGRAM SERVICE ACCOMPLISHMENTS:				
SUPPORT TO FOSTER A BALANCED APPROACH TO SOLVING HEALTH AND				
ENVIRONMENTAL PROBLEMS OF COMMON GLOBAL CONCERN.				
FORM 990, PART III, LINE 4D, OTHER PROGRAM SERVICES:				
ILSI PRESS, PIP/GTF				

EXPENSES \$ 295,006. INCLUDING GRANTS OF \$ 0. REVENUE \$ 444,096.

Schedule O (Form 990 or 990-EZ) (2013)	Page <b>2</b>
Name of the organization INTERNATIONAL LIFE SCIENCES INSTITUTE	Employer identification number 52-1131788
FORM 990, PART VI, SECTION A, LINE 6:	
EXPLANATION: MEMBERS SHALL BE THOSE FIRMS, CORPORATIONS OF	R OTHER ENTITIES
THAT ARE PRODUCERS OF FOOD, BEVERAGES, PHARMACEUTICALS, C	OSMETICS,
AGRICULTURAL AND OTHER CHEMICALS, PERSONAL CARE AND HOUSE	HOLD PRODUCTS, OR
CONTAINERS THEREOF, FORESTRY AND PAPER PRODUCTS, COMMUNIC	ATIONS PRODUCTS,
TRANSPORTATION PRODUCTS, ENERGY PRODUCTS, OR PRODUCERS OF	INGREDIENTS USED
THEREIN OR IN CONNECTION THEREWITH, OR PRODUCERS OF EXERC	ISE EQUIPMENT FOR
HUMAN HEALTH, OR PROVIDERS OF SCIENTIFIC AND TECHNICAL SE	RVICES USED IN THE
SAFETY TESTING OR PRODUCTION OF THE FOREGOING PRODUCTS, A	ND ARE MEMBERS IN
GOOD STANDING OF ANY OF THE BRANCHES OF ILSI (AS DEFINED	IN ARTICLE VIII,
SECTION 1 OF THE BYLAWS), PROVIDED, HOWEVER, THAT NO TRAD	E ASSOCIATION AND
NO FIRM WHOSE BUSINESS CONSISTS PRINCIPALLY OF PROVIDING	PROFESSIONAL
CONSULTING SERVICES OR ADVICE MAY BE A MEMBER OF ILSI. SHO	OULD AN ILSI
BRANCH ELECT TO HAVE A CATEGORY OF MEMBERSHIP WITH LIMITE	D OR RESTRICTED
RIGHTS, THOSE COMPANIES THAT ARE LIMITED OR RESTRICTED ME	MBERS OF SUCH
BRANCH SHALL NOT BE CONSIDERED FULL MEMBERS OF ILSI.	

FORM 990, PART VI, SECTION A, LINE 7A: EXPLANATION: EACH MEMBER SHALL HAVE ONE VOTE FOR EACH BRANCH ELIGIBLE TO VOTE AT ALL MEETINGS OF THE ASSEMBLY OF MEMBERS. AT EACH ANNUAL MEETING, THE ASSEMBLY OF MEMBERS WILL ELECT REPRESENTATIVES TO THE BOARD OF TRUSTEES. THE ASSEMBLY OF MEMBERS SHALL ALSO CONSIDER SUCH OTHER MATTERS AS ARE SUBMITIED TO IT BY THE BOARD OF TRUSTEES FOR CONSIDERATION OR ACTION AT THE ANNUAL MEETING.

FORM 990, PART VI, SECTION B, LINE 11:

EXPLANATION: THE CFO, GENERAL COUNSEL, AND EXECUTIVE DIRECTOR REVIEW THE

RETURN AND ONCE IT IS IN ITS FINAL FORM, A COPY IS SENT ELECTRONICALLY TO 322212 09-04-13
Schedule O (Form 990 or 990-EZ) (2013) Name of the organization

INTERNATIONAL LIFE SCIENCES INSTITUTE

Employer identification number 52-1131788

THE BOARD OF TRUSTEES FOR REVIEW.

FORM 990, PART VI, SECTION B, LINE 12C:

EXPLANATION: THE EXECUTIVE DIRECTOR, TRUSTEES AND KEY EMPLOYEES COMPLETE CONFLICT OF INTEREST FORMS ON AN ANNUAL BASIS. COMPLETED CONFLICT OF INTEREST FORMS ARE REVIEWED BY IN-HOUSE COUNSEL, WHOSE OBSERVATIONS ARE SHARED WITH THE CHAIR AND THE EXECUTIVE COMMITTEE. IN THE EVENT THAT A CONFLICT SHOULD ARISE, THE DISINTERESTED MEMBERS OF THE EXECUTIVE COMMITTEE WILL COMMUNICATE WITH THE INTERESTED TRUSTEE TO DETERMINE THE NATURE OF THE CONFLICT AND WHETHER THE TRUSTEE SHOULD ABSTAIN FROM DECIDING ON MATTERS AFFECTED BY THE INTEREST. THE EXECUTIVE COMMITTEE HAS THE AUTHORITY TO REMOVE THE TRUSTEE, WITH THE INTEREST, FROM CONSIDERATION OF THE MATTER TO WHICH THE INTEREST PERTAINS. THE CONFLICT OF INTEREST DECLARATION FORM, COMPLETED BY THE EXECUTIVE DIRECTOR, IS REVIEWED BY THE PRESIDENT AND THE CHAIR OF THE ILSI BOARD, AND THOSE INDIVIDUALS WILL INTERVENE IN THE EVENT THAT A DECLARED INTEREST PRESENTS A TRUE CONFLICT. THE EXECUTIVE DIRECTOR REVIEWS THE DECLARATIONS OF THE KEY EMPLOYEES AND MANAGES ANY DECLARED CONFLICTS.

FORM 990, PART VI, SECTION B, LINE 15A:

EXPLANATION: THE ILSI BYLAWS ESTABLISH A FORMAL PROCESS FOR SETTING EXECUTIVE COMPENSATION IN ACCORDANCE WITH THE INTERNAL REVENUE SERVICE SAFE HARBOR REGULATION REGARDING EXCESS BENEFITS. UNDER THIS PROCEDURE, THE PRESIDENT OF THE ILSI BOARD OF TRUSTEES APPOINTS A COMPENSATION COMMITTEE COMPOSED OF THREE INDEPENDENT TRUSTEES. THE COMPENSATION COMMITTEE ANNUALLY REVIEWS THE COMPENSATION OF THE ILSI EXECUTIVE DIRECTOR. THE REVIEW INCLUDES CONSIDERATION OF COMPARABILITY DATA. THE COMPENSATION COMMITTEE ESTABLISHES A RANGE OF COMPENSATION THAT THE COMMITTEE DEEMS REASONABLE. <sup>332212</sup> Schedule O (Form 990 or 990-EZ) (2013)

Schedule O (Form 990 or 990-EZ) (2013)	Page <b>2</b>
Name of the organization INTERNATIONAL LIFE SCIENCES INSTITUTE	Employer identification number 52-1131788
THAT RANGE IS PROVIDED TO THE ILSI PRESIDENT BECAUSE ILSI	'S EXECUTIVE
DIRECTOR ALSO SERVES AS EXECUTIVE DIRECTOR OF THE ILSI RE	SEARCH FOUNDATION.
THE ILSI RESEARCH FOUNDATION ALSO ESTABLISHES A COMPENSAT	ION COMMITTEE
WHOSE TERMS OF REFERENCE AND MODE OF OPERATION ARE IDENTI	CAL TO THOSE OF
ILSI. THE ILSI RESEARCH FOUNDATION COMMUNICATES, TO THE I	LSI RESEARCH
FOUNDATION CHAIRMAN OF THE BOARD, A RANGE OF COMPENSATION	I THAT THE
COMMITTEE DEEMS TO BE REASONABLE. THEN, THE ILSI PRESIDEN	T AND THE ILSI
RESEARCH FOUNDATION CHAIR SET THE EXECUTIVE DIRECTOR'S CC	MPENSATION AT A
FIGURE THAT IS CONSISTENT WITH THE RANGES ESTABLISHED BY	THE TWO
COMPENSATION COMMITTEES. THE COMPENSATION COMMITTEES RECO	ORD THEIR DECISION
IN CONTEMPORANEOUS WRITTEN MINUTES. IN ACCORDANCE WITH TH	IE IRS SAFE HARBOR
REGULATION, WITH REGARD TO EXCESS BENEFITS, THE COMPENSAT	ION COMMITTEE IS
ONLY REQUIRED TO PERFORM THE COMPENSATION REVIEW DESCRIBE	D ABOVE WITH
REGARD TO COMPENSATION OF THE EXECUTIVE DIRECTOR. HOWEVER	, THE COMMITTEE
HAS THE DISCRETION TO PERFORM SUCH A REVIEW WITH REGARD T	O ANY ILSI
EMPLOYEE AS IT DETERMINES APPROPRIATE. IF THE COMPENSATIO	N OF AN ILSI
EMPLOYEE, OTHER THAN THE EXECUTIVE DIRECTOR, IS NOT DETER	MINED IN
ACCORDANCE WITH THE PROCEDURE DESCRIBED ABOVE, HIS/HER CO	MPENSATION IS SET
BY THE EXECUTIVE DIRECTOR IN ACCORDANCE WITH HIGH-TO-LOW	RANGES ESTABLISHED
BY THE DIRECTOR OF HUMAN RESOURCES IN COOPERATION WITH TH	IE EXECUTIVE
DIRECTOR. THE COMPENSATION REVIEW FOR THE EXECUTIVE DIREC	TOR, AND ANY OTHER
ILSI EMPLOYEE SUBJECTED TO COMPENSATION COMMITTEE REVIEW,	DOES INCLUDE A
REVIEW AND APPROVAL BY INDEPENDENT PERSONS, COMPARABILITY	DATA, AND
CONTEMPORANEOUS SUBSTANTIATION OF THE DELIBERATION AND DE	CISION.
COMPENSATION OF EMPLOYEES THAT IS NOT SUBJECT TO SUCH A R	EVIEW IS
ESTABLISHED BY THE EXECUTIVE DIRECTOR, WHO IS INDEPENDENT	OF THE EMPLOYEES,
AND IT IS NORMALLY BASED ON AN INFORMAL REVIEW OF COMPARA	BLE COMPENSATION
IN NONPROFIT CORPORATIONS OF THE SAME SIZE IN THE WASHING	TON, DC AREA. THE

Schedule O (Form 990 or 990-EZ) (2013)	Page <b>2</b>
Name of the organization	Employer identification number 52–1131788
DROCESS BY WHICH COMDENSATION IS SET IS DOCIMENTED IN WRI	
PROCESS DI WHICH COMPENSATION IS SET IS DOCUMENTED IN WRI	
NOT DONE IN THE SAME FORMAL MANNER AS REVIEW BY THE COMPE	NSATION COMMITTEE.
FORM 990, PART VI, LINE 17, LIST OF STATES RECEIVING COPY	OF FORM 990:
CA, CO, CT, DC, FL, GA, IL, KY, MD, MA, MI, NH, NJ, NM, NY, NC, OH, PA, TN,	VA,WA,WI
FORM 990, PART VI, SECTION C, LINE 19:	
EXPLANATION: ARTICLES OF INCORPORATION, BY LAWS, CONFLICT	OF INTEREST
POLICY, AND AUDITED FINANCIAL STATEMENTS ARE POSTED ON WE	BSITE.

SCHEDULE R	
(Form 990)	

#### **Related Organizations and Unrelated Partnerships**

Complete if the organization answered "Yes" on Form 990, Part IV, line 33, 34, 35b, 36, or 37. Attach to Form 990. See separate instructions.

Information about Schedule R (Form 990) and its instructions is at www.irs.gov/form990

Department of the Treasury Internal Revenue Service

Name of the organization

# INTERNATIONAL LIFE SCIENCES INSTITUTE

Employer identification number 52-1131788

OMB No. 1545-0047

2013

**Open to Public** 

. Inspection

Part I Identification of Disregarded Entities Complete if the organization answered "Yes" on Form 990, Part IV, line 33.

<b>(a)</b> Name, address, and EIN (if applicable) of disregarded entity	<b>(b)</b> Primary activity	<b>(c)</b> Legal domicile (state or foreign country)	<b>(d)</b> Total income	<b>(e)</b> End-of-year assets	<b>(f)</b> Direct controlling entity

Identification of Related Tax-Exempt Organizations Complete if the organization answered "Yes" on Form 990, Part IV, line 34 because it had one or more related tax-exempt Part II organizations during the tax year.

<b>(a)</b> Name, address, and EIN of related organization	(b) Primary activity	(c) Legal domicile (state or foreign country)	(d) Exempt Code section	(e) Public charity status (if section	harity Direct controlling section entity		<b>g)</b> 512(b)(13) rolled ity?
				501(c)(3))		Yes	No
ILSI RESEARCH FOUNDATION - 52-1745052	TO BUILD A SCIENCE BASE TO						
1156 15TH STREET NW	SUPPORT SOUND PUBLIC						
WASHINGTON, DC 20005-1743	HEALTH DECISION MAKING	DISTRICT OF COLUMBIA	501(C)3	509(A)(3)	ILSI	X	
	_						
	-						
	-						
	4						
	4						

For Paperwork Reduction Act Notice, see the Instructions for Form 990.

Schedule R (Form 990) 2013

#### INTERNATIONAL LIFE SCIENCES INSTITUTE Schedule R (Form 990) 2013

Identification of Related Organizations Taxable as a Partnership Complete if the organization answered "Yes" on Form 990, Part IV, line 34 because it had one or more related organizations treated as a partnership during the tax year. Part III

(a)	(b)	(c)	(d)		(e)	(	f)	(	g)	()	h)	(i)		(j)	(k	()
Name, address, and EIN of related organization	Primary activity	Legal domicile (state or foreign	Direct controlling entity	Predomin (related, excluded fr	ant income unrelated, om tax under	Share inco	of total ome	Sha end-c ass	are of of-year sets	Disprop alloca	ortionate tions?	Code V-UE amount in b 20 of Sched	BI G box <sup>n</sup> Jule	General or managing partner?	Perce owne	ntage rship
		country)		sections	512-514)					Yes	No	K-1 (Form 10	)65) <b>y</b>	es No		
	1															
	1															
	-															
	-															
	-															
														_		
	-															
-	-															
	-															
														_		
	-															
	-															
	-															
Part IV Identification of Related Or organizations treated as a co	ganizations Taxable propration or trust dur	as a Corp	oration or Trust Co vear.	omplete if th	ie organizati	on answe	ered "Yes	" on Fori	m 990, Pa	rt IV, I	ine 34	because it ha	ad one	e or mo	re rela	ted
		0	/h)		(4)		(0)		(4)			( ~)		(h)		
(a)	-15.1		(0)	(C)		ture III an an	(e) Turk (		(1)	e		(9) Obawa a (		(n) 	Sec	tion
of related organizatio	n in	Priff	ary activity	(state or	Direct con entity	v trolling	(C corp. S	S corp.	Snare o inco	n total me		end-of-vear	own	entage ership	contr	olled
				foreign country)		, 	or tru	ist)				assets			enti	ity?
													_		Yes	No
											_					
													1			

Schedule R (Form 990) 2013

Ľ	Б	R	ИΤ.

#### Schedule R (Form 990) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE

Part V	Transactions With	Related Organizations	Complete if the	ne organization answered	"Yes" o	on Form 990,	Part IV, line 34, 35b, or 36.
--------	-------------------	-----------------------	-----------------	--------------------------	---------	--------------	-------------------------------

Not	e. Complete line 1 if any entity is listed in Parts II, III, or IV of this schedule.		Yes	No			
1	During the tax year, did the organization engage in any of the following transactions with one or more related organizations listed in Parts II-IV?						
а	Receipt of (i) interest (ii) annuities (iii) royalties or (iv) rent from a controlled entity	1a		X			
b	Gift, grant, or capital contribution to related organization(s)	1b		X			
с	Gift, grant, or capital contribution from related organization(s)	1c	Х				
d	Loans or loan guarantees to or for related organization(s)	. 1d		X			
е	Loans or loan guarantees by related organization(s)	. 1e		X			
f	Dividends from related organization(s)	1f		Х			
g	Sale of assets to related organization(s)	. 1g		Х			
h	Purchase of assets from related organization(s)	. 1h		X			
i	Exchange of assets with related organization(s)	_ 1i		X			
j	Lease of facilities, equipment, or other assets to related organization(s)	. 1j	X				
k	Lease of facilities, equipment, or other assets from related organization(s)	1k		X			
1	Performance of services or membership or fundraising solicitations for related organization(s)	11		X			
m	Performance of services or membership or fundraising solicitations by related organization(s)	1m	Х				
n	<b>n</b> Sharing of facilities, equipment, mailing lists, or other assets with related organization(s)						
o	Sharing of paid employees with related organization(s)	10	Х				
р	p Reimbursement paid to related organization(s) for expenses						
q	Reimbursement paid by related organization(s) for expenses	1q	Х				
r	Other transfer of cash or property to related organization(s)	1r		Х			
s	Other transfer of cash or property from related organization(s)	1s	Х				
2	If the answer to any of the above is "Yes," see the instructions for information on who must complete this line, including covered relationships and transaction thresholds.			<u> </u>			
	(a) Name of related organization Name of related organization (b) Transaction type (a·s) (c) Amount involved Method of determining amount i	nvolved					
<u>(1)</u>							
<u>(2)</u>							
(3)							
(4)							
(5)							
(0)							
(6)							

#### Schedule R (Form 990) 2013 INTERNATIONAL LIFE SCIENCES INSTITUTE

Part VI Unrelated Organizations Taxable as a Partnership Complete if the organization answered "Yes" on Form 990, Part IV, line 37.

Provide the following information for each entity taxed as a partnership through which the organization conducted more than five percent of its activities (measured by total assets or gross revenue) that was not a related organization. See instructions regarding exclusion for certain investment partnerships.

<b>(a)</b> Name, address, and EIN of entity	<b>(b)</b> Primary activity	(c) Legal domicile (state or foreign country)	(d) Predominant income (related, unrelated, excluded from tax under section 512-514)	(e) Are all partners 501(c)(i orgs.?	(f) Share of total income	<b>(g)</b> Share of end-of-year assets	(F Dispr tior alloca	n) opor- nate tions?	(i) Code V-UBI amount in box 20 of Schedule K-1 (Form 1065)	(j) General o managing partner? Yes NO	<b>(k)</b> Percentage ownership
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		$\sim$	5								
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Schedule R (Form 990) 2013

Schedule R (Form 990) 20	13 INTERI	NATIONAL LIF	E SCIENCES	INSTITUTE	52-1131788 Page 5
Part VII Suppleme	ntal Information				
Provide addit	ional information for resp	oonses to questions on S	Schedule R (see inst	ructions).	
				$\wedge$	
				>	
	•				

From: Sent: To:	Beth Brueggemeyer Monday, October 27, 2014 12:04	PM	
	: 's.chang@gi	riffith.edu.au': scohen@unn	nc.edu:
	,	mdoyle@uga.edu; adamdi	rew@u.washington.edu;
		, , , , ,	a);
	',		<i>,</i> ,
	1		; Joanne Lupton;
		'john.c.peters@ucdenv	er.edu';
	; kwallac	e@d.umn.edu; 'weavercm@	⊉purdue.edu';
	F	Prahlad Seth	;
	1		
			Flavio Zambrone
Cc:			jbradford@unmc.edu;
	'		
		tim.goss@ucdenver.edu	
		В	urnand,Valerie,VEVEY,C1-
	RSA	); 'haan@purdue.edu';	- III
		; Beth-Ellen Berry; Shawn	Sullivan
Subject:	ILSI draft IRS Form 990 for 2013		

To the ILSI Board of Trustees:

Attached is ILSI's draft IRS Form 990 for 2013. This form is the U.S. Internal Revenue Service's primary tax compliance tool for tax-exempt organizations. It is also a public document that is made available by the IRS and other organizations such as GuideStar to the public. The form gives exempt organizations the opportunity to "tell their story" and provide narrative information to supplement the schedules.

The form includes a section on governance practices. One question on the form in particular asks if a copy of the Form 990 was provided to the organization's governing body before it was filed. We believe it is in the best interest of the organization to answer yes to this question and provide you with a copy of ILSI's Form 990. This will give you an opportunity to exercise your fiduciary duty to make sure that the organization is following all laws and best practices.

Please note that descriptions or other narratives that exceed the space allotted on the forms are continued on Schedule O. The Schedules are in alphabetical order. Also, only those contributions in 2013 that exceeded the greater of \$5,000 or 2% of the amount on Form 990, Part VIII, line 1h are included on Schedule B. Because the Form 990 is for calendar year 2013, it is the 2013 trustees and officers whose names appear. Names of trustees who were elected for the first time in January 2014 are not included.

It is not necessary for you to reply to this email or indicate that you approve of the Form 990 and its related schedules. The return has been sent to you for information purposes. However, <u>if you do have any serious concerns or</u> <u>questions about information contained in the form, we would appreciate it if you would let us know by October 31,</u> <u>2014.</u>

Thank you,

Beth-Ellen Berry, CPA Chief Financial Officer International Life Sciences Institute 1156 15th Street, NW, 2nd Floor Washington, DC 20005 Phone: 202-659-0074 Fax: 202-659-3617 www.ilsi.org

Follow ILSI on: 🖪 匡

From: Sent: To:	Suzanne Harris Tuesday, October 21, 2014 10:10 AM '; 's.cha	ang@griffith.edu.au'; ''
	, source Eupton,	1
Cc:	; ' L. Bishop; Beth-Ellen Berry; Shawn Sullivan; Beth Bruegge	'; Chelsea meyer
Subject:	Agenda, briefing documents and dial-in instructions for t Committee conference call Monday, October 27, at 9:0	he ILSI Financial Oversight 0 am EDT
Attachments:	FOC 2014-10-27 agd.doc; FOC 2014-07-28 minutes.docx	

#### Now with the correct date in the body of the email.

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The ILSI Financial Oversight Committee has a conference call scheduled for **Monday, October 27, 2014, beginning at 9:00 a.m. Eastern Daylight Time.** The call is scheduled to last one hour. The dial-in instructions – **using a new conference call provider** – are listed at the end of this message.

The proposed agenda for this call is attached here:

Agenda Item II. Draft minutes from the July 28, 2014 conference call

Agenda Item III. 2014 Year-end projections and proposed 2015 ILSI budget – will be sent later this week

Agenda Item IV. Portfolio report and proposed revision to the investment policy – will be sent later this week

Please let me know if you have any questions.

#### **Dial-in Instructions**

We are using a new conference call system – Citrix – so all new phone numbers.

If you are calling from:	Please dial:
Australia	1-800-064-762
Germany	0-800-723-5123
Mexico	01-800-083-5534
United Kingdom	0-800-169-0430
United States of America	1-888-585-9008

The conference room number for everyone is **476-339-389** #. If you will be calling from a country not on this list, please let me know so that I can send you a number you can use.

#### ILSI Board of Trustees Financial Oversight Committee

#### Conference Call Monday, July 28, 2014

#### **DRAFT MINUTES**

#### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began the conference call at 9:00 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated: Dr. Todd Abraham, Dr. Gerhard Eisenbrand, Dr. Joanne Lupton, Ms. Beth-Ellen Berry, Dr. Suzie Harris and Mr. Shawn Sullivan. Ms. Audrey Newton, Johnson Lambert, LLP, and Mr. Mark Murphy, Raffa Wealth Management participated as guests in portions of the conference call.

Dr. Westring reviewed the agenda (attached). No changes were offered.

#### II. Approval of Minutes of the April 29, 2014 Conference Call

The minutes were approved as distributed.

#### III. 2013 Audit Report – Johnson Lambert

The 2013 ILSI and Affiliate Consolidated Audited Financial Statement and related communications were distributed to the Financial Oversight Committee prior to the conference call. Ms. Newton reviewed these materials with the committee noting that her firm conducted a risk-based audit in two phases – the planning phase and the testing phase. No changes needed to be made to the plan as a result of the subsequent testing, which is a good outcome. This means that ILSI's financial controls are working as expected. In their report (Report of Independent Auditors) Johnson Lambert gave ILSI an unqualified or clean opinion. Under the heading "Other Matters", Ms. Newton called attention to the supplemental information that separates the finances of ILSI from the ILSI Research Foundation. So that the report provides both the consolidated statement for ILSI plus ILSI Research Foundation and then each entity alone. The transactions between ILSI and ILSI Research Foundation were eliminated in the consolidated report as they are not additive transactions.

The Statements of Financial Position (page 3) show the consolidated assets, liabilities and net assets of ILSI and the ILSI Research Foundation. Assets were confirmed by reconciling the records with those of the outside custodians of the funds. The same process was used to reconcile the value of the investments held by external vendors. These were assigned a fair market value. For liabilities, Ms. Newton said the audit team checked to be sure that liabilities were accurately recorded in 2013 as opposed to 2014. Net assets are broken into two categories – restricted and unrestricted. Both categories were tested to ensure that the categorization was correct based on donor instructions. The funds categorized as temporarily restricted were also tested in the same manner.

Pages 4 and 5 provide the consolidated statement of activities for 2013 (page 4) and the previous year (page 5). The audit team tested the revenue and expenses to verify that the proper controls were used,

meaning that appropriate support documentation was available for each entry and each was classified correctly. Expenses were also compared with the prior year expenses to see if the expenses were consistent. They were. The audit team looks at payroll records and compares these to the budget and the prior year. Payments to vendors are also verified to ensure that contracts with each are in place.

Page 6 provides the consolidated statements of cash flow (changes in the operating cash balance) and a change in overall volume is apparent. Part of this is due to the shift to a new investment firm in 2012. Ms. Newton next reviewed the notes. Note A covers the background for key accounting policies. This note was updated as necessary to reflect changes in such policies. Note B covers the investment portfolios in terms of the priority for determining fair market value. All investments were in Level 1, meaning that fair market value is easy to establish. Note C lists property and equipment and includes the transfer of the ILSI Crop Composition Data Base from ILSI to ILSI Research Foundation Center for Safety Assessment of Food and Feed (CSAFF). This transaction occurred in the fall of 2013.

Note D describes related party transactions and is consistent with 2012. The transfer of the International Food Biotechnology Committee's resources to ILSI Research Foundation CSAFF is included. Note E provides data on temporarily restricted net assets and ties back to pages 2 and 3. These were tested to ensure that each was properly classified. Notes F and G address the same topics as 2012, but with updated financial information. The largest commitments and contingencies described in Note G are the office lease and the federal grants received by the ILSI Research Foundation. Both organizations also enter into long-term hotel contracts which carry a cancellation fee. Notes H and I are consistent with the 2012 report.

Ms. Newton called attention to the supplemental information provided on pages 19-22 for ILSI alone and on pages 23-26 for the ILSI Research Foundation alone. The latter was reviewed with the ILSI Research Foundation Board of Trustees Financial Oversight Committee earlier in July.

Two letters – the Board Communications Letter and the Internal Control Letter -- complete the audit report. Ms. Newton reviewed the Board Communications Letter which would call attention to any changes the auditors believed necessary to accounting policies used by ILS and ILSI Research Foundation. None were identified. The accounting policies and procedures are consistent with those used by other non-profit organizations. Specific areas that the audit team reviewed included expense classification and related party transaction, areas that require management judgment. For the latter it is important that an "arm's length" practice be apparent, which it was. Had there been any disagreements with management about the accounting policies, these would have been brought to the attention of the committee much earlier. The transfer of assets from ILSI to ILSI Research Foundation is again noted in the paragraph labeled Related Party Relationships and Transactions.

The Internal Control Letter also discusses the transfer. Ms. Newton noted that Ms. Berry calls throughout the year with questions about guidelines and rules. Her proactive action is of great value as it helps build a relationship with the audit firm and eliminates surprises. In conclusion, Ms. Newton said that Ms. Berry runs a very sound financial shop.

Dr. Westring asked is this report should be considered very good and Ms. Newton concurred that it should. She also said that an audit is a huge intrusion on the day to day activities of the accounting group, yet Ms. Berry and her team are always ready for the audit team and responsive to their requests. Ms. Newton noted that the auditors are responsible to the ILSI Board of Trustees.

#### IV. Review of ILSI Investment Portfolio – Raffa Wealth Management

Two portfolio reviews were distributed to the committee prior to the conference call – one for the ILSI Operative Reserve and the other for the ILSI Board Designated Reserve. Mr. Murphy described the operating reserve report in more detail and said that the other report was very similar as both portfolios are invested in the same way. In general the year is off to a very good start with all asset classes increasing in value. US stocks are up 6.9 percent and international stocks are up 6.0 percent. The European Central Bank recently indicated that it would provide more stimuli which helped drive European stocks higher. In terms of fixed income investments, US Treasury bond yields fell from 3.04 percent at the beginning of 2014 to 2.53 percent at the end of June. For the year-to-date the broad bond market rose 3.93 percent. Both ILSI porfolios are invested in fixed income, currently.

Page 3 of the report shows the actual allocation compared to the target allocation as stated in the ILSI Investment Policy. ILSI holds only AA bonds or higher. These have no fluctuation – no volatility. The actual is equivalent to the targets for each assets class (30 percent in intermediate bonds, 65 percent in short bonds and 5 percent in cash). The portfolio is currently designed to be very conservative with a focus on short term return.

Page 4 shows the values of the portfolio with a starting value of \$613,000 and a gain for the quarter of nearly \$4200. Year-to-date the portfolio gained 1.3 percent. The expected gain is 1 percent. Page 5 shows that a portion was removed into the separate Board designated portfolio in early 2013. Page 6 compares the operating reserve fund performance compared to asset class benchmarks. The increase of 0.7 percent is in line with the expectations based on the asset class benchmarks. Page 7 provides details on the specific investments. The Short Bonds are very high quality government bonds.

Dr. Westring noted that the portfolio had a very low rate of return. The operating reserve acts like a bank account for cash that is not needed immediately. The Board designated reserve is earning a similar return -1.3 percent.

Mr. Murphy reviewed the results of the risk survey he conducted with the members of the committee, Ms. Berry and Dr. Harris. The objective of the survey was to determine if the committee had enough risk tolerance to endorse a change in the investment policy toward higher earning, but riskier investments. Mr. Murphy said there were six respondents. A summary of the results was circulated to the committee prior to the conference call. The respondents were split between the primary objective being stability with growth as a secondary objective and stability and long term growth as equal priorities. In response to question 2, there was support for more growth. For question 3, the majority supported a 5-year time horizon (the current portfolio has a one year horizon). The response to question 4 were more varied with the majority going to a 40 percent equities – 60 percent bonds split, which would be more growth oriented.

Mr. Murphy recommended such a re-allocation of the Board designated portfolio leaving the operating reserve in the more conservative allocation of 95 percent bonds and 5 percent cash. This would allow ILSI access to cash for strategic expenses, while at the same time bringing more balance between growth and stability. Using a 5-year horizon vs one year reduces risk of decline. The new allocation would be expected to earn 6-7 percent per year.

In response to the question about who decides to change the investment policy, Mr. Sullivan said that the Financial Oversight Committee should make a recommendation to the ILSI Board, which can be

acted on by the ILSI Board of Trustees Executive Committee in the absence of a Board meeting. The next ILSI Executive Committee conference call is scheduled for August 13. Ms. Berry noted that ILSI has not needed to take funds from the Board designated reserve, though it had only been in place for a short period.

**Action**: While there was support for moving forward with the recommendation proposed by Raffa Wealth Management, the committee agreed to table the discussion until the next call – October 27. In the interim, Ms. Berry and Mr. Murphy will draft a revised investment policy covering the change in allocation, the types of assets that may be held by the Board designated reserve, and the change in objectives. Ms. Berry will also provide examples of the returns experienced by other ILSI entities in the Washington office whose portfolios are similar to the one being proposed.

#### V. Review of 2014 Year-to-date Financial Report

Ms. Berry said that the report as of June 30, 2014 was the same as she had described during the midyear ILSI Board of Trustees conference call on July 14. This report (attached) was circulated to the committee prior to the conference call. In her opinion, ILSI was in a good place financially.

#### VI. New Business

None was offered.

#### VII. Next Steps

• Ms. Berry and Mr. Murphy will prepare a revised investment policy for the committee to discuss during their call on October 27.

#### VIII. Adjournment

As there was no further business, Dr. Westring adjourned the conference call at 10:00 a.m. Eastern Daylight time.

Signed:\_\_\_\_\_ Date: \_\_\_\_\_

### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

#### Monday, July 28, 2014 9:00 – 10:00 am Eastern Daylight Time

#### AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the April 29, 2014 Conference Call
- III. 2013 Audit Report Johnson and Lambert
- IV. Review of ILSI Investment Policy Raffa Wealth Management
- V. Review of 2014 Year-to-date Financial Report
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

#### Monday, October 27, 2014 9:00 – 10:00 am Eastern Daylight Time

#### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the July 28, 2014 Conference Call
- III. Review of 2014 Year-end Projections and 2015 Budget
- IV. Discussion of Revised Investment Policy Raffa Wealth Management
- V. New Business
- VI. Next Steps
- VII. Adjournment

Suzanne Harris	
Tuesday, October 21, 2014 9:32 AM	
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Lupton; 'felipe	۱ <b>.</b> ۱
	Chelsea
L. Bishop; Beth-Ellen Berry; Shawn Sullivan; Beth Bruegge	emeyer
Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight	
Committee conference call Monday, October 27, at 9:0	00 am EDT
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-inancial Quersight Committee	
F	Suzanne Harris Tuesday, October 21, 2014 9:32 AM 's.ch Lupton; 'felipe ' L. Bishop; Beth-Ellen Berry; Shawn Sullivan; Beth Bruegge Agenda, briefing documents and dial-in instructions for Committee conference call Monday, October 27, at 9: FOC 2014-10-27 agd.doc; FOC 2014-07-28 minutes.doc

FROM: Suzie Harris

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Mexico	01-800-083-5534
United Kingdom	0-800-169-0430
United States of America	1-888-585-9008

The conference room number for everyone is **476-339-389** #. If you will be calling from a country not on this list, please let me know so that I can send you a number you can use.
# ILSI Board of Trustees Financial Oversight Committee

## **Conference Call**

## Monday, October 27, 2014 9:00 – 10:00 am Eastern Daylight Time

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- I. Welcome and Review of Agenda
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- V. New Business
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- VII. Adjournment

#### ILSI Board of Trustees Financial Oversight Committee

## Conference Call Monday, July 28, 2014

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Mr. Murphy recommended such a re-allocation of the Board designated portfolio leaving the operating reserve in the more conservative allocation of 95 percent bonds and 5 percent cash. This would allow ILSI access to cash for strategic expenses, while at the same time bringing more balance between growth and stability. Using a 5-year horizon vs one year reduces risk of decline. The new allocation would be expected to earn 6-7 percent per year.

In response to the question about who decides to change the investment policy, Mr. Sullivan said that the Financial Oversight Committee should make a recommendation to the ILSI Board, which can be

acted on by the ILSI Board of Trustees Executive Committee in the absence of a Board meeting. The next ILSI Executive Committee conference call is scheduled for August 13. Ms. Berry noted that ILSI has not needed to take funds from the Board designated reserve, though it had only been in place for a short period.

**Action**: While there was support for moving forward with the recommendation proposed by Raffa Wealth Management, the committee agreed to table the discussion until the next call – October 27. In the interim, Ms. Berry and Mr. Murphy will draft a revised investment policy covering the change in allocation, the types of assets that may be held by the Board designated reserve, and the change in objectives. Ms. Berry will also provide examples of the returns experienced by other ILSI entities in the Washington office whose portfolios are similar to the one being proposed.

#### V. Review of 2014 Year-to-date Financial Report

Ms. Berry said that the report as of June 30, 2014 was the same as she had described during the midyear ILSI Board of Trustees conference call on July 14. This report (attached) was circulated to the committee prior to the conference call. In her opinion, ILSI was in a good place financially.

#### VI. New Business

None was offered.

#### VII. Next Steps

• Ms. Berry and Mr. Murphy will prepare a revised investment policy for the committee to discuss during their call on October 27.

#### VIII. Adjournment

As there was no further business, Dr. Westring adjourned the conference call at 10:00 a.m. Eastern Daylight time.

Signed:\_\_\_\_\_ Date: \_\_\_\_\_

# ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

## Monday, July 28, 2014 9:00 – 10:00 am Eastern Daylight Time

#### AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the April 29, 2014 Conference Call
- III. 2013 Audit Report Johnson and Lambert
- IV. Review of ILSI Investment Policy Raffa Wealth Management
- V. Review of 2014 Year-to-date Financial Report
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

From:Courtney McComberSent:Thursday, October 16, 2014 2:56 PMTo:Courtney McComberCc:Eric Hentges; Heather Steele; Chor San Khoo;Subject:ILSI North America Emerging Issues SurveyAttachments:Current Trends from 2014 ILSI NA Report rev.docx

Sent on behalf of Dr. John Erdman



#### To the ILSI North America Board of Trustees:

I am writing to you on behalf of the ILSI North America Board Program Assessment & Strategic Collaborations Committee, of which I am Chair. This committee is committed to taking a more active role in the Food Nutrition and Safety Program's (FNSP) annual emerging issues identification process that occurs each fall. We would like to encourage the full Board to participate in this important process as well. To this end, we are requesting your suggestions, comments and feedback on emerging and re-emerging scientific issues that ILSI North America should consider in some way. We are particularly interested in issues not being addressed currently (a list of committees and issues currently being addressed can be found below).

Again this year we are using a survey format and request that you click on this <u>link</u> to access the response form. We greatly appreciate your participation in this process – *the survey should not take more than 5 to 10 minutes of your time*.

This year, we are pleased to provide a list of top line current trends from 2014 as a resource to accompany the survey. This list is from the soon-to-be-released ILSI North America **Trend 2014 Report.** We hope this information will serve as a helpful tool as you consider emerging issues in the nutrition and food safety fields. The full Trend 2014 Report will be available by the end of the year and will be distributed along with our 2014 Annual Report. The impetus for the trend report came from the ILSI North America strategic plan adopted by the Board in 2012.

Please note that we very much appreciate the many suggestions we receive. While we cannot address all topics put forward, we do have a process in place in which we review all the suggested issues. Our FNSP Leadership Team and a committee of Board members review the collected input and we organize a discussion at the annual meeting on prioritized issues. Action on an issue depends on many factors, including member interest and current ILSI North America program areas.

If you have not already done so, please respond to the survey **by next Wednesday**, **22** October. We look forward to hearing back from you with your thoughts on emerging issues.

John Erdman, PhD

Chair, ILSI North America Board of Trustees Program Assessment & Strategic Collaborations

#### Program areas currently being addressed by ILSI North America:

- <u>Carbohydrates</u> (fiber, carbohydrate quality, added sugars, glycemic index)
- <u>Dietary Lipids</u> (interesterified fats, omega-3 and omega-6, stearic acid, inflammation, evidence-based nutrient recommendations)
- <u>Energy Balance and Active Lifestyle (energy intake & expenditure, physical activity, sedentary behavior)</u>
- <u>Bioactives</u> (focus on flavonoids, carotenoids & polyphenols; associated health outcomes, standards of science, framework for dietary recommendations)
- Food Microbiology (research on prevalence; dry sanitation; spices; and salmonella in low moisture foods)
- <u>Food and Chemical Safety</u> (Tox21, chemical mixtures/packaging, processed-formed toxicants, low dose exposure, arsenic, food allergies, nanotechnology)
- <u>Fortification (understanding contribution to nutrient adequacy)</u>
- <u>Sodium (relation to health outcomes, sodium/potassium ratio, mechanism of taste)</u>
- <u>Food Value Decisions</u> (Examining a matrix of decisions including the preparation and cooking time, nutrient profile, food safety considerations, and shelf life in the selection of food
- <u>Low Calorie Sweeteners</u> (role in weight management, standards of science, identification of future research needs)
- <u>Protein</u> (optimal intake for health)
- <u>Caffeine</u> (caffeine exposure study, safety assessment)
- <u>Conflict of Interest/Scientific Integrity</u> (manuscript on principles for building public-private partnerships (PPP) in scientific research and manuscript on "How Experts Are Chosen to Inform Public Policy: Can the Process Be Improved?" and proof of concept using PPP principles)

#### New areas of exploration in 2014:

- Microbiota & Health
- Neurobiology/Food Reward System
- Nutrition & Aging
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- Risk assessment modeling as applied to nutrition and food & chemical safety research

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# **Current Trends**

#### > US diet and dietary patterns remain relatively unchanged in the last decade

- 3 meals and a snack are still most prevalent pattern
- Breakfast skipping highest among adolescents and young adults
- Breakfast meals have higher nutrient density compared to other meals

#### > Nutrients/ingredients of concern in US remain the same

- Overconsumption : Sodium/salt; added sugar; saturated fats
- Caffeine
- Nutrient supplementation (potential to exceed upper limits)
- Under-consumption: Vitamins A, E, and D, folic acid, calcium, magnesium relative to EAR, potassium and fiber relative to adequate intake (AI), and iron (only among adolescents and pre-menopausal women).

#### > Individual variability and nutrigenomics

• Personalized nutrition

#### Big data analysis and analytics

- New knowledge in application, e.g., computational cognition
- > Omics applications in food and nutrition studies
- > Climate change impact on health determinants
- Birth 24 month NIH programs
- Obesity disparities
  - increasing prevalence in males and boys
  - Obesity in women and girls plateauing
  - Obesity increasing in African Americans & Hispanics
  - Severe obesity (BMI >40 ) on the rise with potential to shorten life span by 14 years
- > Microbiome and health influence on nutrition, immune function, brain function and obesity
- > Gut-Brain intersection- to understand obesity pathway and food intake behavior
- Food and addiction is it addiction or addictive behavior?
- > Emerging pathogens and rapid detection methods

From:	Suzanne Harris
Sent:	Friday, October 10, 2014 2:12 PM
То:	's.chang@griffith.edu.au'; 'scohen@unmc.edu';
	'mdoyle@uga.edu';
	'; Catherine Field ; '
	'; ' '; Joanne Lupton;
	'; Rechkemmer, Gerhard
	); Prahlad Seth
	's '; 'kwallace@d.umn.edu';
	'weavercm@purdue.edu'; Flavio Zambrone
Cc:	Chelsea L. Bishop;
	e'; 'haan@purdue.edu'; Beth Brueggemeyer
Subject:	2015 ILSI Annual Meeting reimbursement guidelines
Attachments:	2015 ILSI Reimbursement Guidelines.pdf

TO: ILSI Public Trustees

FROM: Suzie Harris

By now, you should have received an electronic invitation to the 2015 ILSI Annual Meeting at the Sheraton Wild Horse Pass Resort in Chandler, Arizona. Chandler is just south of Phoenix. If you have not received this invitation with links for meeting registration and hotel reservations, please let me or Beth Brueggemeyer know at once. I encourage you to register and make your hotel reservations as soon as possible. Then I will not need to pester you again.

The ILSI Board of Trustees meeting is scheduled for Saturday morning, January 17, beginning at 8:00 am. Please arrive in time to ready for this meeting. The ILSI Branch Staff Meeting will take place on Friday, January 16 -- 8:30 am to 4:30 pm. You are welcome to attend as an observer.

I have attached the reimbursement guidelines for your travel expenses. Please read them carefully and let me know if you have any questions. I encourage you to make your airline reservations early in hopes of finding a less expensive ticket. The guidelines tell you how to contact the ILSI travel agent, if you wish to use this service.

Please let me know if you have any questions.



International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

## Reimbursement Guidelines for ILSI Board of Trustees and Invitees

2015 ILSI Annual Meeting 18-21 January 2015 Sheraton Wild Horse Pass Resort Chandler, Phoenix (Phoenix metropolitan area)

The International Life Sciences Institute ("ILSI") is a public, non-profit organization as described in Section 501(c)(3) of the U.S. Internal Revenue Code. It is, therefore, necessary that we keep a careful record of expenditures in compliance with IRS regulations. ILSI is prepared to reimburse you for costs associated with your travel to Phoenix, Arizona. Information about ILSI reimbursement policies is shown below:

**Travel:** ILSI will reimburse you for the cost of round-trip economy/coach airfare between your home and Phoenix, AZ, along with associated ground transportation costs to and from your local airport and to and from the Phoenix Airport and the meeting venue (Sheraton Wild Horse Pass Resort, 5594 W. Wild Pass Blvd., Chandler, AZ 85226). We will also reimburse the cost of checking one piece of luggage. If you combine this trip with other business or personal travel, ILSI will reimburse you for the portion related to the ILSI 2015 Annual Meeting.

If you wish to book your airline ticket through ILSI's travel agency, Corporate Traveler (and have the cost directbilled to ILSI), please contact Michael Kerr at 703-236-1220 or michael.kerr@corporatetraveler.us and identify yourself as someone for whom ILSI is covering travel costs for the 2015 Annual Meeting.

**Ground transportation:** The easiest and most cost effective way to get to the hotel is via taxi – once you have secured your bags, just head to the taxicab stand at the airport. A one way fare to the hotel will cost around \$45 USD plus tip. For your airport return, it is best to make a reservation with a taxi company at least 24 or 48 hours prior to your departure date, as taxis are not readily available and waiting at the resort. You may also ask the hotel concierge desk for assistance prior to your departure.

**Lodging and Meals:** ILSI will request that costs associated with up to 6 nights hotel lodging be placed on the ILSI master account at the Sheraton Wild Horse Pass Resort and we will reimburse you for the cost of any meals not provided during the meeting. There will be planned receptions/buffet dinners on the evenings of January 18 and January 20 for all attendees. Continental breakfast will be served at the scientific sessions each morning.

<u>Visa</u>: If your travel to the USA requires a visa, ILSI will reimburse you the cost of the visa application fee. A receipt for the visa application fee should be submitted with your Expense Reimbursement Form.

**Incidental Expenses:** You are responsible for any charges of a personal nature and these should not be claimed for reimbursement (i.e., telephone, laundry, movies, bar, gift shop, tours, minibar, etc).

**Spouse Travel**: ILSI cannot cover the cost of a spouse or guest accompanying you to the meeting; however, there is no additional charge for a second person sharing your sleeping room.

**Reimbursement Procedures:** Please use the expense reimbursement form to itemize your expenses and email them to Ms. Beth Brueggemeyer at <u>bbrueggemeyer@ilsi.org</u>, or by regular mail to the ILSI offices, 1156 Fifteenth Street, NW, Suite 200, Washington, DC, 20005. If **you** purchased your airline tickets, copies of the receipt and boarding passes will be required for reimbursement, along with receipts for any other expense items over \$25 USD. Fax and electronic copies can be used for reimbursement purposes.

From: Sent: To: Cc: Subject: Attachments: Courtney McComber Wednesday, October 08, 2014 2:38 PM Courtney McComber Heather Steele 2014-2015 ILSI North America EMERGING ISSUES survey Current Trends from 2014 ILSI NA Report rev.docx

Sent on behalf of Heather Steele



# 2014-2015 Trends Report and Emerging Issues Survey

## Dear ILSI North America members, advisors and friends:

Each fall season, ILSI North America conducts a survey of emerging and re-emerging issues in the nutrition and food safety fields. Your feedback is critical to having ILSI North America address the most pressing issues. This year, we are pleased to provide a list of top line current trends from 2014 as a resource to accompany the survey. This list is from the soon-to-be-released ILSI North America **Trend 2014 Report.** We hope this information will serve as a helpful tool as you consider emerging issues in the nutrition and food safety fields. The full Trend 2014 Report will be available by the end of the year and will be distributed along with our 2014 Annual Report. The impetus for the trend report came from the ILSI North America strategic plan adopted by the Board of Trustees in 2012.

After you take a minute to review this list of trends, please complete the **brief survey** that ILSI North America is conducting to compile a list of emerging and re-emerging issues for 2015. For many years we informally polled members, advisors and friends to better understand the issues of greatest interest -- and over the past few years we have formalized our approach using the linked survey tool. We greatly appreciate your participation in this process – the <u>survey</u> should not take more than 5 to 10 minutes of your time.

As you consider newly emerging or re-emerging issues that you believe ILSI North America should be addressing, we also thought it would be helpful to include a list of the program areas that are currently being addressed by our committees. Additional information related to ILSI North America's programs and committees can be found on the ILSI North America <u>website</u>.

#### Program areas currently being addressed by ILSI North America:

- <u>Carbohydrates</u> (fiber, carbohydrate quality, added sugars, glycemic index)
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Your input helps assure that ILSI North America will continue to address critical emerging issues in the nutrition, food safety and food microbiology areas. Please participate in the survey **by Wednesday, 22 October.** Should you have any questions or comments, please do not hesitate to contact me directly.

#### Heather

Heather H. Steele Associate Director, Program Development ILSI North America 1156 15<sup>th</sup> Street, NW Second Floor Washington, DC 20005

202-659-0074 x150 <u>www.ilsina.org</u> Follow ILSI North America:

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- > Emerging pathogens and rapid detection methods

From:	Chareese Cunningham
Sent:	Wednesday, October 08, 2014 1:23 AM
То:	Joanne Lupton
Subject:	Countdown to ILSI Annual Meeting

# **CONNECT AND SHARE**

If you have not already registered, this is to remind you to register for the **2015 ILSI Annual Meeting** scheduled **16 - 21 January** at the Wild Horse Pass Resort in Chandler (part of the Phoenix metropolitan area), Arizona.

# REGISTRATION

Your registration is fee-waived, but to be considered registered for the meeting, you must complete the online meeting registration process as soon as possible. If you are inviting a guest, be sure to register your guest as well and pay the application fees. <u>Click here</u> to register now!

You don't want to miss the dynamic scientific sessions being planned. A few are listed here:

Science of Science Communications with Dominique Brossard, PhD

Caffeine: Friend or Foe?

I am the Microbiome: It's the Microbio + Me

Global Challenges and Solutions for Sustainability

iFoodExposure: Getting Ahead of New Exposure Data for Food Risk and Nutrition Assessments Hazard vs. Risk

For more details on the sessions and complete scientific program information, please visit the <u>ILSI Annual</u> <u>Meeting Website</u>.

# JOIN US!

The Annual Meeting is the one event each year where you can connect face-to-face with colleagues from around the globe to share new information and to decide how, collectively, we can work together on the science and health challenges we all face.

# SHERATON WILD HORSE PASS RESORT, CHANDLER, ARIZONA

Sheraton Wild Horse Pass is located on an expanse of rugged Arizona landscape in the high Sonoran Desert provides an authentic representation of the Gila River Indian Community's heritage and culture.

You are responsible for making your own hotel room reservations. One of the ILSI entities is paying for your lodging, the hotel will be notified that your room and tax will be paid for by ILSI. Therefore, the credit card used to make your room reservation will only be charged for any incidentals (or for room charges should you elect to extend your stay beyond the number of nights covered by ILSI). Should you need to cancel for any reason, you will be responsible for cancelling your reservation as well, to avoid any cancellation or no show charges. Please be sure to make your hotel reservations by 22 December. To book your room at the Sheraton Wild Horse Pass – <u>click here</u>.

Visit the ILSI Annual Meeting Website to learn more about the annual meeting, make your hotel reservations, what to do in Arizona and more!

Best,

Powered by <u>www.EventRebels.com</u>

From: Sent: To: Cc: Subject: Courtney McComber Friday, September 19, 2014 12:13 PM Courtney McComber Heather Steele Upcoming ILSI North America Event: Healthy Aging Workshop

## Sent on behalf of Heather Steele



"Defining Healthy Aging: From Science to Practice, the Link to Diet and Nutrition" has been accepted as a Pre-Conference Workshop to be held at the 67th Annual Scientific Meeting of the Gerontological Society of America (GSA), November 5-9, at the Marriott Marquis and Walter E. Washington Convention Center in Washington, DC. The workshop, which is being coordinated by the ILSI North America Task Force on Aging, is scheduled for **Wednesday, 5 November 2014 from 8:00 am – 3:30 pm.** 

Although diet and nutritional recommendations have been issued for healthy aging, the definition of healthy aging remains unclear. As a result, definitive assessment and outcome measures to define healthy aging may vary for primary and secondary prevention. Questions are often asked whether healthy aging should be defined as the absence of disease at the cellular or total system level (natural aging) or at the functional performance level. Because aging is a progressive continuum starting from birth to adult life, should aging be defined differently at different age stages as well? The lack of a common vernacular for defining healthy aging, and the lack of agreement on a common set of outcome measures have challenged progress on nutritional guidance for optimizing outcomes of natural aging and for minimizing pathological aging in adults.

Workshop participants include the following individuals:

- Luigi Ferrucci, MD, PhD, National Institute on Aging, Harbor Hospital
- David Klurfeld, PhD, USDA/ARS–Beltsville Human Nutrition Research
- William Joseph Evans, PhD, Center for the Study of Aging and Human Development, Duke University
- Regan Lucas Bailey, PhD, RD, National Institutes of Health
- Beverly Cowart, PhD, Monell Chemical Senses Institute
- Martina Heer, PhD, Institute of Aerospace Medicine, German Aerospace Center, Cologne, Germany
- Gordon Jensen, MD, PhD, The Pennsylvania State University
- Simin Meydani, DVM, PhD, Tufts University

Further details, including the workshop program, are available <u>here</u>.

To register for this GSA pre-conference workshop, click here.

Note: there is a registration cost to participate in our pre-conference workshop (via GSA) but you do not need to register for the full GSA meeting in order to attend our pre-conference event. (However, if you plan to attend other GSA sessions and events, you will need to register for their full meeting.)

Contact Heather Steele (<u>hsteele@ilsi.org</u>) or Courtney McComber (<u>cmccomber@ilsi.org</u>) with any questions.

Courtney McComber ILSI North America Program and Conference Manager 1156 Fifteenth Street NW Suite 200 Washington, DC 20005 202-659-0074 ext. 143 202-659-3859 (fax)

g

From: Sent: Subject: Attachments: John Faulkner Thursday, September 18, 2014 11:03 AM ILSI North America Food and Safety Briefs from August Publications Food Safety Briefs August 2014.pdf; Nutrition Briefs August 2014.pdf

Greetings:

I hope, wherever you are, you are now enjoying Indian Summer! Here in Washington, DC, we have traded the return of our politicians for the departure of our humidity (which really was not too bad this summer).

The attached **Food Safety** and **Nutrition** Science Briefs are compiled each month after a review of articles published in the most recent issues of the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion are those we believe address areas of greatest interest to ILSI North America's technical and project committees.

Our **August** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: <a href="http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx">http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</a>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Nutrition Briefs**

# August 2014

#### **Cardiovascular Disease**

#### Global Sodium Consumption and Death from Cardiovascular Causes

D. Mozaffarian, S. Fahimi, G.M. Singh, R. Micha, S. Khatibzadeh, R.E. Engell, et al. for the Global Burden of Diseases Nutrition and Chronic Diseases Expert Group (NUTRICODE)

New England Journal of Medicine, Vol. 371, No. 7; pp. 624-634, 2014

DOI: 10.1056/NEJMoa1304127

Link to full text: Click here

**Significance:** In this modeling study, 1.65 million deaths from cardiovascular causes that occurred in 2010 were attributed to sodium consumption above a reference level of 2g/day.

The effects of sodium on blood pressure, according to age, race, and the presence or absence of hypertension, were calculated from data in a new meta-analysis of 107 randomized interventions, and the effects of blood pressure on cardiovascular mortality, according to age, were calculated from a meta-analysis of cohorts. Cause-specific mortality was derived from the Global Burden of Disease Study 2010. Using comparative risk assessment, the cardiovascular effects of current sodium intake were estimated, as compared with a reference intake of 2g of sodium/day, according to age, sex, and country. In 2010, the estimated mean level of global sodium consumption was 3.95g/day, and regional mean levels ranged from 2.18-5.51g/day. Globally, 1.65 million annual deaths from cardiovascular causes (95% CI, 1.10-2.22 million) were attributed to sodium intake above the reference level: 61.9% and 38.1% of these deaths occurred in men and women, respectively. These deaths accounted for nearly 1 of every 10 deaths from cardiovascular causes (9.5%). Four of every 5 deaths (84.3%) occurred in low- and middle-income countries, and 2 of every 5 deaths (40.4%) were premature (before 70 years of age). The rate of death from cardiovascular causes associated with sodium intake above the reference level was highest in the country of Georgia and lowest in Kenva.

# Sugar-Sweetened Beverages

# Sugar-Sweetened Beverage Consumption Is Associated with Abdominal Fat Partitioning in Healthy Adults

J. Ma, M. Sloan, C.S. Fox, U. Hoffmann, C.E. Smith, E. Saltzman, et al. Journal of Nutrition, Vol. 144, No. 8; pp. 1283–1290, 2014 DOI: 10.3945/ jn.113.188599 Link to full text: Click here

**Significance:** Consumption of diet soda was not associated with either volume or distribution of visceral adipose tissue.

# **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

This cross-sectional study using previously collected data in 2596 middle-aged adults from the Framingham Heart Study Offspring and Third Generation cohorts examined whether habitual sugar-sweetened beverages (SSBs) consumption and diet soda intakes are differentially associated with deposition of body fat. Results showed that SSB consumption was positively associated with visceral adipose tissue (VAT) after adjustment for subcutaneous adipose tissue (SAT) and other potential confounders (P-trend < 0.001). An inverse association between SSB consumption and SAT (P-trend = 0.04) was observed that persisted after additional adjustment for VAT (P-trend < 0.001). Higher SSB consumption was positively associated with the VAT-to-SAT ratio (P-trend < 0.001). No significant association was found between diet soda consumption and either VAT or the VAT-to-SAT ratio, but diet soda was positively associated with SAT (P-trend < 0.001). Daily consumers of SSBs had a 10% higher absolute VAT volume and a 15% greater VAT-to-SAT ratio compared with nonconsumers.

#### Metabolic Syndrome

# Instant Noodle Intake and Dietary Patterns Are Associated with Distinct Cardiometabolic Risk Factors in Korea

H.J. Shin, E. Cho, H-J. Lee, T.T. Fung, E. Rimm, B. Rosner, et al. Journal of Nutrition, Vol. 144, No. 8; pp. 1247–1255, 2014 DOI: 10.3945/ jn.113.188441 Link to full text: Click here

**Significance:** The consumption of instant noodles was associated with increased prevalence of metabolic syndrome in women, independent of major dietary patterns.

The association between intake of instant noodles and cardiometabolic risk was investigated using the Korean National Health and Nutrition Examination Survey IV 2007-2009. A total of 10,711 adults (54.5% women) 19-64 y of age were analyzed. Two major dietary patterns were identified using principal components analysis: the "traditional dietary pattern" (TP), rich in rice, fish, vegetables, fruit, and potatoes, and the "meat and fast-food pattern" (MP), with less rice intake but rich in meat, soda, fried food, and fast food including instant noodles. The highest MP quintile was associated with increased prevalence of abdominal obesity (OR: 1.41; 95% CI: 1.05, 1.90), LDL-cholesterol ≥130 mg/ dL (1.3 g/L) (OR: 1.57, 95% CI 1.26, 1.95), decreased prevalence of low HDLcholesterol (OR: 0.65; 95% CI: 0.53, 0.80), and high triglycerides [≥150 mg/ dL (1.5 g/L); OR: 0.73; 95% CI: 0.57, 0.93]. The highest quintile for the TP was associated with decreased prevalence of elevated blood pressure (OR: 0.73; 95% CI: 0.59, 0.90) and marginally lower trends for abdominal obesity (OR: 0.76; 95% CI: 0.58, 0.98; P-trend = 0.06), but neither of the dietary patterns was associated with prevalence of metabolic syndrome (MetS). The consumption of instant noodles  $\geq 2$  times/wk was associated with a higher prevalence of MetS (OR: 1.68; 95% CI: 1.10, 2.55) in women but not in men (OR: 0.93; 95% CI: 0.58, 1.49; P-interaction = 0.04). The 2 major dietary patterns were associated with distinct cardiometabolic risk factors.

#### Effects of Whole and Refined Grains in a Weight-Loss Diet on Markers of Metabolic Syndrome in Individuals With Increased Waist Circumference: A Randomized Controlled-Feeding Trial

K.H. Jackson, S.G. West, J.P. Vanden Heuvel, S.S. Jonnalagadda, A.B. Ross, A.M. Hill, et al.



American Journal of Clinical Nutrition, Vol. 100, No. 2; pp. 577–586, 2014 DOI: 10.3945/ ajcn.113.078048 Link to full text: Click here

**Significance:** Replacing refined grains with whole grains within a weight-loss diet does not beneficially affect abdominal adipose tissue loss and has modest effects on markers of metabolic syndrome.

This study hypothesized that consuming whole grains (WGs) in place of refined grains (RGs) would improve metabolic syndrome (MetS) criteria in individuals with or at risk of MetS. A randomized, controlled, open-label parallel study was conducted in 50 overweight and obese individuals with increased waist circumference and ≥1 other MetS criteria. Participants consumed a controlled weight-loss diet containing either WG or RG (control) products for 12 wk. Baseline variables were not significantly different between groups; however, the RG group tended to have higher triglycerides and lower HDL-cholesterol (P=0.06). Alkylresorcinols (compliance markers of WG intake) increased with consumption of the WG diet and did not change with consumption of the RG diet (time × treatment, P<0.0001), which showed dietary compliance. There were no differences in anthropometric changes between groups; however, weight, BMI, and percentage of visceral adipose tissue (AT) decreased at both 6 and 12 wk (P<0.05), and reductions in percentage of abdominal AT occurred by 6 wk and did not change between 6 and 12 wk. Both glucose and HDL-cholesterol were significantly lower with the consumption of the WG compared with the RG diet. However, when noncompliant individuals (n=3) were removed, the glucose effect was stronger (P=0.01) and the HDL-cholesterol effect was no longer significant (P=0.14).

#### **Chronic Diseases**

#### Fried-Food Consumption and Risk of Type 2 Diabetes and Coronary Artery Disease: A Prospective Study in 2 Cohorts of US Women and Men

L.E. Cahill, A. Pan, S.E. Chiuve, Q. Sun, W.C. Willett, F.B. Hu, et al. American Journal of Clinical Nutrition, Vol. 100, No. 2; pp. 667–675, 2014 DOI: 10.3945/ ajcn.114.084129 Link to full text: Click here

Link to full text. Click here

**Significance:** Frequent fried-food consumption was significantly associated with risk of incident type 2 diabetes and moderately with incident coronary artery disease.

Fried-food consumption and risk of developing incident type 2 diabetes (T2D) or coronary artery disease (CAD) were examined. Fried-food consumption was assessed by using a questionnaire in 70,842 women from the Nurses' Health Study (1984–2010) and 40,789 men from the Health Professionals Follow-Up Study (1986–2010) who were free of diabetes, cardiovascular disease, and cancer at baseline. 10,323 incident T2D cases and 5778 incident CAD cases were documented. Multivariate-adjusted RRs (95% CIs) for individuals who consumed fried foods <1, 1–3, 4–6, or  $\geq$ 7 times/wk were 1.00 (reference), 1.15 (0.97, 1.35), 1.39 (1.30, 1.49), and 1.55 (1.32, 1.83), respectively, for T2D and 1.00 (reference), 1.06 (0.98, 1.15), 1.23 (1.14, 1.33), and 1.21 (1.06, 1.39), respectively, for CAD. Associations were largely attenuated when biennially updated hypertension, hypercholesterolemia, and BMI were controlled for.



#### Fatty Acids

#### Higher Erythrocyte n–3 PUFAs Are Associated with Decreased Blood Pressure in Middle-Aged and Elderly Chinese Adults

F-f. Zeng, L-l. Sun, Y-h. Liu, Y. Xu, K. Guan, W-h. Ling, et al. Journal of Nutrition, Vol. 144, No. 8; pp. 1240–1246, 2014 DOI: 10.3945/ jn.114.192286 Link to full text: Click here

**Significance:** A higher content of cis n-3 polyunsaturated fatty acids (mainly very long-chain cis n-3 PUFAs) may benefit blood pressure progress, probably mediated by decreasing serum triglycerides and BMI.

This study evaluated the cross-sectional and prospective associations of erythrocyte fatty acids (FAs) with blood pressure (BP) in 1834 Chinese individuals aged 57±5 years. Baseline measurements of erythrocyte FAs and BP were obtained. A total of 1477 subjects had BP measured again after 3.09±0.32 y. In the cross-sectional analyses (n=1834), the erythrocyte saturated FA (SFA) content was positively associated with BP, whereas total cis polyunsaturated FAs (PUFAs), their subtypes cis n-3 ( $\omega$ -3) PUFAs and cis n-6 ( $\omega$ -6) PUFAs, and the PUFA-to-SFA ratio were inversely associated with BP (all P-trends < 0.05). The longitudinal results (n=1477) showed marginally inverse associations between cis n-3 PUFAs and the n-3:n-6 PUFA ratio and BP. For individual cis n-3 PUFAs, higher contents of 20:5n-3, 22:5n-3, and 22:6n-3 were significantly associated with reduced increases in systolic BP over time (the mean change range between quartile 4 and quartile 1 was -0.917 to -0.749 mm Hg for SBP; all P-trends < 0.01), and 20:5n-3 was inversely associated with diastolic BP change (the mean change between quartile 4 and quartile 1 was -0.631; P-trend < 0.001). Path analyses suggested that the associations between cis n–3 PUFAs and BP might be mediated by decreasing serum triglycerides and BMI.

### **Blood Pressure**

# Association of Urinary Sodium and Potassium Excretion with Blood Pressure

Andrew Mente, Martin J. O'Donnell, Sumathy Rangarajan, Matthew J. McQueen, Paul Poirier, Andreas Wielgosz, et al. for the PURE Investigators

New England Journal of Medicine, Vol. 371, No. 7; pp. 601–611, 2014

DOI: 10.1056/NEJMoa1311989

Link to full text: Click here

**Significance:** The association of estimated intake of sodium and potassium with blood pressure was nonlinear and was most pronounced in persons consuming high-sodium diets, persons with hypertension, and older persons.

This study estimated the levels of sodium and potassium intake (on the basis of urinary-excretion data) and described their associations with blood pressure in 102,216 adults from 18 countries. Estimates of 24-hour sodium and potassium excretion were made from a single fasting morning urine specimen and were used as surrogates for intake. Regression analyses showed increments of 2.11 mmHg in systolic blood pressure (SBP) and 0.78 mmHg in diastolic blood pressure (DBP) for each 1-g increment in estimated sodium excretion. The slope of this association was steeper with higher sodium intake (an increment of 2.58 mmHg in SBP/gram for sodium excretion >5 g/day, 1.74 mmHg/gram for 3-5g/



day, and 0.74 mmHg/gram for <3 g/day; P<0.001 for interaction). The slope of association was steeper for persons with hypertension (2.49 mmHg/gram) than for those without hypertension (1.30 mmHg/gram, P<0.001 for interaction) and was steeper with increased age (2.97 mmHg/gram at >55 years of age, 2.43 mmHg/gram at 45-55 years of age, and 1.96 mmHg/gram at <45 years of age; P<0.001 for interaction). Potassium excretion was inversely associated with SBP, with a steeper slope of association for persons with hypertension than for those without it (P<0.001) and a steeper slope with increased age (P<0.001).

## Sleep

# Sex and Race Differences in Caloric Intake During Sleep Restriction in Healthy Adults

A.M. Spaeth, D.F. Dinges, N. Goel American Journal of Clinical Nutrition, Vol. 100, No. 2; pp. 559–566, 2014 DOI: 10.3945/ ajcn.114.086579 Link to full text: Click here

**Significance:** Men may be more susceptible to weight gain during sleep loss than women due to a larger increase in daily caloric intake, particularly during late-night hours.

This study assessed sex and race differences in caloric intake, macronutrient intake, and meal timing during sleep restriction. Forty-four healthy adults aged 21-50 y (21 women, 16 whites) completed an in-laboratory protocol that included 2 consecutive baseline nights [10 or 12 h time in bed (TIB)/night; 2200-0800 or 2200-1000] followed by 5 consecutive sleep-restriction nights (4 h TIB/night; 0400–0800). During sleep restriction, subjects increased daily caloric intake (P<0.001) and fat intake (P=0.024), including obtaining more calories from condiments, desserts, and salty snacks (P<0.05) and consumed  $532.6 \pm 295.6$  kcal during late-night hours (2200–0359). Relative to women, men consumed more daily calories during baseline and sleep restriction, exhibited a greater increase in caloric intake during sleep restriction, and consumed a higher percentage of daily calories during late-night hours (P<0.05). African Americans and whites did not significantly differ in daily caloric intake, increased caloric intake during sleep restriction, or meal timing. However, African Americans consumed more carbohydrates, less protein, and more caffeine-free soda and juice than whites did during the study (P < 0.05).

## About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org



# **Food Safety Briefs**

# August 2014

# E. Coli

Laboratory and Pilot-Scale Dead-End Ultrafiltration Concentration of Sanitizer-Free and Chlorinated Lettuce Wash Water for Improved Detection of Escherichia coli O157:H7

S. Magaña, S.M. Schlemmer, G.R. Davidson, E.T. Ryser, D.V. Lim

Journal of Food Protection, Vol. 77, No. 8; pp. 1260–1268, 2014

DOI: 10.4315/0362-028X.JFP-13-421

Link to full text: Click here

**Significance:** When combined with standard and rapid detection methods, the Portable Multi-use Automated Concentration System may provide a means to enhance pathogen monitoring of produce wash water.

An automated dead-end (single pass, no recirculation) ultrafiltration device, the Portable Multi-use Automated Concentration System (PMACS), was used to concentrate Escherichia coli O157:H7 from 40L of simulated commercial lettuce wash water. The assessment included generating, sieving, and concentrating sanitizer-free lettuce wash water, either uninoculated or inoculated with green fluorescent protein–transformed E. coli O157:H7 at a high (1.00 log CFU/ml) or low (–1.00 log CFU/ml) concentration. Cells collected within the filters were recovered in approximately 400 ml of buffer to create lettuce wash retentates. The extent of concentration was determined by viable plate counts using a medium selective for the transformed E. coli O157:H7. This concentration method was then evaluated in a pilot-scale production line using chlorinated (100, 30, and 10 ppm of available chlorine) lettuce wash water. The total PMACS processing times were  $82 \pm 6$  and  $65 \pm 5$  min for sanitizer-free and chlorinated washes, respectively. Overall, E. coli O157:H7 populations were approximately 2 log higher in retentates than in unconcentrated lettuce wash samples.

# Characterization of Antibiotic Resistance in Escherichia coli Isolated from Shrimps and Their Environment

K. Changkaew, F. Utrarachkij, K. Siripanichgon, C. Nakajima, O. Suthienkul, Y. Suzuki

Journal of Food Protection, Vol. 77, No. 8; pp. 1394–1401, 2014

DOI: 10.4315/0362-028X.JFP-13-510

Link to full text: Click here

**Significance:** There is a risk of drug-resistant E. coli contamination in shrimp farms and selling places.

To survey the risk of antimicrobial resistance in bacteria associated with food and water, 312 Escherichia coli isolates from shrimp farms and markets in Thailand were examined for susceptibility to 10 antimicrobials. The results showed that 17.6% of isolates were resistant to at least one of the tested drugs, and high

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

resistance rates were observed to tetracycline (14.4%), ampicillin (8.0%), and trimethroprim (6.7%); 29.1% were multidrug resistant. PCR assay of the tet (A), tet (B), tet (C), tet (D), tet (E), and tet (G) genes detected one or more of these genes in 47 of the 55 resistant isolates. Among these genes, tet (A) (69.1%) was the most common followed by tet (B) (56.4%) and tet (C) (3.6%). The resistant isolates were further investigated for class 1 integrons. Of the 55 resistant isolates, 16 carried class 1 integrons and 7 carried gene cassettes encoding trimethoprim resistance (dfrA12 or dfrA17) and aminoglycosides resistance (aadA2 or aadA5). Two class 1 integrons, In54 (dfrA17-aadA5) and In27 (dfrA12-orfF-aadA2), were found in four and three isolates, respectively.

#### **Foodborne Pathogens**

Assessment of Oligogalacturonide from Citrus Pectin as a Potential Antibacterial Agent against Foodborne Pathogens

M-C. Wu, H-C. Li, P-H. Wu, P-H. Huang, Y-T. Wang Journal of Food Science, Vol. 79, No. 8; M1541–M1544, 2014 DOI: 10.1111/1750-3841.12526 Link to full text: Click here

**Significance:** Citrus oligogalacturonide exhibited bactericidal effect against all selected foodborne pathogens.

Antibacterial activities of oligogalacturonide from commercial microbial pectic enzyme (CPE) treated citrus pectin, which exhibits antioxidant and antitumor activities, against 4 foodborne pathogens including Salmonella Typhimurium, Staphylococcus aureus, Listeria monocytogenes, and Pseudomonas aeruginosa was assessed. Pectin hydrolysates from CPE hydrolysis exhibited antibacterial activities. However, no antibacterial activity of pectin was observed. Citrus oligogalacturonide from 24-h hydrolysis exhibited bactericidal effect against all selected foodborne pathogens and displayed minimal inhibitory concentration at 37.5  $\mu$ g/mL for P. aeruginosa, L. monocytogenes, and S. Typhimurium, and at 150.0  $\mu$ g/mL for S. aureus.

#### Growth of Listeria monocytogenes, Salmonella spp., Escherichia coli O157:H7, and Staphylococcus aureus on Cheese during Extended Storage at 25°C

W.M. Leong, R. Geier, S. Engstrom, S. Ingham, B. Ingham, M. Smukowski Journal of Food Protection, Vol. 77, No. 8; pp. 1275–1288, 2014 DOI: 10.4315/0362-028X.JFP-14-047

Link to full text: Click here

**Significance:** Pathogen growth/no-growth could not be predicted for Swiss-style cheeses, mold-ripened or bacterial surface–ripened cheeses, and cheeses made with nonbovine milk.

This study tested the ability of 67 market cheeses to support growth of Listeria monocytogenes (LM), Salmonella spp. (SALM), Escherichia coli O157:H7 (EC), and Staphylococcus aureus (SA) over 15 days at 25°C. Hard (Asiago and Cheddar), semi-hard (Colby and Havarti), and soft cheeses (mozzarella and Mexican-style), and reduced-sodium or reduced-fat types were tested. Single-pathogen cocktails were prepared and individually inoculated onto cheese slices (~105 CFU/g). Cocktails were 10 strains of L. monocytogenes,



#### Food Safety Briefs

6 of Salmonella spp., or 5 of E. coli O157:H7 or S. aureus. Pathogens did not grow on 53 cheeses, while 14 cheeses supported growth of SA, 6 of SALM, 4 of LM, and 3 of EC. Of the cheeses supporting pathogen growth, all supported growth of SA, ranging from 0.57-3.08 log CFU/g (average 1.70 log CFU/g). Growth of SALM, LM, and EC ranged from 1.01-3.02 log CFU/g (average 2.05 log CFU/g), 0.60-2.68 log CFU/g (average 1.60 log CFU/g), and 0.41-2.90 log CFU/g (average 1.69 log CFU/g), respectively. Pathogen growth was influenced by pH and percent salt-in-the-moisture phase, and these two factors were used to establish growth/no-growth boundary conditions for safe, extended storage ( $\leq$ 25°C) of pasteurized milk cheeses.

#### **Heavy Metals**

#### Mercury Content in Commercially Available Finfish in the United States

D.P. Cladis, A.C. Kleiner, C.R. Santerre Journal of Food Protection, Vol. 77, No. 8; pp. 1361–1366, 2014 DOI:10.4315/0362-028X.JFP-14-097 Link to full text: Click here

**Significance:** Consumers may be unaware that species that are high in mercury are being sold in the marketplace.

Seventy-seven finfish species (300 composites of three fish) were obtained from commercial vendors in six regions of the US: Great Lakes, mid-Atlantic, New England, northwest, southeast, and southwest. Total mercury in fish muscle tissue ranged from 1 ppb (channel catfish) to 1,425 ppb (king mackerel). Of the top 10 most commonly consumed seafoods in the US, all finfish species, including salmon species (13 to 62 ppb), Alaskan pollock (11 ppb), tilapia (16 ppb), channel catfish (1 ppb), Atlantic cod (82 ppb), and pangasius (swai) (2 ppb), had low total mercury concentrations. However, two large predatory species, king mackerel and swordfish (1,107 ppb), contained mercury concentrations above the current U.S. FDA action level of 1,000 ppb.

# Comparison of the Concentrations of Metal Elements and Isotopes of Lead Found in Rice and Rice Bran

S. Dai, H. Yang, L. Yang, F. Wang, R. Du, D. Wen Journal of Food Protection, Vol. 77, No. 8; pp. 1424–1427, 2014 DOI: 10.4315/0362-028X.JFP-14-079 Link to full text: Click here

**Significance:** High concentrations of metal elements in bran samples present a potential safety issue for bran products.

In this study, the concentrations of 27 metal elements (Li, Be, Na, Mg, Al, K, Ca, V, Cr, Mn, Fe, Co, Ni, Cu, Zn, Ga, As, Se, Rb, Sr, Ag, Cd, Cs, Ba, Tl, Pb, and U) in 56 polished rice and their corresponding bran samples were determined. A significant difference in concentrations of all elements except Ag and Cd was found between rice and bran, with bran/rice ratios of 1.21-36.3. High concentrations of metal elements, especially that of the heavy metal Cr, in bran samples present a potential safety issue for bran products, such as food and feed containing bran. Pb isotope (204Pb, 206Pb, 207Pb, and 208Pb) ratios also were determined. The 206Pb/207Pb and 208Pb/207Pb ratios in bran were generally higher than those in rice (P < 0.0001), and rice and bran samples were distinctly



different from each other, indicating that Pb isotope composition is effective for discriminating between bran and rice samples.

#### Cadmium and Lead in Chocolates Commercialized in Brazil

J.E.L. Villa, R.R.A. Peixoto, S. Cadore Journal of Agricultural and Food Chemistry, Vol. 62, No. 34; pp. 8759–8763, 2014 DOI: 10.1021/jf5026604 Link to full text: Click here

**Significance:** Chocolate might be a significant source of cadmium and lead ingestion, particularly for children.

Cadmium (Cd) and lead (Pb) concentrations and their relationship to the cocoa content of chocolates commercialized in Brazil were evaluated by graphite furnace atomic absorption spectrometry (GF AAS) after microwave-assisted acid digestion. Several chemical modifiers were tested during method development, and analytical parameters, including the limits of detection and quantification as well as the accuracy and precision of the overall procedure, were assessed. The study examined 30 chocolate samples, and the concentrations of Cd and Pb were in the range of <1.7–107.6 and <21–138.4 ng/g, respectively. Results indicated that dark chocolates have higher concentrations of Cd and Pb than milk and white chocolates. Samples with five different cocoa contents (ranging from 34 to 85%) from the same brand were analyzed, and linear correlations between the cocoa content and the concentrations of Cd ( $R^2 = 0.907$ ) and Pb ( $R^2 = 0.955$ ) were observed.

#### Food Allergy

#### Modified Oral Food Challenge Used With Sensitization Biomarkers Provides More Real-Life Clinical Thresholds for Peanut Allergy

K. Blumchen, A. Beder, J. Beschorner, F. Ahrens, A. Gruebl, E. Hamelmann, et al.

Journal of Allergy and Clinical Immunology, Vol. 134, No. 2; pp. 390–398.e4, 2014

DOI: http://dx.doi.org/10.1016/j.jaci.2014.03.035

Link to full text: Click here

**Significance:** This modified food challenge procedure might better reflect threshold levels for peanut allergy than the standard procedure because most of the patients reacted at a time interval >30 minutes.

This study sought to use a modified oral food challenge (mOFC) regimen in 63 children with peanut allergy that might determine threshold levels for peanut allergy mimicking a more real-life exposure and to correlate the eliciting dose (ED) and severity of clinical reaction in children with peanut allergy with B-cell, T-cell, and effector cell markers. All children received a maximum of 8 semi-log increasing titration steps of roasted peanuts ranging from 3 to 4500 mg of peanut protein until objective allergic reactions occurred. Forty-five of 63 patients showed objective symptoms after >30 minutes, with a median latency of clinical reaction of 55 minutes. By using a log-normal dose-distribution model, the ED5 was calculated to be 1.95 mg of peanut protein. The ED was significantly and inversely correlated with peanut- and Ara h 2–specific IgE levels, skin prick test responses, basophil activation, and TH2 cytokine production by PBMCs. Symptom severity did not correlate with any of the markers or the ED.



#### Food Allergy Population Thresholds: An Evaluation of the Number of Oral Food Challenges and Dosing Schemes on the Accuracy of Threshold Dose Distribution Modeling

R.H. Klein Entink, B.C. Remington, W.M. Blom, C.M. Rubingh, A.G. Kruizinga, J.L. Baumert, et al.

Food and Chemical Toxicology, Vol. 70, August 2014; pp. 134–143, 2014 DOI: 10.1016/j.fct.2014.05.001

Link to full text: Click here

**Significance:** This study may guide risk assessors in minimum sample sizes for new studies and in the allocation of proper dosing schemes for allergens in provocation studies.

The objective of this paper is to provide guidance for selecting an optimal sample size for threshold dosing studies for major allergenic foods and to identify factors influencing the accuracy of estimation. The relationships between sample size, dosing scheme and the employed statistical distribution on the one hand and accuracy of estimation on the other hand were obtained. It showed that the largest relative gains in accuracy are obtained when sample size increases from N=20 to N=60. Moreover, it showed that the EuroPrevall dosing scheme is a useful start, but that it may need revision for a specific allergen as more data become available, because a proper allocation of the dosing steps is important.

#### Nanotechology

#### Optimization of Homogenization–Evaporation Process for Lycopene Nanoemulsion Production and Its Beverage Applications

S.O. Kim, T. Van Anh Ha, Y.J. Choi, S. Ko Journal of Food Science, Vol. 79, No. 8; pp. N1604–N1610, 2014 DOI: 10.1111/1750-3841.12472 Link to full text: Click here

**Significance:** The lycopene nanoemulsion with droplets <100 nm is highly transparent compared to unencapsulated lycopene extract, which makes beverage turbid.

In this study, lycopene nanoemulsions were prepared from a low-concentration lycopene extract using an emulsification–evaporation technique. The effects of the concentrations of the lycopene extract (0.015 to 0.085 mg/mL) and emulsifier (0.3 to 0.7 mg/mL), and the number of homogenization cycles (2 to 4) on the droplet size, emulsification efficiency (EE), and nanoemulsion stability were investigated and optimized by statistical analysis using a Box-Behnken design. Analysis of variance showed that the lycopene extract concentration has the most significant effect on all the response variables. Response surface methodology predicted that a formulation containing 0.085 mg/mL of lycopene extract and 0.7 mg/mL of emulsifier, subjected to 3 homogenization cycles, is optimal for achieving the smallest droplet size, greatest emulsion stability, and acceptable EE. The observed responses were in agreement with the predicted values of the optimized formulation.

#### Norovirus

#### Gaps in Food Safety Professionals' Knowledge about Noroviruses

K.M. Kosa, S.C. Cates, A.J. Hall, J.E. Brophy, A. Fraser Journal of Food Protection, Vol. 77, No. 8; pp. 1336–1341, 2014 DOI:10.4315/0362-028X.JFP-13-550 Link to full text: Click here



**Significance:** This survey identified several important gaps in food safety professionals' knowledge of noroviruses.

A survey of 314 food safety professionals was conducted to characterize their knowledge of noroviruses (NoVs) (e.g., attribution, transmission, and prevention and control strategies, including food handling practices) and to identify gaps in this knowledge. Of the 314 respondents, 66.2% correctly identified NoVs as one of the three most common causes of foodborne disease in the US. Only 5.4% correctly identified the three most common settings for NoV infections, and 65.0% had the misperception that cruise ships are one of the three most common settings. Seventeen respondents (5.4%) answered all 20 true-or-false questions correctly, 33 (10.5%) answered at least 19 of the 20 questions correctly, and 186 (65.0%) answered at least 15 of the 20 questions correctly. The content domain in which respondents had the most incorrect answers was food handling practices. Thirty-eight percent of respondents incorrectly responded that it is safe for restaurant workers infected with NoVs to handle packaged food, food equipment, and utensils. About half of respondents did not know the recommended sanitizing solution for eliminating NoVs from a contaminated surface.

# Mechanisms of Antiviral Action of Plant Antimicrobials against Murine Norovirus

D.H. Gilling, M. Kitajima, J.R. Torrey, K.R. Bright Applied and Environmental Microbiology, Vol. 80, No. 16; pp. 4898–4910, 2014 DOI: 10.1128/AEM.00402-14

Link to full text: Click here

**Significance:** This study demonstrates the antiviral properties of allspice oil, lemongrass oil, and citral against murine norovirus and thus indicates their potential as natural food and surface sanitizers to control noroviruses.

The efficacies of allspice oil (AO), lemongrass oil (LO), and citral were evaluated against the nonenveloped murine norovirus (MNV), a human norovirus surrogate. The antiviral mechanisms of action were also examined using an RNase I protection assay, a host cell binding assay, and transmission electron microscopy. All three antimicrobials produced significant reductions in viral infectivity within 6 h of exposure (0.90 log10 to 1.88 log10). After 24 h, the reductions were 2.74, 3.00, and 3.41 log10 for LO, citral, and AP, respectively. The antiviral effect of AO was both time- and concentration-dependent; the effects of LO and citral were time-dependent. Based on the RNase I assay, AO appeared to act directly upon the viral capsid and RNA. The capsids enlarged from  $\leq$ 35 nm to  $\leq$ 75 nm following treatment. The capsid remained intact following exposure to LO and citral causing nonspecific and nonproductive binding to host cells that did not lead to successful infection.

# Strategies to Enhance High Pressure Inactivation of Murine Norovirus in Strawberry Puree and on Strawberries

#### R. Huang, X. Li, Y. Huang, H. Chen

International Journal of Food Microbiology, Vol. 185, 18 August 2014; pp. 1–6, 2014 DOI: 10.1016/j.ijfoodmicro.2014.05.007

Link to full text: Click here



**Significance:** This study provides practical insights of designing strategies using high hydrostatic pressure (HHP) to inactivate human norovirus (HuNoV) on strawberries and in strawberry puree assuming that HuNoV behaved similarly to murine norovirus 1 when treated by HHP.

This study investigated strategies to enhance high hydrostatic pressure (HHP) inactivation of murine norovirus 1 (MNV-1), a human norovirus (HuNoV) surrogate, on strawberries and in strawberry puree. Strawberry puree was inoculated with ~ 106 PFU/g of MNV-1 and treated at 350 MPa for 2 min at initial sample temperatures of 0, 5, 10 and 20°C. MNV-1 became more sensitive to HHP as initial sample temperature decreased from 20 to 0°C. To determine the effect of presence of water during HHP on MNV-1 inactivation, strawberries inoculated with ~  $4 \times 105$  PFU/g of MNV-1 were either pressure-treated directly (dry state) or immersed in water during pressure treatment. MNV-1 was very resistant to pressure under the dry state condition, but became sensitive to pressure under the wet state condition. The fate of MNV-1 in the un-treated and pressure-treated strawberries and strawberry puree during frozen storage was determined. The virus was relatively stable and only reduced by <1.2 log during the 28-day frozen storage.

## **Special Report**

Selection of Appropriate Tumour Data Sets for Benchmark Dose Modelling (BMD) and Derivation of a Margin of Exposure (Moe) for Substances that are Genotoxic and Carcinogenic: Considerations of Biological Relevance of Tumour Type, Data Quality and Uncertainty Assessment

L. Edler, A. Hart, P. Greaves, P. Carthew, M. Coulet, A. Boobis, et al. Food and Chemical Toxicology, Vol. 70, August 2014; pp. 264–289, 2014 DOI: 10.1016/j.fct.2013.10.030

Link to full text: Click here

**Significance:** This article follows up on the recommendations put forward by ILSI– Europe in 2010 on the application of the Margin of Exposure approach to substances in food that are genotoxic and carcinogenic.

This article addresses a number of concepts related to the selection and modelling of carcinogenicity data for the calculation of a Margin of Exposure. The aims are to provide practical guidance on the relevance of animal tumour data for human carcinogenic hazard assessment, appropriate selection of tumour data for Benchmark Dose Modelling, and approaches for dealing with the uncertainty associated with the selection of data for modelling and, consequently, the derived Point of Departure (PoD) used to calculate the MoE. Each topic is dealt with separately to allow those with specialised knowledge to target key areas of guidance and provide a more in-depth discussion on each subject for those new to the concept of the Margin of Exposure approach.

# About Us

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1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsina.org

From: Sent: To:	Suzanne Harris Monday, September 15, 2014 2:12 PM		
	's.cl	nang@griffith.edu.au'; 'scohen@unmc.edu'; 'mdoyle@uga.edu'; adamdrew@u.washington.edu;	
	'marion@vt.edu'; '	; );	
	Lupton; 'j	'; Joanne 'john.c.peters@ucdenver.edu';	
	;	'; ';	
		'kwallace@d.umn.edu';	
(c	'weavercm@purdue.edu'; ' '		
CC.	'jbradford@unmc.edu'; '	'	
		mri.bund.de'; Burnand,Valerie,VEVEY,CT-RSA ; 'haan@purdue.edu'; ; Beth Brueggemeyer	
Subject:	2015 ILSI Annual Meeting	, beth bracggeneyer	
TO:	ILSI Board of Trustees		

FROM: Suzie Harris

During the first week of September, you should have received an electronic invitation to the 2015 ILSI Annual Meeting in Chandler, Arizona (outside of Phoenix). If you did not receive such an invitation, please let me or Beth Brueggemeyer know as soon as possible.

The meeting begins on Friday, January 16, with the ILSI Branch Staff Meeting. As an ILSI trustee, you are welcome to attend the ILSI Branch Staff Meeting as an observer.

The ILSI Board of Trustees will meet on Saturday morning, January 17. The ILSI Assembly of Members meets Sunday afternoon, January 18, followed by the opening reception. There will be regional branch meetings, scientific sessions, and various other meetings on Monday and Tuesday, January 19 and 20. The meeting ends with the closing reception on Tuesday evening, January 20.

You can find a more complete agenda on the ILSI website -- <u>http://www.ilsi.org/Pages/2015-Annual-Meeting.aspx</u>. Your electronic invitation includes links for meeting registration and hotel (Sheraton Wild Horse Pass Resort and Spa) reservations. I encourage you to make your plans to attend as soon as possible. The deadline for hotel reservations is **Monday, December 22, 2014.** 

Please let me know if you have any questions or need assistance with travel reservations.

From: Sent: To: Subject: Chareese Cunningham Thursday, September 04, 2014 10:52 AM Joanne Lupton 2015 ILSI Annual Meeting

Connect and share at the 2015 ILSI Annual Meeting! 16-21 January 2015 Phoenix, Arizona

You are invited to join your colleagues from around the world at the <u>2015 ILSI ANNUAL MEETING</u>, scheduled for 16-21 January at The Sheraton Wild Horse Pass Resort in Phoenix, Arizona.

ILSI, ILSI North America, the ILSI Research Foundation and HESI are cosponsoring this important event, providing an exciting opportunity to learn about ILSI's recent achievements and to hear first-hand about new scientific challenges and the program opportunities through which ILSI can make a difference.

Exchange ideas face-to-face with your colleagues and international experts on topics such as sustainability, caffeine, and new exposure data for food risk and nutrition assessment. Share your own insights on how ILSI and its partners can help improve our understanding of all these issues and more. To find out more about the 2015 Annual Meeting scientific program, <u>HERE</u>!

REGISTRATION: Your registration fee is waived, but to be considered registered for the meeting, you must complete the online meeting registration process as soon as possible. If you are inviting a guest, be sure to register your guest as well and pay the applicable fees. <u>CLICK HERE</u> to register!

After you register, go to the <u>ILSI Annual Meeting website</u> to get the updated information on the annual meeting program, <u>traveling information</u>, <u>what to do in Phoenix</u>, and how to make your <u>hotel reservations</u>.

Sheraton Wild Horse Pass Resort and Spa RESERVATIONS: An authentic representation of the Gila River Indian Community's heritage and culture, the Sheraton Wild Horse Pass is located on an expanse of rugged Arizona landscape in the high Sonoran Desert.

You are responsible for making your own hotel room reservations. One of the ILSI entities is paying for your lodging, the hotel will be notified that your room and tax will be paid for by ILSI. Therefore, the credit card used to make your room reservation will only be charged for any incidentals (or for room charges should you elect to extend your stay beyond the number of nights covered by ILSI). Should you need to cancel for any reason, you will be responsible for cancelling your reservation as well, to avoid any cancellation or no show charges. Please be sure to make your hotel reservations by 22 December. To book your room at the Sheraton Wild Horse Pass – click here.

In the meantime, I hope to meet you in Arizona!

Sincerely,

Chareese Cunningham ILSI Annual Meeting Manager Powered by <u>www.EventRebels.com</u>

From:	onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of
	nutritionreviews@llsi.org
Sent:	Saturday, August 30, 2014 2:17 AM
То:	Joanne Lupton
Cc:	
Subject:	Second reminder: Request to review

30-Aug-2014

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited by Dr. Sharon Donovan to review a manuscript entitled "Eating Well with Canada's Food Guide (2007): Is it Still Meeting the Needs of Canadians?" [Manuscript ID NUTR-REV-121-NSP-07-2014]. A follow-up to that invitation was also sent, but we do not seem to have received a response.

In order to ensure your preference with regard to this invitation is recorded, and to avoid any undue delay in the processing of the submission, we would be grateful if you could indicate your ability to assist by clicking on the appropriate link below:

Agreed: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=07aa488364e94852b36e9adb031b5503

Declined: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=d3f8f074bb24417f8b7ad5b67be09a79

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Your opinion on the suitability of this submission for possible publication in Nutrition Reviews will be highly valued by the editors. Please let us know if your schedule will permit you to accept.

Kind regards,

**Nutrition Reviews** 

2013 Impact Factor 5.541 www.nutritionreviewsjournal.com, Nutrition Reviews nutritionreviews@ilsi.org

Impact Factor: 4.597 www.nutritionreviewsjournal.com

cc. Dr. Sharon Donovan [email ref: SE-33-a]
From:onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of<br/>nutritionreviews@ilsi.orgSent:Thursday, August 28, 2014 1:32 AMTo:Joanne LuptonCc:Subject:Reminder: Request to review

28-Aug-2014

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited to review a manuscript entitled "Eating Well with Canada's Food Guide (2007): Is it Still Meeting the Needs of Canadians?" [Manuscript ID NUTR-REV-121-NSP-07-2014] for Nutrition Reviews, but a response to that invitation has not yet been received.

In order to ensure the review process proceeds in a timely fashion, this invitation is being extended again. To automatically register your response, please click on the appropriate link below:

Agreed: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=88ce127ae2c442cfaa309b88b599a438

Declined: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=5747c08808814e779a5332a6c33bee1d

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Thank you for considering this invitation. I hope your schedule will allow you to accept.

Sincerely,

Sharon Donovan Associate Editor, Nutrition Reviews 2013 Impact Factor 5.541 www.nutritionreviewsjournal.com

[email ref: SE-32-a]

From: Sent: Subject: Attachments: John Faulkner Wednesday, August 13, 2014 10:10 AM Your ILSI North America Science Briefs for July 2014 Food Safety Briefs July 2014.pdf; Nutrition Briefs July 2014 (2).PDF

Greetings:

I hope you are now enjoying the final weeks of summer!

The attached **Food Safety** and **Nutrition** Science Briefs are compiled each month after a review of articles published in the most recent issues of the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion are those we believe address areas of greatest interest to ILSI North America's technical and project committees.

Our **July** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Nutrition Briefs**

# July 2014

# Carbohydrates

# Amount, Type, and Sources of Carbohydrates in Relation to Ischemic Heart Disease Mortality in a Chinese Population: A Prospective Cohort Study

S.A. Rebello, H. Koh, C. Chen, N. Naidoo, A.O. Odegaard, W-P. Koh, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 53-64, 2014

Link to full text: Click here

**Significance:** The total amount of carbohydrates consumed was not associated with IHD mortality and the shifting of food sources of carbohydrates toward a higher consumption of fruit, vegetables, and whole grains was associated with lower risk of IHD death.

This study assessed whether intakes of total carbohydrates, different types of carbohydrates, and their food sources were associated with ischemic heart disease (IHD) mortality in 53,469 Chinese participants with an average follow-up of 15 y. Total carbohydrate intake was not associated with IHD mortality risk [men: HR per 5% of energy, 0.97 (95% CI: 0.92, 1.03); women: 1.06 (95% CI: 0.99, 1.14)]. When types of carbohydrates were analyzed individually, starch intake was associated with higher risk [men: 1.03 (95% CI: 0.99, 1.08); women: 1.08, (95% CI: 1.02, 1.14)] and fiber intake with lower risk of IHD mortality [men: 0.94 (95% CI: 0.82, 1.08); women: 0.71 (95% CI: 0.60, 0.84)]. The replacement of one daily serving of rice with noodles was associated with higher risk (difference in HR: 26.11%; 95% CI: 10.98%, 43.30%). In contrast, replacing one daily serving of rice with one of vegetables (-23.81%; 95% CI: -33.12%, -13.20%), fruit (-11.94%; 95% CI: -17.49%, -6.00%), or whole-wheat bread (-19.46%; 95% CI: -34.28%, -1.29%) was associated with lower risk of IHD death.

# **Type 2 Diabetes**

Comparative Effect of Two Mediterranean Diets Versus a Low-Fat Diet on Glycaemic Control in Individuals With Type 2 Diabetes

A. Lasa, J. Miranda, M. Bulló, R. Casas, J. Salas-Salvadó, I. Larretxi, et al. European Journal of Clinical Nutrition, Vol. 68, No. 7; pp. 767–772, 2014 Link to full text: Click here

**Significance:** Mediterranean diets supplemented with virgin olive oil or nuts reduced total body weight and improved glucose metabolism to the same extent as the usually recommended low-fat diet.

This multicentric parallel trial compared the effects of two Mediterranean diets supplemented with virgin olive oil (n=67) or mixed nuts (n=74) versus a low-fat diet (n=50) on several parameters and indices related to glycaemic control in type 2 diabetic subjects. Results showed that increased values of adiponectin/ leptin ratio (P=0.043, P=0.001 and P<0.001 for low-fat, olive oil and nut diets, respectively) and adiponectin/HOMA-IR ratio (P=0.061, P=0.027 and P=0.069

# **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

for low-fat, olive oil and nut diets, respectively) and decreased values of waist circumference (P=0.003, P=0.001 and P=0.001 for low-fat, olive oil and nut diets, respectively) were observed in the three groups. In both Mediterranean diet groups, but not in the low-fat diet group, this was associated with a significant reduction in body weight (P=0.347, P=0.003 and P=0.021 for low-fat, olive oil and nut diets, respectively).

#### Glycemic Index, Glycemic Load, and Risk of Type 2 Diabetes: Results From 3 Large US Cohorts and an Updated Meta-Analysis

S.N. Bhupathiraju, D.K. Tobias, V.S. Malik, A. Pan, A. Hruby, J.E. Manson, et al. American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 218–232, 2014 Link to full text: Click here

**Significance:** Higher dietary glycemic index and glycemic load are associated with increased risk of type 2 diabetes.

This prospective study examined the association of dietary glycemic index (GI) and glycemic load (GL) with type 2 diabetes (T2D) risk in 74,248 women from the Nurses' Health Study (1984–2008), 90,411 women from the Nurses' Health Study II (1991–2009), and 40,498 men from the Health Professionals Follow-Up Study (1986–2008) who were free of diabetes, cardiovascular disease, and cancer at baseline. During 3,800,618 person-years of follow-up, 15,027 cases of incident T2D were documented. In pooled multivariable analyses, those in the highest quintile of energy-adjusted GI had a 33% higher risk (95% CI: 26%, 41%) of T2D than those in the lowest quintile. Participants in the highest quintile of energy-adjusted GL had a 10% higher risk (95% CI: 2%, 18%) of T2D. Participants who consumed a combination diet that was high in GI or GL and low in cereal fiber had approximately 50% higher risk of T2D.

# **Cardiovascular Disease**

## Dietary Carotenoids are Associated with Cardiovascular Disease Risk Biomarkers Mediated by Serum Carotenoid Concentrations

Y. Wang, S-J. Chung, M.L. McCullough, W.O. Song, M.L. Fernandez, S.I. Koo, et al.

Journal of Nutrition, Vol. 144, No. 7; pp. 1067–1074, 2014

Link to full text: Click here

Significance: Serum carotenoids were mediators of dietary carotenoids and CVD risk biomarker associations, and serum  $\beta$ -carotene was a moderator of the dietary  $\beta$ -carotene and CRP association.

This population-based cross-sectional study assessed associations between individual dietary carotenoid intake and cardiovascular disease (CVD) risk biomarkers, and tested whether the serum carotenoid concentrations explain (mediate) or influence the strength of (moderate) the associations, if any association exists in 1312 men and 1544 women from the NHANES 2003–2006. After adjustment for covariates, significant inverse associations with LDL-cholesterol were observed for dietary  $\beta$ -carotene (P<0.05) and lutein + zeaxanthin (P<0.001), and with total homocysteine (tHcy) for dietary  $\beta$ -carotene (P<0.05), lycopene (P<0.05), and total carotenoids (P<0.05). Dietary lutein + zeaxanthin intake was also positively associated with HDL-cholesterol concentrations (P<0.01). Most of these associations were null after additional adjustment for corresponding serum carotenoid concentrations, indicating the complete mediation effects of serum carotenoids. Serum  $\beta$ -carotene significantly moderated the associations



between dietary  $\beta$ -carotene and C-reactive protein (CRP) (P-interaction<0.05), and quartile 4 of dietary  $\beta$ -carotene was associated with lower CRP concentrations only among participants with serum  $\beta$ -carotene > 0.43 µmol/L.

#### No Breakfast at Home: Association With Cardiovascular Disease Risk Factors in Childhood

S. Papoutsou, G. Briassoulis, M. Wolters, J. Peplies, L. Iacoviello, G. Eiben, et al. on behalf of the IDEFICS consortium

*European Journal of Clinical Nutrition*, Vol. 68, No. 7; pp. 829–834, 2014 Link to full text: Click here

**Significance:** For preschoolers, breakfast consumption was positively associated with the reduction in cardiovascular disease risk factors but results of regression models were mostly insignificant.

This cross-sectional study from eight European countries investigated the relationship between breakfast routine and cardiovascular disease (CVD) risk factors in 8863 children 2 to <10 years of age. Male school-aged no breakfast (NBrH) consumers compared with daily breakfast at home (DBrH) consumers were more likely to be overweight/obese (OR: 1.37, 95% CI=1.05–1.79), to have higher risk for HDL-cholesterol levels <40 mg/dl (OR: 1.69, 95% CI=1.24–2.30), triglycerides (TG) >75 mg/dl (OR: 1.65, 95% CI=1.24–2.19) and sum of skinfolds > the 90th percentile (OR: 1.32, 95% CI=1.0–1.76). Female school-aged NBrH consumers compared with DBrH consumers had a higher risk for waist circumference > the 90th percentile (OR: 1.70, 95% CI=1.14–2.51), HDL-cholesterol levels <40 mg/dl (OR: 1.65, 95% CI=1.23–2.21), TG >75 mg/dl (OR: 1.65, 95% CI=1.26–2.17) and total cholesterol/HDL-cholesterol ratio >3.5 (OR: 1.39, 95% CI=1.09–1.77). Male DBrH consumers 6 to <10 years of age had longer daily periods of moderate-to-vigorous physical activity periods compared with NBrH consumers ( $32.0\pm21.4 \times 27.5\pm18.8 \min/day$ , P<0.05).

#### Dietary Sugars and Cardiometabolic Risk: Systematic Review and Meta-Analyses of Randomized Controlled Trials of the Effects on Blood Pressure and Lipids

L.A. Te Morenga, A.J. Howatson, R.M. Jones, J. Mann American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 65–79, 2014 Link to full text: Click here

**Significance:** Dietary sugars influence blood pressure and serum lipids independent of effects of sugars on body weight.

This systematic review and meta-analysis of randomized controlled trials examined the effects of the modification of dietary free sugars on blood pressure and lipids. Systematic searches were conducted to August 2013 to identify studies that reported intakes of free sugars and at least one lipid or blood pressure outcome. The minimum trial duration was 2 wk. Thirty-nine of 11,517 trials identified were included; 37 trials reported lipid outcomes, and 12 trials reported blood pressure outcomes. Higher compared with lower sugar intakes significantly raised triglyceride concentrations [mean difference (MD): 0.11 mmol/L; 95% CI: 0.07, 0.15 mmol/L], total cholesterol (MD: 0.16 mmol/L; 95% CI: 0.10, 0.24 mmol/L), LDL-cholesterol (0.12 mmol/L; 95% CI: 0.05, 0.19 mmol/L), and HDLcholesterol (MD: 0.02 mmol/L; 95% CI: 0.00, 0.03 mmol/L). Subgroup analyses showed the most marked relation between sugar intakes and lipids in studies in which efforts were made to ensure an energy balance and when no difference in weight change was reported. Potential explanatory factors, including a weight



change, in most instances explained <15% of the heterogeneity between studies (I<sup>2</sup> = 36–75%). The effect of sugar intake on blood pressure was greatest in trials  $\geq$ 8 wk in duration [MD: 6.9 mm Hg (95% CI: 3.4, 10.3 mm Hg) for systolic blood pressure and 5.6 mm Hg (95% CI: 2.5, 8.8 mm Hg) for diastolic blood pressure].

### DHA-Enriched High–Oleic Acid Canola Oil Improves Lipid Profile and Lowers Predicted Cardiovascular Disease Risk in the Canola Oil Multicenter Randomized Controlled Trial

P.J.H. Jones, V.K. Senanayake, S. Pu, D.J.A. Jenkins, P.W. Connelly, B. Lamarche, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 88–97, 2014

Link to full text: Click here

**Significance:** Consumption of CanolaDHA, a novel DHA-rich canola oil, improves HDLcholesterol, triglycerides, and blood pressure, thereby reducing Framingham 10-y CHD risk scores compared with other oils varying in unsaturated fatty acid composition.

This randomized, double-blind, 5-period, crossover design study examined the effects of varying n-9, n-6, and longer-chain n-3 fatty acid composition on markers of coronary heart disease (CHD) risk. Volunteers with abdominal obesity consumed each of 5 identical fixed-composition diets with one of the following treatment oils (60 g/3000 kcal) in beverages: 1) conventional canola oil (Canola; n-9 rich), 2) high-oleic acid canola oil with docosahexaenoic acid (CanolaDHA; n-9 and n-3 rich), 3) a blend of corn and safflower oil (25:75) (CornSaff; n-6 rich), 4) a blend of flax and safflower oils (60:40) (FlaxSaff; n-6 and short-chain n-3 rich), or 5) high-oleic acid canola oil (CanolaOleic; highest in n-9); 130 individuals completed the trial. At endpoint, total cholesterol (TC) was lowest after the FlaxSaff phase (P<0.05 compared with Canola and CanolaDHA) and highest after the CanolaDHA phase (P<0.05 compared with CornSaff, FlaxSaff, and CanolaOleic). LDL- and HDL-cholesterol were highest, and triglycerides were lowest, after CanolaDHA (P<0.05 compared with the other diets). All diets decreased TC and LDL-cholesterol from baseline to treatment endpoint (P<0.05). CanolaDHA was the only diet that increased HDL-cholesterol from baseline (3.5±1.8%; P<0.05) and produced the greatest reduction in triglycerides (-20.7±3.8%; P<0.001) and in systolic blood pressure (-3.3±0.8%; P<0.001) compared with the other diets (P<0.05). Percentage reductions in Framingham 10-y CHD risk scores (FRS) from baseline were greatest after CanolaDHA  $(-19.0\pm3.1\%; P<0.001)$  than after other treatments (P<0.05).

## Rice Consumption is Not Associated With Risk of Cardiovascular Disease Morbidity or Mortality in Japanese Men and Women: A Large Population-Based, Prospective Cohort Study

E.S. Eshak, H. Iso, K. Yamagishi, Y. Kokubo, I. Saito, H. Yatsuya, et al. American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 199–207, 2014 Link to full text: Click here

**Significance:** Rice consumption is not associated with risk of cardiovascular disease morbidity or mortality.

The association between rice consumption and risk of cardiovascular disease (CVD) incidence and mortality was examined in a prospective study in 91,223 Japanese men and women aged 40–69 y. Follow-up for incidence was from 1990-2009 in cohort I and 1993-2007 in cohort II; for mortality was from 1990-2009 in cohort I and 1993-2009 in cohort II. In 15–18 y of follow-up, 4395 incident cases of stroke, 1088 incident cases of ischemic heart disease (IHD), and 2705



deaths from CVD were ascertained. Rice consumption was not associated with risk of incident stroke or IHD; the multivariable HR (95% CI) in the highest compared with lowest rice consumption quintiles was 1.01 (0.90, 1.14) for total stroke and 1.08 (0.84, 1.38) for IHD. Similarly, there was no association between rice consumption and risk of mortality from CVD; the HR (95% CI) for mortality from total CVD was 0.97 (0.84, 1.13). There were no interactions with sex or effect modifications by body mass index for any endpoint.

# Sugar-Sweetened Beverages

# The Relationship between Health-Related Knowledge and Sugar-Sweetened Beverage Intake among US Adults

S. Park, S. Onufrak, B. Sherry, H.M. Blanck Journal of the Academy of Nutrition and Dietetics, Vol. 114, No. 7; pp. 1059–1066, 2014 Link to full text: Click here

**Significance:** Knowledge about the adverse effects of sugar-sweetened beverage (SSB) intake is significantly associated with SSB intake among adults.

This cross-sectional study examined the association between health-related knowledge and sugar-sweetened beverage (SSB) intake using the 2010 HealthStyles Survey data for 3,926 adults (aged  $\geq$ 18 years). Multivariable logistic regression analysis was used to estimate the adjusted odds ratios and 95% CIs for drinking SSBs  $\geq$ 2 times/day. About 31% of adults consumed SSBs  $\geq$ 1 time/ day, with 20% doing so  $\geq$ 2 times/day. About 8 of 10 adults agreed that drinking SSBs can contribute to weight gain, yet, 8 of 10 adults did not know the actual kilocalorie content of a 24-oz fountain soda. After controlling for covariates, the odds for drinking SSBs  $\geq$ 2 times/day were significantly higher among adults who neither agreed nor disagreed that drinking SSBs can contribute to weight gain (OR=1.61, 95% CI 1.15-2.25 vs agree); however, knowledge about the energy content of regular soda was not associated with SSB intake.

### Consumption of Sugar-Sweetened Beverages Is Positively Related to Insulin Resistance and Higher Plasma Leptin Concentrations in Men and Nonoverweight Women

A. Lana, F. Rodríguez-Artalejo, E. Lopez-Garcia

Journal of Nutrition, Vol. 144, No. 7; pp. 1099-1105, 2014

Link to full text: Click here

**Significance:** The consumption of sugar-sweetened beverages was associated with higher concentrations of insulin and leptin and a higher HOMA-IR in men and in non-overweight women.

This study examined the association of habitual sugar-sweetened beverage (SSB) consumption with biomarkers of energy metabolism, including serum glucose, HgBA<sub>1</sub>C, insulin, homeostasis model assessment of insulin resistance (HOMA-IR), and leptin during 2008–2010 in 7842 individuals representative of the population of Spain aged 18–59 y. In men, a 1-serving (200 mL)/d increase in the consumption of SSBs was associated with higher plasma concentrations of insulin (2.14%, P=0.01), HOMA-IR (1.90%, P=0.04), and leptin (2.73%, P=0.01). Among women, these associations were found only in those with a BMI <25 kg/m<sup>2</sup> (insulin: 2.88%, P=0.004; HOMA-IR: 3.03%, P=0.01; and leptin: 4.57%, P=0.01) or with a waist circumference <80 cm (insulin: 2.79%, P=0.01; HOMA-IR: 3.00%, P=0.01; and leptin: 3.63%, P=0.05).



# Metabolic Syndrome

Added Value of Different Metabolic Syndrome Definitions for Predicting Cardiovascular Disease and Mortality Events among Elderly Population: Tehran Lipid and Glucose Study

A. Mozaffary, M. Bozorgmanesh, F. Sheikholeslami, F. Azizi, F. Eskandari, F. Hadaegh

European Journal of Clinical Nutrition, Vol. 68, No. 7; pp. 853–858, 2014 Link to full text: Click here

**Significance:** The WHO definition of metabolic syndrome was the strongest predictor of CVD and mortality outcomes.

This study examined the association between the different definitions of metabolic syndrome (MetS) and the prediction of incident cardiovascular disease (CVD) and mortality events and determined whether the concept of MetS adds to traditional risk factors among elderly Iranians. The association between MetS and outcomes was examined in 922 adults aged  $\geq$ 65 years and free of CVD at baseline. During a median follow-up of 9.9 years, 207 CVD events and 193 deaths (82 CVD deaths) occurred. World health organization (WHO) and the joint interim statement (JIS) definitions were shown to be the strongest predictors of CVD events. The WHO definition predicted CVD and all-cause mortality events (HR=1.55; 95% CI=1.15–2.09 and 2.08; 95% CI=1.23–3.51, respectively) and the JIS definition showed a risk for CVD mortality (HR=1.65; 95% CI=1.03–2.65)). Different definitions of MetS did not add to traditional risk factors in the prediction of different outcomes.

#### **Chronic Diseases**

### Nut Consumption and Risk of Type 2 Diabetes, Cardiovascular Disease, and All-Cause Mortality: A Systematic Review and Meta-Analysis

C. Luo, Y. Zhang, Y. Ding, Z. Shan, S. Chen, M. Yu, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 256–269, 2014 Link to full text: Click here

LINK to full text: Click here

**Significance:** Nut intake is inversely associated with ischemic heart disease, overall cardiovascular disease, and all-cause mortality but not significantly associated with diabetes and stroke.

The relation between nut intake and incidence of type 2 diabetes (T2DM), cardiovascular disease (CVD), and all-cause mortality were assessed. PubMed and EMBASE databases were searched for all prospective cohort studies published through March 2013 with RRs and 95% CIs for outcomes of interest. In 31 reports from 18 prospective studies, there were 12,655 T2DM, 8862 CVD, 6623 ischemic heart disease (IHD), 6487 stroke, and 48,818 mortality cases. The RR (95% CIs) for each incremental serving per day of nut intake was 0.80 (95% CI: 0.69, 0.94) for T2DM without adjustment for BMI; with adjustment, the association was attenuated [RR: 1.03; 95% CI: 0.91, 1.16; NS]. In the multivariable-adjusted model, pooled RRs for each serving per day of nut consumption were 0.72 (0.64, 0.81) for IHD, 0.71 (0.59, 0.85) for CVD, and 0.83 (0.76, 0.91) for all-cause mortality. Pooled RRs for the comparison of extreme quantiles of nut intake were 1.00 (0.84, 1.19) for T2DM, 0.66 (0.55, 0.78) for IHD, 0.70 (0.60, 0.81) for CVD, 0.91 (0.81, 1.02) for stroke, and 0.85 (0.79, 0.91) for allcause mortality.



### Consumption of Nuts and Legumes and Risk of Incident Ischemic Heart Disease, Stroke, and Diabetes: A Systematic Review and Meta-Analysis

A. Afshin, R. Micha, S. Khatibzadeh, D. Mozaffarian American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 278–288, 2014 Link to full text: Click here

Significance: This systematic review supports inverse associations between eating nuts and incident ischemic heart disease and diabetes, and eating legumes and incident IHD.

This study systematically investigated and quantified associations of nut and legume consumption with incident ischemic heart disease (IHD), stroke, and diabetes. Multiple databases were searched to identify randomized controlled trials or observational studies that examined the relations. Of 3851 abstracts, 25 observational studies (23 prospective and 2 retrospective studies) and 2 trial reports met inclusion criteria and comprised 501,791 unique individuals and 11,869 IHD, 8244 stroke, and 14,449 diabetes events. The consumption of nuts was inversely associated with fatal IHD (6 studies; 6749 events; RR per 4 weekly 28.4-g servings: 0.76; 95% CI: 0.69, 0.84; I2 = 28%), nonfatal IHD (4 studies; 2101 events; RR: 0.78; 0.67, 0.92; I2 = 0%), and diabetes (6 studies; 13,308 events; RR: 0.87; 0.81,0.94; I2 = 22%) but not stroke (4 studies; 5544 events). Legume consumption was inversely associated with total IHD (5 studies; 6514 events; RR per 4 weekly 100-g servings: 0.86; 0.78, 0.94; I2 = 0%) but not significantly associated with stroke (6 studies; 6690 events) or diabetes (2 studies; 2746 events).

# About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org



# **Food Safety Briefs**

# July 2014

# Listeria

# Metal-Chelating Active Packaging Film Enhances Lysozyme Inhibition of Listeria monocytogenes

M.J. Roman, E.A. Decker, J.M. Goddard

Journal of Food Protection, Vol. 77, No. 7; pp. 1153-1160, 2014

Link to full text: Click here

**Significance:** Metal-chelating active packaging, which chelates metal ions based on ligand-specific interactions, in contrast to electrostatic interactions, may improve antimicrobial synergy.

This study examined the effect of metal-chelating active packaging film on the antimicrobial activity of lysozyme against Listeria monocytogenes. Polypropylene films were surface modified by photoinitiated graft polymerization of acrylic acid (PP-g-PAA) from the food contact surface of the films to impart chelating activity based on electrostatic interactions. PP-g-PAA exhibited a carboxylic acid density of  $113 \pm 5.4$  nmol cm–2 and an iron chelating activity of  $53.7 \pm 9.8$  nmol cm–2. PP-g-PAA hindered lysozyme activity at low ionic strength (2.48-log increase at 64.4 mM total ionic strength) and enhanced lysozyme activity at moderate ionic strength (5.22-log reduction at 120 mM total ionic strength). These data support the hypothesis that at neutral pH, synergy between carboxylate metal-chelating films (pKa bulk 6.45) and lysozyme (pI 11.35) is optimal in solutions of moderate to high ionic strength to minimize undesirable charge interactions, such as lysozyme absorption onto film.

## Stress Response and Adaptation of Listeria monocytogenes 08-5923 Exposed to a Sublethal Dose of Carnocyclin A

X. Liu, U. Basu, P. Miller, L.M. McMullen

Applied and Environmental Microbiology, Vol. 80, No. 13; pp. 3835-3841, 2014

Link to full text: Click here

**Significance:** A sublethal dose of Carnocyclin A induced adaptation in Listeria monocytogenes 08-5923 by inhibition of expression of genes and proteins critical for synthesis of cell wall structures and maintaining metabolic functions.

Carnocyclin A (CCLA) is an antimicrobial peptide produced by Carnobacterium maltaromaticum ATCC PTA-5313, which can be used to control the growth of Listeria monocytogenes in ready-to-eat meat products. The aim of this research was to elucidate the cellular responses of L. monocytogenes 08-5923 exposed to a sublethal dose of CCLA. Microarray, quantitative reverse transcription-PCR, tandem mass spectrometry, and electron microscopy were used to investigate the alteration in gene expression, protein production, and morphological changes in cells of Listeria following treatment with CCLA. The genes involved in metabolism, cell wall synthesis, and cell division were upregulated following a 15-min exposure to CCLA as a result of stress responses. Genes involved in cell division, cell wall synthesis, flagellar synthesis, and metabolism were downregulated after

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

4 h as a result of adaptation. Analysis of total soluble proteins confirmed the downregulation of pykA and gnd after 4 h of exposure to CCLA. The absence of flagella was observed in L. monocytogenes following 30 h of exposure to CCLA.

#### E. Coli

## Non-O157 Shiga Toxin–Producing Escherichia coli in U. S. Retail Ground Beef

Y-T. Liao, M.F. Miller, G.H. Loneragan, J.C. Brooks, A. Echeverry, M.M. Brashears Journal of Food Protection, Vol. 77, No. 7; pp. 1188-1192, 2014 Link to full text: Click here

**Significance:** The current research provides updated surveillance data for non-O157 STEC isolates among commercial ground beef products and information about potential sources of contamination from beef trims destined for ground beef production.

This study provided an estimate of the burden of the six serogroups (O26, O45, O103, O111, O121, and O145) of non-O157 Shiga toxin–producing Escherichia coli (STEC) in ground beef obtained from retail stores across the U.S. A convenience sample of commercial ground beef products (n=1,129) of various lean/ fat proportions, muscle group of origin (chuck, round, sirloin, or not specified), and packaging types were purchased from retail stores in 24 states from October 2011 to May 2012. For each ground beef sample, 25 g was inoculated in 225 ml of modified tryptic soy broth, stomached for 1 min, and then incubated at 41°C for 18 ± 2 h. Nine (0.8%) of the ground beef samples were potentially positive for at least one STEC serogroup after PCR screening. The serogroups detected by PCR assay were O26 (four samples), O103 (four samples), O145 (three samples), O45 (two samples), and O121 (one sample). No STEC isolates belonging to these serogroups were recovered from the sample cultures.

# Thermal Inactivation of Escherichia coli O157:H7 and Non-O157 Shiga Toxin–Producing Escherichia coli Cells in Mechanically Tenderized Veal

J.B. Luchansky, A.C.S. Porto-Fett, B.A. Shoyer, H. Thippareddi, J.R. Amaya, M. Lemler

Journal of Food Protection, Vol. 77, No. 7; pp. 1201-1206, 2014

Link to full text: Click here

**Significance:** Cooking times and temperatures effective for inactivating serotype O157:H7 strains of E. coli in tenderized veal are equally effective against the additional six non-O157 Shiga toxin-producing strains.

Preflattened veal cutlets were surface inoculated with a multistrain cocktail of Escherichia coli O157:H7 (ECOH) or a cocktail made of single strains of serogroups O26, O45, O103, O104, O111, O121, and O145 of Shiga toxin–producing E. coli (STEC) cells and then mechanically tenderized. For each cooking time in each of at least three trials, three inoculated and tenderized cutlets, with and without breading, were individually cooked in 15 or 30 ml of canola oil for 0.0, 0.75, 1.0, 1.25, 1.5, 1.75, or 2.25 min/side on an electric skillet set at 191.5°C. Regardless of the breading or volume of oil used to cook the meat, the longer the cooking times the higher the internal temperature of the meat, along with a greater reduction of both ECOH and STEC. The average final internal temperature at the approximate geometric center ranged from 56.8 to 93.1°C. Microbial reductions of ca. 2.0-6.7 log CFU/g and ca. 2.6-6.2 log CFU/g were achieved for ECOH and STEC, respectively. When cooking breaded cutlets, the use of more (30 ml) compared with less (15 ml) cooking oil resulted in greater reductions in pathogen numbers. To deliver about a 5.0-log reduction of ECOH and STEC,



and to achieve the recommended internal temperature of 71.1°C, it was necessary to cook mechanically tenderized veal cutlets for at least 1.5 min/side on a preheated electric skillet set at 191.5°C and containing 15 ml of cooking oil.

# Salmonella

# Salmonella Transfer Potential onto Tomatoes during Laboratory-Simulated In-Field Debris Removal

A. Sreedharan, K.R. Schneider, M.D. Danyluk Journal of Food Protection, Vol. 77, No. 7; pp. 1062-1068, 2014 Link to full text: Click here

**Significance:** The use of dirty cloths did not increase the risk of Salmonella cross-contamination.

This study examined Salmonella transfer from inoculated green tomatoes to uninoculated cloths and from inoculated cloths to uninoculated tomatoes, upon single and multiple touches. Tomatoes were spot inoculated with a rifampin-resistant Salmonella cocktail (107 CFU/ tomato) and were touched with clean, dirty-dry, and dirty-wet cloths at 0, 1, or 24 h postinoculation. The transfer direction was then reversed by touching freshly inoculated cloths with uninoculated tomatoes. Salmonella transfer coefficients (TCs) from inoculated tomato and cloth were highest when the inoculum was wet  $(0.44\pm0.13 \text{ to } 0.32\pm0.12)$ , regardless of the condition of the cloth. Although Salmonella TCs from inoculated tomato to uninoculated cloth decreased significantly when the inoculum was dried (0.17±0.23 to 0.01±0.00), low levels of Salmonella were detected on cloth even after 24 h of drying. Inoculated dirty cloth did not transfer more Salmonella compared with inoculated clean cloth, and Salmonella survival was not higher on dirty cloth. When inoculated clean cloth (wet) was touched with 25 tomatoes, significantly higher levels of Salmonella were transferred to the first, second, and fourth tomatoes (0.03±0.10 to 0.09±0.02). However, inoculated dirty-wet and dirty-dry (0.00 to 0.04±0.01) cloths transferred similar levels of Salmonella to all 25 tomatoes.

# Use of Enrichment Real-Time PCR To Enumerate Salmonella on Chicken Parts

T.P. Oscar

Journal of Food Protection, Vol. 77, No. 7; pp. 1086-1092, 2014 Link to full text: Click here

**Significance:** Retail chicken parts examined were contaminated with low levels of Salmonella, which resulted in low levels of cross-contamination during simulated meal preparation and serving.

Enrichment real-time PCR (qPCR) was used to enumerate Salmonella bacteria that contaminate raw chicken parts at retail or that cross-contaminate cooked chicken during simulated meal preparation and serving. Whole raw chickens obtained at retail were partitioned into wings, breasts, thighs, and drumsticks using a sterilized knife and cutting board, which were then used to partition a cooked chicken breast to assess cross-contamination. After enrichment in buffered peptone water (400 ml, 8 h, 40°C, 80 rpm), subsamples were used for qPCR and cultural isolation of Salmonella. Of 10 raw chickens examined, 7 (70%) had one or more parts contaminated with Salmonella. Of 80 raw parts examined, 15 (19%) were contaminated with Salmonella. Of 20 cooked chicken parts examined, 2 (10%) were cross-contaminated with Salmonella. Predominant serotypes identified were Typhimurium (71%) and its variants (var. 5–, monophasic,



and nonmotile) and Kentucky (18%). The number of Salmonella bacteria on contaminated parts ranged from one to two per part.

#### Survival of Salmonella on Dried Fruits and in Aqueous Dried Fruit Homogenates as Affected by Temperature

L.R. Beuchat, D.A. Mann

Journal of Food Protection, Vol. 77, No. 7; pp. 1102-1109, 2014

Link to full text: Click here

**Significance:** Dried fruits that may be contaminated with Salmonella should be subjected to a lethal process to prevent postprocess contamination before they are eaten out-of-hand or used as ingredients in ready-to-eat foods.

This study determined the ability of Salmonella to survive on dried cranberries, raisins, and strawberries and in date paste, as affected by storage temperature. Acid-adapted Salmonella, initially at 6.57 to 7.01 log CFU/g, was recovered from mist-inoculated cranberries (water activity [aw] 0.47) and raisins (aw 0.46) stored at 25°C for 21 days but not 42 days, strawberries (aw 0.21) for 42 days but not 84 days, and date paste (aw 0.69) for 84 days but not 126 days. In contrast, the pathogen was detected in strawberries stored at 4°C for 182 days (6 months) but not 242 days (8 months) and in cranberries, date paste, and raisins stored for 242 days. Surface-grown cells survived longer than broth-grown cells in date paste. The order of rate of inactivation at 4°C was cranberry > strawberry > raisin > date paste. Survival of Salmonella in aqueous homogenates of dried fruits as affected by fruit concentration and temperature was also studied. Growth was not observed in 10% (aw 0.995 to 0.999) and 50% (aw 0.955 to 0.962) homogenates of the four fruits held at 4°C, 50% homogenates at 25°C, and 10% cranberry and strawberry homogenates at 25°C. Growth of the pathogen in 10% date paste and raisin homogenates stored at 25°C was followed by rapid inactivation.

# In Situ Evaluation of Paenibacillus alvei in Reducing Carriage of Salmonella enterica Serovar Newport on Whole Tomato Plants

S. Allard, A. Enurah, E. Strain, P. Millner, S.L. Rideout, E.W. Brown, et al. Applied and Environmental Microbiology, Vol. 80, No. 13; pp. 3842-3849, 2014 Link to full text: Click here

**Significance:** The naturally occurring antagonist strain TS-15 is highly effective in reducing the carriage of Salmonella Newport on whole tomato plants.

A naturally occurring bacterium identified by 16S rRNA gene sequencing as Paenibacillus alvei was isolated epiphytically from tomato plants native to the Virginia Eastern Shore tomato-growing region. After initial antimicrobial activity screening against Salmonella and 10 other bacterial pathogens associated with the human food supply, strain TS-15 was further used to challenge an attenuated strain of Salmonella Newport on inoculated fruits, leaves, and blossoms of tomato plants in an insect-screened high tunnel with a split-plot design. Survival of Salmonella after inoculation was measured for groups with and those without the antagonist at days 0, 1, 2, and 3 and either day 5 for blossoms or day 6 for fruits and leaves. Strain TS-15 exhibited broad-range antimicrobial activity against both major food-borne pathogens and major bacterial phytopathogens of tomato. After P. alvei strain TS-15 was applied onto the fruits, leaves, and blossoms of tomato plants, the concentration of S. Newport declined significantly compared with controls. Astonishingly, >90% of the plants had no detectable levels of Salmonella by day 5 for blossoms.



#### Effect of Egg Washing and Correlation Between Cuticle and Egg Penetration by Various Salmonella Strains

V.C. Gole, J.R. Roberts, M. Sexton, D. May, A. Kiermeier, K.K. Chousalkar, et al. International Journal of Food Microbiology, Volumes 182–183, 16 July 2014; pp. 18–25, 2014

Link to full text: Click here

**Significance:** S. Singapore, S. Worthington, and S. Livingstone were not detected in egg internal contents whereas S. Adelaide was detected in one egg's internal contents.

The ability of four Salmonella isolates (S. Singapore, S. Adelaide, S. Worthington and S. Livingstone) to penetrate washed and unwashed eggs using whole egg and agar egg penetration methods were investigated in the current study. The results of the agar penetration experiment indicated that all the isolates used have the capacity to penetrate the eggshell. Eggshell penetration by the S. Worthington isolate was higher but not significant in washed eggs compared to unwashed eggs. There was no significant difference in penetration of washed and unwashed eggs for S. Singapore, S. Adelaide and S. Livingstone. Whole egg penetration results showed that all of the Salmonella isolates used were capable of surviving on the eggshell surface after 21 days of incubation (at 20 °C) following a high dose of inoculation (105 CFU/mL). The combined data of all isolates demonstrated that the survival rate of Salmonella on eggshells (inoculated with 105 CFU/mL) was significantly higher (p=0.002) at 20 °C as compared to 37 °C.

# **Mycotoxins**

# Exposure Assessment to Mycotoxins in Gluten-free Diet for Celiac Patients

C. Brera, F. Debegnach, B. De Santis, S. Di Ianni, E. Gregori, S. Neuhold, et al. Food and Chemical Toxicology, Vol. 69, July 2014; pp. 13–17, 2014 Link to full text: Click here

**Significance:** Exposure values of fumonisins and zearalenone were lower than the toxicological thresholds

The exposure of celiac patients to fumonisins (FBs) and zearalenone (ZON) was assessed in this study. The higher exposures, for all the matrices and for both the selected mycotoxins, were for children age group. The lower and upper bound exposure ranged between 348 and 582 ng/kg bw/day for FBs and 22 and 83 ng/kg bw/day for ZON; these values result well below the TDI for the selected mycotoxins, representing 17 to 29% and 9 to 33% of the TDI set for FBs and ZON, respectively. Even considering the worst scenario, the exposure values reported for children were lower, namely 1385 ng/kg bw/day for FBs and 237 ng/kg bw/day for ZON, than the corresponding toxicological thresholds.

# **Foodborne Pathogens**

# Fate of Escherichia coli O157:H7 and Salmonella on Whole Strawberries and Blueberries of Two Maturities under Different Storage Conditions

T.P. Nguyen, L.M. Friedrich, M.D. Danyluk Journal of Food Protection, Vol. 77, No. 7; pp. 1093-1101, 2014 Link to full text: Click here



**Significance:** E. coli O157:H7 and Salmonella do not grow on strawberries at shipping or retail display temperatures, even when they are harvested at a maturity prone to bruising.

This research determined the fate of Escherichia coli O157:H7 and Salmonella on bruised and intact surfaces of whole strawberries and blueberries at shipping (2°C) and retail display (15.5°C) temperatures. Strawberries and blueberries were either purchased from a supermarket or were harvested immediately prior to use; they were bruised using established protocols, were spot inoculated, and were incubated at 2 and 15.5°C. Strawberries were sampled at 0, 2, 5, and 24 h and on days 3 and 7; blueberries were sampled on days 0, 1, 3, and 7. At both storage temperatures, population declines for both E. coli O157:H7 and Salmonella were seen under all conditions for strawberries. At  $2 \pm 2°$ C, E. coli O157:H7 and Salmonella populations on blueberries declined over 7 days under all conditions. At  $15.5 \pm 2°$ C, E. coli O157:H7 populations declined; however, Salmonella populations over 7 days on blueberries. Modified atmospheric conditions did not affect the behavior of E. coli O157:H7 and Salmonella on strawberries at both temperatures.

# Inactivation Kinetics of Escherichia coli O157:H7, Salmonella enterica Serovar Typhimurium, and Listeria monocytogenes in Ready-to-Eat Sliced Ham by Near-Infrared Heating at Different Radiation Intensities J-W. Ha, D-H. Kang

Journal of Food Protection, Vol. 77, No. 7; pp. 1224-1228, 2014

Link to full text: Click here

**Significance:** This study and the proposed kinetics model would be beneficial to the deli meat industry for selecting the optimum processing conditions of near-infrared heating to meet the target pathogen inactivation on ready-to-eat sliced ham.

The aim of this study was to investigate the inactivation kinetics of Salmonella enterica serovar Typhimurium, Escherichia coli O157:H7, and Listeria monocytogenes on ready-to-eat sliced ham by near-infrared (NIR) heating as a function of the processing parameter, radiation intensity. Precooked ham slices inoculated with the three pathogens were treated at different NIR intensities (ca. 100, 150, and 200  $\mu$ W/cm2/nm). An increase in the applied radiation intensity resulted in a gradual increase of inactivation of all pathogens. The survival curves of the three pathogens exhibited both shoulder and tailing behavior at all light intensities. The log-logistic model more accurately described survival curves of the three pathogens than did the Weibull distribution at all radiation intensities.

# **Heavy Metals**

Study of the Migration Phenomena of Specific Metals in Canned Tomato Paste Before and After Opening. Validation of a New Quality Indicator for Opened Cans

K.G. Raptopoulou, I.N. Pasias, N.S. Thomaidis, C. Proestos Food and Chemical Toxicology, Vol. 69, July 2014; pp. 25–31, 2014 Link to full text: Click here

Significance: Fe and Pb were the main metals migrating in tomato paste samples.

A method for the simultaneous determination of Cd–Pb, As–Cu, Cr–Ni and Fe–Mn in canned tomato paste samples by Electrothermal Atomic Absorption



Spectrometry was developed and validated. The validated method was applied for the determination of these metals and metalloids in 13 different tomato paste samples and the results showed that Cd content was higher than the maximum permissible value of 0.050 mg kg–1. Furthermore, a new quality indicator was evaluated in order to provide information about tomato paste quality and the appropriate storage time of an opened canned tomato paste. A migration test was accomplished based on the calculation of mass balance and the comparison of the elemental content in canned tomato paste samples and in aseptic paper pack.

# Toxicity of Naturally-Contaminated Manganese Soil to Selected Crops

J. Kováčik, D. Štěrbová, P. Babula, P. Švec, J. Hedbavny Journal of Agricultural and Food Chemistry, Vol. 62, No. 29; pp. 7287–7296, 2014 Link to full text: Click here

**Significance:** Observed toxicity of manganese excess to common crops urges for selection of cultivars with higher tolerance.

The impact of manganese excess using naturally contaminated soil (Mn-soil, pseudototal Mn 6494 vs 675 µg g<sup>-1</sup> DW in control soil) in the shoots of four crops was studied. Mn content decreased in the order Brassica napus > Hordeum vulgare > Zea mays > Triticum aestivum. Growth was strongly depressed in Brassica (containing 13696 µg Mn g<sup>-1</sup> DW). Some essential metals (Zn, Fe) increased in Mn-cultured Brassica and Zea, while macronutrients (K, Ca, Mg) decreased in almost all species. Toxic metals (Ni and Cd) were elevated in Mn-soil. Microscopy of ROS, NO, lipid peroxidation, and thiols revealed stimulation in all Mn-cultured crops, but changes were less visible in Triticum, a species with low shoot Mn (2363  $\mu$ g g<sup>-1</sup> DW). Antioxidative enzyme activities were typically enhanced in Mn-cultured plants. Soluble phenols increased in Brassica only while proteins decreased in response to Mn excess. Inorganic anions (chloride, sulfate, and phosphate) were less accumulated in almost all Mn-cultured crops, while the nitrate level increased. Organic anions (malate, citrate, oxalate, acetate, and formate) decreased or remained unaffected in response to Mn-soil culture in Brassica, Hordeum, and Triticum but not in Zea. Because control and Mn-soil differed in pH (6.5 and 3.7), its impact on Mn uptake in solution culture was studied. Shoot Mn contents in Mn-treated plants were similar to those observed in soil culture (high in Brassica and low in Triticum) and pH had negligible impact.

# About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

From: Sent: Subject: Attachments: John Faulkner Wednesday, August 13, 2014 10:10 AM Your ILSI North America Science Briefs for July 2014 Food Safety Briefs July 2014.pdf; Nutrition Briefs July 2014 (2).PDF

Greetings:

I hope you are now enjoying the final weeks of summer!

The attached **Food Safety** and **Nutrition** Science Briefs are compiled each month after a review of articles published in the most recent issues of the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion are those we believe address areas of greatest interest to ILSI North America's technical and project committees.

Our **July** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

If you know someone in your organization who would like to receive these briefs, please pass their contact information along and I will add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Nutrition Briefs**

# July 2014

# Carbohydrates

# Amount, Type, and Sources of Carbohydrates in Relation to Ischemic Heart Disease Mortality in a Chinese Population: A Prospective Cohort Study

S.A. Rebello, H. Koh, C. Chen, N. Naidoo, A.O. Odegaard, W-P. Koh, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 53-64, 2014

Link to full text: Click here

**Significance:** The total amount of carbohydrates consumed was not associated with IHD mortality and the shifting of food sources of carbohydrates toward a higher consumption of fruit, vegetables, and whole grains was associated with lower risk of IHD death.

This study assessed whether intakes of total carbohydrates, different types of carbohydrates, and their food sources were associated with ischemic heart disease (IHD) mortality in 53,469 Chinese participants with an average follow-up of 15 y. Total carbohydrate intake was not associated with IHD mortality risk [men: HR per 5% of energy, 0.97 (95% CI: 0.92, 1.03); women: 1.06 (95% CI: 0.99, 1.14)]. When types of carbohydrates were analyzed individually, starch intake was associated with higher risk [men: 1.03 (95% CI: 0.99, 1.08); women: 1.08, (95% CI: 1.02, 1.14)] and fiber intake with lower risk of IHD mortality [men: 0.94 (95% CI: 0.82, 1.08); women: 0.71 (95% CI: 0.60, 0.84)]. The replacement of one daily serving of rice with noodles was associated with higher risk (difference in HR: 26.11%; 95% CI: 10.98%, 43.30%). In contrast, replacing one daily serving of rice with one of vegetables (-23.81%; 95% CI: -33.12%, -13.20%), fruit (-11.94%; 95% CI: -17.49%, -6.00%), or whole-wheat bread (-19.46%; 95% CI: -34.28%, -1.29%) was associated with lower risk of IHD death.

# **Type 2 Diabetes**

Comparative Effect of Two Mediterranean Diets Versus a Low-Fat Diet on Glycaemic Control in Individuals With Type 2 Diabetes

A. Lasa, J. Miranda, M. Bulló, R. Casas, J. Salas-Salvadó, I. Larretxi, et al. European Journal of Clinical Nutrition, Vol. 68, No. 7; pp. 767–772, 2014 Link to full text: Click here

**Significance:** Mediterranean diets supplemented with virgin olive oil or nuts reduced total body weight and improved glucose metabolism to the same extent as the usually recommended low-fat diet.

This multicentric parallel trial compared the effects of two Mediterranean diets supplemented with virgin olive oil (n=67) or mixed nuts (n=74) versus a low-fat diet (n=50) on several parameters and indices related to glycaemic control in type 2 diabetic subjects. Results showed that increased values of adiponectin/ leptin ratio (P=0.043, P=0.001 and P<0.001 for low-fat, olive oil and nut diets, respectively) and adiponectin/HOMA-IR ratio (P=0.061, P=0.027 and P=0.069

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

for low-fat, olive oil and nut diets, respectively) and decreased values of waist circumference (P=0.003, P=0.001 and P=0.001 for low-fat, olive oil and nut diets, respectively) were observed in the three groups. In both Mediterranean diet groups, but not in the low-fat diet group, this was associated with a significant reduction in body weight (P=0.347, P=0.003 and P=0.021 for low-fat, olive oil and nut diets, respectively).

#### Glycemic Index, Glycemic Load, and Risk of Type 2 Diabetes: Results From 3 Large US Cohorts and an Updated Meta-Analysis

S.N. Bhupathiraju, D.K. Tobias, V.S. Malik, A. Pan, A. Hruby, J.E. Manson, et al. American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 218–232, 2014 Link to full text: Click here

**Significance:** Higher dietary glycemic index and glycemic load are associated with increased risk of type 2 diabetes.

This prospective study examined the association of dietary glycemic index (GI) and glycemic load (GL) with type 2 diabetes (T2D) risk in 74,248 women from the Nurses' Health Study (1984–2008), 90,411 women from the Nurses' Health Study II (1991–2009), and 40,498 men from the Health Professionals Follow-Up Study (1986–2008) who were free of diabetes, cardiovascular disease, and cancer at baseline. During 3,800,618 person-years of follow-up, 15,027 cases of incident T2D were documented. In pooled multivariable analyses, those in the highest quintile of energy-adjusted GI had a 33% higher risk (95% CI: 26%, 41%) of T2D than those in the lowest quintile. Participants in the highest quintile of energy-adjusted GL had a 10% higher risk (95% CI: 2%, 18%) of T2D. Participants who consumed a combination diet that was high in GI or GL and low in cereal fiber had approximately 50% higher risk of T2D.

# **Cardiovascular Disease**

## Dietary Carotenoids are Associated with Cardiovascular Disease Risk Biomarkers Mediated by Serum Carotenoid Concentrations

Y. Wang, S-J. Chung, M.L. McCullough, W.O. Song, M.L. Fernandez, S.I. Koo, et al.

Journal of Nutrition, Vol. 144, No. 7; pp. 1067–1074, 2014

Link to full text: Click here

Significance: Serum carotenoids were mediators of dietary carotenoids and CVD risk biomarker associations, and serum  $\beta$ -carotene was a moderator of the dietary  $\beta$ -carotene and CRP association.

This population-based cross-sectional study assessed associations between individual dietary carotenoid intake and cardiovascular disease (CVD) risk biomarkers, and tested whether the serum carotenoid concentrations explain (mediate) or influence the strength of (moderate) the associations, if any association exists in 1312 men and 1544 women from the NHANES 2003–2006. After adjustment for covariates, significant inverse associations with LDL-cholesterol were observed for dietary  $\beta$ -carotene (P<0.05) and lutein + zeaxanthin (P<0.001), and with total homocysteine (tHcy) for dietary  $\beta$ -carotene (P<0.05), lycopene (P<0.05), and total carotenoids (P<0.05). Dietary lutein + zeaxanthin intake was also positively associated with HDL-cholesterol concentrations (P<0.01). Most of these associations were null after additional adjustment for corresponding serum carotenoid concentrations, indicating the complete mediation effects of serum carotenoids. Serum  $\beta$ -carotene significantly moderated the associations



between dietary  $\beta$ -carotene and C-reactive protein (CRP) (P-interaction<0.05), and quartile 4 of dietary  $\beta$ -carotene was associated with lower CRP concentrations only among participants with serum  $\beta$ -carotene > 0.43 µmol/L.

#### No Breakfast at Home: Association With Cardiovascular Disease Risk Factors in Childhood

S. Papoutsou, G. Briassoulis, M. Wolters, J. Peplies, L. Iacoviello, G. Eiben, et al. on behalf of the IDEFICS consortium

*European Journal of Clinical Nutrition*, Vol. 68, No. 7; pp. 829–834, 2014 Link to full text: Click here

**Significance:** For preschoolers, breakfast consumption was positively associated with the reduction in cardiovascular disease risk factors but results of regression models were mostly insignificant.

This cross-sectional study from eight European countries investigated the relationship between breakfast routine and cardiovascular disease (CVD) risk factors in 8863 children 2 to <10 years of age. Male school-aged no breakfast (NBrH) consumers compared with daily breakfast at home (DBrH) consumers were more likely to be overweight/obese (OR: 1.37, 95% CI=1.05–1.79), to have higher risk for HDL-cholesterol levels <40 mg/dl (OR: 1.69, 95% CI=1.24–2.30), triglycerides (TG) >75 mg/dl (OR: 1.65, 95% CI=1.24–2.19) and sum of skinfolds > the 90th percentile (OR: 1.32, 95% CI=1.0–1.76). Female school-aged NBrH consumers compared with DBrH consumers had a higher risk for waist circumference > the 90th percentile (OR: 1.70, 95% CI=1.14–2.51), HDL-cholesterol levels <40 mg/dl (OR: 1.65, 95% CI=1.23–2.21), TG >75 mg/dl (OR: 1.65, 95% CI=1.26–2.17) and total cholesterol/HDL-cholesterol ratio >3.5 (OR: 1.39, 95% CI=1.09–1.77). Male DBrH consumers 6 to <10 years of age had longer daily periods of moderate-to-vigorous physical activity periods compared with NBrH consumers ( $32.0\pm21.4 \times 27.5\pm18.8 \min/day$ , P<0.05).

#### Dietary Sugars and Cardiometabolic Risk: Systematic Review and Meta-Analyses of Randomized Controlled Trials of the Effects on Blood Pressure and Lipids

L.A. Te Morenga, A.J. Howatson, R.M. Jones, J. Mann American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 65–79, 2014 Link to full text: Click here

**Significance:** Dietary sugars influence blood pressure and serum lipids independent of effects of sugars on body weight.

This systematic review and meta-analysis of randomized controlled trials examined the effects of the modification of dietary free sugars on blood pressure and lipids. Systematic searches were conducted to August 2013 to identify studies that reported intakes of free sugars and at least one lipid or blood pressure outcome. The minimum trial duration was 2 wk. Thirty-nine of 11,517 trials identified were included; 37 trials reported lipid outcomes, and 12 trials reported blood pressure outcomes. Higher compared with lower sugar intakes significantly raised triglyceride concentrations [mean difference (MD): 0.11 mmol/L; 95% CI: 0.07, 0.15 mmol/L], total cholesterol (MD: 0.16 mmol/L; 95% CI: 0.10, 0.24 mmol/L), LDL-cholesterol (0.12 mmol/L; 95% CI: 0.05, 0.19 mmol/L), and HDLcholesterol (MD: 0.02 mmol/L; 95% CI: 0.00, 0.03 mmol/L). Subgroup analyses showed the most marked relation between sugar intakes and lipids in studies in which efforts were made to ensure an energy balance and when no difference in weight change was reported. Potential explanatory factors, including a weight



change, in most instances explained <15% of the heterogeneity between studies (I<sup>2</sup> = 36–75%). The effect of sugar intake on blood pressure was greatest in trials  $\geq$ 8 wk in duration [MD: 6.9 mm Hg (95% CI: 3.4, 10.3 mm Hg) for systolic blood pressure and 5.6 mm Hg (95% CI: 2.5, 8.8 mm Hg) for diastolic blood pressure].

### DHA-Enriched High–Oleic Acid Canola Oil Improves Lipid Profile and Lowers Predicted Cardiovascular Disease Risk in the Canola Oil Multicenter Randomized Controlled Trial

P.J.H. Jones, V.K. Senanayake, S. Pu, D.J.A. Jenkins, P.W. Connelly, B. Lamarche, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 88–97, 2014

Link to full text: Click here

**Significance:** Consumption of CanolaDHA, a novel DHA-rich canola oil, improves HDLcholesterol, triglycerides, and blood pressure, thereby reducing Framingham 10-y CHD risk scores compared with other oils varying in unsaturated fatty acid composition.

This randomized, double-blind, 5-period, crossover design study examined the effects of varying n-9, n-6, and longer-chain n-3 fatty acid composition on markers of coronary heart disease (CHD) risk. Volunteers with abdominal obesity consumed each of 5 identical fixed-composition diets with one of the following treatment oils (60 g/3000 kcal) in beverages: 1) conventional canola oil (Canola; n-9 rich), 2) high-oleic acid canola oil with docosahexaenoic acid (CanolaDHA; n-9 and n-3 rich), 3) a blend of corn and safflower oil (25:75) (CornSaff; n-6 rich), 4) a blend of flax and safflower oils (60:40) (FlaxSaff; n-6 and short-chain n-3 rich), or 5) high-oleic acid canola oil (CanolaOleic; highest in n-9); 130 individuals completed the trial. At endpoint, total cholesterol (TC) was lowest after the FlaxSaff phase (P<0.05 compared with Canola and CanolaDHA) and highest after the CanolaDHA phase (P<0.05 compared with CornSaff, FlaxSaff, and CanolaOleic). LDL- and HDL-cholesterol were highest, and triglycerides were lowest, after CanolaDHA (P<0.05 compared with the other diets). All diets decreased TC and LDL-cholesterol from baseline to treatment endpoint (P<0.05). CanolaDHA was the only diet that increased HDL-cholesterol from baseline (3.5±1.8%; P<0.05) and produced the greatest reduction in triglycerides (-20.7±3.8%; P<0.001) and in systolic blood pressure (-3.3±0.8%; P<0.001) compared with the other diets (P<0.05). Percentage reductions in Framingham 10-y CHD risk scores (FRS) from baseline were greatest after CanolaDHA  $(-19.0\pm3.1\%; P<0.001)$  than after other treatments (P<0.05).

## Rice Consumption is Not Associated With Risk of Cardiovascular Disease Morbidity or Mortality in Japanese Men and Women: A Large Population-Based, Prospective Cohort Study

E.S. Eshak, H. Iso, K. Yamagishi, Y. Kokubo, I. Saito, H. Yatsuya, et al. American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 199–207, 2014 Link to full text: Click here

**Significance:** Rice consumption is not associated with risk of cardiovascular disease morbidity or mortality.

The association between rice consumption and risk of cardiovascular disease (CVD) incidence and mortality was examined in a prospective study in 91,223 Japanese men and women aged 40–69 y. Follow-up for incidence was from 1990-2009 in cohort I and 1993-2007 in cohort II; for mortality was from 1990-2009 in cohort I and 1993-2009 in cohort II. In 15–18 y of follow-up, 4395 incident cases of stroke, 1088 incident cases of ischemic heart disease (IHD), and 2705



deaths from CVD were ascertained. Rice consumption was not associated with risk of incident stroke or IHD; the multivariable HR (95% CI) in the highest compared with lowest rice consumption quintiles was 1.01 (0.90, 1.14) for total stroke and 1.08 (0.84, 1.38) for IHD. Similarly, there was no association between rice consumption and risk of mortality from CVD; the HR (95% CI) for mortality from total CVD was 0.97 (0.84, 1.13). There were no interactions with sex or effect modifications by body mass index for any endpoint.

# Sugar-Sweetened Beverages

# The Relationship between Health-Related Knowledge and Sugar-Sweetened Beverage Intake among US Adults

S. Park, S. Onufrak, B. Sherry, H.M. Blanck Journal of the Academy of Nutrition and Dietetics, Vol. 114, No. 7; pp. 1059–1066, 2014 Link to full text: Click here

**Significance:** Knowledge about the adverse effects of sugar-sweetened beverage (SSB) intake is significantly associated with SSB intake among adults.

This cross-sectional study examined the association between health-related knowledge and sugar-sweetened beverage (SSB) intake using the 2010 HealthStyles Survey data for 3,926 adults (aged  $\geq$ 18 years). Multivariable logistic regression analysis was used to estimate the adjusted odds ratios and 95% CIs for drinking SSBs  $\geq$ 2 times/day. About 31% of adults consumed SSBs  $\geq$ 1 time/ day, with 20% doing so  $\geq$ 2 times/day. About 8 of 10 adults agreed that drinking SSBs can contribute to weight gain, yet, 8 of 10 adults did not know the actual kilocalorie content of a 24-oz fountain soda. After controlling for covariates, the odds for drinking SSBs  $\geq$ 2 times/day were significantly higher among adults who neither agreed nor disagreed that drinking SSBs can contribute to weight gain (OR=1.61, 95% CI 1.15-2.25 vs agree); however, knowledge about the energy content of regular soda was not associated with SSB intake.

### Consumption of Sugar-Sweetened Beverages Is Positively Related to Insulin Resistance and Higher Plasma Leptin Concentrations in Men and Nonoverweight Women

A. Lana, F. Rodríguez-Artalejo, E. Lopez-Garcia

Journal of Nutrition, Vol. 144, No. 7; pp. 1099-1105, 2014

Link to full text: Click here

**Significance:** The consumption of sugar-sweetened beverages was associated with higher concentrations of insulin and leptin and a higher HOMA-IR in men and in non-overweight women.

This study examined the association of habitual sugar-sweetened beverage (SSB) consumption with biomarkers of energy metabolism, including serum glucose, HgBA<sub>1</sub>C, insulin, homeostasis model assessment of insulin resistance (HOMA-IR), and leptin during 2008–2010 in 7842 individuals representative of the population of Spain aged 18–59 y. In men, a 1-serving (200 mL)/d increase in the consumption of SSBs was associated with higher plasma concentrations of insulin (2.14%, P=0.01), HOMA-IR (1.90%, P=0.04), and leptin (2.73%, P=0.01). Among women, these associations were found only in those with a BMI <25 kg/m<sup>2</sup> (insulin: 2.88%, P=0.004; HOMA-IR: 3.03%, P=0.01; and leptin: 4.57%, P=0.01) or with a waist circumference <80 cm (insulin: 2.79%, P=0.01; HOMA-IR: 3.00%, P=0.01; and leptin: 3.63%, P=0.05).



# Metabolic Syndrome

Added Value of Different Metabolic Syndrome Definitions for Predicting Cardiovascular Disease and Mortality Events among Elderly Population: Tehran Lipid and Glucose Study

A. Mozaffary, M. Bozorgmanesh, F. Sheikholeslami, F. Azizi, F. Eskandari, F. Hadaegh

European Journal of Clinical Nutrition, Vol. 68, No. 7; pp. 853–858, 2014 Link to full text: Click here

**Significance:** The WHO definition of metabolic syndrome was the strongest predictor of CVD and mortality outcomes.

This study examined the association between the different definitions of metabolic syndrome (MetS) and the prediction of incident cardiovascular disease (CVD) and mortality events and determined whether the concept of MetS adds to traditional risk factors among elderly Iranians. The association between MetS and outcomes was examined in 922 adults aged  $\geq$ 65 years and free of CVD at baseline. During a median follow-up of 9.9 years, 207 CVD events and 193 deaths (82 CVD deaths) occurred. World health organization (WHO) and the joint interim statement (JIS) definitions were shown to be the strongest predictors of CVD events. The WHO definition predicted CVD and all-cause mortality events (HR=1.55; 95% CI=1.15–2.09 and 2.08; 95% CI=1.23–3.51, respectively) and the JIS definition showed a risk for CVD mortality (HR=1.65; 95% CI=1.03–2.65)). Different definitions of MetS did not add to traditional risk factors in the prediction of different outcomes.

#### **Chronic Diseases**

### Nut Consumption and Risk of Type 2 Diabetes, Cardiovascular Disease, and All-Cause Mortality: A Systematic Review and Meta-Analysis

C. Luo, Y. Zhang, Y. Ding, Z. Shan, S. Chen, M. Yu, et al.

American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 256–269, 2014 Link to full text: Click here

LINK to full text: Click here

**Significance:** Nut intake is inversely associated with ischemic heart disease, overall cardiovascular disease, and all-cause mortality but not significantly associated with diabetes and stroke.

The relation between nut intake and incidence of type 2 diabetes (T2DM), cardiovascular disease (CVD), and all-cause mortality were assessed. PubMed and EMBASE databases were searched for all prospective cohort studies published through March 2013 with RRs and 95% CIs for outcomes of interest. In 31 reports from 18 prospective studies, there were 12,655 T2DM, 8862 CVD, 6623 ischemic heart disease (IHD), 6487 stroke, and 48,818 mortality cases. The RR (95% CIs) for each incremental serving per day of nut intake was 0.80 (95% CI: 0.69, 0.94) for T2DM without adjustment for BMI; with adjustment, the association was attenuated [RR: 1.03; 95% CI: 0.91, 1.16; NS]. In the multivariable-adjusted model, pooled RRs for each serving per day of nut consumption were 0.72 (0.64, 0.81) for IHD, 0.71 (0.59, 0.85) for CVD, and 0.83 (0.76, 0.91) for all-cause mortality. Pooled RRs for the comparison of extreme quantiles of nut intake were 1.00 (0.84, 1.19) for T2DM, 0.66 (0.55, 0.78) for IHD, 0.70 (0.60, 0.81) for CVD, 0.91 (0.81, 1.02) for stroke, and 0.85 (0.79, 0.91) for allcause mortality.



### Consumption of Nuts and Legumes and Risk of Incident Ischemic Heart Disease, Stroke, and Diabetes: A Systematic Review and Meta-Analysis

A. Afshin, R. Micha, S. Khatibzadeh, D. Mozaffarian American Journal of Clinical Nutrition, Vol. 100, No. 1; pp. 278–288, 2014 Link to full text: Click here

Significance: This systematic review supports inverse associations between eating nuts and incident ischemic heart disease and diabetes, and eating legumes and incident IHD.

This study systematically investigated and quantified associations of nut and legume consumption with incident ischemic heart disease (IHD), stroke, and diabetes. Multiple databases were searched to identify randomized controlled trials or observational studies that examined the relations. Of 3851 abstracts, 25 observational studies (23 prospective and 2 retrospective studies) and 2 trial reports met inclusion criteria and comprised 501,791 unique individuals and 11,869 IHD, 8244 stroke, and 14,449 diabetes events. The consumption of nuts was inversely associated with fatal IHD (6 studies; 6749 events; RR per 4 weekly 28.4-g servings: 0.76; 95% CI: 0.69, 0.84; I2 = 28%), nonfatal IHD (4 studies; 2101 events; RR: 0.78; 0.67, 0.92; I2 = 0%), and diabetes (6 studies; 13,308 events; RR: 0.87; 0.81,0.94; I2 = 22%) but not stroke (4 studies; 5544 events). Legume consumption was inversely associated with total IHD (5 studies; 6514 events; RR per 4 weekly 100-g servings: 0.86; 0.78, 0.94; I2 = 0%) but not significantly associated with stroke (6 studies; 6690 events) or diabetes (2 studies; 2746 events).

# About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org



# **Food Safety Briefs**

# July 2014

# Listeria

# Metal-Chelating Active Packaging Film Enhances Lysozyme Inhibition of Listeria monocytogenes

M.J. Roman, E.A. Decker, J.M. Goddard

Journal of Food Protection, Vol. 77, No. 7; pp. 1153-1160, 2014

Link to full text: Click here

**Significance:** Metal-chelating active packaging, which chelates metal ions based on ligand-specific interactions, in contrast to electrostatic interactions, may improve antimicrobial synergy.

This study examined the effect of metal-chelating active packaging film on the antimicrobial activity of lysozyme against Listeria monocytogenes. Polypropylene films were surface modified by photoinitiated graft polymerization of acrylic acid (PP-g-PAA) from the food contact surface of the films to impart chelating activity based on electrostatic interactions. PP-g-PAA exhibited a carboxylic acid density of  $113 \pm 5.4$  nmol cm–2 and an iron chelating activity of  $53.7 \pm 9.8$  nmol cm–2. PP-g-PAA hindered lysozyme activity at low ionic strength (2.48-log increase at 64.4 mM total ionic strength) and enhanced lysozyme activity at moderate ionic strength (5.22-log reduction at 120 mM total ionic strength). These data support the hypothesis that at neutral pH, synergy between carboxylate metal-chelating films (pKa bulk 6.45) and lysozyme (pI 11.35) is optimal in solutions of moderate to high ionic strength to minimize undesirable charge interactions, such as lysozyme absorption onto film.

## Stress Response and Adaptation of Listeria monocytogenes 08-5923 Exposed to a Sublethal Dose of Carnocyclin A

X. Liu, U. Basu, P. Miller, L.M. McMullen

Applied and Environmental Microbiology, Vol. 80, No. 13; pp. 3835-3841, 2014

Link to full text: Click here

**Significance:** A sublethal dose of Carnocyclin A induced adaptation in Listeria monocytogenes 08-5923 by inhibition of expression of genes and proteins critical for synthesis of cell wall structures and maintaining metabolic functions.

Carnocyclin A (CCLA) is an antimicrobial peptide produced by Carnobacterium maltaromaticum ATCC PTA-5313, which can be used to control the growth of Listeria monocytogenes in ready-to-eat meat products. The aim of this research was to elucidate the cellular responses of L. monocytogenes 08-5923 exposed to a sublethal dose of CCLA. Microarray, quantitative reverse transcription-PCR, tandem mass spectrometry, and electron microscopy were used to investigate the alteration in gene expression, protein production, and morphological changes in cells of Listeria following treatment with CCLA. The genes involved in metabolism, cell wall synthesis, and cell division were upregulated following a 15-min exposure to CCLA as a result of stress responses. Genes involved in cell division, cell wall synthesis, flagellar synthesis, and metabolism were downregulated after

# **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

4 h as a result of adaptation. Analysis of total soluble proteins confirmed the downregulation of pykA and gnd after 4 h of exposure to CCLA. The absence of flagella was observed in L. monocytogenes following 30 h of exposure to CCLA.

#### E. Coli

## Non-O157 Shiga Toxin–Producing Escherichia coli in U. S. Retail Ground Beef

Y-T. Liao, M.F. Miller, G.H. Loneragan, J.C. Brooks, A. Echeverry, M.M. Brashears Journal of Food Protection, Vol. 77, No. 7; pp. 1188-1192, 2014 Link to full text: Click here

**Significance:** The current research provides updated surveillance data for non-O157 STEC isolates among commercial ground beef products and information about potential sources of contamination from beef trims destined for ground beef production.

This study provided an estimate of the burden of the six serogroups (O26, O45, O103, O111, O121, and O145) of non-O157 Shiga toxin–producing Escherichia coli (STEC) in ground beef obtained from retail stores across the U.S. A convenience sample of commercial ground beef products (n=1,129) of various lean/ fat proportions, muscle group of origin (chuck, round, sirloin, or not specified), and packaging types were purchased from retail stores in 24 states from October 2011 to May 2012. For each ground beef sample, 25 g was inoculated in 225 ml of modified tryptic soy broth, stomached for 1 min, and then incubated at 41°C for 18 ± 2 h. Nine (0.8%) of the ground beef samples were potentially positive for at least one STEC serogroup after PCR screening. The serogroups detected by PCR assay were O26 (four samples), O103 (four samples), O145 (three samples), O45 (two samples), and O121 (one sample). No STEC isolates belonging to these serogroups were recovered from the sample cultures.

# Thermal Inactivation of Escherichia coli O157:H7 and Non-O157 Shiga Toxin–Producing Escherichia coli Cells in Mechanically Tenderized Veal

J.B. Luchansky, A.C.S. Porto-Fett, B.A. Shoyer, H. Thippareddi, J.R. Amaya, M. Lemler

Journal of Food Protection, Vol. 77, No. 7; pp. 1201-1206, 2014

Link to full text: Click here

**Significance:** Cooking times and temperatures effective for inactivating serotype O157:H7 strains of E. coli in tenderized veal are equally effective against the additional six non-O157 Shiga toxin-producing strains.

Preflattened veal cutlets were surface inoculated with a multistrain cocktail of Escherichia coli O157:H7 (ECOH) or a cocktail made of single strains of serogroups O26, O45, O103, O104, O111, O121, and O145 of Shiga toxin–producing E. coli (STEC) cells and then mechanically tenderized. For each cooking time in each of at least three trials, three inoculated and tenderized cutlets, with and without breading, were individually cooked in 15 or 30 ml of canola oil for 0.0, 0.75, 1.0, 1.25, 1.5, 1.75, or 2.25 min/side on an electric skillet set at 191.5°C. Regardless of the breading or volume of oil used to cook the meat, the longer the cooking times the higher the internal temperature of the meat, along with a greater reduction of both ECOH and STEC. The average final internal temperature at the approximate geometric center ranged from 56.8 to 93.1°C. Microbial reductions of ca. 2.0-6.7 log CFU/g and ca. 2.6-6.2 log CFU/g were achieved for ECOH and STEC, respectively. When cooking breaded cutlets, the use of more (30 ml) compared with less (15 ml) cooking oil resulted in greater reductions in pathogen numbers. To deliver about a 5.0-log reduction of ECOH and STEC,



and to achieve the recommended internal temperature of 71.1°C, it was necessary to cook mechanically tenderized veal cutlets for at least 1.5 min/side on a preheated electric skillet set at 191.5°C and containing 15 ml of cooking oil.

# Salmonella

# Salmonella Transfer Potential onto Tomatoes during Laboratory-Simulated In-Field Debris Removal

A. Sreedharan, K.R. Schneider, M.D. Danyluk Journal of Food Protection, Vol. 77, No. 7; pp. 1062-1068, 2014 Link to full text: Click here

**Significance:** The use of dirty cloths did not increase the risk of Salmonella cross-contamination.

This study examined Salmonella transfer from inoculated green tomatoes to uninoculated cloths and from inoculated cloths to uninoculated tomatoes, upon single and multiple touches. Tomatoes were spot inoculated with a rifampin-resistant Salmonella cocktail (107 CFU/ tomato) and were touched with clean, dirty-dry, and dirty-wet cloths at 0, 1, or 24 h postinoculation. The transfer direction was then reversed by touching freshly inoculated cloths with uninoculated tomatoes. Salmonella transfer coefficients (TCs) from inoculated tomato and cloth were highest when the inoculum was wet  $(0.44\pm0.13 \text{ to } 0.32\pm0.12)$ , regardless of the condition of the cloth. Although Salmonella TCs from inoculated tomato to uninoculated cloth decreased significantly when the inoculum was dried (0.17±0.23 to 0.01±0.00), low levels of Salmonella were detected on cloth even after 24 h of drying. Inoculated dirty cloth did not transfer more Salmonella compared with inoculated clean cloth, and Salmonella survival was not higher on dirty cloth. When inoculated clean cloth (wet) was touched with 25 tomatoes, significantly higher levels of Salmonella were transferred to the first, second, and fourth tomatoes (0.03±0.10 to 0.09±0.02). However, inoculated dirty-wet and dirty-dry (0.00 to 0.04±0.01) cloths transferred similar levels of Salmonella to all 25 tomatoes.

# Use of Enrichment Real-Time PCR To Enumerate Salmonella on Chicken Parts

T.P. Oscar

Journal of Food Protection, Vol. 77, No. 7; pp. 1086-1092, 2014 Link to full text: Click here

**Significance:** Retail chicken parts examined were contaminated with low levels of Salmonella, which resulted in low levels of cross-contamination during simulated meal preparation and serving.

Enrichment real-time PCR (qPCR) was used to enumerate Salmonella bacteria that contaminate raw chicken parts at retail or that cross-contaminate cooked chicken during simulated meal preparation and serving. Whole raw chickens obtained at retail were partitioned into wings, breasts, thighs, and drumsticks using a sterilized knife and cutting board, which were then used to partition a cooked chicken breast to assess cross-contamination. After enrichment in buffered peptone water (400 ml, 8 h, 40°C, 80 rpm), subsamples were used for qPCR and cultural isolation of Salmonella. Of 10 raw chickens examined, 7 (70%) had one or more parts contaminated with Salmonella. Of 80 raw parts examined, 15 (19%) were contaminated with Salmonella. Of 20 cooked chicken parts examined, 2 (10%) were cross-contaminated with Salmonella. Predominant serotypes identified were Typhimurium (71%) and its variants (var. 5–, monophasic,



and nonmotile) and Kentucky (18%). The number of Salmonella bacteria on contaminated parts ranged from one to two per part.

#### Survival of Salmonella on Dried Fruits and in Aqueous Dried Fruit Homogenates as Affected by Temperature

L.R. Beuchat, D.A. Mann

Journal of Food Protection, Vol. 77, No. 7; pp. 1102-1109, 2014

Link to full text: Click here

**Significance:** Dried fruits that may be contaminated with Salmonella should be subjected to a lethal process to prevent postprocess contamination before they are eaten out-of-hand or used as ingredients in ready-to-eat foods.

This study determined the ability of Salmonella to survive on dried cranberries, raisins, and strawberries and in date paste, as affected by storage temperature. Acid-adapted Salmonella, initially at 6.57 to 7.01 log CFU/g, was recovered from mist-inoculated cranberries (water activity [aw] 0.47) and raisins (aw 0.46) stored at 25°C for 21 days but not 42 days, strawberries (aw 0.21) for 42 days but not 84 days, and date paste (aw 0.69) for 84 days but not 126 days. In contrast, the pathogen was detected in strawberries stored at 4°C for 182 days (6 months) but not 242 days (8 months) and in cranberries, date paste, and raisins stored for 242 days. Surface-grown cells survived longer than broth-grown cells in date paste. The order of rate of inactivation at 4°C was cranberry > strawberry > raisin > date paste. Survival of Salmonella in aqueous homogenates of dried fruits as affected by fruit concentration and temperature was also studied. Growth was not observed in 10% (aw 0.995 to 0.999) and 50% (aw 0.955 to 0.962) homogenates of the four fruits held at 4°C, 50% homogenates at 25°C, and 10% cranberry and strawberry homogenates at 25°C. Growth of the pathogen in 10% date paste and raisin homogenates stored at 25°C was followed by rapid inactivation.

# In Situ Evaluation of Paenibacillus alvei in Reducing Carriage of Salmonella enterica Serovar Newport on Whole Tomato Plants

S. Allard, A. Enurah, E. Strain, P. Millner, S.L. Rideout, E.W. Brown, et al. Applied and Environmental Microbiology, Vol. 80, No. 13; pp. 3842-3849, 2014 Link to full text: Click here

**Significance:** The naturally occurring antagonist strain TS-15 is highly effective in reducing the carriage of Salmonella Newport on whole tomato plants.

A naturally occurring bacterium identified by 16S rRNA gene sequencing as Paenibacillus alvei was isolated epiphytically from tomato plants native to the Virginia Eastern Shore tomato-growing region. After initial antimicrobial activity screening against Salmonella and 10 other bacterial pathogens associated with the human food supply, strain TS-15 was further used to challenge an attenuated strain of Salmonella Newport on inoculated fruits, leaves, and blossoms of tomato plants in an insect-screened high tunnel with a split-plot design. Survival of Salmonella after inoculation was measured for groups with and those without the antagonist at days 0, 1, 2, and 3 and either day 5 for blossoms or day 6 for fruits and leaves. Strain TS-15 exhibited broad-range antimicrobial activity against both major food-borne pathogens and major bacterial phytopathogens of tomato. After P. alvei strain TS-15 was applied onto the fruits, leaves, and blossoms of tomato plants, the concentration of S. Newport declined significantly compared with controls. Astonishingly, >90% of the plants had no detectable levels of Salmonella by day 5 for blossoms.



#### Effect of Egg Washing and Correlation Between Cuticle and Egg Penetration by Various Salmonella Strains

V.C. Gole, J.R. Roberts, M. Sexton, D. May, A. Kiermeier, K.K. Chousalkar, et al. International Journal of Food Microbiology, Volumes 182–183, 16 July 2014; pp. 18–25, 2014

Link to full text: Click here

**Significance:** S. Singapore, S. Worthington, and S. Livingstone were not detected in egg internal contents whereas S. Adelaide was detected in one egg's internal contents.

The ability of four Salmonella isolates (S. Singapore, S. Adelaide, S. Worthington and S. Livingstone) to penetrate washed and unwashed eggs using whole egg and agar egg penetration methods were investigated in the current study. The results of the agar penetration experiment indicated that all the isolates used have the capacity to penetrate the eggshell. Eggshell penetration by the S. Worthington isolate was higher but not significant in washed eggs compared to unwashed eggs. There was no significant difference in penetration of washed and unwashed eggs for S. Singapore, S. Adelaide and S. Livingstone. Whole egg penetration results showed that all of the Salmonella isolates used were capable of surviving on the eggshell surface after 21 days of incubation (at 20 °C) following a high dose of inoculation (105 CFU/mL). The combined data of all isolates demonstrated that the survival rate of Salmonella on eggshells (inoculated with 105 CFU/mL) was significantly higher (p=0.002) at 20 °C as compared to 37 °C.

# **Mycotoxins**

# Exposure Assessment to Mycotoxins in Gluten-free Diet for Celiac Patients

C. Brera, F. Debegnach, B. De Santis, S. Di Ianni, E. Gregori, S. Neuhold, et al. Food and Chemical Toxicology, Vol. 69, July 2014; pp. 13–17, 2014 Link to full text: Click here

**Significance:** Exposure values of fumonisins and zearalenone were lower than the toxicological thresholds

The exposure of celiac patients to fumonisins (FBs) and zearalenone (ZON) was assessed in this study. The higher exposures, for all the matrices and for both the selected mycotoxins, were for children age group. The lower and upper bound exposure ranged between 348 and 582 ng/kg bw/day for FBs and 22 and 83 ng/kg bw/day for ZON; these values result well below the TDI for the selected mycotoxins, representing 17 to 29% and 9 to 33% of the TDI set for FBs and ZON, respectively. Even considering the worst scenario, the exposure values reported for children were lower, namely 1385 ng/kg bw/day for FBs and 237 ng/kg bw/day for ZON, than the corresponding toxicological thresholds.

# **Foodborne Pathogens**

# Fate of Escherichia coli O157:H7 and Salmonella on Whole Strawberries and Blueberries of Two Maturities under Different Storage Conditions

T.P. Nguyen, L.M. Friedrich, M.D. Danyluk Journal of Food Protection, Vol. 77, No. 7; pp. 1093-1101, 2014 Link to full text: Click here



**Significance:** E. coli O157:H7 and Salmonella do not grow on strawberries at shipping or retail display temperatures, even when they are harvested at a maturity prone to bruising.

This research determined the fate of Escherichia coli O157:H7 and Salmonella on bruised and intact surfaces of whole strawberries and blueberries at shipping (2°C) and retail display (15.5°C) temperatures. Strawberries and blueberries were either purchased from a supermarket or were harvested immediately prior to use; they were bruised using established protocols, were spot inoculated, and were incubated at 2 and 15.5°C. Strawberries were sampled at 0, 2, 5, and 24 h and on days 3 and 7; blueberries were sampled on days 0, 1, 3, and 7. At both storage temperatures, population declines for both E. coli O157:H7 and Salmonella were seen under all conditions for strawberries. At  $2 \pm 2°$ C, E. coli O157:H7 and Salmonella populations on blueberries declined over 7 days under all conditions. At  $15.5 \pm 2°$ C, E. coli O157:H7 populations declined; however, Salmonella populations over 7 days on blueberries. Modified atmospheric conditions did not affect the behavior of E. coli O157:H7 and Salmonella on strawberries at both temperatures.

# Inactivation Kinetics of Escherichia coli O157:H7, Salmonella enterica Serovar Typhimurium, and Listeria monocytogenes in Ready-to-Eat Sliced Ham by Near-Infrared Heating at Different Radiation Intensities J-W. Ha, D-H. Kang

Journal of Food Protection, Vol. 77, No. 7; pp. 1224-1228, 2014

Link to full text: Click here

**Significance:** This study and the proposed kinetics model would be beneficial to the deli meat industry for selecting the optimum processing conditions of near-infrared heating to meet the target pathogen inactivation on ready-to-eat sliced ham.

The aim of this study was to investigate the inactivation kinetics of Salmonella enterica serovar Typhimurium, Escherichia coli O157:H7, and Listeria monocytogenes on ready-to-eat sliced ham by near-infrared (NIR) heating as a function of the processing parameter, radiation intensity. Precooked ham slices inoculated with the three pathogens were treated at different NIR intensities (ca. 100, 150, and 200  $\mu$ W/cm2/nm). An increase in the applied radiation intensity resulted in a gradual increase of inactivation of all pathogens. The survival curves of the three pathogens exhibited both shoulder and tailing behavior at all light intensities. The log-logistic model more accurately described survival curves of the three pathogens than did the Weibull distribution at all radiation intensities.

# **Heavy Metals**

Study of the Migration Phenomena of Specific Metals in Canned Tomato Paste Before and After Opening. Validation of a New Quality Indicator for Opened Cans

K.G. Raptopoulou, I.N. Pasias, N.S. Thomaidis, C. Proestos Food and Chemical Toxicology, Vol. 69, July 2014; pp. 25–31, 2014 Link to full text: Click here

Significance: Fe and Pb were the main metals migrating in tomato paste samples.

A method for the simultaneous determination of Cd–Pb, As–Cu, Cr–Ni and Fe–Mn in canned tomato paste samples by Electrothermal Atomic Absorption



Spectrometry was developed and validated. The validated method was applied for the determination of these metals and metalloids in 13 different tomato paste samples and the results showed that Cd content was higher than the maximum permissible value of 0.050 mg kg–1. Furthermore, a new quality indicator was evaluated in order to provide information about tomato paste quality and the appropriate storage time of an opened canned tomato paste. A migration test was accomplished based on the calculation of mass balance and the comparison of the elemental content in canned tomato paste samples and in aseptic paper pack.

# Toxicity of Naturally-Contaminated Manganese Soil to Selected Crops

J. Kováčik, D. Štěrbová, P. Babula, P. Švec, J. Hedbavny Journal of Agricultural and Food Chemistry, Vol. 62, No. 29; pp. 7287–7296, 2014 Link to full text: Click here

**Significance:** Observed toxicity of manganese excess to common crops urges for selection of cultivars with higher tolerance.

The impact of manganese excess using naturally contaminated soil (Mn-soil, pseudototal Mn 6494 vs 675 µg g<sup>-1</sup> DW in control soil) in the shoots of four crops was studied. Mn content decreased in the order Brassica napus > Hordeum vulgare > Zea mays > Triticum aestivum. Growth was strongly depressed in Brassica (containing 13696 µg Mn g<sup>-1</sup> DW). Some essential metals (Zn, Fe) increased in Mn-cultured Brassica and Zea, while macronutrients (K, Ca, Mg) decreased in almost all species. Toxic metals (Ni and Cd) were elevated in Mn-soil. Microscopy of ROS, NO, lipid peroxidation, and thiols revealed stimulation in all Mn-cultured crops, but changes were less visible in Triticum, a species with low shoot Mn (2363  $\mu$ g g<sup>-1</sup> DW). Antioxidative enzyme activities were typically enhanced in Mn-cultured plants. Soluble phenols increased in Brassica only while proteins decreased in response to Mn excess. Inorganic anions (chloride, sulfate, and phosphate) were less accumulated in almost all Mn-cultured crops, while the nitrate level increased. Organic anions (malate, citrate, oxalate, acetate, and formate) decreased or remained unaffected in response to Mn-soil culture in Brassica, Hordeum, and Triticum but not in Zea. Because control and Mn-soil differed in pH (6.5 and 3.7), its impact on Mn uptake in solution culture was studied. Shoot Mn contents in Mn-treated plants were similar to those observed in soil culture (high in Brassica and low in Triticum) and pH had negligible impact.

# About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

From:	Ray DeVirgiliis
Sent:	Wednesday, August 06, 2014 1:32 PM
То:	Ray DeVirgiliis
Subject:	Report on Future Research Needs for Sugars & Health - Public Comment Request

# To: ILSI North America Colleagues Subject: Report on Future Research Needs for Sugars & Health available for public comment

The ILSI North America Carbohydrates Committee is funding a project conducted by investigators at Tufts University. The project, "The Future Research Needs (FRN) Assessment for Sugars & Health," is aiming to identify methodological strengths and limitations of previous studies to inform future research designs, identify and consolidate research gaps, and transform the research gaps into research needs, through an iterative process with a broad range of stakeholders. Stakeholder comments have been incorporated into the draft report, which is now available for public comment.

This FRN assessment identified and prioritized 14 research questions, covering 7 broad topic areas -- body weight, body composition, appetite or satiety, diet quality, diabetes risk, liver fat or liver health, and cardiovascular disease risks. The report is focused on the top three FRN topics and crosscutting research design issues. The investigators are seeking public comments on the research questions as well as feedback on this new FRN assessment approach in general.

# <u>Please help to strengthen the report by reading it and providing comments to the investigators by Wednesday, 13</u> <u>August 2014.</u> Please pass this notice along to colleagues who may be interested in providing comments.

Read and comment on the report here: Report on Sugar and Health Future Research Needs (FRN).

Ray DeVirgiliis Science Program Associate ILSI North America 1156 15<sup>th</sup> Street NW suite 200 Washington, D.C. 20005 (202) 659-0074 ext. 134 www.ILSINA.org Follow ILSI North America:

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with "unsubscribe" in the subject line".

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with "unsubscribe" in the subject line".

From: Sent: To:	Suzanne Harris > Monday, July 21, 2014 1:32 PM 's.chang@griffith.edu.au'; 'e	'; Joanne Lupton;								
Cc:	; Chelsea L. Bisho	op; ' '; Beth-								
	Ellen Berry; Shawn Sullivan; Beth Brueg	Ellen Berry; Shawn Sullivan; Beth Brueggemeyer								
Subject:	Agenda, briefing documents and dial-i	n instructions for the ILSI Financial Oversight								
	Committee conference call Monday,	Committee conference call Monday, July 28, beginning at 9:00 am EDT								
Attachments:	hments: FOC 2014-07-28 agd.doc; FOC 2014-04-29 minutes.docx; Final Survey Resul									
	Summary Memo ILSI BD 6-13-14.pdf; 2	Summary Memo ILSI BD 6-13-14.pdf; 2013 ILSI Consolidated Board Book.pdf; ILSI Ops								
	Q2 2014.pdf; ILSI Financial Statements	Q2 2014.pdf; ILSI Financial Statements 06302014.pdf; ILSI Board Q2 2014.pdf; ILSI								
	Financial Statements 06302014.pdf									

Please use this copy of the 2014 ILSI Year-to-date Financial report, rather than the one attached in the original email. This new one has more data.

Suzie

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The next quarterly conference call of the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Monday**, **July 28**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour. The dial-in instructions are at the end of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the April 29, 2014 conference call

Agenda Item III. 2013 Consolidated Audit report

Agenda Item IV. Investment recommendations and second quarter reports (operating reserve and Board-designated reserve)

Agenda Item V. 2014 Year-to-date financial report

Please let me know if you have any questions.

## **Dial-in Instructions**

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/3	30/2014 <sup>(1)</sup>		12/31/2013		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	687 794	\$	229 748	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ψ	617.528	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		17.780		104,586		169.244		119.954		257.151
Due From DC-Based ILSI Entities		301,588		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		22,963		27,908		16,979		24,342		31,626
Total Current Assets		1,647,653		1,494,421		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		339,461		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Total Other Assets		913,552		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		398,013		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
Leasehold Improvements		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		476,618		441,818		759,904		820,069		726,324
Total Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	-	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		102,965		104,768		103,744		80,695		79,435
Deferred Revenue		11,315		77,059		102,343		86,498		94,645
Total Current Liabilities		114,280		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		739,075		758,189		833,414		891,432		932,650
Total Long-Term Liabilities		985,075		1,004,189		1,079,414		1,137,432		1,178,650
Total Liabilities		1,099,355		1,270,336		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		348,497		(217,562)		(130,090)		323,092		453,081
I otal Net Assets		1,938,468		1,569,971		1,807,533		1,937,023		1,014,532
Total Liabilities and Net Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	695,824	\$	471,248	\$	681,148	\$	559,848	\$	418,355
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Strategic Planning Resources		36,504		43,411		-		-		-
Restricted Programs (PIP, GTF, Africa, Other)		477,803		360,036		107,907		151,425		38,850
International Branches (2012 and earlier included IFBiC)		154,247		148,772		748,871		957,905		892,430
I otal Net Assets	\$	1,938,468	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,533,372	\$	1,228,274	\$	1,493,287	\$	1,629,792	\$	1,467,396
Current Ratio <sup>(2)</sup>		14.42		5.62		6.18		6.29		6.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio s vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			COM	MUNICATION	S	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>			
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014 2014		% YTD/	2014	2014	% YTD/	
For the Six Months Ended June 30, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	
REVENUE	500.000	- 40 000	000/							500.000	740.000	000/	
BRANCH/INSTITUTE ASSESSMENT	509,339	740,000	69%	-	-	- N/A				509,339	740,000	69%	
CONTRIBUTIONS	30,034	35,000	00%	-	-	IN/A			IN/A	30,034	35,000	00% N/A	
	40 404	-	IN/A	-	-	IN/A			IN/A	49,421	97.069	IN/A	
	40,431	07,000	00%	-	-	IN/A			IN/A	40,431	07,000	00%	
	16 505	-	N/A	-	-	N/A	100.000	100.000		116 505	-	IN/A	
	10,595	-	N/A	-	-	N/A	100,000	207 050	E10/	100,595	207 050	N/A	
FUBLICATIONS - NOTRITION REVIEWS	-	-	IN/A	-	-	IN/A	199,204	327,032	0170	199,204	327,032	01%	
TOTAL REVENUE	604,399	862,068	70%	-	-	N/A	299,204	327,852	91%	903,603	1,189,920	76%	
EVENNER													
	E 400	6.640	0.00/	10,400	14 200	700/	225	2 250	1 4 0/	16 000	22.200	700/	
COMMUNICATIONS	5,490	6,640	03%	10,409	14,300	13%	325	2,350	14 %	10,229	23,290	70%	
FINANCIAL/PROFESSIONAL FEES	16,937	31,900	53%	-	-	N/A	-	-	N/A	16,937	31,900	53%	
											-		
GENERAL & ADMINISTRATIVE	64 477	107.000	E10/			N1/A			NI/A	64 477	107.000	E10/	
Snared Services Overnead	64,477	127,000	51%	-	-	N/A	-	-	N/A	64,477	127,000	51%	
Rent	24,607	47,146	52%	-	-	N/A	-	-	N/A	24,607	47,140	52%	
Depreciation	-	24,621	0%	-	-	N/A	-	-	N/A	-	24,621	0%	
Other Indirect Deimburgement	1,480	9,520	16%	4,988	6,000	83%	2,102	4,580	40%	8,576	20,100	43%	
Indirect Reimbursement	(127,453)	(290,906)	44%	70,035	145,905	40%	51,530	109,142	47 %	(5,200)	(35,001)	15%	
STAFFING											-		
Salaries	132,462	249.744	53%	64.330	130,739	49%	46.931	97,797	48%	243,723	478.280	51%	
Benefits	34,779	59.938	58%	14,153	31.377	45%	10.325	23,471	44%	59.257	114,787	52%	
Outside Services	2.684	1.400	192%	-	-	N/A			N/A	2.684	1.400	192%	
	,	,								,	-		
CONSULTANTS	6,000	10,550	57%	10,691	36,500	29%	1,800	-	N/A	18,491	47,050	39%	
			N1/A	05 050	50.000	E40/			N//A	05 050	-	E40/	
II SUPPORT SERVICES	-	-	N/A	25,350	50,000	51%	-	-	N/A	25,350	50,000	51%	
PUBLICATIONS	4,578	4,750	96%	4,974	15,000	33%	28,097	66,100	43%	37,648	85,850	44%	
											-		
MEETINGS											-		
I ravel - Board	57,380	46,000	125%	-	-	N/A	-	-	N/A	57,380	46,000	125%	
Travel - Staff	4,584	1,122	409%	3,838	4,000	96%	4,581	9,605	48%	13,002	14,727	88%	
I ravel - Advisors/Speakers/Invitees	8,676	14,484	60%	-	-	N/A	3,274 2,568		127%	11,950	17,052	70%	
I ravel - Credits	(25,614)	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A	
Group Functions/Business Meals	67,323	82,325	82%	-	-	N/A	162	750	22%	67,485	83,075	81%	
Other Expenses (Audiovisual/Mgmt Fee)	39,763	47,650	83%	939	1,000	94%	-	-	N/A	40,703	48,650	84%	
SUBTOTAL MEETINGS	152,112	191,581	79%	4,777	5,000	96%	8,017	12,923	62%	164,906	209,504	79%	
OTHER PROGRAM EXPENSES	750		N/A	-	-	N/A	-	-	N/A	750	-	N/A	
TOTAL EXPENSES	318,914	473,882	67%	210,307	434,821	48%	149,126	316,363	47%	678,347	1,225,066	55%	
CHANGE IN NET ASSETS	285,484	388,187		(210,307)	(434,821)		150,078	11,489		225,255	(35,146)		
NET ASSETS, BEGINNING OF PERIOD	1,812,896	1,812,896		(1,806,780)	(1,806,780)		1,075,046	1,075,046		- 1,081,163	- 1,081,163		
				(0.0/7.00									
NET ASSETS, END OF PERIOD	2,098,380	2,201,083		(2,017,087)	(2,241,601)		1,225,124	1,086,535		1,306,418	1,046,017		
	======			======			======	=======		======			

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.
INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTR	ICTED PROGR	AMS	INT'L BR	ANCH ACT	IVITY	SHAR	ED SERVICE	S		TOTAL	
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/
For the Six Months Ended June 30, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENUE												
BRANCH/INSTITUTE ASSESSMENT	-	-	N/A	-	-	N/A	-	-	N/A	509,339	740,000	69%
CONFERENCE/ REGISTRATION FEES			N/A	-		N/A	-	-	N/A	30,034	35,000	86%
CONTRIBUTIONS	269,331	168,000	160%	42,836	12,600	340%	-	-	N/A	312,167	180,600	173%
FEE FOR SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	48,431	87,068	56%
SHARED SERVICES REIMBURSEMENT	-	-	N/A	-	-	N/A	741,210	1,494,100	50%	741,210	1,494,100	50%
INVESTMENT AND OTHER INCOME	-	-	N/A	-	-	N/A	-	-	N/A	116,595	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	199,204	327,852	61%
TOTAL REVENUE	269,331	168,000	160%	42,836	12,600	 N/A	741,210	1,494,100	50%	1,956,980	2,864,620	68%
EXPENSES												
	311	1 555	20%	107	160	67%	28 444	42 000	68%	45 091	67 005	67%
COMMENCATIONS	511	1,000	2070	107	100	0770	20,444	42,000	0070	+0,001	07,000	01 /0
FINANCIAL/PROFESSIONAL FEES	40	-	N/A	12	-	N/A	20,554	56,700	36%	37,542	88,600	42%
GENERAL & ADMINISTRATIVE												
Shared Services Overhead	-	-	N/A	-	-	N/A	-	-	N/A	64,477	127,000	51%
Rent	-	-	N/A	-	-	N/A	72,647	143,700	51%	97,253	190,846	51%
Depreciation	-	-	N/A	-	-	N/A	-	18,000	0%	-	42.621	0%
Other	-	-	N/A	-	-	N/A	102.970	165.000	62%	111.546	185,100	60%
Indirect Reimbursement	2,872	30,539	9%	2,417	5,323	45%	-	-	N/A	-	-	N/A
				,								
STAFFING												
Salaries	2,615	27,364	10%	2,201	4,770	46%	413,081	840,000	49%	661,620	1,350,414	49%
Benefits	575	6,567	9%	484	1,145	42%	90,878	202,000	45%	151,194	324,499	47%
Outside Services	-	-	N/A	-	-	N/A	-	-	N/A	2,684	1,400	192%
CONSULTANTS	11,004	-	N/A	-	-	N/A	-	-	N/A	29,496	47,050	63%
IT SUPPORT SERVICES	-	-	N/A	-	-	N/A	1.395	9.000	15%	26.745	59.000	45%
							,	.,		-, -	,	
PUBLICATIONS	-	-	N/A	-	-	N/A	-	-	N/A	37,648	85,850	44%
MEETINGS												
Travel - Board	-	-	N/A	-	-	N/A	-	-	N/A	57.380	46.000	125%
Travel - Staff	1.472	5.000	29%	5.502	7.800	71%	9.274	10.000	93%	29,250	37.527	78%
Travel - Advisors/Speakers/Invitees	24,707	2.200	1123%	2.425	25.000	10%		-	N/A	39,082	44,252	88%
Travel - Credits	-	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A
Group Functions/Business Meals	1.232	1.300	95%	5.411	8.900	61%	1.969	7,700	26%	76.097	100.975	75%
Other Expenses (Audiovisual/Mamt Fee)	2.453	1.200	204%	3.283	2.860	115%	-	-	N/A	46,438	52,710	88%
SUBTOTAL MEETINGS	29,864	9,700	308%	16,621	44,560	37%	11,242	17,700	64%	222,634	281,464	79%
OTHER PROGRAM EXPENSES	104,282	5,000	2086%	15,520	13,500	115%	-	-	N/A	120,552	18,500	652%
TOTAL EXPENSES	151,564	80,725	188%	37,361	69,458	54%	741,210	1,494,100	50%	1,608,483	2,869,348	56%
CHANGE IN NET ASSETS	117,767	87,275		5,475	(56,858)		-			348,497	(4,728)	
NET ASSETS, BEGINNING OF PERIOD	360,036	360,036		148,772	148,772		-	-		1,589,971	1,589,971	
NET ASSETS, END OF PERIOD	477,803	447,311		154,247	91,914		-	-		1,938,468	1,585,243	
	================			======	=======		======	========		======	=========	

# **Portfolio Review**

# **ILSI - Board Designated Reserve**

1156 15th Street, NW Washington, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC



# **Market Commentary**

**ILSI - Board Designated Reserve** 

# **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### ILSI - Board Designated Reserve

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.42%	\$174,642.57	30.00%	\$172,227.31	(0.42%)	(\$2,415.26)
Short Bond	64.88%	\$372,467.31	65.00%	\$373,159.16	0.12%	\$691.85
Cash	4.70%	\$26,981.14	5.00%	\$28,704.55	0.30%	\$1,723.41
TOTAL		\$574,091.02		\$574,091.02		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Board Designated Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	570,177.85	566,503.83	269,574.23
Net Contributions	0.00	0.00	300,140.66
Capital Appreciation	2,625.44	5,483.62	(3,415.13)
Income	1,502.72	2,533.54	9,067.84
Management Fees	(214.99)	(429.97)	(1,276.58)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	574,091.02	574,091.02	574,091.02
INVESTMENT GAIN	3,913.17	7,587.19	4,376.13

# **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5), the Ministrate Borne benchmark (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012

**ILSI - Board Designated Reserve** 



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# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### ILSI - Board Designated Reserve

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	174,643	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	372,467	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	26,981	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	574,091	0.72%	1.42%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	574,091	0.69%	1.34%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Board Designated Reserve**

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	564,907	0	4,046	5,138	574,091	1.6%	1.6%
Intermediate Bond	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Vanguard Total Bond Market Fund	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Short Bond	369,813	0	1,050	1,604	372,467	0.7%	0.7%
DFA One Year Fixed	256,535	0	199	837	257,571	0.4%	0.4%
Vanguard Short-Term	113,278	0	851	767	114,896	1.4%	1.4%
Cash	27,833	0	0	(852)	26,981		
Sch Adv Cash Resrv Prem	27,833	0	0	(852)	26,981		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Disclaimers

**ILSI - Board Designated Reserve** 

## Disclosure

Any economic and/or performance information cited is historical and not indicative of future results. Performance results prepared by Raffa Wealth Management are compiled solely by Raffa Wealth Management and have not been independently verified. All information is obtained from sources believed to be reliable, but Raffa Wealth Management does not guarantee its reliability. You are encouraged to compare any account balance information communicated to you by Raffa Wealth Management to the account information sent to you from the account custodian. Indicies are not available for direct investment and performance does not reflect expenses of an actual portfolio. Returns are shown net of mutual fund expenses and RWM's advisory fee.

## **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/3	30/2014 <sup>(1)</sup>		12/31/2013		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	687 794	\$	229 748	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ψ	617.528	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		17.780		104.586		169.244		119.954		257.151
Due From DC-Based ILSI Entities		301,588		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		22,963		27,908		16,979		24,342		31,626
Total Current Assets		1,647,653		1,494,421		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		339,461		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Total Other Assets		913,552		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		398,013		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
Leasehold Improvements		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		476,618		441,818		759,904		820,069		726,324
Total Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	-	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		102,965		104,768		103,744		80,695		79,435
Deferred Revenue		11,315		77,059		102,343		86,498		94,645
Total Current Liabilities		114,280		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		739,075		758,189		833,414		891,432		932,650
Total Long-Term Liabilities		985,075		1,004,189		1,079,414		1,137,432		1,178,650
Total Liabilities		1,099,355		1,270,336		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		348,497		(217,562)		(130,090)		323,092		453,081
I otal Net Assets		1,938,468		1,569,971		1,807,533		1,937,023		1,014,532
Total Liabilities and Net Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	695,824	\$	471,248	\$	681,148	\$	559,848	\$	418,355
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Strategic Planning Resources		36,504		43,411		-		-		-
Restricted Programs (PIP, GTF, Africa, Other)		477,803		360,036		107,907		151,425		38,850
International Branches (2012 and earlier included IFBiC)		154,247		148,772		748,871		957,905		892,430
I otal Net Assets	\$	1,938,468	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,533,372	\$	1,228,274	\$	1,493,287	\$	1,629,792	\$	1,467,396
Current Ratio <sup>(2)</sup>		14.42		5.62		6.18		6.29		6.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio s vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

# **Portfolio Review**

ILSI - Operating Reserve 1156 15th Street, NW

Washingon, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC



# **Market Commentary**

**ILSI - Operating Reserve** 

# **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### **ILSI - Operating Reserve**

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.20%	\$186,463.44	30.00%	\$185,258.52	(0.20%)	(\$1,204.92)
Short Bond	65.16%	\$402,361.36	65.00%	\$401,393.45	(0.16%)	(\$967.91)
Cash	4.65%	\$28,703.59	5.00%	\$30,876.42	0.35%	\$2,172.83
TOTAL		\$617,528.39		\$617,528.39		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Operating Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	613,343.47	609,413.54	914,179.08
Net Contributions	0.00	0.00	(300,135.84)
Capital Appreciation	2,807.47	5,864.67	(7,054.33)
Income	1,608.71	2,712.71	12,399.20
Management Fees	(231.26)	(462.53)	(1,859.72)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	617,528.39	617,528.39	617,528.39
INVESTMENT GAIN	4,184.92	8,114.85	3,485.15

# **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

ILSI - Operating Reserve

\$900,000.00-					
\$850,000.00-					
\$800,000.00					
\$750,000.00-					
\$700,000.00-					
\$650,000.00-					
\$600,000.00					
\$550,000.00-					
\$500,000.00-					
\$450,000.00-					
\$400,000.00-					
\$350,000.00-					
\$300,000.00-					
\$250,000.00-					
\$200,000.00-					
\$150,000.00-					
\$100,000.00-					
\$50,000.00-					
\$0.00					
9/30/2012	12/31/2012	6/30/2013		12/31/2013	6/30/2014
		Portfolio Value	Cumulative Net Investment		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	186,463	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	402,361	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	28,704	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	617,528	0.72%	1.41%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	617,528	0.68%	1.33%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	607,699	0	4,331	5,498	617,528	1.6%	1.6%
Intermediate Bond	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Vanguard Total Bond Market Fund	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Short Bond	399,497	0	1,132	1,732	402,361	0.7%	0.7%
DFA One Year Fixed	277,404	0	215	905	278,525	0.4%	0.4%
Vanguard Short-Term	122,093	0	917	827	123,837	1.4%	1.4%
Cash	29,620	0	0	(917)	28,704		
Sch Adv Cash Resrv Prem	29,620	0	0	(917)	28,704		



# Disclaimers

**ILSI - Operating Reserve** 

## Disclosure

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## **Market Terms**

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#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.



Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

# Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

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- Board Communications Letter
- Internal Control Letter

# TAB 1



Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012 with Report of Independent Auditors

# Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012

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International Life Sciences Institute Statements of Financial Position
ILSI Research Foundation Statements of Financial Position



## Report of Independent Auditors

Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the accompanying consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization"), which comprise the consolidated statements of financial position as of December 31, 2013 and 2012 and the related consolidated statements of activities and cash flows for the years then ended and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Organization as of December 31, 2013 and 2012 and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

#### **Other Matters**

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The International Life Sciences Institute statements of financial position, statements of activities and statements of functional expenses and the ILSI Research Foundation statements of financial position, statements of activities and statements of functional expenses included within the supplemental information are presented for purposes of additional analysis rather than to present the financial position and changes in net assets of the individual entities and are not a required part of the consolidated financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the consolidated financial statements. The information has been subjected to the auditing procedures applied in the audit of the consolidated financial statements or to the consolidated financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the consolidated financial statements as a whole.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014

# Consolidated Statements of Financial Position

	December 31,				
	 2013		2012		
Assets					
Cash and cash equivalents - Note A	\$ 826,709	\$	1,330,090		
Investments - Note B	13,152,315		12,899,834		
Accounts and grants receivable	425,346		423,805		
Contributions receivable - Note H	321,866		801,500		
Amounts due from affiliates - Note D	449,121		113,619		
Rent receivable under shared services agreement - Note D	264,324		269,073		
Prepaid expenses and other assets	39,580		17,233		
Property and equipment, net - Note C	 847,914		825,089		
Total assets	\$ 16,327,175	\$	16,680,243		
Liabilities and net assets					
Liabilities:					
Accounts payable	\$ 238,593	\$	246,097		
Accrued expenses	195,455		181,753		
Deferred revenue	152,668		272,499		
Deposits payable to affiliates - Note D	206,000		206,000		
Deferred rent	 758,189		833,414		
Total liabilities	1,550,905		1,739,763		
Net assets:					
Unrestricted:					
Undesignated	540,746		766,071		
Board-designated	 12,105,683		11,856,077		
Total unrestricted net assets	12,646,429		12,622,148		
Temporarily restricted net assets - Note E	 2,129,841		2,318,332		
Total net assets	 14,776,270		14,940,480		
Total liabilities and net assets	\$ 16,327,175	\$	16,680,243		

# Consolidated Statement of Activities

# Year ended December 31, 2013

	 Unrestricted	 Temporarily Restricted		Total
Revenue:				
Contributions	\$ 155,000	\$ 1,011,189	\$	1,166,189
Nongovernment grants	1,331,156	-		1,331,156
Fees from affiliates - Note D	865,820	-		865,820
Branch assessments	608,894	-		608,894
Committee assessments	704,000	-		704,000
Publications	363,831	-		363,831
Investment income - Note B	286,573	-		286,573
Government grants	127,085	-		127,085
Meeting registration fees	47,194	-		47,194
Professional fees	 10,125	-		10,125
	4,499,678	1,011,189		5,510,867
Net assets released from restrictions - Note E	 1,199,680	(1,199,680)	_	-
Total revenue	5,699,358	(188,491)		5,510,867
Expenses:				
Program services:				
Center for Environmental Risk Assessment	1,680,680	-		1,680,680
Center for Risk Science Innovation and Application	459,696	-		459,696
Center for Nutrition and Health Promotion	138,332	-		138,332
Center for Integrated Modeling of Sustainable Agriculture and Nutrition				
Security	357,916	-		357,916
Center for Safety Assessment of Food and Feed	162,784	-		162,784
Global coordination	76,052	-		76,052
Communications	462,442	-		462,442
Annual meeting	308,837	-		308,837
Press	294,657	-		294,657
International Food Biotechnology Committee	698,751	-		698,751
Platform for International Partnerships/GTF	175,001	-		175,001
Branch international activity	139,156	-		139,156
Shared services	861,920	-		861,920
Total program services	 5,816,224	-		5,816,224
General and administrative	422,275	-		422,275
Program development	124,345	-		124,345
Total expenses	6,362,844	-		6,362,844
Change in net assets from operations	(663,486)	(188.491)		(851,977)
Net change in fair value of investments - Note B	687,767			687,767
Change in net assets	24.281	 (188.491)		(164.210)
Net assets, beginning of year	 12,622,148	 2,318,332		14,940,480
Net assets, end of year	\$ 12,646,429	\$ 2,129,841	\$	14,776,270

# Consolidated Statement of Activities

# Year ended December 31, 2012

		Unrestricted		Temporarily Restricted	 Total
Revenue:					
Grants and contributions	\$	26,500	\$	2,425,442	\$ 2,451,942
Nongovernment grants		899,037		-	899,037
Fees from affiliates - Note D		825,169		-	825,169
Branch assessments		585,179		-	585,179
Committee assessments		550,000		-	550,000
Publications		398,045		-	398,045
Investment income - Note B		377,788		-	377,788
Government grants		302,506		-	302,506
Meeting registration fees		45,397		-	45,397
Professional fees	_	25,030	_	-	 25,030
		4,034,651		2,425,442	6,460,093
Transfers between funds - Note E		(67,158)		67,158	-
Net assets released from restrictions - Note E		1,714,167		(1,714,167)	 -
Total revenue		5,681,660		778,433	 6,460,093
Expenses:					
Program services:					
Center for Environmental Risk Assessment		1,624,464		-	1,624,464
Center for Risk Science Innovation and Application		646,073		-	646,073
Center for Nutrition and Health Promotion		211,601		-	211,601
Center for Integrated Modeling of Sustainable Agriculture and Nutrition					
Security		65,674		-	65,674
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		221,790		-	221,790
Press		285,140		-	285,140
International Food Biotechnology Committee		681,323		-	681,323
International Organizations Committee/GTF		164,173		-	164,173
Branch international activity		221,771		-	221,771
Shared services		823,145		-	 823,145
Total program services		5,466,055		-	 5,466,055
General and administrative		355,875		-	355,875
Program development		56,171		-	 56,171
Total expenses		5,878,101		-	 5,878,101
Change in net assets from operations		(196,441)		778,433	 581,992
Net change in fair value of investments - Note B		60,518		-	60,518
Change in net assets		(135,923)		778,433	 642,510
Net assets, beginning of year		12,758,071		1,539,899	 14,297,970
Net assets, end of year	\$	12,622,148	\$	2,318,332	\$ 14,940,480

# Consolidated Statements of Cash Flows

		Years ended	ember 31, 2012	
Cash flows from operating activities		2013		2012
Change in net assets	\$	(164.210)	\$	642,510
Adjustments to reconcile change in net assets to net cash	Ψ	(101,210)	Ψ	012,010
used in operating activities:				
Depreciation		152,318		177,060
Net change in fair value of investments		(687,767)		(60,518)
Allowance for doubtful accounts		-		(4,000)
Changes in operating assets and liabilities:				
Accounts and grants receivable		(1,541)		(103,045)
Contributions receivable		479,634		(801,500)
Amounts due from affiliates		(359,624)		(88,229)
Rent receivable under shared services agreement		4,749		(6,369)
Prepaid expenses and other assets		(22,347)		13,802
Inventory		_		8,564
Accounts payable and accrued expenses		7,629		81,988
Deferred revenue		(119,832)		110,073
Deferred rent		(75,225)		(58,018)
Deposits payable to affiliates		22,694		51,519
Total adjustments		(599,312)	_	(678,673)
Net cash used in operating activities		(763,522)		(36,163)
Cash flows from investing activities				
Proceeds from sales or maturities of investments		1,280,654		13,540,936
Purchases and reinvestments of investments		(845,368)		(13,095,556)
Purchases of property and equipment		(175,145)		(148,292)
Net cash provided by investing activities		260,141		297,088
Net change in cash and cash equivalents		(503,381)		260,925
Cash and cash equivalents, beginning of year		1,330,090		1,069,165
Cash and cash equivalents, end of year	\$	826,709	\$	1,330,090

# Notes to the Consolidated Financial Statements

Years ended December 31, 2013 and 2012

## Note A - Organization and Summary of Significant Accounting Policies

#### Organization

International Life Sciences Institute ("ILSI") was incorporated under the laws of the District of Columbia in July 1978 in order to promote an understanding and resolution of nutrition, food safety, toxicology, risk assessment, and environmental issues worldwide. Through ILSI, scientific experts from the academic, government, industrial, and public sectors throughout the world collaborate on research and education programs at national and international levels.

ILSI has also established and chartered several branches located throughout the world. ILSI does not maintain a majority voting interest in the governing bodies of these branches; accordingly, these consolidated financial statements do not reflect the financial positions, changes in net assets, and cash flows of these branches.

The ILSI Research Foundation (the "Foundation"), an affiliate of ILSI, was formed in 1984 to create a philanthropic vehicle for ILSI to support original research. Its Board of Trustees, from public and private entities around the world, guide the Foundation in its mission to deliver ground-breaking science that is useful now and into the future. The Foundation's current priority areas of work are currently grouped into five centers of excellence, including The Center for Environmental Risk Assessment ("CERA"), The Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security ("CIMSANS"), The Center for Nutrition and Health Promotion ("CNHP"), The Center for Risk Science Innovation and Application ("RSIA") and The Center for Safety Assessment of Food and Feed ("CSAFF").

## Principles of consolidation

The consolidated financial statements include the accounts of ILSI and the Foundation (collectively, the "Organization"). Significant intra-entity accounts and transactions have been eliminated in consolidation.

## Income taxes

The Organization is exempt from the payment of income taxes on their exempt activities under Section 501(c)(3) of the Internal Revenue Code and is classified by the Internal Revenue Service ("IRS") as other than a private foundation within the meaning of Section 509(a)(1) of the Internal Revenue Code. They also believe that they have appropriate support for any tax positions taken, and as such, do not have any uncertain tax positions that are material to the consolidated financial statements as of December 31, 2013. Tax returns are generally subject to examination by the IRS and state authorities for three years after they were filed; there are no examinations being conducted.

# Notes to the Consolidated Financial Statements (Continued)

## Note A - Organization and Summary of Significant Accounting Policies (Continued)

## Basis of accounting

The Organization prepares its consolidated financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Accordingly, revenues are recognized when earned and expenses are recognized when the underlying obligations are incurred.

## Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from estimates.

## Cash and cash equivalents

For consolidated financial statement purposes, the Organization considers all demand deposit accounts and highly liquid instruments which are held for current operations to be cash and cash equivalents. All other highly liquid instruments, which are included within the Organization's investment portfolio are set aside for investment purposes.

## Investments and fair value measurement

Investments in money market funds, mutual funds and exchange traded funds are carried at fair value in accordance with U.S. GAAP. Interest and dividends are recorded in the consolidated statements of activities as investment income. Realized gains and losses and unrealized gains and losses are recorded as changes in fair value in the consolidated statements of activities. Gains and losses arising from the sale, maturity and other dispositions are accounted for on a specific identification basis calculated as of the trade date.

U.S. GAAP establishes a three-level hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities traded in active markets that the Organization has the ability to access.

Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability, for substantially the entire period, and market-corroborated inputs.

# Notes to the Consolidated Financial Statements (Continued)

## Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Investments and fair value measurement (continued)

Level 3 – Inputs to the valuation methodology are unobservable for the asset or liability and are significant to the fair value measurement.

## Credit risk

The Organization maintains demand deposits with commercial banks and money market funds with financial institutions. At times, certain balances held within these accounts may not be fully guaranteed or insured by the U.S. federal government. The uninsured portions of cash and money market accounts are backed solely by the assets of the underlying institution. As such, the failure of an underlying institution could result in financial loss to the Organization.

#### Market value risk

The Organization also invests some of its funds in professionally managed portfolios containing various types of equity securities. Such investments are exposed to market and credit risks. Therefore, the investment balances reported in the accompanying consolidated financial statements may not be reflective of the portfolio's value during subsequent periods.

## Accounts and grants receivable

Accounts and grants receivable primarily consist of amounts due for federal and non-federal grants and branch assessments. Accounts and grants receivable are presented net of an allowance for doubtful accounts, if any. The Organization's management periodically reviews the status of all accounts receivable balances for collectibility based on its knowledge of and relationship with the customer and the age of the receivable balance. As a result of these reviews, the Organization does not believe an allowance for doubtful accounts is necessary as of December 31, 2013 and 2012.

## Contributions receivable

Unconditional promises are recorded at their net realizable value. Conditional promises to give are not included as support until such time as the conditions set forth in the promise are substantially met.

## Property and equipment

Acquisitions of property and equipment greater than \$5,000 are capitalized at cost and depreciated, using the straight-line method, over the following estimated useful lives: furniture and equipment – four to ten years; computer software and equipment – three to five years; and leasehold improvements – over the ten-year term of the office lease or remaining portion thereof, unless the asset's useful life is estimated to be shorter. As discussed in Note C, certain property and equipment is restricted based on donor limitations.

# Notes to the Consolidated Financial Statements (Continued)

## Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Net assets

For consolidated financial statement purposes, net assets are classified as follows:

<u>Unrestricted</u>: Represents the portion of net assets whose use is not restricted by donors, even though their use may be limited in other respects, such as by board designation. Undesignated net assets represent the funds that are available to support the Organization's general operations. Board-designated net assets represent the funds that the Organization's Board of Trustees has determined should be reserved for long-term investment purposes. The Board has the right to approve expenditures from these reserved funds at any time.

<u>Temporarily restricted</u>: Represents the portion of net assets for which the the Organization has been restricted by donors with specified time or purpose limitations (see Note E).

#### *Contributions*

Contributions are recognized as revenue when received or unconditionally promised. Contributions are recorded as unrestricted, temporarily restricted, or permanently restricted support depending upon the existence and/or nature of donor restrictions. Support that is restricted by the donor is reported as an increase in temporarily or permanently restricted net assets when the contribution is recognized. When a restriction expires (that is, when a stipulated time restriction ends or a purpose restriction is accomplished), the amounts are reclassified to unrestricted net assets and reported in the consolidated statements of activities as net assets released from restriction. The Organization has not received any support with permanent donor restrictions.

## Grants

Grants received by the Organization are recognized as revenue on a cost reimbursement basis or based on significant milestones of the grant, depending on the nature of the agreement.

## Committee and branch assessments

Assessments are charged to committee members based on the activity budgeted for the respective committees each year and to the branches based on a percentage of their revenue. Assessments received in advance of the period to which they apply are recorded as deferred revenue until that period occurs.

# Notes to the Consolidated Financial Statements (Continued)

## Note A - Organization and Summary of Significant Accounting Policies (Continued)

## Functional allocation of expenses

The costs of providing various programs and other activities have been summarized on a functional basis in the consolidated statements of activities. Accordingly, indirect expenses have been allocated among the programs and supporting services benefited.

#### Subsequent events

The Organization has performed an evaluation of subsequent events through July 17, 2014, which is the date the consolidated financial statements were available to be issued and has considered any relevant matters in preparation of the consolidated financial statements and footnotes.

## Note B - Investments and Fair Value Measurements

Investments, recorded at fair value in accordance with the U.S. GAAP hierarchy, consist of the following at December 31:

			Fair Value
	2013	2012	Level
Money market funds	\$ 199,504	\$ 205,958	Level 1
Fixed income exchange traded funds	4,683,659	4,764,946	Level 1
Fixed income mutual funds	3,706,998	3,838,769	Level 1
Equity mutual funds	3,604,335	3,137,368	Level 1
Equity exchange traded funds	957,819	952,793	Level 1
Total investments, at fair value	\$13,152,315	\$12,899,834	

The Organization recognizes transfers between levels of the fair value hierarchy at the end of the period in which circumstances occur causing changes in availability of the fair value inputs. There were no transfers between levels during the years ended December 31, 2013 and 2012.

Investment return consists of the following for the years ended December 31:

	2013			2012
Investment income	\$	286,573	\$	377,788
Net change in fair value of investments		687,767		60,518
Total return on investments	\$	974,340	\$	438,306

Investment fees were \$21,859 and \$50,507 for the years ending December 31, 2013 and 2012, respectively.

# Notes to the Consolidated Financial Statements (Continued)

## Note C - Property and Equipment

Property and equipment consists of the following at December 31:

		2013		2012
Computer software and equipment	\$	845,507	\$	717,508
Furniture and equipment		125,470		125,470
Leasehold improvements		723,762		723,762
		1,694,739		1,566,740
Less accumulated depreciation		(846,825)		(741,651)
Property and equipment, net	<u>\$</u>	847,914	<u>\$</u>	825,089

Certain software included above is restricted for use in the Center for Safety Assessment of Food and Feed based on donor restrictions.

## **Note D - Related Party Transactions**

The Organization is part of an affiliated group of non-profit organizations, which includes ILSI North America ("ILSI N.A.") and ILSI Health and Environmental Sciences Institute ("HESI"), located in Washington, DC (the "Affiliated Organizations"), as well as several international branches. In the ordinary course of doing business, the Organization has a variety of financial transactions with these Affiliated Organizations.

Common expenses (such as accounting, legal, information technology, human resources, and business services) that benefit all of the Affiliated Organizations are governed by a shared services agreement, under which ILSI allocates these costs to each affiliate based on their total number of full-time equivalents. During the years ended December 31, 2013 and 2012, ILSI allocated \$439,474 and \$434,257, respectively, of the cost for these shared services to ILSI N.A., and allocated \$422,446 and \$388,888, respectively, of the cost for these shared services to HESI.

# Notes to the Consolidated Financial Statements (Continued)

## Note D - Related Party Transactions (Continued)

The following other transactions occurred between the Organization and a member of the above Affiliated Organizations during the years ended December 31, 2013 and 2012:

<u>Grants and contributions</u>: The Affiliated Organizations periodically award grants amongst each other for various scientific and research endeavors. During the years ended December 31, 2013 and 2012, the Organization paid ILSI N.A. \$28,000 and \$48,750, respectively, for grant projects. During each year ended December 31, 2013 and 2012, ILSI N.A. Food and Chemical Safety committee paid the Organization \$25,000 to conduct a Nano Release Food Additives study. During the year ended December 31, 2013, the Organization disbanded the ILSI International Food Biotechnology Committee and awarded a grant of \$88,702 to the HESI Protein Allergenicity Technical Committee ("PATC"). There were no grants awarded to HESI from the Organization during the year ended December 31, 2012. During the year ended December 31, 2013, ILSI awarded a grant totaling \$504,409 to the Foundation to form the Center for Safety Assessment of Food and Feed ("CCDB"). Use of the grant funds and software is restricted to the activities of CSAFF by ILSI. As of December 31, 2013, the stand-alone statements issued for the Foundation include \$260,092 of net assets restricted to the CSAFF CCDB and \$106,077 of net assets restricted to CSAFF. This intra-entity transaction has been eliminated in the consolidation.

<u>ILSI branch assessments</u>: As specified in its branch charter agreements, all members of an ILSI branch are automatically members of ILSI. Since ILSI does not collect its own dues from these members, ILSI instead charges an annual assessment to the branches in order to provide support for governance and coordination for ILSI's branches. During the years ended December 31, 2013 and 2012, ILSI charged \$150,000 for each of the years to both ILSI N.A. and HESI.

<u>Joint annual meeting</u>: The Organization and its affiliates participate in a joint annual meeting, and the affiliates hold their own board meetings and scientific sessions in conjunction with the meeting. ILSI collects each affiliate's share of the annual meeting income and pays in advance for a portion of the affiliates' share of the joint expenses of the meeting.

ILSI N.A. reimbursed ILSI a net of \$91,043 and \$52,525, respectively, for annual meeting activity for the years ended December 31, 2013 and 2012. HESI reimbursed ILSI a net of \$44,262 and \$34,835 for annual meeting activity for the years ended December 31, 2013 and 2012.
#### Notes to the Consolidated Financial Statements (Continued)

#### **Note D - Related Party Transactions (Continued)**

<u>Professional service fees</u>: From time to time, the Organization will utilize staff or other resources from another affiliate in carrying out its projects, or conversely, another affiliate will utilize staff or other resources of the Organization. The extent and use of these services is agreed to by the two affiliates in advance, and the affiliate requesting the resources is charged a professional fee as compensation. During both years ended December 31, 2013 and 2012, the Organization charged ILSI N.A. \$12,825 for providing these services.

<u>Due from affiliates</u>: At December 31, 2013 and 2012, ILSI N.A. owed the Organization \$384,877 and \$56,724, respectively, for shared services cost allocations, professional service fees, and various other reimbursements of expenses. At December 31, 2013 and 2012, HESI owed the Organization \$65,675 and \$56,895, respectively, for shared services cost allocations and professional service fees.

<u>Rent receivable under shared services agreement</u>: During 2008, ILSI entered into a lease for office space in Washington, D.C. (see Note G). Since the above affiliates all share the same office space with ILSI, ILSI allocated a portion of its deferred rent liability to each of the affiliates based on the number of full-time equivalents. As such, \$127,533 was allocated to ILSI N.A. and \$136,790 to HESI as of December 31, 2013. For the year ended December 31, 2012, ILSI allocated deferred rent of \$129,977 to ILSI N.A. and \$139,096 to HESI.

<u>Deposits</u>: As part of the shared services agreement, ILSI charged each affiliate a deposit to cover the period of time between when ILSI pays the shared service cost and when the affiliate reimburses ILSI. Deposits held by ILSI on behalf of each affiliate were as follows as of December 31:

	 2013	 2012
ILSI North America	\$ 116,000	\$ 116,000
ILSI Health and Environmental Sciences Institute	 90,000	 90,000
	\$ 206,000	\$ 206,000

### Notes to the Consolidated Financial Statements (Continued)

#### **Note E - Temporarily Restricted Net Assets**

Temporarily restricted net assets represent amounts contributed for the following donor-specified purposes:

	Ba	lance at				Transfers	Releases		Balance at
	Dec	ember 31,				Between	from	D	ecember 31,
		2012	Con	tributions		Funds	 Restriction		2013
Marketing department	\$	3,872	\$	-	\$	(3,872)	\$ -	\$	-
Platform in International Partnerships		56,509		96,000		(50,000)	(102,509)		-
ILSI Presence in Africa		-		10,000		3,872	(12,845)		1,027
Indonesian Food Safety Program		-		-		50,000	(22,187)		27,813
TCCC Fund		-		325,000		-	-		325,000
Staff Global Travel Fund		47,526		-		-	(9,885)		37,641
ILSI Focal Point in China		230,519		17,600		-	(112,636)		135,483
PAN		110,050		-		-	(3,973)		106,077
TAKE 10! program support		2,165		-		-	(2,165)		-
WIC		33,477		-		-	(24,197)		9,280
Branch activity		119,443		-		-	-		119,443
Global threshold/IAATFS		173,453		-		(173,453)	-		-
Translational nutrition		295,345		35,000		-	(97,951)		232,394
CERA		550,000		7,104		-	(307,104)		250,000
CSAFF		-		28,485		-	(28,485)		-
CIMSANS		567,061		320,000		-	(357,915)		529,146
ENAT		-		-		173,453	(17,362)		156,091
RSIA Risk perception		118,550		100,000		-	(46,586)		171,964
RSIA Nano III		-		47,000		-	(27,142)		19,858
RSIA Nano Release Food Additives		-		25,000		-	(25,000)		-
CARES CLA		10,362			_	-	 (1,738)		8,624
Total	\$	2,318,332	\$	1,011,189	\$	-	\$ (1,199,680)	\$	2,129,841
	Ba	lance at					Releases		Balance at
	Dec	ember 31.					from	D	ecember 31.
		2011	Con	tributions		Transfers	Restriction		2012
Marketing	\$	29.216	\$		\$	-	\$ (25,344)	\$	3.872
Platform in International Partnerships	·	-		146.000		67.158	(156.649)		56.509
Staff Global Travel Fund		55.050				-	(7,524)		47.526
ILSI Focal Point in China		327,634		27.667		-	(124,782)		230.519
PAN		110.050		-		-	-		110.050
TAKE 10! program support		5,000		-		-	(2.836)		2.164
WIC		50,950		30,000		-	(47,473)		33,477
Branch Activity		48,397		84,500		-	(13,454)		119.443
Global threshold/IAATFS		-		-		175,430	(1,977)		173,453

ILSI Focal Point in China	327,634	27,667	-	(124,782)	230,519
PAN	110,050	-	-	-	110,050
TAKE 10! program support	5,000	-	-	(2,836)	2,164
WIC	50,950	30,000	-	(47,473)	33,477
Branch Activity	48,397	84,500	-	(13,454)	119,443
Global threshold/IAATFS	-	-	175,430	(1,977)	173,453
Translational nutrition	-	50,000	385,472	(140,126)	295,346
CERA	144,395	1,136,118	-	(730,513)	550,000
CIMSANS	92,734	540,000	-	(65,673)	567,061
RSIA Risk perception	99,700	100,000	-	(81,150)	118,550
RSIA Nano	-	15,000	-	(15,000)	-
RSIA Nano Release Food Additives	-	112,500	-	(112,500)	-
CARES CLA	10,739	-	-	(377)	10,362
Meetings	-	3,882	-	(3,882)	-
Priority research campaign	560,902	-	(560,902)	-	-
RSIA Water re-use	-	60,000	-	(60,000)	-
JIFSAN Workshop report	5,132	-	-	(5,132)	-
IFBiC Committees	-	22,500	-	(22,500)	-
RSIA Nano Release		97,275		(97,275)	
Total	\$ 1,539,899	\$ 2,425,442	\$ 67,158	\$ (1,714,167)	\$ 2,318,332

#### Notes to the Consolidated Financial Statements (Continued)

#### Note F - Defined Contribution Pension Plan

The Organization has a Section 403(b) defined contribution retirement plan, which covers substantially all of its employees. Employer contributions to the plan are calculated at 7% of each participant's salary. Participants may also make voluntary elective deferrals to the plan. For the years ended December 31, 2013 and 2012, pension contribution expense totaled \$150,785 and \$130,751, respectively.

#### Note G - Commitments and Contingencies

#### Office Lease

In May 2008, ILSI entered into an operating lease for office space in Washington, DC, which commenced in September 2008 and expires in January 2019. ILSI received certain concessions from the lease agreement, which have been amortized over the lease term on a straightline basis. The unamortized portion of these incentives is reported as deferred rent in the consolidated statements of financial position.

Rent expense, net of amortized rent abatements and amounts allocated to affiliates that share space (see Note D), under the office space lease agreement totaled \$347,801 and \$265,307 for the years ended December 31, 2013 and 2012, respectively.

Approximate future annual minimum lease payments, subject to an annual operating expense increase, under various leases are as follows:

Year ending December 31,		
2014	\$	740,100
2015		760,100
2016		779,100
2017		798,600
2018		818,600
Thereafter		68,400
	<u>\$</u>	3,964,900

#### Federal Grants

The Foundation participates in some federally assisted grant programs which are subject to financial and compliance audits by federal agencies or their representatives. As such, there exists a contingent liability for potential questioned costs that may result from such an audit. Management does not anticipate any significant adjustments as a result of such an audit.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note G - Commitments and Contingencies (Continued)

#### Hotel Commitments

As of December 31, 2013, the Organization has entered into contracts with several hotels pertaining to future meetings. In the event that the Organization cancels or reduces its contracted provisions, it may be liable for certain penalties or liquidated damages, depending upon the date of cancellation. Minimum future cancellation fees for signed hotel contracts (excluding any applicable sales tax) is approximately \$713,000.

#### **Note H - Contributions Receivable**

Total contributions receivable outstanding as of December 31 are as follows:

	 2013	 2012
Due within 1 year	\$ 321,866	\$ 251,500
Due between 1 and 5 years	 _	 550,000
-	\$ 321,866	\$ 801,500

#### **Note I - In-Kind Contributions**

The Organization received in-kind program management services of \$120,000 and \$40,000 in 2013 and 2012, respectively. These amounts have been included in the consolidated statements of activities as contribution revenue and Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security expense.

Supplemental Information

# Statements of Financial Position

		Decem	ber 31	Ι,
	/	2013		2012
Assets				
Cash and cash equivalents	\$	229,748	\$	509,439
Investments		1,175,918		1,183,906
Accounts and grants receivable		104,586		169,244
Amounts due from affiliates		522,765		171,783
Rent receivable under shared services agreement		357,566		364,147
Prepaid expenses and other assets		27,898		16,977
Property and equipment, net		441,818		759,905
Total assets	\$	2,860,299	\$	3,175,401
Liabilities and net assets				
Liabilities:				
Accounts payable S	\$	84,320	\$	82,372
Accrued expenses		104,768		103,744
Deferred revenue		77,059		102,344
Deposits payable to affiliates		246,000		246,000
Deferred rent		758,189		833,414
Total liabilities		1,270,336		1,367,874
Net assets:				
Unrestricted:				
Undesignated		439,795		681,148
Board-designated		623,204		787,953
Total unrestricted net assets		1,062,999		1,469,101
Temporarily restricted		526,964		338,426
Total net assets		1,589,963		1,807,527
Total liabilities and net assets	\$	2,860,299	\$	3,175,401

# Statement of Activities

### Year ended December 31, 2013

	<u> </u>	Inrestricted	 Restricted		Total
Revenue:					
Fees from affiliates	\$	1,287,953	\$ -	\$	1,287,953
Committee assessments		704,000	-		704,000
Branch assessments		748,894	-		748,894
Publications		352,745	-		352,745
Conference registration fees		42,046	-		42,046
Investment income		13,494	-		13,494
Grants and contributions	_	95,000	 448,600		543,600
		3,244,132	448,600		3,692,732
Net assets released from restriction		260,062	 (260,062)		_
Total revenue		3,504,194	188,538		3,692,732
Expenses:					
Program services:					
Global coordination		76,052	-		76,052
Communications		462,442	-		462,442
Annual meeting		192,317	-		192,317
Press		294,657	-		294,657
International Food Biotechnology Committee (IFBiC)		1,203,160	-		1,203,160
Platform for International Partnerships (PIP)/GTF		175,001	-		175,001
International branches		118,533	-		118,533
Shared services		1,196,602	 		1,196,602
Total program services		3,718,764	-		3,718,764
General and administrative		171,809	 		171,809
Total expenses		3,890,573	 		3,890,573
Change in net assets from operations		(386,379)	188,538		(197,841)
Net change in fair value of investments		(19,723)	 		(19,723)
Change in net assets		(406,102)	188,538		(217,564)
Net assets, beginning of year		1,469,101	 338,426		1,807,527
Net assets, end of year	\$	1,062,999	\$ 526,964	<u>\$</u>	1,589,963

# Statement of Activities

### Year ended December 31, 2012

			Т	emporarily	
	U	nrestricted	]	Restricted	 Total
Revenue:					
Fees from affiliates	\$	1,208,934	\$	-	\$ 1,208,934
Committee assessments		550,000		-	550,000
Branch assessments		725,179		-	725,179
Publications		370,009		-	370,009
Conference registration fees		35,824		-	35,824
Investment income		32,640		-	32,640
Grants and contributions		_		196,167	 196,167
		2,922,586		196,167	3,118,753
Transfers between funds		(67,158)		67,158	-
Net assets released from restriction		336,799		(336,799)	 -
Total revenue		3,192,227		(73,474)	3,118,753
Expenses:					
Program services:					
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		133,156		-	133,156
Press		285,140		-	285,140
International Food Biotechnology Committee (IFBiC)		681,323		-	681,323
Platform for International Partnerships (PIP)/GTF		164,173		-	164,173
International branches		128,123		-	128,123
Shared services		1,115,458			 1,115,458
Total program services		3,028,274		-	3,028,274
General and administrative		193,322			 193,322
Total expenses		3,221,596			 3,221,596
Change in net assets from operations		(29,369)		(73,474)	(102,843)
Net change in fair value of investments		(27,246)			 (27,246)
Change in net assets		(56,615)		(73,474)	(130,089)
Net assets, beginning of year		1,525,716		411,900	 1,937,616
Net assets, end of year	\$	1,469,101	\$	338,426	\$ 1,807,527

# Statements of Functional Expenses

#### Years ended December 31, 2013 and 2012

							Program	m S	ervices										
	Coo	Global ordination	C	Commun- ications	1	Annual Meeting	 Press		IFBiC	Р	IP/GTF	-	International Branches		Shared Services	 Total	G Ad	eneral and ministrative	 2013 Total
Salaries and benefits	\$	22,225	\$	193,558	\$	6,450	\$ 114,199	\$	163,222	\$	35,638	\$	5,533	\$	949,664	\$ 1,490,489	\$	250,230	\$ 1,740,719
Research and program support		3,872		-		-	-		623,112		80,469		62,713		-	770,166		-	770,166
Travel and meetings		26,761		8,071		163,010	10,634		172,481		9,809		45,060		14,618	450,444		31,915	482,359
Rent		-		-		-	-		-		-		-		131,277	131,277		12,878	144,155
Depreciation		-		-		-	-		8,320		-		-		23,253	31,573		105,122	136,695
Publications		-		10,874		4,747	61,436		49,735		2,400		-		-	129,192		-	129,192
Consultants		1,145		53,191		-	-		25,913		12,845		-		6,374	99,468		19,893	119,361
Communications		1,661		13,772		3,820	1,644		10,739		1,416		137		55,497	88,686		2,915	91,601
Financial and professional services		-		-		4,170	-		70		-		-		52,328	56,568		26,665	83,233
Equipment and supplies		-		-		-	-		1,379		-		-		73,681	75,060		107	75,167
Other		386		8,774		4,315	3,965		1,289		350		110		30,872	50,061		11,030	61,091
Insurance		-		-		-	-		-		-		-		56,834	56,834		-	56,834
Overhead allocation		20,002		174,202		5,805	 102,779		146,900	_	32,074	_	4,980	_	(197,796)	 288,946		(288,946)	 
Total	\$	76,052	\$	462,442	\$	192,317	\$ 294,657	\$	1,203,160	\$	175,001	\$	118,533	\$	1,196,602	\$ 3,718,764	\$	171,809	\$ 3,890,573

								Program	m S	ervices										
	Co	Global ordination	(	Commun- ications	1	Annual Meeting	_	Press	_	IFBiC	F	PIP/GTF	_	International Branches	_	Shared Services	 Total		eneral and ministrative	 2012 Total
Salaries and benefits	\$	22,650	\$	150,929	\$	11,050	\$	111,715	\$	220,633	\$	35,825	\$	11,594	\$	821,893	\$ 1,386,289	\$	254,388	\$ 1,640,677
Research and program support		16,751		-		-		3,500		-		84,024		46,216		100	150,591		-	150,591
Travel and meetings		27,888		4,945		95,219		6,903		185,447		8,100		58,698		19,781	406,981		39,484	446,465
Rent		-		-		-		· -		-		· -		-		93,570	93,570		25,096	118,666
Depreciation		-		-		-		-		16,639		-		-		22,253	38,892		125,318	164,210
Publications		-		4,154		5,597		55,294		10,518		2,000		-		-	77,563		-	77,563
Consultants		3,000		107,243		595		-		34,631		900		-		125,989	272,358		10,797	283,155
Communications		886		15,130		3,158		2,817		13,118		1,081		80		47,627	83,897		5,712	89,609
Financial and professional services		-		-		3,019		355		-		-		-		40,532	43,906		25,762	69,668
Equipment and supplies		159		-		-		-		718		-		-		75,105	75,982		1,281	77,263
Other		-		10,943		4,575		4,014		1,047		-		1,100		28,946	50,625		4,738	55,363
Insurance		-		-		-		-		-		-		-		48,366	48,366		-	48,366
Overhead allocation		20,387		135,836		9,943	_	100,542	_	198,572	_	32,243	_	10,435		(208,704)	 299,254		(299,254)	 
Total	\$	91,721	\$	429,180	\$	133,156	\$	285,140	\$	681,323	\$	164,173	\$	128,123	\$	1,115,458	\$ 3,028,274	\$	193,322	\$ 3,221,596

# Statements of Financial Position

	December 31,							
		2013		2012				
Assets								
Cash and cash equivalents	\$	596,961	\$	820,651				
Investments		11,976,397		11,715,928				
Accounts and grants receivable, net		320,760		254,561				
Contributions receivable		321,866		801,500				
Prepaid expenses and other assets		11,682		257				
Property and equipment, net		406,096		65,183				
Deposit held by ILSI		40,000		40,000				
Total assets	\$	13,673,762	\$	13,698,080				
Liabilities and net assets								
Liabilities:								
Accounts payable	\$	154,273	\$	163,725				
Accrued expenses		90,687		78,009				
Deferred revenue		75,609		170,155				
Amounts due to affiliates		73,644		58,164				
Rent payable under shared services agreement		93,242		95,074				
Total liabilities		487,455		565,127				
Net assets:								
Unrestricted:								
Undesignated		100,951		84,923				
Board-designated		11,112,367		11,068,124				
Total unrestricted net assets		11,213,318		11,153,047				
Temporarily restricted net assets		1,972,989		1,979,906				
Total net assets		13,186,307		13,132,953				
Total liabilities and net assets	\$	13,673,762	\$	13,698,080				

# Statement of Activities

### Year ended December 31, 2013

		Temporarily	
	<u>Unrestricted</u>	Restricted	Total
Revenue:			
Nongovernment grants	\$ 1,331,156	\$-	\$ 1,331,156
Investment income	273,079	-	273,079
Publications	11,086	-	11,086
Government grants	127,085	-	127,085
Professional fees	10,320	-	10,320
Meeting registration fees	5,148	-	5,148
Contributions	60,000	1,066,998	1,126,998
	1,817,874	1,066,998	2,884,872
Net assets released from restriction	1,073,915	(1,073,915)	
Total revenue	2,891,789	(6,917)	2,884,872
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,680,680	-	1,680,680
Center for Risk Science Innovation and Application (RSIA)	459,696	-	459,696
Center for Nutrition and Health Promotion (CNHP)	138,332	-	138,332
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	357,916	-	357,916
Center for Safety Assessment of Food and Feed (CSAFF)	162,784	-	162,784
Annual meeting	116,520	-	116,520
Branch international activity	20,623		20,623
Total program services	2,936,551	-	2,936,551
Program development	124,345	-	124,345
General and administrative	478,112		478,112
Total expenses	3,539,008		3,539,008
Change in net assets from operations	(647,219)	(6,917)	(654,136)
Net change in fair value of investments	707,490		707,490
Change in net assets	60,271	(6,917)	53,354
Net assets, beginning of year	11,153,047	1,979,906	13,132,953
Net assets, end of year	<u>\$ 11,213,318</u>	\$ 1,972,989	\$ 13,186,307

# Statement of Activities

### Year ended December 31, 2012

		Temporarily	
	Unrestricted	Restricted	Total
Revenue:			
Nongovernment grants	\$ 899,037	\$ -	\$ 899,037
Investment income	345,148	-	345,148
Publications	28,036	-	28,036
Government grants	302,506	-	302,506
Professional fees	27,030	-	27,030
Meeting registration fees	9,573	-	9,573
Contributions	26,500	2,229,275	2,255,775
	1,637,830	2,229,275	3,867,105
Net assets released from restriction	1,377,368	(1,377,368)	
Total revenue	3,015,198	851,907	3,867,105
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,624,464	-	1,624,464
Center for Risk Science Innovation and Application (RSIA)	646,073	-	646,073
Center for Nutrition and Health Promotion (CNHP)	211,601	-	211,601
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	65,674	-	65,674
Annual meeting	88,634	-	88,634
Branch international activity	93,648		93,648
Total program services	2,730,094	-	2,730,094
Program development	56,171	-	56,171
General and administrative	396,005		396,005
Total expenses	3,182,270		3,182,270
Change in net assets from operations	(167,072)	851,907	684,835
Net change in fair value of investments	87,764		87,764
Change in net assets	(79,308)	851,907	772,599
Net assets, beginning of year	11,232,355	1,127,999	12,360,354
Net assets, end of year	<u>\$ 11,153,047</u>	<u>\$ 1,979,906</u>	<u>\$ 13,132,953</u>

# Statements of Functional Expenses

#### Years ended December 31, 2013 and 2012

				Program	ı Se	rvices									
	 CERA	 RSIA	 CNHP	 CIMSANS		CSAFF	 Annual Meeting	I	Branch nternational Activity	Total Program Expenses	 Program Development	A	General and Administrative		2013 Total
Salaries and benefits	\$ 647,892	\$ 218,658	\$ 20,799	\$ 137,432	\$	35,807	\$ 34,678	\$	7,063	\$ 1,102,329	\$ 83,000	\$	287,968 \$	5	1,473,297
Travel and meetings	359,496	10,283	28,746	47,625		5,845	62,982		332	515,309	3,796		5,397		524,502
Grants and research awards	104,214	43,000	67,500	130,100		80,000	-		10,000	434,814	-		-		434,814
Shared services costs	-	-	-	-		-	-		-	-	-		334,682		334,682
Consultants	208,379	70,391	4,887	33,481		5,430	-		-	322,568	-		-		322,568
ILSI assessment	-	-	-	-		-	-		-	-	-		140,000		140,000
Rent	-	-	-	-		-	-		-	-	-		136,131		136,131
Communications	26,567	8,062	2,375	1,399		2,663	544		50	41,660	200		1,382		43,242
Other	19,731	3,077	1,224	-		390	1,288		-	25,710	-		13,487		39,197
Financial and professional services	388	-	-	35		-	-		-	423	-		38,365		38,788
Publications	12,615	7,830	442	-		13,763	1,514		-	36,164	-		-		36,164
Depreciation	9,850	-	3,000	-		2,773	-		-	15,623	-		-		15,623
Overhead allocation	 291,548	 98,395	 9,359	 7,844		16,113	 15,514		3,178	 441,951	 37,349		(479,300)		-
Total	\$ 1,680,680	\$ 459,696	\$ 138,332	\$ 357,916	\$	162,784	\$ 116,520	\$	20,623	\$ 2,936,551	\$ 124,345	\$	478,112 \$	5	3,539,008

					<b>Program Service</b>	s								
	 CERA		RSIA	 CNHP	CIMSANS		Annual Meeting	I	Branch International Activity	Total Program Expenses	 Program Development	A	General and dministrative	 2012 Total
Salaries and benefits	\$ 562,233	\$	305,490	\$ 23,726	\$ 52,899	\$	31,733	\$	29,111	\$ 1,005,192	\$ 38,356	\$	202,431	\$ 1,245,979
Travel and meetings	462,252		68,698	2,381	6,664		37,828		5,705	583,528	362		1,340	585,230
Grants and research awards	94,065		50,000	148,590	-		-		43,500	336,155	-		-	336,155
Shared services costs	-		-	-	-		-		-	-	-		292,313	292,313
Consultants	212,674		66,255	10,996	-		145		650	290,720	-		300	291,020
ILSI assessment	-		-	-	-		-		-	-	-		140,000	140,000
Rent	-		-	-	-		-		-	-	-		129,797	129,797
Communications	17,506		13,097	526	307		1,499		1,190	34,125	183		1,103	35,411
Other	7,192		3,539	735	-		1,053		-	12,519	-		8,556	21,075
Financial and professional services	241		25	50	-		734		-	1,050	10		71,012	72,072
Publications	5,446		1,500	11,669	-		1,361		392	20,368	-		-	20,368
Depreciation	9,850		-	3,000	-		-		-	12,850	-		-	12,850
Overhead allocation	 253,005	· —	137,469	 9,928	5,804		14,281		13,100	 433,587	 17,260		(450,847)	 -
Total	\$ 1,624,464	\$	646,073	\$ 211,601	\$ 65,674	\$	88,634	\$	93,648	\$ 2,730,094	\$ 56,171	\$	396,005	\$ 3,182,270

# TAB 2



#### **Board Communications Letter**

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the consolidated financial statements of the International Life Sciences Institute and Affiliate (the "Organization") for the year ended December 31, 2013, and have issued our report thereon dated July 17, 2014.

The auditor is responsible for forming and expressing an opinion about whether the consolidated financial statements that have been prepared by management with the oversight of those charged with governance are presented fairly, in all material respects, in conformity with accounting principles generally accepted in the United States ("U.S. GAAP").

The auditor is also responsible for communicating significant matters related to the consolidated financial statement audit that are, in the auditor's professional judgment, relevant to the responsibilities of those charged with governance in overseeing the financial reporting process. Generally accepted auditing standards do not require the auditor to design procedures for the purpose of identifying other matters to communicate with those charged with governance.

Consistent with our professional standards, the policy of our firm and our personal commitments to keep the lines of communication open with you, management, and our audit team, we would like to share with you the following.

#### **Significant Accounting Policies and Their Application**

Management is responsible for the selection and use of appropriate accounting policies. As is the case with virtually all organizations, the Organization has available alternative accounting principles from which to choose. The significant accounting policies used by the Organization are described in Note A to the consolidated financial statements.

The accounting policies selected and applied by the Organization are appropriate under the circumstances and are consistent with those used by other not-for-profit organizations. No new significant accounting policies were adopted and the application of existing policies was not changed during 2013. We noted no transactions entered into by the Organization during the year for which there is a lack of authoritative guidance or consensus. We noted no significant transactions that have been recognized in the consolidated financial statements in a different period than when the transaction occurred.

#### Management's Judgments and Accounting Estimates

Financial statements require the use of accounting estimates and management judgments. Certain accounting estimates are particularly sensitive because of their significance to the consolidated financial statements and because of the possibility that future events affecting them may differ significantly from those expected. The most sensitive estimates affecting the consolidated financial statements were expense classification and the allowance for doubtful accounts. We performed procedures to gather sufficient evidence to support management's conclusions regarding these estimates and found them to be reasonable.

Certain consolidated financial statement disclosures are particularly sensitive because of management judgments involved and/or their significance to financial statement users. The most sensitive disclosures affecting the consolidated financial statements were:

- Note B: Investments and Fair Value Measurements
- Note D: Related Party Transactions
- Note E: Temporarily Restricted Net Assets
- Note G: Commitments and Contingencies

#### **Related Party Relationships and Transactions**

An objective of the audit with respect to related party relationships and transactions is to obtain an understanding of such matters sufficient to be able to recognize fraud risk factors that are relevant to the identification and assessment of the risks of material misstatement due to fraud and conclude whether the consolidated financial statements, insofar as they are affected by those relationships and transactions, achieve fair presentation. An objective of the audit also is to obtain sufficient appropriate audit evidence about whether related party relationships and transactions have been appropriately identified, accounted for and disclosed in the consolidated financial statements. Note D of the consolidated financial statements includes the disclosure of significant related party transactions.

#### Significant Difficulties in Performing the Audit

We are responsible for discussing with those charged with governance any significant difficulties encountered in dealing with management related to the performance of the audit. No significant difficulties were encountered in performing the audit.

#### **Management Representations and Uncorrected Misstatements**

We have requested certain representations from management that are included in the management representation letter dated July 17, 2014. We have included the management representation letter as an exhibit to this document. We did not identify any significant uncorrected misstatements.

#### Disagreements with Management, Including Matters Discussed and Resolved

We are responsible for discussing with those charged with governance any disagreements with management, whether or not satisfactorily resolved, about matters that individually or in the aggregate could be significant to the Organization's consolidated financial statements or the auditor's report. There were no disagreements with Management.

#### Audit and Management Post-Closing Adjustments

We did not propose any adjustments as a result of our audit.

#### Management's Consultations with Other Accountants

We are not aware of consultations with other accountants regarding audit or accounting issues.

#### Significant Issues Discussed, or Subject to Correspondence with Management

We are responsible for communicating with those charged with governance any significant issues that were discussed or were the subject of correspondence with management. We discussed the accounting and disclosure for the disbandment of the ILSI International Food Biotechnology Committee ("IFBiC").

#### **Consolidated Financial Statements Included in Client-Prepared Documents**

We are responsible for reading the information contained in client-prepared documents outside of the consolidated financial statements to determine if such information is materially consistent with the audited consolidated financial statements. We are not aware of any client-prepared documents that will contain the audited consolidated financial statements.

#### Independence

Johnson Lambert LLP is independent with respect to in accordance with the applicable independence rules.

This letter is intended solely for the information and use of you, the Board of Trustees and management and is not intended to be and should not be used by anyone other than these specified parties.

We appreciate the cooperation and courtesies extended to us by the Organization's personnel. Should you wish additional clarification of these or any other matters please ask.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

July 17, 2014

Johnson Lambert LLP 3110 Fairview Park Drive, Suite 800 Falls Church, VA 22042

Attn: Alex Murray

This representation letter is provided in connection with your audit of the consolidated financial statements of the International Life Sciences Institute (ILSI) and Affiliate ("the Organization") as of and for the years ended December 31, 2013 and 2012 for the purpose of expressing an opinion as to whether the consolidated financial statements present fairly, in all material respects, the consolidated financial position, activities, and cash flows of the Organization in accordance with accounting principles generally accepted in the United States (U.S.GAAP) and for the presentation of the supplemental information in accordance with the applicable criteria.

Certain representations in this letter are described as being limited to matters that are material. Items are considered material, regardless of size, if they involve an omission or misstatement of accounting information that, in the light of surrounding circumstances, makes it probable that the judgment of a reasonable person relying on the information would be changed or influenced by the omission or misstatement.

We confirm that, to the best of our knowledge and belief, as of the date of this letter, having made such inquiries as we considered necessary for the purpose of appropriately informing ourselves:

#### Financial Statements

- We have fulfilled our responsibilities, as set out in the terms of the audit engagement dated December 2, 2013 for the preparation and fair presentation of the consolidated financial statements in accordance with U.S. GAAP.
- We acknowledge our responsibility for the design, implementation, and maintenance of internal controls and programs relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.
- We acknowledge our responsibility to ensure that the Organization's operations are conducted in accordance with the provisions of laws and regulations, including compliance with the provisions of laws and regulations that determine the reported amounts in the Organization's consolidated financial statements.



- We acknowledge our responsibility for the design, implementation, and maintenance of internal control to prevent and detect fraud.
- Significant assumptions used by us in making accounting estimates, including those measured at fair value, are reasonable.
- All liabilities resulting from retirement obligations, deferred compensation agreements, and severance packages have been recorded in the consolidated financial statements and disclosed in the notes to the consolidated financial statements.
- Related party relationships and transactions have been appropriately accounted for and disclosed in accordance with the requirements of U.S. GAAP.
- All events subsequent to the date of the consolidated financial statements and for which U.S. GAAP requires adjustment or disclosure have been adjusted or disclosed.
- You did not bring to our attention any uncorrected audit differences during this engagement.
- The effects of all known actual or possible litigation and claims have been accounted for and disclosed in accordance with U.S. GAAP.
- Arrangements with financial institutions involving compensating balances or other arrangements involving restrictions on cash balances, line of credit, or similar arrangements have been properly disclosed.
- The Organization has no plans or intentions that may materially affect the carrying value or classification of assets and liabilities.
- Guarantees, whether written or oral, under which the Organization is contingently liable have been properly reported or disclosed in the consolidated financial statements.
- Material concentrations known to management have been properly disclosed in accordance with U.S.GAAP. Concentrations refer to volumes of business, revenues, available sources of supply, or markets or geographic areas for which events could occur that would significantly disrupt normal finances within the next year.



- The methods and significant assumptions as disclosed in the consolidated financial statements were used to determine fair values of financial instruments and result in a measure of fair value appropriate for consolidated financial statement measurement and disclosure purposes. The categorization of the Organization's investments into the hierarchical levels as defined by the accounting guidance, ASC 820, Fair Value Measurements, is based on the lowest level of significant input to the securities' valuation.
- In regards to the fact that your firm assisted us by drafting the consolidated financial statements and supplementary information, including appropriate disclosures required by U.S. GAAP, we have:
  - o Made all management decisions and performed all management functions.
  - Designated an individual, Beth-Ellen Berry, who possesses suitable skill, knowledge or experience to oversee the services.
  - Evaluated the adequacy and results of the draft preparation by reviewing and accepting the consolidated financial statements and supplementary information as complete and accurate.
  - Accepted responsibility for the consolidated financial statements and supplementary information.
- In regards to the supplemental information, we:
  - Note the methods of measurement or presentation have not changes from those used in the prior period.
  - Have notified you of any significant assumptions or interpretations underlying the measurement or presentation of the supplementary information; and
  - Note that when the supplementary information is not presented with the audited consolidated financial statements, management will make the audited consolidated financial statements readily available to the intended users of the supplementary information and the auditor's report thereon.
- The Organization has satisfactory title to all owned assets, and there are no liens or encumbrances on such assets nor has any asset been pledged as collateral.
- ILSI and the Affiliate are exempt organizations under 501(c)(3) of the Internal Revenue Code. Any activities that we are aware that would jeopardize the organizations' tax exempt status and all activities subject to tax on unrelated business income or excise tax or other tax have been disclosed to you. All required filings with tax authorities are up to date. We have not been informed of any tax reviews by federal or tax taxing authorities. There is no tax position considered to be uncertain if it was to undergo an inspection by the IRS or state authorities.



• Based on relevant information and discussion with the Board of Trustees, ILSI and the Affiliate appropriately recorded the disbandment of the IFBiC program and the recording of the temporarily restricted activity related to CSAFF resulting from this transaction.

#### Information Provided

- We have provided you with:
  - Access to all information, of which we are aware that is relevant to the preparation and fair presentation of the consolidated financial statements such as records, documentation and other matters;
  - Additional information that you have requested from us for the purpose of the audit; and
  - Unrestricted access to persons within the entity from whom you determined it necessary to obtain audit evidence.
- All transactions have been recorded in the accounting records and are reflected in the consolidated financial statements and supplementary information.
- All in-kind contributions have been reflected and disclosed appropriately in the consolidated financial statements.
- We have disclosed to you the results of our risk assessment as to how and where the consolidated financial statements may be materially misstated as a result of fraud.
- We have no knowledge of any fraud or suspected fraud that affects the entity and involves:
  - o Management;
  - o Employees who have significant roles in internal control; or
  - Others when the fraud could have a material effect on the consolidated financial statements.
- We have no knowledge of any allegations of fraud, or suspected fraud, affecting the entity's consolidated financial statements communicated by employees, former employees, analysts, regulators or others.
- We have disclosed to you all known instances of non-compliance or suspected noncompliance with laws and regulations whose effects should be considered when preparing consolidated financial statements.



- There have been no communications from regulatory agencies concerning noncompliance with or deficiencies in financial reporting that could have a material effect on the consolidated financial statements.
- We are not aware of any pending or threatened litigation and claims whose effects should be considered when preparing the consolidated financial statements.
- We have disclosed to you the identity of the entity's related parties and all the related party relationships and transactions of which we are aware.

Beth-Ellen Berry

Chief Financial Officer

Suzanne Harris Executive Director



#### Internal Control Letter

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

In planning and performing our audit of the consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization") as of and for the year ended December 31, 2013, in accordance with auditing standards generally accepted in the United States of America, we considered its internal control over financial reporting ("internal control") as a basis for designing our auditing procedures for the purpose of expressing our opinion on the consolidated financial statements, but not for the purpose of expressing our opinion on the effectiveness of the Organization's internal control. Accordingly, we do not express an opinion on the effectiveness of the Organization's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct misstatements on a timely basis. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis.

Our consideration of internal control was for the limited purpose described in the first paragraph and was not designed to identify all deficiencies in internal control that might be deficiencies, significant deficiencies, or material weaknesses We did not identify any deficiencies in internal control that we consider to be material weaknesses, as defined above.

This communication is intended solely for the information and use of you, the Board of Trustees, management and others within the Organization and is not intended to be and should not be used by anyone other than these specified parties.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014



# Memorandum

То:	Beth-Ellen Berry
From:	Mark Murphy, CFA Raffa Wealth Management, LLC
Date:	June 13, 2014
Subject:	Summary of Survey Results and Recommendations

Members of the International Life Sciences Institute (ILSI) staff and Financial Oversight Committee completed a survey in an effort to gain consensus on the appropriate risk level for the Board Designated Reserve portfolio. Six individuals participated in the survey. The following outline summarizes the results of the survey and Raffa Wealth Management's evaluation and recommended asset allocation strategy for the portfolio.

RWM evaluated the survey results as well as used conversations it had with key personnel and reviewed the organization's financial documents to gain better clarity of ILSI's ability to take risk. RWM then considered all of this information to propose our recommended target asset allocations for ILSI.

#### **Board Designated Reserve:**

# 1) Which of the following statements most accurately reflects the objective(s) of the investments in the portfolio?

- A) 0 To provide stability and safety of principal, growth is not a consideration
- B) 3 Primary objective is to provide stability, secondary is long term growth
- C) 3 Providing stability and long term growth are equal priorities
- D) 0 Primary objective is long term growth, secondary is to provide stability.
- E) 0 Maximize growth of principal, stability is not a consideration.

# Question 1



# *2) How concerned are you with variability in the market value of the Portfolio?*

- A) 2 Very concerned with the variability in the portfolio value
- B) 3 Somewhat concerned with the year-to-year variability, but more concerned with long term growth
- C) 1 Focused on the long-term growth of the Portfolio, unconcerned with the short-term variability



# 3) Please select the time horizon you have in mind for the investments in the Long Term Reserve portfolio.

- A) 1 Three Years
- B) 5 Five Years
- C) 0 Seven Years
- D) 0 Ten Years



**Question 3** 

# 4) Based on the time period you selected in Question 3 select the portfolio which you think best describes your tolerance for loss:

- A) 2 Portfolio A (20% Stock, 80% Bond)
- B) 3 Portfolio B (40% Stock, 60% Bond)
- C) 0 Portfolio C (60% Stock, 40% Bond)
- D) 1 Portfolio D (80% Stock, 20% Bond)



#### **Recommendation:**

It is our recommendation that the target asset allocation for the Board Designated Reserve be a mix of 40% stocks and 60% bonds. This recommendation is based on the following:

- 1. Respondents' opinion of the primary objective of the portfolio tilts towards stability (bonds) over growth (stocks).
- 2. Consensus that the year to year volatility can be accepted and that the portfolio is to be evaluated over a period of five years.
- 3. Indication that the respondents' tolerance for loss skewed towards a more conservative portfolio with higher allocations to fixed income than stocks.
- 4. Considering the portfolio's long term focus, the overall desire of the Financial Oversight Committee to take a more growth oriented stance with the portfolio, the lack of need to withdraw funds from the portfolio historically, but the potential for the reserve to be used to cover strategic initiatives, and the survey results; RWM recommends the portfolio have a balanced portfolio tilted towards a more stability oriented asset allocation.

#### ILSI Board of Trustees Financial Oversight Committee

#### Conference Call Tuesday, April 29, 2014

#### **DRAFT MINUTES**

#### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began the conference call at approximately 9:00 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated: Dr. Todd Abraham, Dr. Sushila Chang, Dr. Gerhart Eisenbrand, Dr. Lewis Smith, Ms. Beth-Ellen Berry, Dr. Suzie Harris, and Mr. Shawn Sullivan. Mr. Mark Murphy, Raffa Wealth Management joined the call for his presentation.

Dr. Westring asked if there were any items to be added to the agenda (attached). None were offered.

#### II. Approval of Minutes from the November 5, 2013 Conference Call

The minutes were approved as distributed.

#### III. ILSI Reserve Fund Performance Report

Mr. Murphy reviewed the portfolio review for the ILSI-Operating Reserve. This document along with the portfolio review for the ILSI Board-restricted Reserve was distributed to the committee prior to the conference call. The operating reserve holds extra cash and is invested in exactly the same way as the Board-restricted reserve. The Raffa Wealth Management reports cover the period since September 2012, when Raffa took on the responsibility for managing these funds.

Page 2 of the operating reserve report contained commentary on the current market environment. Both ILSI funds are invested solely in fixed income instruments. Interest rates declined in the first quarter of 2014 and the yield on bonds rose, yielding a 1.84 percent return. There are concerns about the pace of global growth as well as political issues, e.g. Russia and Ukraine. However, the first quarter 2014 undid the negative returns of 2013.

The operating reserve is invested as called for in the investment policy – 5 percent in cash and 95 percent in fixed income instruments. These are further divided as 65 percent in short term, high quality bonds and 30 percent in intermediate bonds. This is a very conservative allocation which allows ILSI to access its fund rapidly should the need arise. The portfolio is also protected from the volatility of the stock market.

Page 4 of the report shows the actual earnings -- \$1100 over the past three months. For 2013, there was a net loss of \$356.88. Interest rates rose in the second quarter of 2013 and remained flat for the rest of the year. The portfolio is performing very close to the benchmark. Mr. Murphy noted that intermediate bonds perform less well as interest rates rise, but short term bonds are doing better. However, once the Raffa fee is accounted for, there has not been much gain in the value of the operating reserve portfolio. If the current environment holds for the full year, the portfolio will likely

show a 2.4 percent return. The expected return for short-term, high-quality bonds is between 0.75 and 2.0 percent over time.

The Board-designated reserve portfolio is invested in exactly the same way, so Mr. Murphy did not take time to review that report. He suggested that if the committee was interested in a more growth oriented allocation, Raffa would be pleased to undertake a policy review at no cost to the organization. The review would entail looking at the organization's financial needs for the foreseeable future (1-2 years) and surveying the committee for their risk tolerance related to the organization's funds. The process could be completed by the end of May. Ms. Berry said that the \$600,000 operating reserve is enough of a cushion for the organization, thus allowing some flexibility with the Board-designated reserve.

In response to a question about how ILSI's portfolio compares to those of other similarly situated nonprofit organizations, Mr. Murphy said that the operating reserve is appropriately invested, but that other groups are less conservative with long-term reserves. In his view, adding equities to the ILSI Board-designated reserve portfolio would be appropriate, a 40-60 percent ratio of equity to fixed income. Such a change could lead to an increase return of 1.5-3.5 percent.

**Action**: The committee agreed to ask Raffa to perform a policy review and to make recommendations for re-allocating the Board-designated reserve portfolio based on the results of the review.

#### IV. Review of 2014 Year-to-date Financial Report

The ILSI financial report for 2014 through March 31, 2014, (attached) was distributed to the committee prior to the conference call. Ms. Berry began her report with the balance sheet, which shows assets, liabilities and net assets as of a specific day – March 31, 2014 and the year-end for the past four years. The December 31, 2013 data are still unaudited. The audit will begin on May 5, but the balances listed for 2013 should be final. Current assets totaled \$1,634 million of which \$628,000 is cash in the SunTrust account. Ms. Berry noted that 2013 ILSI assessments for ILSI Brasil and ILSI Mexico have not been completely paid. ILSI Brasil owes \$17,780 and has been slowing in paying because of the difficulty of moving funds out of Brazil. ILSI Mexico owes \$3341 and is continuing to make payments.

Ms. Berry noted that the fixed assets line for computer software and equipment is increased because of capitalization of the ILSI website software. The cost of the 2014 ILSI Annual meeting (\$308,000) is included in the first quarter report. The remaining liabilities are all normal.

The Net Assets – Detail includes a list of restricted funds (including contribution from The Coca-Cola Company and assets held by ILSI Focal Point in China) as well as unrestricted funds and total \$1.536 million.

Next Ms. Berry reviewed the functional activity statement (income statement) for both the unrestricted functions (ILSI Governance and Coordination, Communications, and ILSI Press) and restricted functions. The branch assessments for 2014 will begin to be collected in June after the branches submit their 2013 financial statements. For ILSI GC (Governance and Coordination), the revenue from the 2014 ILSI Annual Meeting (conference/registration fee) was less than budgeted by about \$5000. The fee for service line captures Dr. Harris' time for serving as the ILSI Research Foundation executive director. Expenses for ILSI GC appear high in terms of percentages of the 2014 budget, because of the annual meeting expenses. The total meetings expenses are at 73 percent of budget. The 2014 annual meeting expenses

were under budget due to the credit provided by the Bermuda Tourism Bureau. ILSI GC received a \$25,000 credit. Total expenses for ILSI GC are at 48 percent of budget.

The revenue and expenses for Communications is as expected. ILSI Press revenue includes the editorial stipend (~\$80,000) from Wiley, ILSI's publishing partner for Nutrition Reviews, and the first quarter guaranteed royalty payment (~\$220,000). Besides the quarterly guaranteed royalty payments, ILSI Press usually receives a little extra from Wiley at the end of each year.

Ms. Berry then reviewed the restricted functions beginning with ILSI Platform for International Partnerships (PIP), which is in the Restricted Programs column. In terms of revenue, ILSI PIP received \$80,000 from the former Industry Council for Development (ICD) to support continuation of food safety capacity building programs in Ghana and Indonesia. The University of Ghana received its first 2014 payment of \$25,334 from ILSI PIP.

The International Branch Activity is comprised of funds belonging to the ILSI Focal Point in China, but kept in the ILSI account. These funds are used to cover the costs of the ILSI Focal Point in China participants at the ILSI Annual Meeting and to support fellows in food safety and physical activity. No fellows have been paid to date in 2014.

The Shared Services function includes the pooled costs for operating the four entities in the Washington DC office. These pooled costs for accounting, business administration, human resources, IT and legal are allocated back to the four entities based on full time equivalent staff. The costs at the end of the first quarter are in line with the 2014 budget.

#### V. **New Business**

None was offered.

#### VI. Next Steps

- Ms. Berry will work with Raffa Wealth Management to complete an investment policy review.
- The next conference call will be held on Monday, July 28, at 9:00 a.m. Eastern Daylight Time.

#### VII. Adjournment

As there was no further business, Dr. Westring ended the conference call at 9:50 a.m. Eastern Daylight Time.

#### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

#### Tuesday, April 29, 2014 9:00 – 10:00 am Eastern Daylight Time

#### AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the November 5, 2013 Conference Call
- III. ILSI Reserve Fund Performance Report Raffa Wealth Management
- IV. Review of 2014 Year-to-date Financial Report
- V. New Business
- VI. Next Steps
- VII. Adjournment

#### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

#### Monday, July 28, 2014 9:00 – 10:00 am Eastern Daylight Time

#### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the April 29, 2014 Conference Call
- III. 2013 Audit Report Johnson and Lambert
- IV. Review of ILSI Investment Policy Raffa Wealth Management
- V. Review of 2014 Year-to-date Financial Report
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

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#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on:

From:	Suzanne Harris <sharris@ilsi.org></sharris@ilsi.org>		
Sent:	Monday, July 21, 2014 1:32 PM		
То:	's.chang@griffith.edu.au'; '	e'; Joanne Lupton;	
	1		
Cc:	'; Chelsea L. Bish	op; ' ';	Beth-
	Ellen Berry; Shawn Sullivan; Beth Brueg	gemeyer	
Subject:	Agenda, briefing documents and dial-i	instructions for the ILSI Financial Over	sight
	Committee conference call Monday,	July 28, beginning at 9:00 am EDT	
Attachments:	FOC 2014-07-28 agd.doc; FOC 2014-04	-29 minutes.docx; Final Survey Results	and
	Summary Memo ILSI BD 6-13-14.pdf; 2	013 ILSI Consolidated Board Book.pdf; J	íLSI Ops
	Q2 2014.pdf; ILSI Financial Statements	06302014.pdf; ILSI Board Q2 2014.pdf; I	LSI
	Financial Statements 06302014.pdf		

Please use this copy of the 2014 ILSI Year-to-date Financial report, rather than the one attached in the original email. This new one has more data.

Suzie

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The next quarterly conference call of the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Monday**, **July 28**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour. The dial-in instructions are at the end of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the April 29, 2014 conference call

Agenda Item III. 2013 Consolidated Audit report

Agenda Item IV. Investment recommendations and second quarter reports (operating reserve and Board-designated reserve)

Agenda Item V. 2014 Year-to-date financial report

Please let me know if you have any questions.

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#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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# **Portfolio Review**

ILSI - Operating Reserve 1156 15th Street, NW

Washingon, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC


# **Market Commentary**

**ILSI - Operating Reserve** 

# **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### **ILSI - Operating Reserve**

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.20%	\$186,463.44	30.00%	\$185,258.52	(0.20%)	(\$1,204.92)
Short Bond	65.16%	\$402,361.36	65.00%	\$401,393.45	(0.16%)	(\$967.91)
Cash	4.65%	\$28,703.59	5.00%	\$30,876.42	0.35%	\$2,172.83
TOTAL		\$617,528.39		\$617,528.39		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Operating Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	613,343.47	609,413.54	914,179.08
Net Contributions	0.00	0.00	(300,135.84)
Capital Appreciation	2,807.47	5,864.67	(7,054.33)
Income	1,608.71	2,712.71	12,399.20
Management Fees	(231.26)	(462.53)	(1,859.72)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	617,528.39	617,528.39	617,528.39
INVESTMENT GAIN	4,184.92	8,114.85	3,485.15

# **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

ILSI - Operating Reserve

\$900,000.00-					
\$850,000.00-					
\$800,000.00					
\$750,000.00-					
\$700,000.00-					
\$650,000.00-					
\$600,000.00					
\$550,000.00-					
\$500,000.00-					
\$450,000.00-					
\$400,000.00-					
\$350,000.00-					
\$300,000.00-					
\$250,000.00-					
\$200,000.00-					
\$150,000.00-					
\$100,000.00-					
\$50,000.00-					
\$0.00					
9/30/2012	12/31/2012	6/30/2013		12/31/2013	6/30/2014
		Portfolio Value	Cumulative Net Investment		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	186,463	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	402,361	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	28,704	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	617,528	0.72%	1.41%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	617,528	0.68%	1.33%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	607,699	0	4,331	5,498	617,528	1.6%	1.6%
Intermediate Bond	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Vanguard Total Bond Market Fund	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Short Bond	399,497	0	1,132	1,732	402,361	0.7%	0.7%
DFA One Year Fixed	277,404	0	215	905	278,525	0.4%	0.4%
Vanguard Short-Term	122,093	0	917	827	123,837	1.4%	1.4%
Cash	29,620	0	0	(917)	28,704		
Sch Adv Cash Resrv Prem	29,620	0	0	(917)	28,704		



# Disclaimers

**ILSI - Operating Reserve** 

#### Disclosure

Any economic and/or performance information cited is historical and not indicative of future results. Performance results prepared by Raffa Wealth Management are compiled solely by Raffa Wealth Management and have not been independently verified. All information is obtained from sources believed to be reliable, but Raffa Wealth Management does not guarantee its reliability. You are encouraged to compare any account balance information communicated to you by Raffa Wealth Management to the account information sent to you from the account custodian. Indicies are not available for direct investment and performance does not reflect expenses of an actual portfolio. Returns are shown net of mutual fund expenses and RWM's advisory fee.

#### **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.



Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

# Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

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- Internal Control Letter

# TAB 1



Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012 with Report of Independent Auditors

# Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012

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Supplemental Information
International Life Sciences Institute Statements of Financial Position
ILSI Research Foundation Statements of Financial Position



#### Report of Independent Auditors

Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the accompanying consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization"), which comprise the consolidated statements of financial position as of December 31, 2013 and 2012 and the related consolidated statements of activities and cash flows for the years then ended and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Organization as of December 31, 2013 and 2012 and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

#### **Other Matters**

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The International Life Sciences Institute statements of financial position, statements of activities and statements of functional expenses and the ILSI Research Foundation statements of financial position, statements of activities and statements of functional expenses included within the supplemental information are presented for purposes of additional analysis rather than to present the financial position and changes in net assets of the individual entities and are not a required part of the consolidated financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the consolidated financial statements. The information has been subjected to the auditing procedures applied in the audit of the consolidated financial statements or to the consolidated financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the consolidated financial statements as a whole.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014

# Consolidated Statements of Financial Position

	December 31,				
		2013		2012	
Assets					
Cash and cash equivalents - Note A	\$	826,709	\$	1,330,090	
Investments - Note B		13,152,315		12,899,834	
Accounts and grants receivable		425,346		423,805	
Contributions receivable - Note H		321,866		801,500	
Amounts due from affiliates - Note D		449,121		113,619	
Rent receivable under shared services agreement - Note D		264,324		269,073	
Prepaid expenses and other assets		39,580		17,233	
Property and equipment, net - Note C		847,914		825,089	
Total assets	\$	16,327,175	\$	16,680,243	
Liabilities and net assets					
Liabilities:					
Accounts payable	\$	238,593	\$	246,097	
Accrued expenses		195,455		181,753	
Deferred revenue		152,668		272,499	
Deposits payable to affiliates - Note D		206,000		206,000	
Deferred rent		758,189		833,414	
Total liabilities		1,550,905		1,739,763	
Net assets:					
Unrestricted:					
Undesignated		540,746		766,071	
Board-designated		12,105,683		11,856,077	
Total unrestricted net assets		12,646,429		12,622,148	
Temporarily restricted net assets - Note E		2,129,841		2,318,332	
Total net assets		14,776,270		14,940,480	
Total liabilities and net assets	\$	16,327,175	\$	16,680,243	

# Consolidated Statement of Activities

## Year ended December 31, 2013

	 Unrestricted	 Temporarily Restricted		Total
Revenue:				
Contributions	\$ 155,000	\$ 1,011,189	\$	1,166,189
Nongovernment grants	1,331,156	-		1,331,156
Fees from affiliates - Note D	865,820	-		865,820
Branch assessments	608,894	-		608,894
Committee assessments	704,000	-		704,000
Publications	363,831	-		363,831
Investment income - Note B	286,573	-		286,573
Government grants	127,085	-		127,085
Meeting registration fees	47,194	-		47,194
Professional fees	 10,125	-		10,125
	4,499,678	1,011,189		5,510,867
Net assets released from restrictions - Note E	 1,199,680	(1,199,680)	_	-
Total revenue	5,699,358	(188,491)		5,510,867
Expenses:				
Program services:				
Center for Environmental Risk Assessment	1,680,680	-		1,680,680
Center for Risk Science Innovation and Application	459,696	-		459,696
Center for Nutrition and Health Promotion	138,332	-		138,332
Center for Integrated Modeling of Sustainable Agriculture and Nutrition				
Security	357,916	-		357,916
Center for Safety Assessment of Food and Feed	162,784	-		162,784
Global coordination	76,052	-		76,052
Communications	462,442	-		462,442
Annual meeting	308,837	-		308,837
Press	294,657	-		294,657
International Food Biotechnology Committee	698,751	-		698,751
Platform for International Partnerships/GTF	175,001	-		175,001
Branch international activity	139,156	-		139,156
Shared services	861,920	-		861,920
Total program services	 5,816,224	-		5,816,224
General and administrative	422,275	-		422,275
Program development	124,345	-		124,345
Total expenses	6,362,844	-		6,362,844
Change in net assets from operations	(663,486)	(188.491)		(851,977)
Net change in fair value of investments - Note B	687,767			687,767
Change in net assets	24.281	 (188.491)		(164.210)
Net assets, beginning of year	 12,622,148	 2,318,332		14,940,480
Net assets, end of year	\$ 12,646,429	\$ 2,129,841	\$	14,776,270

# Consolidated Statement of Activities

## Year ended December 31, 2012

		Unrestricted		Temporarily Restricted	 Total
Revenue:					
Grants and contributions	\$	26,500	\$	2,425,442	\$ 2,451,942
Nongovernment grants		899,037		-	899,037
Fees from affiliates - Note D		825,169		-	825,169
Branch assessments		585,179		-	585,179
Committee assessments		550,000		-	550,000
Publications		398,045		-	398,045
Investment income - Note B		377,788		-	377,788
Government grants		302,506		-	302,506
Meeting registration fees		45,397		-	45,397
Professional fees	_	25,030	_	-	 25,030
		4,034,651		2,425,442	6,460,093
Transfers between funds - Note E		(67,158)		67,158	-
Net assets released from restrictions - Note E		1,714,167		(1,714,167)	 -
Total revenue		5,681,660		778,433	 6,460,093
Expenses:					
Program services:					
Center for Environmental Risk Assessment		1,624,464		-	1,624,464
Center for Risk Science Innovation and Application		646,073		-	646,073
Center for Nutrition and Health Promotion		211,601		-	211,601
Center for Integrated Modeling of Sustainable Agriculture and Nutrition					
Security		65,674		-	65,674
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		221,790		-	221,790
Press		285,140		-	285,140
International Food Biotechnology Committee		681,323		-	681,323
International Organizations Committee/GTF		164,173		-	164,173
Branch international activity		221,771		-	221,771
Shared services		823,145			 823,145
Total program services		5,466,055		-	 5,466,055
General and administrative		355,875		-	355,875
Program development		56,171		-	 56,171
Total expenses		5,878,101		-	 5,878,101
Change in net assets from operations		(196,441)		778,433	 581,992
Net change in fair value of investments - Note B		60,518		-	60,518
Change in net assets		(135,923)		778,433	 642,510
Net assets, beginning of year		12,758,071		1,539,899	 14,297,970
Net assets, end of year	\$	12,622,148	\$	2,318,332	\$ 14,940,480

# Consolidated Statements of Cash Flows

		Years ended	Dec	ember 31, 2012
Cash flows from operating activities		2013		2012
Change in net assets	\$	(164.210)	\$	642,510
Adjustments to reconcile change in net assets to net cash	Ψ	(101,210)	Ψ	012,010
used in operating activities:				
Depreciation		152,318		177,060
Net change in fair value of investments		(687,767)		(60,518)
Allowance for doubtful accounts		-		(4,000)
Changes in operating assets and liabilities:				
Accounts and grants receivable		(1,541)		(103,045)
Contributions receivable		479,634		(801,500)
Amounts due from affiliates		(359,624)		(88,229)
Rent receivable under shared services agreement		4,749		(6,369)
Prepaid expenses and other assets		(22,347)		13,802
Inventory		_		8,564
Accounts payable and accrued expenses		7,629		81,988
Deferred revenue		(119,832)		110,073
Deferred rent		(75,225)		(58,018)
Deposits payable to affiliates		22,694		51,519
Total adjustments		(599,312)	_	(678,673)
Net cash used in operating activities		(763,522)		(36,163)
Cash flows from investing activities				
Proceeds from sales or maturities of investments		1,280,654		13,540,936
Purchases and reinvestments of investments		(845,368)		(13,095,556)
Purchases of property and equipment		(175,145)		(148,292)
Net cash provided by investing activities		260,141		297,088
Net change in cash and cash equivalents		(503,381)		260,925
Cash and cash equivalents, beginning of year		1,330,090		1,069,165
Cash and cash equivalents, end of year	\$	826,709	\$	1,330,090

## Notes to the Consolidated Financial Statements

Years ended December 31, 2013 and 2012

#### Note A - Organization and Summary of Significant Accounting Policies

#### Organization

International Life Sciences Institute ("ILSI") was incorporated under the laws of the District of Columbia in July 1978 in order to promote an understanding and resolution of nutrition, food safety, toxicology, risk assessment, and environmental issues worldwide. Through ILSI, scientific experts from the academic, government, industrial, and public sectors throughout the world collaborate on research and education programs at national and international levels.

ILSI has also established and chartered several branches located throughout the world. ILSI does not maintain a majority voting interest in the governing bodies of these branches; accordingly, these consolidated financial statements do not reflect the financial positions, changes in net assets, and cash flows of these branches.

The ILSI Research Foundation (the "Foundation"), an affiliate of ILSI, was formed in 1984 to create a philanthropic vehicle for ILSI to support original research. Its Board of Trustees, from public and private entities around the world, guide the Foundation in its mission to deliver ground-breaking science that is useful now and into the future. The Foundation's current priority areas of work are currently grouped into five centers of excellence, including The Center for Environmental Risk Assessment ("CERA"), The Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security ("CIMSANS"), The Center for Nutrition and Health Promotion ("CNHP"), The Center for Risk Science Innovation and Application ("RSIA") and The Center for Safety Assessment of Food and Feed ("CSAFF").

#### Principles of consolidation

The consolidated financial statements include the accounts of ILSI and the Foundation (collectively, the "Organization"). Significant intra-entity accounts and transactions have been eliminated in consolidation.

#### Income taxes

The Organization is exempt from the payment of income taxes on their exempt activities under Section 501(c)(3) of the Internal Revenue Code and is classified by the Internal Revenue Service ("IRS") as other than a private foundation within the meaning of Section 509(a)(1) of the Internal Revenue Code. They also believe that they have appropriate support for any tax positions taken, and as such, do not have any uncertain tax positions that are material to the consolidated financial statements as of December 31, 2013. Tax returns are generally subject to examination by the IRS and state authorities for three years after they were filed; there are no examinations being conducted.

## Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Basis of accounting

The Organization prepares its consolidated financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Accordingly, revenues are recognized when earned and expenses are recognized when the underlying obligations are incurred.

#### Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from estimates.

#### Cash and cash equivalents

For consolidated financial statement purposes, the Organization considers all demand deposit accounts and highly liquid instruments which are held for current operations to be cash and cash equivalents. All other highly liquid instruments, which are included within the Organization's investment portfolio are set aside for investment purposes.

#### Investments and fair value measurement

Investments in money market funds, mutual funds and exchange traded funds are carried at fair value in accordance with U.S. GAAP. Interest and dividends are recorded in the consolidated statements of activities as investment income. Realized gains and losses and unrealized gains and losses are recorded as changes in fair value in the consolidated statements of activities. Gains and losses arising from the sale, maturity and other dispositions are accounted for on a specific identification basis calculated as of the trade date.

U.S. GAAP establishes a three-level hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities traded in active markets that the Organization has the ability to access.

Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability, for substantially the entire period, and market-corroborated inputs.

## Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Investments and fair value measurement (continued)

Level 3 – Inputs to the valuation methodology are unobservable for the asset or liability and are significant to the fair value measurement.

#### Credit risk

The Organization maintains demand deposits with commercial banks and money market funds with financial institutions. At times, certain balances held within these accounts may not be fully guaranteed or insured by the U.S. federal government. The uninsured portions of cash and money market accounts are backed solely by the assets of the underlying institution. As such, the failure of an underlying institution could result in financial loss to the Organization.

#### Market value risk

The Organization also invests some of its funds in professionally managed portfolios containing various types of equity securities. Such investments are exposed to market and credit risks. Therefore, the investment balances reported in the accompanying consolidated financial statements may not be reflective of the portfolio's value during subsequent periods.

#### Accounts and grants receivable

Accounts and grants receivable primarily consist of amounts due for federal and non-federal grants and branch assessments. Accounts and grants receivable are presented net of an allowance for doubtful accounts, if any. The Organization's management periodically reviews the status of all accounts receivable balances for collectibility based on its knowledge of and relationship with the customer and the age of the receivable balance. As a result of these reviews, the Organization does not believe an allowance for doubtful accounts is necessary as of December 31, 2013 and 2012.

#### Contributions receivable

Unconditional promises are recorded at their net realizable value. Conditional promises to give are not included as support until such time as the conditions set forth in the promise are substantially met.

#### Property and equipment

Acquisitions of property and equipment greater than \$5,000 are capitalized at cost and depreciated, using the straight-line method, over the following estimated useful lives: furniture and equipment – four to ten years; computer software and equipment – three to five years; and leasehold improvements – over the ten-year term of the office lease or remaining portion thereof, unless the asset's useful life is estimated to be shorter. As discussed in Note C, certain property and equipment is restricted based on donor limitations.

# Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Net assets

For consolidated financial statement purposes, net assets are classified as follows:

<u>Unrestricted</u>: Represents the portion of net assets whose use is not restricted by donors, even though their use may be limited in other respects, such as by board designation. Undesignated net assets represent the funds that are available to support the Organization's general operations. Board-designated net assets represent the funds that the Organization's Board of Trustees has determined should be reserved for long-term investment purposes. The Board has the right to approve expenditures from these reserved funds at any time.

<u>Temporarily restricted</u>: Represents the portion of net assets for which the the Organization has been restricted by donors with specified time or purpose limitations (see Note E).

#### *Contributions*

Contributions are recognized as revenue when received or unconditionally promised. Contributions are recorded as unrestricted, temporarily restricted, or permanently restricted support depending upon the existence and/or nature of donor restrictions. Support that is restricted by the donor is reported as an increase in temporarily or permanently restricted net assets when the contribution is recognized. When a restriction expires (that is, when a stipulated time restriction ends or a purpose restriction is accomplished), the amounts are reclassified to unrestricted net assets and reported in the consolidated statements of activities as net assets released from restriction. The Organization has not received any support with permanent donor restrictions.

#### Grants

Grants received by the Organization are recognized as revenue on a cost reimbursement basis or based on significant milestones of the grant, depending on the nature of the agreement.

#### Committee and branch assessments

Assessments are charged to committee members based on the activity budgeted for the respective committees each year and to the branches based on a percentage of their revenue. Assessments received in advance of the period to which they apply are recorded as deferred revenue until that period occurs.

# Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Functional allocation of expenses

The costs of providing various programs and other activities have been summarized on a functional basis in the consolidated statements of activities. Accordingly, indirect expenses have been allocated among the programs and supporting services benefited.

#### Subsequent events

The Organization has performed an evaluation of subsequent events through July 17, 2014, which is the date the consolidated financial statements were available to be issued and has considered any relevant matters in preparation of the consolidated financial statements and footnotes.

#### Note B - Investments and Fair Value Measurements

Investments, recorded at fair value in accordance with the U.S. GAAP hierarchy, consist of the following at December 31:

			Fair Value
	2013	2012	Level
Money market funds	\$ 199,504	\$ 205,958	Level 1
Fixed income exchange traded funds	4,683,659	4,764,946	Level 1
Fixed income mutual funds	3,706,998	3,838,769	Level 1
Equity mutual funds	3,604,335	3,137,368	Level 1
Equity exchange traded funds	957,819	952,793	Level 1
Total investments, at fair value	\$13,152,315	\$12,899,834	

The Organization recognizes transfers between levels of the fair value hierarchy at the end of the period in which circumstances occur causing changes in availability of the fair value inputs. There were no transfers between levels during the years ended December 31, 2013 and 2012.

Investment return consists of the following for the years ended December 31:

		 2012	
Investment income	\$	286,573	\$ 377,788
Net change in fair value of investments		687,767	 60,518
Total return on investments	\$	974,340	\$ 438,306

Investment fees were \$21,859 and \$50,507 for the years ending December 31, 2013 and 2012, respectively.

# Notes to the Consolidated Financial Statements (Continued)

#### Note C - Property and Equipment

Property and equipment consists of the following at December 31:

	2013			2012
Computer software and equipment	\$	845,507	\$	717,508
Furniture and equipment		125,470		125,470
Leasehold improvements		723,762		723,762
		1,694,739		1,566,740
Less accumulated depreciation		(846,825)		(741,651)
Property and equipment, net	<u>\$</u>	847,914	<u>\$</u>	825,089

Certain software included above is restricted for use in the Center for Safety Assessment of Food and Feed based on donor restrictions.

#### **Note D - Related Party Transactions**

The Organization is part of an affiliated group of non-profit organizations, which includes ILSI North America ("ILSI N.A.") and ILSI Health and Environmental Sciences Institute ("HESI"), located in Washington, DC (the "Affiliated Organizations"), as well as several international branches. In the ordinary course of doing business, the Organization has a variety of financial transactions with these Affiliated Organizations.

Common expenses (such as accounting, legal, information technology, human resources, and business services) that benefit all of the Affiliated Organizations are governed by a shared services agreement, under which ILSI allocates these costs to each affiliate based on their total number of full-time equivalents. During the years ended December 31, 2013 and 2012, ILSI allocated \$439,474 and \$434,257, respectively, of the cost for these shared services to ILSI N.A., and allocated \$422,446 and \$388,888, respectively, of the cost for these shared services to HESI.

## Notes to the Consolidated Financial Statements (Continued)

#### Note D - Related Party Transactions (Continued)

The following other transactions occurred between the Organization and a member of the above Affiliated Organizations during the years ended December 31, 2013 and 2012:

<u>Grants and contributions</u>: The Affiliated Organizations periodically award grants amongst each other for various scientific and research endeavors. During the years ended December 31, 2013 and 2012, the Organization paid ILSI N.A. \$28,000 and \$48,750, respectively, for grant projects. During each year ended December 31, 2013 and 2012, ILSI N.A. Food and Chemical Safety committee paid the Organization \$25,000 to conduct a Nano Release Food Additives study. During the year ended December 31, 2013, the Organization disbanded the ILSI International Food Biotechnology Committee and awarded a grant of \$88,702 to the HESI Protein Allergenicity Technical Committee ("PATC"). There were no grants awarded to HESI from the Organization during the year ended December 31, 2012. During the year ended December 31, 2013, ILSI awarded a grant totaling \$504,409 to the Foundation to form the Center for Safety Assessment of Food and Feed ("CCDB"). Use of the grant funds and software is restricted to the activities of CSAFF by ILSI. As of December 31, 2013, the stand-alone statements issued for the Foundation include \$260,092 of net assets restricted to the CSAFF CCDB and \$106,077 of net assets restricted to CSAFF. This intra-entity transaction has been eliminated in the consolidation.

<u>ILSI branch assessments</u>: As specified in its branch charter agreements, all members of an ILSI branch are automatically members of ILSI. Since ILSI does not collect its own dues from these members, ILSI instead charges an annual assessment to the branches in order to provide support for governance and coordination for ILSI's branches. During the years ended December 31, 2013 and 2012, ILSI charged \$150,000 for each of the years to both ILSI N.A. and HESI.

<u>Joint annual meeting</u>: The Organization and its affiliates participate in a joint annual meeting, and the affiliates hold their own board meetings and scientific sessions in conjunction with the meeting. ILSI collects each affiliate's share of the annual meeting income and pays in advance for a portion of the affiliates' share of the joint expenses of the meeting.

ILSI N.A. reimbursed ILSI a net of \$91,043 and \$52,525, respectively, for annual meeting activity for the years ended December 31, 2013 and 2012. HESI reimbursed ILSI a net of \$44,262 and \$34,835 for annual meeting activity for the years ended December 31, 2013 and 2012.

## Notes to the Consolidated Financial Statements (Continued)

#### **Note D - Related Party Transactions (Continued)**

<u>Professional service fees</u>: From time to time, the Organization will utilize staff or other resources from another affiliate in carrying out its projects, or conversely, another affiliate will utilize staff or other resources of the Organization. The extent and use of these services is agreed to by the two affiliates in advance, and the affiliate requesting the resources is charged a professional fee as compensation. During both years ended December 31, 2013 and 2012, the Organization charged ILSI N.A. \$12,825 for providing these services.

<u>Due from affiliates</u>: At December 31, 2013 and 2012, ILSI N.A. owed the Organization \$384,877 and \$56,724, respectively, for shared services cost allocations, professional service fees, and various other reimbursements of expenses. At December 31, 2013 and 2012, HESI owed the Organization \$65,675 and \$56,895, respectively, for shared services cost allocations and professional service fees.

<u>Rent receivable under shared services agreement</u>: During 2008, ILSI entered into a lease for office space in Washington, D.C. (see Note G). Since the above affiliates all share the same office space with ILSI, ILSI allocated a portion of its deferred rent liability to each of the affiliates based on the number of full-time equivalents. As such, \$127,533 was allocated to ILSI N.A. and \$136,790 to HESI as of December 31, 2013. For the year ended December 31, 2012, ILSI allocated deferred rent of \$129,977 to ILSI N.A. and \$139,096 to HESI.

<u>Deposits</u>: As part of the shared services agreement, ILSI charged each affiliate a deposit to cover the period of time between when ILSI pays the shared service cost and when the affiliate reimburses ILSI. Deposits held by ILSI on behalf of each affiliate were as follows as of December 31:

	2013			2012
ILSI North America	\$	116,000	\$	116,000
ILSI Health and Environmental Sciences Institute		90,000		90,000
	\$	206,000	\$	206,000

# Notes to the Consolidated Financial Statements (Continued)

#### **Note E - Temporarily Restricted Net Assets**

Temporarily restricted net assets represent amounts contributed for the following donor-specified purposes:

	Ba	lance at				Transfers	Releases		Balance at
	Dec	ember 31,			Between		from	D	ecember 31,
		2012	Con	tributions		Funds	 Restriction		2013
Marketing department	\$	3,872	\$	-	\$	(3,872)	\$ -	\$	-
Platform in International Partnerships		56,509		96,000		(50,000)	(102,509)		-
ILSI Presence in Africa		-		10,000		3,872	(12,845)		1,027
Indonesian Food Safety Program		-		-		50,000	(22,187)		27,813
TCCC Fund		-		325,000		-	-		325,000
Staff Global Travel Fund		47,526		-		-	(9,885)		37,641
ILSI Focal Point in China		230,519		17,600		-	(112,636)		135,483
PAN		110,050		-		-	(3,973)		106,077
TAKE 10! program support		2,165		-		-	(2,165)		-
WIC		33,477		-		-	(24,197)		9,280
Branch activity		119,443		-		-	-		119,443
Global threshold/IAATFS		173,453		-		(173,453)	-		-
Translational nutrition		295,345		35,000		-	(97,951)		232,394
CERA		550,000		7,104		-	(307,104)		250,000
CSAFF		-		28,485		-	(28,485)		-
CIMSANS		567,061		320,000		-	(357,915)		529,146
ENAT		-		-		173,453	(17,362)		156,091
RSIA Risk perception		118,550		100,000		-	(46,586)		171,964
RSIA Nano III		-		47,000		-	(27,142)		19,858
RSIA Nano Release Food Additives		-		25,000		-	(25,000)		-
CARES CLA		10,362			_	-	 (1,738)		8,624
Total	\$	2,318,332	\$	1,011,189	\$	-	\$ (1,199,680)	\$	2,129,841
	Ba	lance at					Releases		Balance at
	Dec	ember 31.					from	D	ecember 31.
		2011	Con	tributions		Transfers	Restriction		2012
Marketing	\$	29.216	\$	_	\$	-	\$ (25,344)	\$	3.872
Platform in International Partnerships	·	-		146.000		67.158	(156.649)		56.509
Staff Global Travel Fund		55,050				-	(7,524)		47.526
ILSI Focal Point in China		327.634		27.667		-	(124,782)		230.519
PAN		110.050		-		-	-		110.050
TAKE 10! program support		5,000		-		-	(2.836)		2.164
WIC		50,950		30,000		-	(47,473)		33,477
Branch Activity		48,397		84,500		-	(13,454)		119.443
Global threshold/IAATFS		-		-		175,430	(1,977)		173,453

ILSI Focal Point in China	327,634	27,667	-	(124,782)	230,519
PAN	110,050	-	-	-	110,050
TAKE 10! program support	5,000	-	-	(2,836)	2,164
WIC	50,950	30,000	-	(47,473)	33,477
Branch Activity	48,397	84,500	-	(13,454)	119,443
Global threshold/IAATFS	-	-	175,430	(1,977)	173,453
Translational nutrition	-	50,000	385,472	(140,126)	295,346
CERA	144,395	1,136,118	-	(730,513)	550,000
CIMSANS	92,734	540,000	-	(65,673)	567,061
RSIA Risk perception	99,700	100,000	-	(81,150)	118,550
RSIA Nano	-	15,000	-	(15,000)	-
RSIA Nano Release Food Additives	-	112,500	-	(112,500)	-
CARES CLA	10,739	-	-	(377)	10,362
Meetings	-	3,882	-	(3,882)	-
Priority research campaign	560,902	-	(560,902)	-	-
RSIA Water re-use	-	60,000	-	(60,000)	-
JIFSAN Workshop report	5,132	-	-	(5,132)	-
IFBiC Committees	-	22,500	-	(22,500)	-
RSIA Nano Release		97,275		(97,275)	
Total	\$ 1,539,899	\$ 2,425,442	\$ 67,158	\$ (1,714,167)	\$ 2,318,332

## Notes to the Consolidated Financial Statements (Continued)

#### Note F - Defined Contribution Pension Plan

The Organization has a Section 403(b) defined contribution retirement plan, which covers substantially all of its employees. Employer contributions to the plan are calculated at 7% of each participant's salary. Participants may also make voluntary elective deferrals to the plan. For the years ended December 31, 2013 and 2012, pension contribution expense totaled \$150,785 and \$130,751, respectively.

#### Note G - Commitments and Contingencies

#### Office Lease

In May 2008, ILSI entered into an operating lease for office space in Washington, DC, which commenced in September 2008 and expires in January 2019. ILSI received certain concessions from the lease agreement, which have been amortized over the lease term on a straightline basis. The unamortized portion of these incentives is reported as deferred rent in the consolidated statements of financial position.

Rent expense, net of amortized rent abatements and amounts allocated to affiliates that share space (see Note D), under the office space lease agreement totaled \$347,801 and \$265,307 for the years ended December 31, 2013 and 2012, respectively.

Approximate future annual minimum lease payments, subject to an annual operating expense increase, under various leases are as follows:

Year ending December 31,		
2014	\$	740,100
2015		760,100
2016		779,100
2017		798,600
2018		818,600
Thereafter		68,400
	<u>\$</u>	3,964,900

#### Federal Grants

The Foundation participates in some federally assisted grant programs which are subject to financial and compliance audits by federal agencies or their representatives. As such, there exists a contingent liability for potential questioned costs that may result from such an audit. Management does not anticipate any significant adjustments as a result of such an audit.

## Notes to the Consolidated Financial Statements (Continued)

#### Note G - Commitments and Contingencies (Continued)

#### Hotel Commitments

As of December 31, 2013, the Organization has entered into contracts with several hotels pertaining to future meetings. In the event that the Organization cancels or reduces its contracted provisions, it may be liable for certain penalties or liquidated damages, depending upon the date of cancellation. Minimum future cancellation fees for signed hotel contracts (excluding any applicable sales tax) is approximately \$713,000.

#### **Note H - Contributions Receivable**

Total contributions receivable outstanding as of December 31 are as follows:

	2013			2012
Due within 1 year	\$	321,866	\$	251,500
Due between 1 and 5 years		_		550,000
-	\$	321,866	\$	801,500

#### **Note I - In-Kind Contributions**

The Organization received in-kind program management services of \$120,000 and \$40,000 in 2013 and 2012, respectively. These amounts have been included in the consolidated statements of activities as contribution revenue and Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security expense.

Supplemental Information

# Statements of Financial Position

	December 31,				
	/	2013		2012	
Assets					
Cash and cash equivalents	\$	229,748	\$	509,439	
Investments		1,175,918		1,183,906	
Accounts and grants receivable		104,586		169,244	
Amounts due from affiliates		522,765		171,783	
Rent receivable under shared services agreement		357,566		364,147	
Prepaid expenses and other assets		27,898		16,977	
Property and equipment, net		441,818		759,905	
Total assets	\$	2,860,299	\$	3,175,401	
Liabilities and net assets					
Liabilities:					
Accounts payable S	\$	84,320	\$	82,372	
Accrued expenses		104,768		103,744	
Deferred revenue		77,059		102,344	
Deposits payable to affiliates		246,000		246,000	
Deferred rent		758,189		833,414	
Total liabilities		1,270,336		1,367,874	
Net assets:					
Unrestricted:					
Undesignated		439,795		681,148	
Board-designated		623,204		787,953	
Total unrestricted net assets		1,062,999		1,469,101	
Temporarily restricted		526,964		338,426	
Total net assets		1,589,963		1,807,527	
Total liabilities and net assets	\$	2,860,299	\$	3,175,401	

# Statement of Activities

# Year ended December 31, 2013

			Т	emporarily		
	<u> </u>	Inrestricted		Restricted		Total
Revenue:						
Fees from affiliates	\$	1,287,953	\$	-	\$	1,287,953
Committee assessments		704,000		-		704,000
Branch assessments		748,894		-		748,894
Publications		352,745		-		352,745
Conference registration fees		42,046		-		42,046
Investment income		13,494		-		13,494
Grants and contributions	_	95,000		448,600		543,600
		3,244,132		448,600		3,692,732
Net assets released from restriction		260,062		(260,062)		_
Total revenue		3,504,194		188,538		3,692,732
Expenses:						
Program services:						
Global coordination		76,052		-		76,052
Communications		462,442		-		462,442
Annual meeting		192,317		-		192,317
Press		294,657		-		294,657
International Food Biotechnology Committee (IFBiC)		1,203,160		-		1,203,160
Platform for International Partnerships (PIP)/GTF		175,001		-		175,001
International branches		118,533		-		118,533
Shared services		1,196,602				1,196,602
Total program services		3,718,764		-		3,718,764
General and administrative		171,809				171,809
Total expenses		3,890,573				3,890,573
Change in net assets from operations		(386,379)		188,538		(197,841)
Net change in fair value of investments		(19,723)				(19,723)
Change in net assets		(406,102)		188,538		(217,564)
Net assets, beginning of year		1,469,101		338,426		1,807,527
Net assets, end of year	\$	1,062,999	\$	526,964	<u>\$</u>	1,589,963

# Statement of Activities

# Year ended December 31, 2012

			Т	emporarily	
	U	nrestricted	]	Restricted	 Total
Revenue:					
Fees from affiliates	\$	1,208,934	\$	-	\$ 1,208,934
Committee assessments		550,000		-	550,000
Branch assessments		725,179		-	725,179
Publications		370,009		-	370,009
Conference registration fees		35,824		-	35,824
Investment income		32,640		-	32,640
Grants and contributions		_		196,167	 196,167
		2,922,586		196,167	3,118,753
Transfers between funds		(67,158)		67,158	-
Net assets released from restriction		336,799		(336,799)	 -
Total revenue		3,192,227		(73,474)	3,118,753
Expenses:					
Program services:					
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		133,156		-	133,156
Press		285,140		-	285,140
International Food Biotechnology Committee (IFBiC)		681,323		-	681,323
Platform for International Partnerships (PIP)/GTF		164,173		-	164,173
International branches		128,123		-	128,123
Shared services		1,115,458			 1,115,458
Total program services		3,028,274		-	3,028,274
General and administrative		193,322			 193,322
Total expenses		3,221,596			 3,221,596
Change in net assets from operations		(29,369)		(73,474)	(102,843)
Net change in fair value of investments		(27,246)			 (27,246)
Change in net assets		(56,615)		(73,474)	(130,089)
Net assets, beginning of year		1,525,716		411,900	 1,937,616
Net assets, end of year	\$	1,469,101	\$	338,426	\$ 1,807,527

# Statements of Functional Expenses

## Years ended December 31, 2013 and 2012

	Program Services																					
	Global Coordination		Commun- ications		Annual Meeting		Press		IFBiC		PIP/GTF		-	International Branches		Shared Services		Total		General and Administrative		2013 Total
Salaries and benefits	\$	22,225	\$	193,558	\$	6,450	\$	114,199	\$	163,222	\$	35,638	\$	5,533	\$	949,664	\$	1,490,489	\$	250,230	\$	1,740,719
Research and program support		3,872		-		-		-		623,112		80,469		62,713		-		770,166		-		770,166
Travel and meetings		26,761		8,071		163,010		10,634		172,481		9,809		45,060		14,618		450,444		31,915		482,359
Rent		-		-		-		-		-		-		-		131,277		131,277		12,878		144,155
Depreciation		-		-		-		-		8,320		-		-		23,253		31,573		105,122		136,695
Publications		-		10,874		4,747		61,436		49,735		2,400		-		-		129,192		-		129,192
Consultants		1,145		53,191		-		-		25,913		12,845		-		6,374		99,468		19,893		119,361
Communications		1,661		13,772		3,820		1,644		10,739		1,416		137		55,497		88,686		2,915		91,601
Financial and professional services		-		-		4,170		-		70		-		-		52,328		56,568		26,665		83,233
Equipment and supplies		-		-		-		-		1,379		-		-		73,681		75,060		107		75,167
Other		386		8,774		4,315		3,965		1,289		350		110		30,872		50,061		11,030		61,091
Insurance		-		-		-		-		-		-		-		56,834		56,834		-		56,834
Overhead allocation		20,002	_	174,202		5,805		102,779		146,900	_	32,074		4,980	_	(197,796)		288,946		(288,946)		
Total	\$	76,052	\$	462,442	\$	192,317	\$	294,657	\$	1,203,160	\$	175,001	\$	118,533	\$	1,196,602	\$	3,718,764	\$	171,809	\$	3,890,573

	Program Services																					
	Global Coordination		(	Commun- ications		Annual Meeting		Press		IFBiC		PIP/GTF		International Branches		Shared Services		Total		General and Administrative		2012 Total
Salaries and benefits	\$	22,650	\$	150,929	\$	11,050	\$	111,715	\$	220,633	\$	35,825	\$	11,594	\$	821,893	\$	1,386,289	\$	254,388	\$	1,640,677
Research and program support		16,751		-		-		3,500		-		84,024		46,216		100		150,591		-		150,591
Travel and meetings		27,888		4,945		95,219		6,903		185,447		8,100		58,698		19,781		406,981		39,484		446,465
Rent		-		-		-		· -		-		· -		-		93,570		93,570		25,096		118,666
Depreciation		-		-		-		-		16,639		-		-		22,253		38,892		125,318		164,210
Publications		-		4,154		5,597		55,294		10,518		2,000		-		-		77,563		-		77,563
Consultants		3,000		107,243		595		-		34,631		900		-		125,989		272,358		10,797		283,155
Communications		886		15,130		3,158		2,817		13,118		1,081		80		47,627		83,897		5,712		89,609
Financial and professional services		-		-		3,019		355		-		-		-		40,532		43,906		25,762		69,668
Equipment and supplies		159		-		-		-		718		-		-		75,105		75,982		1,281		77,263
Other		-		10,943		4,575		4,014		1,047		-		1,100		28,946		50,625		4,738		55,363
Insurance		-		-		-		-		-		-		-		48,366		48,366		-		48,366
Overhead allocation		20,387		135,836		9,943	_	100,542	_	198,572	_	32,243	_	10,435		(208,704)		299,254		(299,254)		
Total	\$	91,721	\$	429,180	\$	133,156	\$	285,140	\$	681,323	\$	164,173	\$	128,123	\$	1,115,458	\$	3,028,274	\$	193,322	\$	3,221,596

# ILSI Research Foundation

# Statements of Financial Position

	December 31,					
		2013		2012		
Assets						
Cash and cash equivalents	\$	596,961	\$	820,651		
Investments		11,976,397		11,715,928		
Accounts and grants receivable, net		320,760		254,561		
Contributions receivable		321,866		801,500		
Prepaid expenses and other assets		11,682		257		
Property and equipment, net		406,096		65,183		
Deposit held by ILSI		40,000		40,000		
Total assets	\$	13,673,762	\$	13,698,080		
Liabilities and net assets						
Liabilities:						
Accounts payable	\$	154,273	\$	163,725		
Accrued expenses		90,687		78,009		
Deferred revenue		75,609		170,155		
Amounts due to affiliates		73,644		58,164		
Rent payable under shared services agreement		93,242		95,074		
Total liabilities		487,455		565,127		
Net assets:						
Unrestricted:						
Undesignated		100,951		84,923		
Board-designated		11,112,367		11,068,124		
Total unrestricted net assets		11,213,318		11,153,047		
Temporarily restricted net assets		1,972,989		1,979,906		
Total net assets		13,186,307		13,132,953		
Total liabilities and net assets	\$	13,673,762	\$	13,698,080		

# ILSI Research Foundation

# Statement of Activities

# Year ended December 31, 2013

		Temporarily	
	<u>Unrestricted</u>	Restricted	Total
Revenue:			
Nongovernment grants	\$ 1,331,156	\$-	\$ 1,331,156
Investment income	273,079	-	273,079
Publications	11,086	-	11,086
Government grants	127,085	-	127,085
Professional fees	10,320	-	10,320
Meeting registration fees	5,148	-	5,148
Contributions	60,000	1,066,998	1,126,998
	1,817,874	1,066,998	2,884,872
Net assets released from restriction	1,073,915	(1,073,915)	
Total revenue	2,891,789	(6,917)	2,884,872
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,680,680	-	1,680,680
Center for Risk Science Innovation and Application (RSIA)	459,696	-	459,696
Center for Nutrition and Health Promotion (CNHP)	138,332	-	138,332
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	357,916	-	357,916
Center for Safety Assessment of Food and Feed (CSAFF)	162,784	-	162,784
Annual meeting	116,520	-	116,520
Branch international activity	20,623		20,623
Total program services	2,936,551	-	2,936,551
Program development	124,345	-	124,345
General and administrative	478,112		478,112
Total expenses	3,539,008		3,539,008
Change in net assets from operations	(647,219)	(6,917)	(654,136)
Net change in fair value of investments	707,490		707,490
Change in net assets	60,271	(6,917)	53,354
Net assets, beginning of year	11,153,047	1,979,906	13,132,953
Net assets, end of year	<u>\$ 11,213,318</u>	\$ 1,972,989	\$ 13,186,307
### **ILSI Research Foundation**

### Statement of Activities

### Year ended December 31, 2012

		Temporarily	
	Unrestricted	Restricted	Total
Revenue:			
Nongovernment grants	\$ 899,037	\$ -	\$ 899,037
Investment income	345,148	-	345,148
Publications	28,036	-	28,036
Government grants	302,506	-	302,506
Professional fees	27,030	-	27,030
Meeting registration fees	9,573	-	9,573
Contributions	26,500	2,229,275	2,255,775
	1,637,830	2,229,275	3,867,105
Net assets released from restriction	1,377,368	(1,377,368)	
Total revenue	3,015,198	851,907	3,867,105
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,624,464	-	1,624,464
Center for Risk Science Innovation and Application (RSIA)	646,073	-	646,073
Center for Nutrition and Health Promotion (CNHP)	211,601	-	211,601
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	65,674	-	65,674
Annual meeting	88,634	-	88,634
Branch international activity	93,648		93,648
Total program services	2,730,094	-	2,730,094
Program development	56,171	-	56,171
General and administrative	396,005		396,005
Total expenses	3,182,270		3,182,270
Change in net assets from operations	(167,072)	851,907	684,835
Net change in fair value of investments	87,764		87,764
Change in net assets	(79,308)	851,907	772,599
Net assets, beginning of year	11,232,355	1,127,999	12,360,354
Net assets, end of year	<u>\$ 11,153,047</u>	<u>\$ 1,979,906</u>	<u>\$ 13,132,953</u>

### ILSI Research Foundation

# Statements of Functional Expenses

### Years ended December 31, 2013 and 2012

	Program Services																				
		CERA		RSIA		CNHP	C	IMSANS		CSAFF		Annual Meeting	I	Branch nternational Activity		Total Program Expenses	I	Program Development	A	General and Administrative	2013 Total
Salaries and benefits	\$	647,892	\$	218,658	\$	20,799	\$	137,432	\$	35,807	\$	34,678	\$	7,063	\$	1,102,329	\$	83,000	\$	287,968 \$	\$ 1,473,297
Travel and meetings		359,496		10,283		28,746		47,625		5,845		62,982		332		515,309		3,796		5,397	524,502
Grants and research awards		104,214		43,000		67,500		130,100		80,000		-		10,000		434,814		-		-	434,814
Shared services costs		-		-		-		-		-		-		-		-		-		334,682	334,682
Consultants		208,379		70,391		4,887		33,481		5,430		-		-		322,568		-		-	322,568
ILSI assessment		-		-		-		-		-		-		-		-		-		140,000	140,000
Rent		-		-		-		-		-		-		-		-		-		136,131	136,131
Communications		26,567		8,062		2,375		1,399		2,663		544		50		41,660		200		1,382	43,242
Other		19,731		3,077		1,224		-		390		1,288		-		25,710		-		13,487	39,197
Financial and professional services		388		-		-		35		-		-		-		423		-		38,365	38,788
Publications		12,615		7,830		442		-		13,763		1,514		-		36,164		-		-	36,164
Depreciation		9,850		-		3,000		-		2,773		-		-		15,623		-		-	15,623
Overhead allocation		291,548		98,395		9,359		7,844	_	16,113	_	15,514		3,178		441,951		37,349	_	(479,300)	-
Total	\$	1,680,680	\$	459,696	\$	138,332	\$	357,916	\$	162,784	\$	116,520	\$	20,623	\$	2,936,551	\$	124,345	\$	478,112 \$	\$ 3,539,008

	Program Services															
		CERA		RSIA		CNHP	CIMSANS		Annual Meeting	I	Branch International Activity	Total Program Expenses	 Program Development	A	General and dministrative	 2012 Total
Salaries and benefits	\$	562,233	\$	305,490	\$	23,726	\$ 52,899	\$	31,733	\$	29,111	\$ 1,005,192	\$ 38,356	\$	202,431	\$ 1,245,979
Travel and meetings		462,252		68,698		2,381	6,664		37,828		5,705	583,528	362		1,340	585,230
Grants and research awards		94,065		50,000		148,590	-		-		43,500	336,155	-		-	336,155
Shared services costs		-		-		-	-		-		-	-	-		292,313	292,313
Consultants		212,674		66,255		10,996	-		145		650	290,720	-		300	291,020
ILSI assessment		-		-		-	-		-		-	-	-		140,000	140,000
Rent		-		-		-	-		-		-	-	-		129,797	129,797
Communications		17,506		13,097		526	307		1,499		1,190	34,125	183		1,103	35,411
Other		7,192		3,539		735	-		1,053		-	12,519	-		8,556	21,075
Financial and professional services		241		25		50	-		734		-	1,050	10		71,012	72,072
Publications		5,446		1,500		11,669	-		1,361		392	20,368	-		-	20,368
Depreciation		9,850		-		3,000	-		-		-	12,850	-		-	12,850
Overhead allocation		253,005	· —	137,469		9,928	5,804		14,281		13,100	 433,587	 17,260		(450,847)	 -
Total	\$	1,624,464	\$	646,073	\$	211,601	\$ 65,674	\$	88,634	\$	93,648	\$ 2,730,094	\$ 56,171	\$	396,005	\$ 3,182,270

# TAB 2



### **Board Communications Letter**

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the consolidated financial statements of the International Life Sciences Institute and Affiliate (the "Organization") for the year ended December 31, 2013, and have issued our report thereon dated July 17, 2014.

The auditor is responsible for forming and expressing an opinion about whether the consolidated financial statements that have been prepared by management with the oversight of those charged with governance are presented fairly, in all material respects, in conformity with accounting principles generally accepted in the United States ("U.S. GAAP").

The auditor is also responsible for communicating significant matters related to the consolidated financial statement audit that are, in the auditor's professional judgment, relevant to the responsibilities of those charged with governance in overseeing the financial reporting process. Generally accepted auditing standards do not require the auditor to design procedures for the purpose of identifying other matters to communicate with those charged with governance.

Consistent with our professional standards, the policy of our firm and our personal commitments to keep the lines of communication open with you, management, and our audit team, we would like to share with you the following.

### **Significant Accounting Policies and Their Application**

Management is responsible for the selection and use of appropriate accounting policies. As is the case with virtually all organizations, the Organization has available alternative accounting principles from which to choose. The significant accounting policies used by the Organization are described in Note A to the consolidated financial statements.

The accounting policies selected and applied by the Organization are appropriate under the circumstances and are consistent with those used by other not-for-profit organizations. No new significant accounting policies were adopted and the application of existing policies was not changed during 2013. We noted no transactions entered into by the Organization during the year for which there is a lack of authoritative guidance or consensus. We noted no significant transactions that have been recognized in the consolidated financial statements in a different period than when the transaction occurred.

### Management's Judgments and Accounting Estimates

Financial statements require the use of accounting estimates and management judgments. Certain accounting estimates are particularly sensitive because of their significance to the consolidated financial statements and because of the possibility that future events affecting them may differ significantly from those expected. The most sensitive estimates affecting the consolidated financial statements were expense classification and the allowance for doubtful accounts. We performed procedures to gather sufficient evidence to support management's conclusions regarding these estimates and found them to be reasonable.

Certain consolidated financial statement disclosures are particularly sensitive because of management judgments involved and/or their significance to financial statement users. The most sensitive disclosures affecting the consolidated financial statements were:

- Note B: Investments and Fair Value Measurements
- Note D: Related Party Transactions
- Note E: Temporarily Restricted Net Assets
- Note G: Commitments and Contingencies

### **Related Party Relationships and Transactions**

An objective of the audit with respect to related party relationships and transactions is to obtain an understanding of such matters sufficient to be able to recognize fraud risk factors that are relevant to the identification and assessment of the risks of material misstatement due to fraud and conclude whether the consolidated financial statements, insofar as they are affected by those relationships and transactions, achieve fair presentation. An objective of the audit also is to obtain sufficient appropriate audit evidence about whether related party relationships and transactions have been appropriately identified, accounted for and disclosed in the consolidated financial statements. Note D of the consolidated financial statements includes the disclosure of significant related party transactions.

### Significant Difficulties in Performing the Audit

We are responsible for discussing with those charged with governance any significant difficulties encountered in dealing with management related to the performance of the audit. No significant difficulties were encountered in performing the audit.

### **Management Representations and Uncorrected Misstatements**

We have requested certain representations from management that are included in the management representation letter dated July 17, 2014. We have included the management representation letter as an exhibit to this document. We did not identify any significant uncorrected misstatements.

### Disagreements with Management, Including Matters Discussed and Resolved

We are responsible for discussing with those charged with governance any disagreements with management, whether or not satisfactorily resolved, about matters that individually or in the aggregate could be significant to the Organization's consolidated financial statements or the auditor's report. There were no disagreements with Management.

### Audit and Management Post-Closing Adjustments

We did not propose any adjustments as a result of our audit.

#### Management's Consultations with Other Accountants

We are not aware of consultations with other accountants regarding audit or accounting issues.

#### Significant Issues Discussed, or Subject to Correspondence with Management

We are responsible for communicating with those charged with governance any significant issues that were discussed or were the subject of correspondence with management. We discussed the accounting and disclosure for the disbandment of the ILSI International Food Biotechnology Committee ("IFBiC").

#### **Consolidated Financial Statements Included in Client-Prepared Documents**

We are responsible for reading the information contained in client-prepared documents outside of the consolidated financial statements to determine if such information is materially consistent with the audited consolidated financial statements. We are not aware of any client-prepared documents that will contain the audited consolidated financial statements.

#### Independence

Johnson Lambert LLP is independent with respect to in accordance with the applicable independence rules.

This letter is intended solely for the information and use of you, the Board of Trustees and management and is not intended to be and should not be used by anyone other than these specified parties.

We appreciate the cooperation and courtesies extended to us by the Organization's personnel. Should you wish additional clarification of these or any other matters please ask.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014



International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

July 17, 2014

Johnson Lambert LLP 3110 Fairview Park Drive, Suite 800 Falls Church, VA 22042

Attn: Alex Murray

This representation letter is provided in connection with your audit of the consolidated financial statements of the International Life Sciences Institute (ILSI) and Affiliate ("the Organization") as of and for the years ended December 31, 2013 and 2012 for the purpose of expressing an opinion as to whether the consolidated financial statements present fairly, in all material respects, the consolidated financial position, activities, and cash flows of the Organization in accordance with accounting principles generally accepted in the United States (U.S.GAAP) and for the presentation of the supplemental information in accordance with the applicable criteria.

Certain representations in this letter are described as being limited to matters that are material. Items are considered material, regardless of size, if they involve an omission or misstatement of accounting information that, in the light of surrounding circumstances, makes it probable that the judgment of a reasonable person relying on the information would be changed or influenced by the omission or misstatement.

We confirm that, to the best of our knowledge and belief, as of the date of this letter, having made such inquiries as we considered necessary for the purpose of appropriately informing ourselves:

### Financial Statements

- We have fulfilled our responsibilities, as set out in the terms of the audit engagement dated December 2, 2013 for the preparation and fair presentation of the consolidated financial statements in accordance with U.S. GAAP.
- We acknowledge our responsibility for the design, implementation, and maintenance of internal controls and programs relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.
- We acknowledge our responsibility to ensure that the Organization's operations are conducted in accordance with the provisions of laws and regulations, including compliance with the provisions of laws and regulations that determine the reported amounts in the Organization's consolidated financial statements.



- We acknowledge our responsibility for the design, implementation, and maintenance of internal control to prevent and detect fraud.
- Significant assumptions used by us in making accounting estimates, including those measured at fair value, are reasonable.
- All liabilities resulting from retirement obligations, deferred compensation agreements, and severance packages have been recorded in the consolidated financial statements and disclosed in the notes to the consolidated financial statements.
- Related party relationships and transactions have been appropriately accounted for and disclosed in accordance with the requirements of U.S. GAAP.
- All events subsequent to the date of the consolidated financial statements and for which U.S. GAAP requires adjustment or disclosure have been adjusted or disclosed.
- You did not bring to our attention any uncorrected audit differences during this engagement.
- The effects of all known actual or possible litigation and claims have been accounted for and disclosed in accordance with U.S. GAAP.
- Arrangements with financial institutions involving compensating balances or other arrangements involving restrictions on cash balances, line of credit, or similar arrangements have been properly disclosed.
- The Organization has no plans or intentions that may materially affect the carrying value or classification of assets and liabilities.
- Guarantees, whether written or oral, under which the Organization is contingently liable have been properly reported or disclosed in the consolidated financial statements.
- Material concentrations known to management have been properly disclosed in accordance with U.S.GAAP. Concentrations refer to volumes of business, revenues, available sources of supply, or markets or geographic areas for which events could occur that would significantly disrupt normal finances within the next year.



- The methods and significant assumptions as disclosed in the consolidated financial statements were used to determine fair values of financial instruments and result in a measure of fair value appropriate for consolidated financial statement measurement and disclosure purposes. The categorization of the Organization's investments into the hierarchical levels as defined by the accounting guidance, ASC 820, Fair Value Measurements, is based on the lowest level of significant input to the securities' valuation.
- In regards to the fact that your firm assisted us by drafting the consolidated financial statements and supplementary information, including appropriate disclosures required by U.S. GAAP, we have:
  - o Made all management decisions and performed all management functions.
  - Designated an individual, Beth-Ellen Berry, who possesses suitable skill, knowledge or experience to oversee the services.
  - Evaluated the adequacy and results of the draft preparation by reviewing and accepting the consolidated financial statements and supplementary information as complete and accurate.
  - Accepted responsibility for the consolidated financial statements and supplementary information.
- In regards to the supplemental information, we:
  - Note the methods of measurement or presentation have not changes from those used in the prior period.
  - Have notified you of any significant assumptions or interpretations underlying the measurement or presentation of the supplementary information; and
  - Note that when the supplementary information is not presented with the audited consolidated financial statements, management will make the audited consolidated financial statements readily available to the intended users of the supplementary information and the auditor's report thereon.
- The Organization has satisfactory title to all owned assets, and there are no liens or encumbrances on such assets nor has any asset been pledged as collateral.
- ILSI and the Affiliate are exempt organizations under 501(c)(3) of the Internal Revenue Code. Any activities that we are aware that would jeopardize the organizations' tax exempt status and all activities subject to tax on unrelated business income or excise tax or other tax have been disclosed to you. All required filings with tax authorities are up to date. We have not been informed of any tax reviews by federal or tax taxing authorities. There is no tax position considered to be uncertain if it was to undergo an inspection by the IRS or state authorities.



• Based on relevant information and discussion with the Board of Trustees, ILSI and the Affiliate appropriately recorded the disbandment of the IFBiC program and the recording of the temporarily restricted activity related to CSAFF resulting from this transaction.

### Information Provided

- We have provided you with:
  - Access to all information, of which we are aware that is relevant to the preparation and fair presentation of the consolidated financial statements such as records, documentation and other matters;
  - Additional information that you have requested from us for the purpose of the audit; and
  - Unrestricted access to persons within the entity from whom you determined it necessary to obtain audit evidence.
- All transactions have been recorded in the accounting records and are reflected in the consolidated financial statements and supplementary information.
- All in-kind contributions have been reflected and disclosed appropriately in the consolidated financial statements.
- We have disclosed to you the results of our risk assessment as to how and where the consolidated financial statements may be materially misstated as a result of fraud.
- We have no knowledge of any fraud or suspected fraud that affects the entity and involves:
  - o Management;
  - o Employees who have significant roles in internal control; or
  - Others when the fraud could have a material effect on the consolidated financial statements.
- We have no knowledge of any allegations of fraud, or suspected fraud, affecting the entity's consolidated financial statements communicated by employees, former employees, analysts, regulators or others.
- We have disclosed to you all known instances of non-compliance or suspected noncompliance with laws and regulations whose effects should be considered when preparing consolidated financial statements.



- There have been no communications from regulatory agencies concerning noncompliance with or deficiencies in financial reporting that could have a material effect on the consolidated financial statements.
- We are not aware of any pending or threatened litigation and claims whose effects should be considered when preparing the consolidated financial statements.
- We have disclosed to you the identity of the entity's related parties and all the related party relationships and transactions of which we are aware.

Beth-Ellen Berry

Chief Financial Officer

Suzanne Harris Executive Director



#### Internal Control Letter

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

In planning and performing our audit of the consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization") as of and for the year ended December 31, 2013, in accordance with auditing standards generally accepted in the United States of America, we considered its internal control over financial reporting ("internal control") as a basis for designing our auditing procedures for the purpose of expressing our opinion on the consolidated financial statements, but not for the purpose of expressing our opinion on the effectiveness of the Organization's internal control. Accordingly, we do not express an opinion on the effectiveness of the Organization's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct misstatements on a timely basis. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis.

Our consideration of internal control was for the limited purpose described in the first paragraph and was not designed to identify all deficiencies in internal control that might be deficiencies, significant deficiencies, or material weaknesses We did not identify any deficiencies in internal control that we consider to be material weaknesses, as defined above.

This communication is intended solely for the information and use of you, the Board of Trustees, management and others within the Organization and is not intended to be and should not be used by anyone other than these specified parties.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014



# Memorandum

То:	Beth-Ellen Berry
From:	Mark Murphy, CFA Raffa Wealth Management, LLC
Date:	June 13, 2014
Subject:	Summary of Survey Results and Recommendations

Members of the International Life Sciences Institute (ILSI) staff and Financial Oversight Committee completed a survey in an effort to gain consensus on the appropriate risk level for the Board Designated Reserve portfolio. Six individuals participated in the survey. The following outline summarizes the results of the survey and Raffa Wealth Management's evaluation and recommended asset allocation strategy for the portfolio.

RWM evaluated the survey results as well as used conversations it had with key personnel and reviewed the organization's financial documents to gain better clarity of ILSI's ability to take risk. RWM then considered all of this information to propose our recommended target asset allocations for ILSI.

### **Board Designated Reserve:**

# 1) Which of the following statements most accurately reflects the objective(s) of the investments in the portfolio?

- A) 0 To provide stability and safety of principal, growth is not a consideration
- B) 3 Primary objective is to provide stability, secondary is long term growth
- C) 3 Providing stability and long term growth are equal priorities
- D) 0 Primary objective is long term growth, secondary is to provide stability.
- E) 0 Maximize growth of principal, stability is not a consideration.

# Question 1



# *2) How concerned are you with variability in the market value of the Portfolio?*

- A) 2 Very concerned with the variability in the portfolio value
- B) 3 Somewhat concerned with the year-to-year variability, but more concerned with long term growth
- C) 1 Focused on the long-term growth of the Portfolio, unconcerned with the short-term variability



# 3) Please select the time horizon you have in mind for the investments in the Long Term Reserve portfolio.

- A) 1 Three Years
- B) 5 Five Years
- C) 0 Seven Years
- D) 0 Ten Years



**Question 3** 

# 4) Based on the time period you selected in Question 3 select the portfolio which you think best describes your tolerance for loss:

- A) 2 Portfolio A (20% Stock, 80% Bond)
- B) 3 Portfolio B (40% Stock, 60% Bond)
- C) 0 Portfolio C (60% Stock, 40% Bond)
- D) 1 Portfolio D (80% Stock, 20% Bond)



### **Recommendation:**

It is our recommendation that the target asset allocation for the Board Designated Reserve be a mix of 40% stocks and 60% bonds. This recommendation is based on the following:

- 1. Respondents' opinion of the primary objective of the portfolio tilts towards stability (bonds) over growth (stocks).
- 2. Consensus that the year to year volatility can be accepted and that the portfolio is to be evaluated over a period of five years.
- 3. Indication that the respondents' tolerance for loss skewed towards a more conservative portfolio with higher allocations to fixed income than stocks.
- 4. Considering the portfolio's long term focus, the overall desire of the Financial Oversight Committee to take a more growth oriented stance with the portfolio, the lack of need to withdraw funds from the portfolio historically, but the potential for the reserve to be used to cover strategic initiatives, and the survey results; RWM recommends the portfolio have a balanced portfolio tilted towards a more stability oriented asset allocation.

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/3	30/2014 <sup>(1)</sup>		12/31/2013		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	687 794	\$	229 748	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ψ	617.528	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		17.780		104.586		169.244		119.954		257.151
Due From DC-Based ILSI Entities		301,588		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		22,963		27,908		16,979		24,342		31,626
Total Current Assets		1,647,653		1,494,421		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		339,461		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Total Other Assets		913,552		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		398,013		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
Leasehold Improvements		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		476,618		441,818		759,904		820,069		726,324
Total Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	-	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		102,965		104,768		103,744		80,695		79,435
Deferred Revenue		11,315		77,059		102,343		86,498		94,645
Total Current Liabilities		114,280		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		739,075		758,189		833,414		891,432		932,650
Total Long-Term Liabilities		985,075		1,004,189		1,079,414		1,137,432		1,178,650
Total Liabilities		1,099,355		1,270,336		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		348,497		(217,562)		(130,090)		323,092		453,081
I otal Net Assets		1,938,468		1,569,971		1,807,533		1,937,023		1,014,532
Total Liabilities and Net Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	695,824	\$	471,248	\$	681,148	\$	559,848	\$	418,355
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Strategic Planning Resources		36,504		43,411		-		-		-
Restricted Programs (PIP, GTF, Africa, Other)		477,803		360,036		107,907		151,425		38,850
International Branches (2012 and earlier included IFBiC)		154,247		148,772		748,871		957,905		892,430
I otal Net Assets	\$	1,938,468	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,533,372	\$	1,228,274	\$	1,493,287	\$	1,629,792	\$	1,467,396
Current Ratio <sup>(2)</sup>		14.42		5.62		6.18		6.29		6.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio s vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			COM	MUNICATION	S	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>			
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	
For the Six Months Ended June 30, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	
	500 000	740.000	000/			N1/A			N1/A	500 000	740.000	000/	
BRANCH/INSTITUTE ASSESSMENT	509,339	740,000	69%	-	-	N/A	-	-	N/A	509,339	740,000	69%	
CONTRIBUTIONS	30,034	35,000	00%	-	-	IN/A	-	-	IN/A	30,034	35,000	00% N/A	
	40 401	-	IN/A	-	-	IN/A	-	-	IN/A	49,421	97.069	IN/A	
	40,431	07,000	00%	-	-	IN/A	-	-	IN/A	40,431	07,000	00%	
	16 505	-	N/A	-	-	N/A	100.000	-	IN/A	116 505	-	IN/A	
	10,595	-	N/A	-	-	N/A	100,000	207 052	E10/	100,595	207.050	N/A	
FUBLICATIONS - NOTRITION REVIEWS	-	-	IN/A	-	-	IN/A	199,204	327,032	0170	199,204	327,032	01%	
TOTAL REVENUE	604,399	862,068	70%	-	-	N/A	299,204	327,852	91%	903,603	1,189,920	76%	
EVENNER													
	E 400	6.640	0.00/	10,400	14 200	700/	225	2 250	1 4 0/	16 000	22.200	700/	
COMMUNICATIONS	5,490	6,640	03%	10,409	14,300	13%	325	2,350	14 %	10,229	23,290	70%	
FINANCIAL/PROFESSIONAL FEES	16,937	31,900	53%	-	-	N/A	-	-	N/A	16,937	31,900	53%	
											-		
GENERAL & ADMINISTRATIVE	04.477	407.000	<b>E40</b> /			N1/A			N1/A	04 477	-	<b>E40</b> (	
Snared Services Overnead	64,477	127,000	51%	-	-	N/A	-	-	N/A	64,477	127,000	51%	
Rent	24,607	47,146	52%	-	-	N/A	-	-	N/A	24,607	47,146	52%	
Depreciation	-	24,621	0%	-	-	N/A	-	-	N/A	-	24,621	0%	
Other Indirect Deimburgement	1,480	9,520	16%	4,988	6,000	83%	2,102	4,580	40%	8,576	20,100	43%	
Indirect Reimbursement	(127,453)	(290,906)	44%	70,035	145,905	40%	51,530	109,142	47 %	(5,200)	(35,001)	15%	
STAFFING													
Salaries	132,462	249.744	53%	64.330	130,739	49%	46.931	97,797	48%	243,723	478,280	51%	
Benefits	34,779	59.938	58%	14,153	31.377	45%	10.325	23,471	44%	59.257	114,787	52%	
Outside Services	2.684	1.400	192%	-	-	N/A			N/A	2.684	1.400	192%	
	,	,								,	-		
CONSULTANTS	6,000	10,550	57%	10,691	36,500	29%	1,800	-	N/A	18,491	47,050	39%	
			N1/A	05 050	50.000	E40/			N//A	05 050	-	E40/	
II SUPPORT SERVICES	-	-	N/A	25,350	50,000	51%	-	-	N/A	25,350	50,000	51%	
PUBLICATIONS	4,578	4,750	96%	4,974	15,000	33%	28,097	66,100	43%	37,648	85,850	44%	
											-		
MEETINGS											-		
I ravel - Board	57,380	46,000	125%	-	-	N/A	-	-	N/A	57,380	46,000	125%	
Travel - Staff	4,584	1,122	409%	3,838	4,000	96%	4,581	9,605	48%	13,002	14,727	88%	
I ravel - Advisors/Speakers/Invitees	8,676	14,484	60%	-	-	N/A	3,274	2,568	127%	11,950	17,052	70%	
I ravel - Credits	(25,614)	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A	
Group Functions/Business Meals	67,323	82,325	82%	-	-	N/A	162	750	22%	67,485	83,075	81%	
Other Expenses (Audiovisual/Mgmt Fee)	39,763	47,650	83%	939	1,000	94%	-	-	N/A	40,703	48,650	84%	
SUBTOTAL MEETINGS	152,112	191,581	79%	4,777	5,000	96%	8,017	12,923	62%	164,906	209,504	79%	
OTHER PROGRAM EXPENSES	750		N/A	-	-	N/A	-	-	N/A	750	-	N/A	
TOTAL EXPENSES	318,914	473,882	67%	210,307	434,821	48%	149,126	316,363	47%	678,347	1,225,066	55%	
CHANGE IN NET ASSETS	285,484	388,187		(210,307)	(434,821)		150,078	11,489		225,255	(35,146)		
NET ASSETS, BEGINNING OF PERIOD	1,812,896	1,812,896		(1,806,780)	(1,806,780)		1,075,046	1,075,046		- 1,081,163	- 1,081,163		
				(0.0/7.00-	(0.04/.00)								
NET ASSETS, END OF PERIOD	2,098,380	2,201,083		(2,017,087)	(2,241,601)		1,225,124	1,086,535		1,306,418	1,046,017		
	======			======			=======	=======		======			

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTR	ICTED PROGR	AMS	INT'L BRANCH ACTIVITY			SHAR	ED SERVICE	S	TOTAL			
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	
For the Six Months Ended June 30, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	
REVENUE													
BRANCH/INSTITUTE ASSESSMENT	-	-	N/A	-	-	N/A	-	-	N/A	509,339	740,000	69%	
CONFERENCE/ REGISTRATION FEES			N/A	-		N/A	-	-	N/A	30,034	35,000	86%	
CONTRIBUTIONS	269,331	168,000	160%	42,836	12,600	340%	-	-	N/A	312,167	180,600	173%	
FEE FOR SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	48,431	87,068	56%	
SHARED SERVICES REIMBURSEMENT	-	-	N/A	-	-	N/A	741,210	1,494,100	50%	741,210	1,494,100	50%	
INVESTMENT AND OTHER INCOME	-	-	N/A	-	-	N/A	-	-	N/A	116,595	-	N/A	
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	199,204	327,852	61%	
TOTAL REVENUE	269,331	168,000	160%	42,836	12,600	 N/A	741,210	1,494,100	50%	1,956,980	2,864,620	68%	
EXPENSES													
	311	1 555	20%	107	160	67%	28 444	42 000	68%	45 091	67 005	67%	
COMMENCATIONS	511	1,000	2070	107	100	0770	20,444	42,000	0070	+0,001	07,000	01 /0	
FINANCIAL/PROFESSIONAL FEES	40	-	N/A	12	-	N/A	20,554	56,700	36%	37,542	88,600	42%	
GENERAL & ADMINISTRATIVE													
Shared Services Overhead	-	-	N/A	-	-	N/A	-	-	N/A	64,477	127,000	51%	
Rent	-	-	N/A	-	-	N/A	72,647	143,700	51%	97,253	190,846	51%	
Depreciation	-	-	N/A	-	-	N/A	-	18,000	0%	-	42.621	0%	
Other	-	-	N/A	-	-	N/A	102.970	165.000	62%	111.546	185,100	60%	
Indirect Reimbursement	2,872	30,539	9%	2,417	5,323	45%	-	-	N/A	-	-	N/A	
				,									
STAFFING													
Salaries	2,615	27,364	10%	2,201	4,770	46%	413,081	840,000	49%	661,620	1,350,414	49%	
Benefits	575	6,567	9%	484	1,145	42%	90,878	202,000	45%	151,194	324,499	47%	
Outside Services	-	-	N/A	-	-	N/A	-	-	N/A	2,684	1,400	192%	
CONSULTANTS	11,004	-	N/A	-	-	N/A	-	-	N/A	29,496	47,050	63%	
IT SUPPORT SERVICES	-	-	N/A	-	-	N/A	1.395	9.000	15%	26.745	59.000	45%	
							,	.,		-, -	,		
PUBLICATIONS	-	-	N/A	-	-	N/A	-	-	N/A	37,648	85,850	44%	
MEETINGS													
Travel - Board	-	-	N/A	-	-	N/A	-	-	N/A	57.380	46.000	125%	
Travel - Staff	1.472	5.000	29%	5.502	7.800	71%	9.274	10.000	93%	29,250	37.527	78%	
Travel - Advisors/Speakers/Invitees	24,707	2.200	1123%	2.425	25.000	10%		-	N/A	39,082	44,252	88%	
Travel - Credits	-	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A	
Group Functions/Business Meals	1.232	1.300	95%	5.411	8.900	61%	1.969	7,700	26%	76.097	100.975	75%	
Other Expenses (Audiovisual/Mamt Fee)	2.453	1.200	204%	3.283	2.860	115%	-	-	N/A	46,438	52,710	88%	
SUBTOTAL MEETINGS	29,864	9,700	308%	16,621	44,560	37%	11,242	17,700	64%	222,634	281,464	79%	
OTHER PROGRAM EXPENSES	104,282	5,000	2086%	15,520	13,500	115%	-	-	N/A	120,552	18,500	652%	
TOTAL EXPENSES	151,564	80,725	188%	37,361	69,458	54%	741,210	1,494,100	50%	1,608,483	2,869,348	56%	
CHANGE IN NET ASSETS	117,767	87,275		5,475	(56,858)		-			348,497	(4,728)		
NET ASSETS, BEGINNING OF PERIOD	360,036	360,036		148,772	148,772		-	-		1,589,971	1,589,971		
NET ASSETS, END OF PERIOD	477,803	447,311		154,247	91,914		-	-		1,938,468	1,585,243		
	================			======	=======		======	========		======	=========		

# **Portfolio Review**

### **ILSI - Board Designated Reserve**

1156 15th Street, NW Washington, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC



# **Market Commentary**

**ILSI - Board Designated Reserve** 

### **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### ILSI - Board Designated Reserve

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.42%	\$174,642.57	30.00%	\$172,227.31	(0.42%)	(\$2,415.26)
Short Bond	64.88%	\$372,467.31	65.00%	\$373,159.16	0.12%	\$691.85
Cash	4.70%	\$26,981.14	5.00%	\$28,704.55	0.30%	\$1,723.41
TOTAL		\$574,091.02		\$574,091.02		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Board Designated Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	570,177.85	566,503.83	269,574.23
Net Contributions	0.00	0.00	300,140.66
Capital Appreciation	2,625.44	5,483.62	(3,415.13)
Income	1,502.72	2,533.54	9,067.84
Management Fees	(214.99)	(429.97)	(1,276.58)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	574,091.02	574,091.02	574,091.02
INVESTMENT GAIN	3,913.17	7,587.19	4,376.13

### **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5), the Ministrate Borne benchmark (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012

**ILSI - Board Designated Reserve** 



This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### ILSI - Board Designated Reserve

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	174,643	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	372,467	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	26,981	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	574,091	0.72%	1.42%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	574,091	0.69%	1.34%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Board Designated Reserve**

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	564,907	0	4,046	5,138	574,091	1.6%	1.6%
Intermediate Bond	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Vanguard Total Bond Market Fund	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Short Bond	369,813	0	1,050	1,604	372,467	0.7%	0.7%
DFA One Year Fixed	256,535	0	199	837	257,571	0.4%	0.4%
Vanguard Short-Term	113,278	0	851	767	114,896	1.4%	1.4%
Cash	27,833	0	0	(852)	26,981		
Sch Adv Cash Resrv Prem	27,833	0	0	(852)	26,981		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Disclaimers

**ILSI - Board Designated Reserve** 

### Disclosure

Any economic and/or performance information cited is historical and not indicative of future results. Performance results prepared by Raffa Wealth Management are compiled solely by Raffa Wealth Management and have not been independently verified. All information is obtained from sources believed to be reliable, but Raffa Wealth Management does not guarantee its reliability. You are encouraged to compare any account balance information communicated to you by Raffa Wealth Management to the account information sent to you from the account custodian. Indicies are not available for direct investment and performance does not reflect expenses of an actual portfolio. Returns are shown net of mutual fund expenses and RWM's advisory fee.

### **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/3	30/2014 <sup>(1)</sup>		12/31/2013		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	687 794	\$	229 748	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ψ	617.528	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		17.780		104.586		169.244		119.954		257,151
Due From DC-Based ILSI Entities		301,588		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		22,963		27,908		16,979		24,342		31,626
Total Current Assets		1,647,653		1,494,421		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		339,461		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Total Other Assets		913,552		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		398,013		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
Leasehold Improvements		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
I otal Net Fixed Assets		476,618		441,818		759,904		820,069		726,324
Total Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	-	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		102,965		104,768		103,744		80,695		79,435
Deferred Revenue		11,315		77,059		102,343		86,498		94,645
Total Current Liabilities		114,280		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		739,075		758,189		833,414		891,432		932,650
Total Long-Term Liabilities		985,075		1,004,189		1,079,414		1,137,432		1,178,650
Total Liabilities		1,099,355		1,270,336		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		348,497		(217,562)		(130,090)		323,092		453,081
lotal net Assets		1,938,468		1,589,971		1,807,533		1,937,623		1,014,532
Total Liabilities and Net Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	695,824	\$	471,248	\$	681,148	\$	559,848	\$	418,355
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Strategic Planning Resources		36,504		43,411		-		-		-
Restricted Programs (PIP, GTF, Africa, Other)		477,803		360,036		107,907		151,425		38,850
International Branches (2012 and earlier included IFBiC)		154,247		148,772		748,871		957,905		892,430
Total Net Assets	\$	1,938,468	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,533,372	\$	1,228,274	\$	1,493,287	\$	1,629,792	\$	1,467,396
Current Ratio <sup>(2)</sup>		14.42		5.62		6.18		6.29		6.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratio s vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

From:	Suzanne Harris >				
To:	's.chang@griffith.edu.au'; '	'; Joanne Lupton;			
Cc:	'; Chelsea L. Bisho	op; ' '; Beth-			
	Ellen Berry; Shawn Sullivan; Beth Bruege	gemeyer			
Subject:	Agenda, briefing documents and dial-in instructions for the ILSI Financial Oversight				
	Committee conference call Monday,	July 28, beginning at 9:00 am EDT			
Attachments:	FOC 2014-07-28 agd.doc; FOC 2014-04	-29 minutes.docx; Final Survey Results and			
	Summary Memo ILSI BD 6-13-14.pdf; 2	013 ILSI Consolidated Board Book.pdf; ILSI Ops			
	Q2 2014.pdf; ILSI Financial Statements	06302014.pdf; ILSI Board Q2 2014.pdf			

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The next quarterly conference call of the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Monday**, **July 28**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour. The dial-in instructions are at the end of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the April 29, 2014 conference call

Agenda Item III. 2013 Consolidated Audit report

Agenda Item IV. Investment recommendations and second quarter reports (operating reserve and Board-designated reserve)

Agenda Item V. 2014 Year-to-date financial report

Please let me know if you have any questions.

### **Dial-in Instructions**

If you are calling from:	Please dial this toll-free number
Australia	1-800-21-2361
Germany	0800-182-9571
Mexico	001-888-706-6468
United Kingdom	0808-234-3676
Spain	900-98-1198
USA	1-888-706-6468

The access code for everyone is **4498699 #**. If you are going to be in another country, please let me know so that I can send you the toll free number from that country.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on:

# **Portfolio Review**

### **ILSI - Board Designated Reserve**

1156 15th Street, NW Washington, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC



# **Market Commentary**

**ILSI - Board Designated Reserve** 

### **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### ILSI - Board Designated Reserve

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.42%	\$174,642.57	30.00%	\$172,227.31	(0.42%)	(\$2,415.26)
Short Bond	64.88%	\$372,467.31	65.00%	\$373,159.16	0.12%	\$691.85
Cash	4.70%	\$26,981.14	5.00%	\$28,704.55	0.30%	\$1,723.41
TOTAL		\$574,091.02		\$574,091.02		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Board Designated Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	570,177.85	566,503.83	269,574.23
Net Contributions	0.00	0.00	300,140.66
Capital Appreciation	2,625.44	5,483.62	(3,415.13)
Income	1,502.72	2,533.54	9,067.84
Management Fees	(214.99)	(429.97)	(1,276.58)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	574,091.02	574,091.02	574,091.02
INVESTMENT GAIN	3,913.17	7,587.19	4,376.13

### **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5), the Ministrate Borne benchmark (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012

**ILSI - Board Designated Reserve** 



This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### ILSI - Board Designated Reserve

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	174,643	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	372,467	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	26,981	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	574,091	0.72%	1.42%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	574,091	0.69%	1.34%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.


# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Board Designated Reserve**

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	564,907	0	4,046	5,138	574,091	1.6%	1.6%
Intermediate Bond	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Vanguard Total Bond Market Fund	167,261	0	2,996	4,386	174,643	4.4%	4.4%
Short Bond	369,813	0	1,050	1,604	372,467	0.7%	0.7%
DFA One Year Fixed	256,535	0	199	837	257,571	0.4%	0.4%
Vanguard Short-Term	113,278	0	851	767	114,896	1.4%	1.4%
Cash	27,833	0	0	(852)	26,981		
Sch Adv Cash Resrv Prem	27,833	0	0	(852)	26,981		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



### Disclaimers

**ILSI - Board Designated Reserve** 

#### Disclosure

Any economic and/or performance information cited is historical and not indicative of future results. Performance results prepared by Raffa Wealth Management are compiled solely by Raffa Wealth Management and have not been independently verified. All information is obtained from sources believed to be reliable, but Raffa Wealth Management does not guarantee its reliability. You are encouraged to compare any account balance information communicated to you by Raffa Wealth Management to the account information sent to you from the account custodian. Indicies are not available for direct investment and performance does not reflect expenses of an actual portfolio. Returns are shown net of mutual fund expenses and RWM's advisory fee.

#### **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/3	30/2014 <sup>(1)</sup>		12/31/2013		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	687 794	\$	229 748	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ψ	617.528	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		17.780		104.586		169.244		119.954		257.151
Due From DC-Based ILSI Entities		301,588		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		22,963		27,908		16,979		24,342		31,626
Total Current Assets		1,647,653		1,494,421		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		339,461		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Total Other Assets		913,552		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		398,013		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
Leasehold Improvements		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		476,618		441,818		759,904		820,069		726,324
Total Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	-	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		102,965		104,768		103,744		80,695		79,435
Deferred Revenue		11,315		77,059		102,343		86,498		94,645
Total Current Liabilities		114,280		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		739,075		758,189		833,414		891,432		932,650
Total Long-Term Liabilities		985,075		1,004,189		1,079,414		1,137,432		1,178,650
Total Liabilities		1,099,355		1,270,336		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		348,497		(217,562)		(130,090)		323,092		453,081
I otal Net Assets		1,938,468		1,569,971		1,807,533		1,937,023		1,014,532
Total Liabilities and Net Assets	\$	3,037,823	\$	2,860,306	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	695,824	\$	471,248	\$	681,148	\$	559,848	\$	418,355
Board-Designated Reserve Fund		574,091		566,504		269,608		268,446		264,897
Strategic Planning Resources		36,504		43,411		-		-		-
Restricted Programs (PIP, GTF, Africa, Other)		477,803		360,036		107,907		151,425		38,850
International Branches (2012 and earlier included IFBiC)		154,247		148,772		748,871		957,905		892,430
I otal Net Assets	\$	1,938,468	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,533,372	\$	1,228,274	\$	1,493,287	\$	1,629,792	\$	1,467,396
Current Ratio <sup>(2)</sup>		14.42		5.62		6.18		6.29		6.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses, including accounts payable, accounts receivable, and depreciation. All balances will be fully adjusted and reported on the 2014 financial statement audit.

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# **Portfolio Review**

ILSI - Operating Reserve 1156 15th Street, NW

Washingon, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2014

Wealth Management, LLC



### **Market Commentary**

**ILSI - Operating Reserve** 

#### **Overview**

US stocks saw another strong month in June as stocks have continued their march higher with more records broken. Gains were driven by stronger economic readings and additional stimulus measures in Europe. While the revised 1Q GDP numbers showed the economy contracted 2.9%, personal spending was weak, and the inflation rate moved over 2%, home sales jumped, manufacturing improved, auto sales rose yet again, the jobs report topped expectations with all jobs lost during the financial crisis regained and retail sales grew. US stocks rose 2.51% in June bringing the second quarter gain to 4.87%. For the year to date US stocks are up 6.94%.

Foreign Stocks posted gains slightly below US stocks, but were the top performing asset class for the second quarter. Gains were driven by the ECB taking action to help improve growth in Europe. The inflation rate sank to 0.5% in Europe and drove the ECB to finally act. The bank cut its main lending rate to 0.15%, cut the rate on bank deposits they hold to negative 0.1% and will make \$545 billion in cheap loans to banks later this year. Japan's Prime minster unveiled a new package of measures designed to spur growth and the country revised up its first quarter GDP from 5.9% to 6.7%. China's factory activity showed improvement hitting a seven month high. Emerging markets topped developed markets for June and the second quarter. International stocks were up 1.81% for the month and rose 5.35% for the quarter. In the first half international stocks gained 5.96%.

Bonds were flat for the month as interest rates rose on positive economic news. The Fed once again cut its monthly bond purchases and revised up its expectation for short term rates over the next two years. The 10 year Treasury yield rose over the month ending at 2.53%, however that is down from 3.04% to start the year. Munis and credit bonds were the top performing sectors for June and the quarter with longer term bonds outpacing shorter term bonds. The broad bond market was flat in June up 0.05%, but gained 2.04% for the second quarter. For the year to date bonds have gained 3.93%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	2.51%	6.94%	25.22%
Foreign Stock (FTSE AW ex US)	1.81%	5.96%	22.27%
Total US Bond Mkt. (BarCap Aggregate)	0.05%	3.93%	4.37%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.09%	0.77%	1.14%
Municipal Bonds (BarCap 1-10yr Muni)	0.01%	3.20%	4.27%
Cash (ML 3Month T-Bill)	0.01%	0.02%	0.05%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



### Actual vs. Target Allocation

#### **ILSI - Operating Reserve**

Period Ending: 6/30/2014 Portfolio Inception Date: 9/30/2012





Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.20%	\$186,463.44	30.00%	\$185,258.52	(0.20%)	(\$1,204.92)
Short Bond	65.16%	\$402,361.36	65.00%	\$401,393.45	(0.16%)	(\$967.91)
Cash	4.65%	\$28,703.59	5.00%	\$30,876.42	0.35%	\$2,172.83
TOTAL		\$617,528.39		\$617,528.39		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



### **Performance Summary**

**ILSI - Operating Reserve** 

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

### **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	613,343.47	609,413.54	914,179.08
Net Contributions	0.00	0.00	(300,135.84)
Capital Appreciation	2,807.47	5,864.67	(7,054.33)
Income	1,608.71	2,712.71	12,399.20
Management Fees	(231.26)	(462.53)	(1,859.72)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	617,528.39	617,528.39	617,528.39
INVESTMENT GAIN	4,184.92	8,114.85	3,485.15

### **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	0.7%	1.3%	0.4%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



## Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

ILSI - Operating Reserve

\$900,000.00-					
\$850,000.00-					
\$800,000.00					
\$750,000.00-					
\$700,000.00-					
\$650,000.00-					
\$600,000.00					
\$550,000.00-					
\$500,000.00-					
\$450,000.00-					
\$400,000.00-					
\$350,000.00-					
\$300,000.00-					
\$250,000.00-					
\$200,000.00-					
\$150,000.00-					
\$100,000.00-					
\$50,000.00-					
\$0.00					
9/30/2012	12/31/2012	6/30/2013		12/31/2013	6/30/2014
		Portfolio Value	Cumulative Net Investment		

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# **Asset Class Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	186,463	1.95%	3.84%	0.94%
BarCap US Agg.			2.04%	3.93%	1.16%
Short Bond	9/30/2012	402,361	0.21%	0.42%	0.38%
BarCap 1-5 Yr Gov			0.52%	0.77%	0.40%
Cash	9/30/2012	28,704	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.02%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	617,528	0.72%	1.41%	0.53%
Total Portfolio (Net of Fees)	9/30/2012	617,528	0.68%	1.33%	0.38%
Portfolio Benchmark			0.70%	1.33%	0.57%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Description	6/30/2013 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	607,699	0	4,331	5,498	617,528	1.6%	1.6%
Intermediate Bond	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Vanguard Total Bond Market Fund	178,582	0	3,198	4,683	186,463	4.4%	4.4%
Short Bond	399,497	0	1,132	1,732	402,361	0.7%	0.7%
DFA One Year Fixed	277,404	0	215	905	278,525	0.4%	0.4%
Vanguard Short-Term	122,093	0	917	827	123,837	1.4%	1.4%
Cash	29,620	0	0	(917)	28,704		
Sch Adv Cash Resrv Prem	29,620	0	0	(917)	28,704		



### Disclaimers

**ILSI - Operating Reserve** 

#### Disclosure

Any economic and/or performance information cited is historical and not indicative of future results. Performance results prepared by Raffa Wealth Management are compiled solely by Raffa Wealth Management and have not been independently verified. All information is obtained from sources believed to be reliable, but Raffa Wealth Management does not guarantee its reliability. You are encouraged to compare any account balance information communicated to you by Raffa Wealth Management to the account information sent to you from the account custodian. Indicies are not available for direct investment and performance does not reflect expenses of an actual portfolio. Returns are shown net of mutual fund expenses and RWM's advisory fee.

#### **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.



# Memorandum

То:	Beth-Ellen Berry
From:	Mark Murphy, CFA Raffa Wealth Management, LLC
Date:	June 13, 2014
Subject:	Summary of Survey Results and Recommendations

Members of the International Life Sciences Institute (ILSI) staff and Financial Oversight Committee completed a survey in an effort to gain consensus on the appropriate risk level for the Board Designated Reserve portfolio. Six individuals participated in the survey. The following outline summarizes the results of the survey and Raffa Wealth Management's evaluation and recommended asset allocation strategy for the portfolio.

RWM evaluated the survey results as well as used conversations it had with key personnel and reviewed the organization's financial documents to gain better clarity of ILSI's ability to take risk. RWM then considered all of this information to propose our recommended target asset allocations for ILSI.

#### **Board Designated Reserve:**

# 1) Which of the following statements most accurately reflects the objective(s) of the investments in the portfolio?

- A) 0 To provide stability and safety of principal, growth is not a consideration
- B) 3 Primary objective is to provide stability, secondary is long term growth
- C) 3 Providing stability and long term growth are equal priorities
- D) 0 Primary objective is long term growth, secondary is to provide stability.
- E) 0 Maximize growth of principal, stability is not a consideration.

### Question 1



# *2) How concerned are you with variability in the market value of the Portfolio?*

- A) 2 Very concerned with the variability in the portfolio value
- B) 3 Somewhat concerned with the year-to-year variability, but more concerned with long term growth
- C) 1 Focused on the long-term growth of the Portfolio, unconcerned with the short-term variability



# 3) Please select the time horizon you have in mind for the investments in the Long Term Reserve portfolio.

- A) 1 Three Years
- B) 5 Five Years
- C) 0 Seven Years
- D) 0 Ten Years



**Question 3** 

# 4) Based on the time period you selected in Question 3 select the portfolio which you think best describes your tolerance for loss:

- A) 2 Portfolio A (20% Stock, 80% Bond)
- B) 3 Portfolio B (40% Stock, 60% Bond)
- C) 0 Portfolio C (60% Stock, 40% Bond)
- D) 1 Portfolio D (80% Stock, 20% Bond)



#### **Recommendation:**

It is our recommendation that the target asset allocation for the Board Designated Reserve be a mix of 40% stocks and 60% bonds. This recommendation is based on the following:

- 1. Respondents' opinion of the primary objective of the portfolio tilts towards stability (bonds) over growth (stocks).
- 2. Consensus that the year to year volatility can be accepted and that the portfolio is to be evaluated over a period of five years.
- 3. Indication that the respondents' tolerance for loss skewed towards a more conservative portfolio with higher allocations to fixed income than stocks.
- 4. Considering the portfolio's long term focus, the overall desire of the Financial Oversight Committee to take a more growth oriented stance with the portfolio, the lack of need to withdraw funds from the portfolio historically, but the potential for the reserve to be used to cover strategic initiatives, and the survey results; RWM recommends the portfolio have a balanced portfolio tilted towards a more stability oriented asset allocation.



Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

#### Consolidated Audited Financial Statements and Related Communications

For the Years ended December 31, 2013 and 2012

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# TAB 1



Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012 with Report of Independent Auditors

#### Consolidated Audited Financial Statements and Supplemental Information

Years ended December 31, 2013 and 2012

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#### Report of Independent Auditors

Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the accompanying consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization"), which comprise the consolidated statements of financial position as of December 31, 2013 and 2012 and the related consolidated statements of activities and cash flows for the years then ended and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Organization as of December 31, 2013 and 2012 and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

#### **Other Matters**

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The International Life Sciences Institute statements of financial position, statements of activities and statements of functional expenses and the ILSI Research Foundation statements of financial position, statements of activities and statements of functional expenses included within the supplemental information are presented for purposes of additional analysis rather than to present the financial position and changes in net assets of the individual entities and are not a required part of the consolidated financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the consolidated financial statements. The information has been subjected to the auditing procedures applied in the audit of the consolidated financial statements or to the consolidated financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the consolidated financial statements as a whole.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014

### Consolidated Statements of Financial Position

	December 31,				
		2013		2012	
Assets					
Cash and cash equivalents - Note A	\$	826,709	\$	1,330,090	
Investments - Note B		13,152,315		12,899,834	
Accounts and grants receivable		425,346		423,805	
Contributions receivable - Note H		321,866		801,500	
Amounts due from affiliates - Note D		449,121		113,619	
Rent receivable under shared services agreement - Note D		264,324		269,073	
Prepaid expenses and other assets		39,580		17,233	
Property and equipment, net - Note C		847,914		825,089	
Total assets	\$	16,327,175	\$	16,680,243	
Liabilities and net assets					
Liabilities:					
Accounts payable	\$	238,593	\$	246,097	
Accrued expenses		195,455		181,753	
Deferred revenue		152,668		272,499	
Deposits payable to affiliates - Note D		206,000		206,000	
Deferred rent		758,189		833,414	
Total liabilities		1,550,905		1,739,763	
Net assets:					
Unrestricted:					
Undesignated		540,746		766,071	
Board-designated		12,105,683		11,856,077	
Total unrestricted net assets		12,646,429		12,622,148	
Temporarily restricted net assets - Note E		2,129,841		2,318,332	
Total net assets		14,776,270		14,940,480	
Total liabilities and net assets	\$	16,327,175	\$	16,680,243	

#### Consolidated Statement of Activities

#### Year ended December 31, 2013

	 Unrestricted		Temporarily Restricted		Total
Revenue:					
Contributions	\$ 155,000	\$	1,011,189	\$	1,166,189
Nongovernment grants	1,331,156		-		1,331,156
Fees from affiliates - Note D	865,820		-		865,820
Branch assessments	608,894		-		608,894
Committee assessments	704,000		-		704,000
Publications	363,831		-		363,831
Investment income - Note B	286,573		-		286,573
Government grants	127,085		-		127,085
Meeting registration fees	47,194		-		47,194
Professional fees	 10,125	_	-		10,125
	4,499,678		1,011,189		5,510,867
Net assets released from restrictions - Note E	 1,199,680	_	(1,199,680)		-
Total revenue	5,699,358		(188,491)		5,510,867
Expenses:					
Program services:					
Center for Environmental Risk Assessment	1,680,680		-		1,680,680
Center for Risk Science Innovation and Application	459,696		-		459,696
Center for Nutrition and Health Promotion	138,332		-		138,332
Center for Integrated Modeling of Sustainable Agriculture and Nutrition					
Security	357,916		-		357,916
Center for Safety Assessment of Food and Feed	162,784		-		162,784
Global coordination	76,052		-		76,052
Communications	462,442		-		462,442
Annual meeting	308,837		-		308,837
Press	294,657		-		294,657
International Food Biotechnology Committee	698,751		-		698,751
Platform for International Partnerships/GTF	175,001		-		175,001
Branch international activity	139,156		-		139,156
Shared services	861,920		-		861,920
Total program services	5,816,224		-		5,816,224
General and administrative	422,275		-		422,275
Program development	124,345		-		124,345
Total expenses	6,362,844		-		6,362,844
Change in net assets from operations	(663,486)		(188,491)		(851.977)
Net change in fair value of investments - Note B	687,767		-		687.767
Change in net assets	 24.281		(188.491)	_	(164.210)
Net assets, beginning of year	 12,622,148		2,318,332	_	14,940,480
Net assets, end of year	\$ 12,646,429	\$	2,129,841	\$	14,776,270

#### Consolidated Statement of Activities

#### Year ended December 31, 2012

	 Unrestricted		Temporarily Restricted	 Total
Revenue:				
Grants and contributions	\$ 26,500	\$	2,425,442	\$ 2,451,942
Nongovernment grants	899,037		-	899,037
Fees from affiliates - Note D	825,169		-	825,169
Branch assessments	585,179		-	585,179
Committee assessments	550,000		-	550,000
Publications	398,045		-	398,045
Investment income - Note B	377,788		-	377,788
Government grants	302,506		-	302,506
Meeting registration fees	45,397		-	45,397
Professional fees	 25,030	_	-	 25,030
	4,034,651		2,425,442	6,460,093
Transfers between funds - Note E	(67,158)		67,158	-
Net assets released from restrictions - Note E	 1,714,167		(1,714,167)	 -
Total revenue	 5,681,660		778,433	 6,460,093
Expenses:				
Program services:				
Center for Environmental Risk Assessment	1,624,464		-	1,624,464
Center for Risk Science Innovation and Application	646,073		-	646,073
Center for Nutrition and Health Promotion	211,601		-	211,601
Center for Integrated Modeling of Sustainable Agriculture and Nutrition				
Security	65,674		-	65,674
Global coordination	91,721		-	91,721
Communications	429,180		-	429,180
Annual meeting	221,790		-	221,790
Press	285,140		-	285,140
International Food Biotechnology Committee	681,323		-	681,323
International Organizations Committee/GTF	164,173		-	164,173
Branch international activity	221,771		-	221,771
Shared services	 823,145			 823,145
Total program services	 5,466,055		-	 5,466,055
General and administrative	355,875		-	355,875
Program development	 56,171		-	 56,171
Total expenses	5,878,101		-	 5,878,101
Change in net assets from operations	(196,441)		778,433	 581.992
Net change in fair value of investments - Note B	60,518		-	60,518
Change in net assets	 (135,923)		778,433	 642,510
Net assets, beginning of year	 12,758,071		1,539,899	 14,297,970
Net assets, end of year	\$ 12,622,148	\$	2,318,332	\$ 14,940,480

#### Consolidated Statements of Cash Flows

		Years ended	d December 31, 2012		
Cash flows from operating activities		2013		2012	
Change in net assets	\$	(164.210)	\$	642,510	
Adjustments to reconcile change in net assets to net cash	Ψ	(101,210)	Ψ	0.12,010	
used in operating activities:					
Depreciation		152,318		177,060	
Net change in fair value of investments		(687,767)		(60,518)	
Allowance for doubtful accounts		-		(4,000)	
Changes in operating assets and liabilities:					
Accounts and grants receivable		(1,541)		(103,045)	
Contributions receivable		479,634		(801,500)	
Amounts due from affiliates		(359,624)		(88,229)	
Rent receivable under shared services agreement		4,749		(6,369)	
Prepaid expenses and other assets		(22,347)		13,802	
Inventory		-		8,564	
Accounts payable and accrued expenses		7,629		81,988	
Deferred revenue		(119,832)		110,073	
Deferred rent		(75,225)		(58,018)	
Deposits payable to affiliates		22,694	_	51,519	
Total adjustments		(599,312)	_	(678,673)	
Net cash used in operating activities		(763,522)		(36,163)	
Cash flows from investing activities					
Proceeds from sales or maturities of investments		1,280,654		13,540,936	
Purchases and reinvestments of investments		(845,368)		(13,095,556)	
Purchases of property and equipment		(175,145)		(148,292)	
Net cash provided by investing activities		260,141		297,088	
Net change in cash and cash equivalents		(503,381)		260,925	
Cash and cash equivalents, beginning of year		1,330,090		1,069,165	
Cash and cash equivalents, end of year	\$	826,709	\$	1,330,090	

#### Notes to the Consolidated Financial Statements

Years ended December 31, 2013 and 2012

#### Note A - Organization and Summary of Significant Accounting Policies

#### Organization

International Life Sciences Institute ("ILSI") was incorporated under the laws of the District of Columbia in July 1978 in order to promote an understanding and resolution of nutrition, food safety, toxicology, risk assessment, and environmental issues worldwide. Through ILSI, scientific experts from the academic, government, industrial, and public sectors throughout the world collaborate on research and education programs at national and international levels.

ILSI has also established and chartered several branches located throughout the world. ILSI does not maintain a majority voting interest in the governing bodies of these branches; accordingly, these consolidated financial statements do not reflect the financial positions, changes in net assets, and cash flows of these branches.

The ILSI Research Foundation (the "Foundation"), an affiliate of ILSI, was formed in 1984 to create a philanthropic vehicle for ILSI to support original research. Its Board of Trustees, from public and private entities around the world, guide the Foundation in its mission to deliver ground-breaking science that is useful now and into the future. The Foundation's current priority areas of work are currently grouped into five centers of excellence, including The Center for Environmental Risk Assessment ("CERA"), The Center for Integrated Modeling of Sustainable Agriculture & Nutrition Security ("CIMSANS"), The Center for Nutrition and Health Promotion ("CNHP"), The Center for Risk Science Innovation and Application ("RSIA") and The Center for Safety Assessment of Food and Feed ("CSAFF").

#### Principles of consolidation

The consolidated financial statements include the accounts of ILSI and the Foundation (collectively, the "Organization"). Significant intra-entity accounts and transactions have been eliminated in consolidation.

#### Income taxes

The Organization is exempt from the payment of income taxes on their exempt activities under Section 501(c)(3) of the Internal Revenue Code and is classified by the Internal Revenue Service ("IRS") as other than a private foundation within the meaning of Section 509(a)(1) of the Internal Revenue Code. They also believe that they have appropriate support for any tax positions taken, and as such, do not have any uncertain tax positions that are material to the consolidated financial statements as of December 31, 2013. Tax returns are generally subject to examination by the IRS and state authorities for three years after they were filed; there are no examinations being conducted.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Basis of accounting

The Organization prepares its consolidated financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Accordingly, revenues are recognized when earned and expenses are recognized when the underlying obligations are incurred.

#### Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from estimates.

#### Cash and cash equivalents

For consolidated financial statement purposes, the Organization considers all demand deposit accounts and highly liquid instruments which are held for current operations to be cash and cash equivalents. All other highly liquid instruments, which are included within the Organization's investment portfolio are set aside for investment purposes.

#### Investments and fair value measurement

Investments in money market funds, mutual funds and exchange traded funds are carried at fair value in accordance with U.S. GAAP. Interest and dividends are recorded in the consolidated statements of activities as investment income. Realized gains and losses and unrealized gains and losses are recorded as changes in fair value in the consolidated statements of activities. Gains and losses arising from the sale, maturity and other dispositions are accounted for on a specific identification basis calculated as of the trade date.

U.S. GAAP establishes a three-level hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities traded in active markets that the Organization has the ability to access.

Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability, for substantially the entire period, and market-corroborated inputs.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Investments and fair value measurement (continued)

Level 3 – Inputs to the valuation methodology are unobservable for the asset or liability and are significant to the fair value measurement.

#### Credit risk

The Organization maintains demand deposits with commercial banks and money market funds with financial institutions. At times, certain balances held within these accounts may not be fully guaranteed or insured by the U.S. federal government. The uninsured portions of cash and money market accounts are backed solely by the assets of the underlying institution. As such, the failure of an underlying institution could result in financial loss to the Organization.

#### Market value risk

The Organization also invests some of its funds in professionally managed portfolios containing various types of equity securities. Such investments are exposed to market and credit risks. Therefore, the investment balances reported in the accompanying consolidated financial statements may not be reflective of the portfolio's value during subsequent periods.

#### Accounts and grants receivable

Accounts and grants receivable primarily consist of amounts due for federal and non-federal grants and branch assessments. Accounts and grants receivable are presented net of an allowance for doubtful accounts, if any. The Organization's management periodically reviews the status of all accounts receivable balances for collectibility based on its knowledge of and relationship with the customer and the age of the receivable balance. As a result of these reviews, the Organization does not believe an allowance for doubtful accounts is necessary as of December 31, 2013 and 2012.

#### Contributions receivable

Unconditional promises are recorded at their net realizable value. Conditional promises to give are not included as support until such time as the conditions set forth in the promise are substantially met.

#### Property and equipment

Acquisitions of property and equipment greater than \$5,000 are capitalized at cost and depreciated, using the straight-line method, over the following estimated useful lives: furniture and equipment – four to ten years; computer software and equipment – three to five years; and leasehold improvements – over the ten-year term of the office lease or remaining portion thereof, unless the asset's useful life is estimated to be shorter. As discussed in Note C, certain property and equipment is restricted based on donor limitations.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Net assets

For consolidated financial statement purposes, net assets are classified as follows:

<u>Unrestricted</u>: Represents the portion of net assets whose use is not restricted by donors, even though their use may be limited in other respects, such as by board designation. Undesignated net assets represent the funds that are available to support the Organization's general operations. Board-designated net assets represent the funds that the Organization's Board of Trustees has determined should be reserved for long-term investment purposes. The Board has the right to approve expenditures from these reserved funds at any time.

<u>Temporarily restricted</u>: Represents the portion of net assets for which the the Organization has been restricted by donors with specified time or purpose limitations (see Note E).

#### *Contributions*

Contributions are recognized as revenue when received or unconditionally promised. Contributions are recorded as unrestricted, temporarily restricted, or permanently restricted support depending upon the existence and/or nature of donor restrictions. Support that is restricted by the donor is reported as an increase in temporarily or permanently restricted net assets when the contribution is recognized. When a restriction expires (that is, when a stipulated time restriction ends or a purpose restriction is accomplished), the amounts are reclassified to unrestricted net assets and reported in the consolidated statements of activities as net assets released from restriction. The Organization has not received any support with permanent donor restrictions.

#### Grants

Grants received by the Organization are recognized as revenue on a cost reimbursement basis or based on significant milestones of the grant, depending on the nature of the agreement.

#### Committee and branch assessments

Assessments are charged to committee members based on the activity budgeted for the respective committees each year and to the branches based on a percentage of their revenue. Assessments received in advance of the period to which they apply are recorded as deferred revenue until that period occurs.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Functional allocation of expenses

The costs of providing various programs and other activities have been summarized on a functional basis in the consolidated statements of activities. Accordingly, indirect expenses have been allocated among the programs and supporting services benefited.

#### Subsequent events

The Organization has performed an evaluation of subsequent events through July 17, 2014, which is the date the consolidated financial statements were available to be issued and has considered any relevant matters in preparation of the consolidated financial statements and footnotes.

#### Note B - Investments and Fair Value Measurements

Investments, recorded at fair value in accordance with the U.S. GAAP hierarchy, consist of the following at December 31:

			Fair Value
	2013	2012	Level
Money market funds	\$ 199,504	\$ 205,958	Level 1
Fixed income exchange traded funds	4,683,659	4,764,946	Level 1
Fixed income mutual funds	3,706,998	3,838,769	Level 1
Equity mutual funds	3,604,335	3,137,368	Level 1
Equity exchange traded funds	957,819	952,793	Level 1
Total investments, at fair value	\$13,152,315	\$12,899,834	

The Organization recognizes transfers between levels of the fair value hierarchy at the end of the period in which circumstances occur causing changes in availability of the fair value inputs. There were no transfers between levels during the years ended December 31, 2013 and 2012.

Investment return consists of the following for the years ended December 31:

	2013			2012
Investment income	\$	286,573	\$	377,788
Net change in fair value of investments		687,767		60,518
Total return on investments	\$	974,340	\$	438,306

Investment fees were \$21,859 and \$50,507 for the years ending December 31, 2013 and 2012, respectively.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note C - Property and Equipment

Property and equipment consists of the following at December 31:

	 2013	 2012
Computer software and equipment	\$ 845,507	\$ 717,508
Furniture and equipment	125,470	125,470
Leasehold improvements	 723,762	 723,762
	1,694,739	1,566,740
Less accumulated depreciation	 (846,825)	 (741,651)
Property and equipment, net	\$ 847,914	\$ 825,089

Certain software included above is restricted for use in the Center for Safety Assessment of Food and Feed based on donor restrictions.

#### **Note D - Related Party Transactions**

The Organization is part of an affiliated group of non-profit organizations, which includes ILSI North America ("ILSI N.A.") and ILSI Health and Environmental Sciences Institute ("HESI"), located in Washington, DC (the "Affiliated Organizations"), as well as several international branches. In the ordinary course of doing business, the Organization has a variety of financial transactions with these Affiliated Organizations.

Common expenses (such as accounting, legal, information technology, human resources, and business services) that benefit all of the Affiliated Organizations are governed by a shared services agreement, under which ILSI allocates these costs to each affiliate based on their total number of full-time equivalents. During the years ended December 31, 2013 and 2012, ILSI allocated \$439,474 and \$434,257, respectively, of the cost for these shared services to ILSI N.A., and allocated \$422,446 and \$388,888, respectively, of the cost for these shared services to HESI.

#### Notes to the Consolidated Financial Statements (Continued)

#### Note D - Related Party Transactions (Continued)

The following other transactions occurred between the Organization and a member of the above Affiliated Organizations during the years ended December 31, 2013 and 2012:

<u>Grants and contributions</u>: The Affiliated Organizations periodically award grants amongst each other for various scientific and research endeavors. During the years ended December 31, 2013 and 2012, the Organization paid ILSI N.A. \$28,000 and \$48,750, respectively, for grant projects. During each year ended December 31, 2013 and 2012, ILSI N.A. Food and Chemical Safety committee paid the Organization \$25,000 to conduct a Nano Release Food Additives study. During the year ended December 31, 2013, the Organization disbanded the ILSI International Food Biotechnology Committee and awarded a grant of \$88,702 to the HESI Protein Allergenicity Technical Committee ("PATC"). There were no grants awarded to HESI from the Organization during the year ended December 31, 2012. During the year ended December 31, 2013, ILSI awarded a grant totaling \$504,409 to the Foundation to form the Center for Safety Assessment of Food and Feed ("CCDB"). Use of the grant funds and software is restricted to the activities of CSAFF by ILSI. As of December 31, 2013, the stand-alone statements issued for the Foundation include \$260,092 of net assets restricted to the CSAFF CCDB and \$106,077 of net assets restricted to CSAFF. This intra-entity transaction has been eliminated in the consolidation.

<u>ILSI branch assessments</u>: As specified in its branch charter agreements, all members of an ILSI branch are automatically members of ILSI. Since ILSI does not collect its own dues from these members, ILSI instead charges an annual assessment to the branches in order to provide support for governance and coordination for ILSI's branches. During the years ended December 31, 2013 and 2012, ILSI charged \$150,000 for each of the years to both ILSI N.A. and HESI.

<u>Joint annual meeting</u>: The Organization and its affiliates participate in a joint annual meeting, and the affiliates hold their own board meetings and scientific sessions in conjunction with the meeting. ILSI collects each affiliate's share of the annual meeting income and pays in advance for a portion of the affiliates' share of the joint expenses of the meeting.

ILSI N.A. reimbursed ILSI a net of \$91,043 and \$52,525, respectively, for annual meeting activity for the years ended December 31, 2013 and 2012. HESI reimbursed ILSI a net of \$44,262 and \$34,835 for annual meeting activity for the years ended December 31, 2013 and 2012.

#### Notes to the Consolidated Financial Statements (Continued)

#### **Note D - Related Party Transactions (Continued)**

<u>Professional service fees</u>: From time to time, the Organization will utilize staff or other resources from another affiliate in carrying out its projects, or conversely, another affiliate will utilize staff or other resources of the Organization. The extent and use of these services is agreed to by the two affiliates in advance, and the affiliate requesting the resources is charged a professional fee as compensation. During both years ended December 31, 2013 and 2012, the Organization charged ILSI N.A. \$12,825 for providing these services.

<u>Due from affiliates</u>: At December 31, 2013 and 2012, ILSI N.A. owed the Organization \$384,877 and \$56,724, respectively, for shared services cost allocations, professional service fees, and various other reimbursements of expenses. At December 31, 2013 and 2012, HESI owed the Organization \$65,675 and \$56,895, respectively, for shared services cost allocations and professional service fees.

<u>Rent receivable under shared services agreement</u>: During 2008, ILSI entered into a lease for office space in Washington, D.C. (see Note G). Since the above affiliates all share the same office space with ILSI, ILSI allocated a portion of its deferred rent liability to each of the affiliates based on the number of full-time equivalents. As such, \$127,533 was allocated to ILSI N.A. and \$136,790 to HESI as of December 31, 2013. For the year ended December 31, 2012, ILSI allocated deferred rent of \$129,977 to ILSI N.A. and \$139,096 to HESI.

<u>Deposits</u>: As part of the shared services agreement, ILSI charged each affiliate a deposit to cover the period of time between when ILSI pays the shared service cost and when the affiliate reimburses ILSI. Deposits held by ILSI on behalf of each affiliate were as follows as of December 31:

	2013			2012
ILSI North America	\$	116,000	\$	116,000
ILSI Health and Environmental Sciences Institute		90,000		90,000
	\$	206,000	\$	206,000

#### Notes to the Consolidated Financial Statements (Continued)

#### **Note E - Temporarily Restricted Net Assets**

Temporarily restricted net assets represent amounts contributed for the following donor-specified purposes:

	Ba	lance at			Transfers		ers Releases		Balance at	
	Dec	ember 31,			Between		Between from		December 3	
		2012	Con	tributions		Funds		Restriction		2013
Marketing department	\$	3,872	\$	-	\$	(3,872)	\$	-	\$	-
Platform in International Partnerships		56,509		96,000		(50,000)		(102,509)		-
ILSI Presence in Africa		-		10,000		3,872		(12,845)		1,027
Indonesian Food Safety Program		-		-		50,000		(22,187)		27,813
TCCC Fund		-		325,000		-		-		325,000
Staff Global Travel Fund		47,526		-		-		(9,885)		37,641
ILSI Focal Point in China		230,519		17,600		-		(112,636)		135,483
PAN		110,050		-		-		(3,973)		106,077
TAKE 10! program support		2,165		-		-		(2,165)		-
WIC		33,477		-		-		(24,197)		9,280
Branch activity		119,443		-		-		-		119,443
Global threshold/IAATFS		173,453		-		(173,453)		-		-
Translational nutrition		295,345		35,000		-		(97,951)		232,394
CERA		550,000		7,104		-		(307,104)		250,000
CSAFF		-		28,485		-		(28,485)		-
CIMSANS		567,061		320,000		-		(357,915)		529,146
ENAT		-		-		173,453		(17,362)		156,091
RSIA Risk perception		118,550		100,000		-		(46,586)		171,964
RSIA Nano III		-		47,000		-		(27,142)		19,858
RSIA Nano Release Food Additives		-		25,000		-		(25,000)		-
CARES CLA		10,362			_	-		(1,738)		8,624
Total	\$	2,318,332	\$	1,011,189	\$	-	\$	(1,199,680)	\$	2,129,841
	Ba	lance at						Releases		Balance at
	Dec	ember 31.						from	D	ecember 31.
		2011	Con	tributions		Transfers		Restriction		2012
Marketing	\$	29.216	\$	-	\$	-	\$	(25,344)	\$	3.872
Platform in International Partnerships	·	-		146.000		67.158		(156.649)		56,509
Staff Global Travel Fund		55.050				-		(7,524)		47.526
ILSI Focal Point in China		327,634		27.667		-		(124,782)		230,519
PAN		110.050		-		-		-		110.050
TAKE 10! program support		5,000		-		-		(2.836)		2.164
WIC		50,950		30,000		-		(47,473)		33,477
Branch Activity		48,397		84,500		-		(13,454)		119,443
Global threshold/IAATFS		-		-		175,430		(1,977)		173,453

ILSI Focal Point in China	327,634	27,667	-	(124,782)	230,519
PAN	110,050	-	-	-	110,050
TAKE 10! program support	5,000	-	-	(2,836)	2,164
WIC	50,950	30,000	-	(47,473)	33,477
Branch Activity	48,397	84,500	-	(13,454)	119,443
Global threshold/IAATFS	-	-	175,430	(1,977)	173,453
Translational nutrition	-	50,000	385,472	(140,126)	295,346
CERA	144,395	1,136,118	-	(730,513)	550,000
CIMSANS	92,734	540,000	-	(65,673)	567,061
RSIA Risk perception	99,700	100,000	-	(81,150)	118,550
RSIA Nano	-	15,000	-	(15,000)	-
RSIA Nano Release Food Additives	-	112,500	-	(112,500)	-
CARES CLA	10,739	-	-	(377)	10,362
Meetings	-	3,882	-	(3,882)	-
Priority research campaign	560,902	-	(560,902)	-	-
RSIA Water re-use	-	60,000	-	(60,000)	-
JIFSAN Workshop report	5,132	-	-	(5,132)	-
IFBiC Committees	-	22,500	-	(22,500)	-
RSIA Nano Release		97,275		(97,275)	
Total	\$ 1,539,899	\$ 2,425,442	\$ 67,158	\$ (1,714,167)	\$ 2,318,332

#### Notes to the Consolidated Financial Statements (Continued)

#### Note F - Defined Contribution Pension Plan

The Organization has a Section 403(b) defined contribution retirement plan, which covers substantially all of its employees. Employer contributions to the plan are calculated at 7% of each participant's salary. Participants may also make voluntary elective deferrals to the plan. For the years ended December 31, 2013 and 2012, pension contribution expense totaled \$150,785 and \$130,751, respectively.

#### Note G - Commitments and Contingencies

#### Office Lease

In May 2008, ILSI entered into an operating lease for office space in Washington, DC, which commenced in September 2008 and expires in January 2019. ILSI received certain concessions from the lease agreement, which have been amortized over the lease term on a straightline basis. The unamortized portion of these incentives is reported as deferred rent in the consolidated statements of financial position.

Rent expense, net of amortized rent abatements and amounts allocated to affiliates that share space (see Note D), under the office space lease agreement totaled \$347,801 and \$265,307 for the years ended December 31, 2013 and 2012, respectively.

Approximate future annual minimum lease payments, subject to an annual operating expense increase, under various leases are as follows:

Year ending December 31,	
2014	\$ 740,100
2015	760,100
2016	779,100
2017	798,600
2018	818,600
Thereafter	 68,400
	\$ 3,964,900

#### Federal Grants

The Foundation participates in some federally assisted grant programs which are subject to financial and compliance audits by federal agencies or their representatives. As such, there exists a contingent liability for potential questioned costs that may result from such an audit. Management does not anticipate any significant adjustments as a result of such an audit.
## International Life Sciences Institute and Affiliate

## Notes to the Consolidated Financial Statements (Continued)

#### Note G - Commitments and Contingencies (Continued)

#### Hotel Commitments

As of December 31, 2013, the Organization has entered into contracts with several hotels pertaining to future meetings. In the event that the Organization cancels or reduces its contracted provisions, it may be liable for certain penalties or liquidated damages, depending upon the date of cancellation. Minimum future cancellation fees for signed hotel contracts (excluding any applicable sales tax) is approximately \$713,000.

#### **Note H - Contributions Receivable**

Total contributions receivable outstanding as of December 31 are as follows:

	 2013	 2012
Due within 1 year	\$ 321,866	\$ 251,500
Due between 1 and 5 years	 _	 550,000
-	\$ 321,866	\$ 801,500

#### **Note I - In-Kind Contributions**

The Organization received in-kind program management services of \$120,000 and \$40,000 in 2013 and 2012, respectively. These amounts have been included in the consolidated statements of activities as contribution revenue and Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security expense.

Supplemental Information

# Statements of Financial Position

		Decem	ber 31	Ι,
	/	2013		2012
Assets				
Cash and cash equivalents	\$	229,748	\$	509,439
Investments		1,175,918		1,183,906
Accounts and grants receivable		104,586		169,244
Amounts due from affiliates		522,765		171,783
Rent receivable under shared services agreement		357,566		364,147
Prepaid expenses and other assets		27,898		16,977
Property and equipment, net		441,818		759,905
Total assets	\$	2,860,299	\$	3,175,401
Liabilities and net assets				
Liabilities:				
Accounts payable S	\$	84,320	\$	82,372
Accrued expenses		104,768		103,744
Deferred revenue		77,059		102,344
Deposits payable to affiliates		246,000		246,000
Deferred rent		758,189		833,414
Total liabilities		1,270,336		1,367,874
Net assets:				
Unrestricted:				
Undesignated		439,795		681,148
Board-designated		623,204		787,953
Total unrestricted net assets		1,062,999		1,469,101
Temporarily restricted		526,964		338,426
Total net assets		1,589,963		1,807,527
Total liabilities and net assets	\$	2,860,299	\$	3,175,401

# Statement of Activities

## Year ended December 31, 2013

			Т	emporarily		
	<u> </u>	Inrestricted		Restricted		Total
Revenue:						
Fees from affiliates	\$	1,287,953	\$	-	\$	1,287,953
Committee assessments		704,000		-		704,000
Branch assessments		748,894		-		748,894
Publications		352,745		-		352,745
Conference registration fees		42,046		-		42,046
Investment income		13,494		-		13,494
Grants and contributions	_	95,000		448,600		543,600
		3,244,132		448,600		3,692,732
Net assets released from restriction		260,062		(260,062)		_
Total revenue		3,504,194		188,538		3,692,732
Expenses:						
Program services:						
Global coordination		76,052		-		76,052
Communications		462,442		-		462,442
Annual meeting		192,317		-		192,317
Press		294,657		-		294,657
International Food Biotechnology Committee (IFBiC)		1,203,160		-		1,203,160
Platform for International Partnerships (PIP)/GTF		175,001		-		175,001
International branches		118,533		-		118,533
Shared services		1,196,602				1,196,602
Total program services		3,718,764		-		3,718,764
General and administrative		171,809				171,809
Total expenses		3,890,573				3,890,573
Change in net assets from operations		(386,379)		188,538		(197,841)
Net change in fair value of investments		(19,723)				(19,723)
Change in net assets		(406,102)		188,538		(217,564)
Net assets, beginning of year		1,469,101		338,426		1,807,527
Net assets, end of year	\$	1,062,999	\$	526,964	<u>\$</u>	1,589,963

# Statement of Activities

## Year ended December 31, 2012

			Т	emporarily	
	U	nrestricted	]	Restricted	 Total
Revenue:					
Fees from affiliates	\$	1,208,934	\$	-	\$ 1,208,934
Committee assessments		550,000		-	550,000
Branch assessments		725,179		-	725,179
Publications		370,009		-	370,009
Conference registration fees		35,824		-	35,824
Investment income		32,640		-	32,640
Grants and contributions		_		196,167	 196,167
		2,922,586		196,167	3,118,753
Transfers between funds		(67,158)		67,158	-
Net assets released from restriction		336,799		(336,799)	 -
Total revenue		3,192,227		(73,474)	3,118,753
Expenses:					
Program services:					
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		133,156		-	133,156
Press		285,140		-	285,140
International Food Biotechnology Committee (IFBiC)		681,323		-	681,323
Platform for International Partnerships (PIP)/GTF		164,173		-	164,173
International branches		128,123		-	128,123
Shared services		1,115,458			 1,115,458
Total program services		3,028,274		-	3,028,274
General and administrative		193,322			 193,322
Total expenses		3,221,596			 3,221,596
Change in net assets from operations		(29,369)		(73,474)	(102,843)
Net change in fair value of investments		(27,246)			 (27,246)
Change in net assets		(56,615)		(73,474)	(130,089)
Net assets, beginning of year		1,525,716		411,900	 1,937,616
Net assets, end of year	\$	1,469,101	\$	338,426	\$ 1,807,527

# Statements of Functional Expenses

## Years ended December 31, 2013 and 2012

							Program	m S	ervices													
	Coo	Global ordination	C	Commun- ications	1	Annual Meeting	 Press		IFBiC	Р	IP/GTF	-	International Branches		Shared Services		Total		Total		eneral and ministrative	 2013 Total
Salaries and benefits	\$	22,225	\$	193,558	\$	6,450	\$ 114,199	\$	163,222	\$	35,638	\$	5,533	\$	949,664	\$	1,490,489	\$	250,230	\$ 1,740,719		
Research and program support		3,872		-		-	-		623,112		80,469		62,713		-		770,166		-	770,166		
Travel and meetings		26,761		8,071		163,010	10,634		172,481		9,809		45,060		14,618		450,444		31,915	482,359		
Rent		-		-		-	-		-		-		-		131,277		131,277		12,878	144,155		
Depreciation		-		-		-	-		8,320		-		-		23,253		31,573		105,122	136,695		
Publications		-		10,874		4,747	61,436		49,735		2,400		-		-		129,192		-	129,192		
Consultants		1,145		53,191		-	-		25,913		12,845		-		6,374		99,468		19,893	119,361		
Communications		1,661		13,772		3,820	1,644		10,739		1,416		137		55,497		88,686		2,915	91,601		
Financial and professional services		-		-		4,170	-		70		-		-		52,328		56,568		26,665	83,233		
Equipment and supplies		-		-		-	-		1,379		-		-		73,681		75,060		107	75,167		
Other		386		8,774		4,315	3,965		1,289		350		110		30,872		50,061		11,030	61,091		
Insurance		-		-		-	-		-		-		-		56,834		56,834		-	56,834		
Overhead allocation		20,002		174,202		5,805	 102,779		146,900	_	32,074		4,980	_	(197,796)		288,946		(288,946)	 		
Total	\$	76,052	\$	462,442	\$	192,317	\$ 294,657	\$	1,203,160	\$	175,001	\$	118,533	\$	1,196,602	\$	3,718,764	\$	171,809	\$ 3,890,573		

								Program	m S	ervices											
	Co	Global Commun- Coordination ications		Annual Meeting			Press IFBiC			PIP/GTF			International Branches		Shared Services		Total	Go Adı	eneral and ministrative	 2012 Total	
Salaries and benefits	\$	22,650	\$	150,929	\$	11,050	\$	111,715	\$	220,633	\$	35,825	\$	11,594	\$	821,893	\$	1,386,289	\$	254,388	\$ 1,640,677
Research and program support		16,751		-		-		3,500		-		84,024		46,216		100		150,591		-	150,591
Travel and meetings		27,888		4,945		95,219		6,903		185,447		8,100		58,698		19,781		406,981		39,484	446,465
Rent		-		-		-		· -		-		· -		-		93,570		93,570		25,096	118,666
Depreciation		-		-		-		-		16,639		-		-		22,253		38,892		125,318	164,210
Publications		-		4,154		5,597		55,294		10,518		2,000		-		-		77,563		-	77,563
Consultants		3,000		107,243		595		-		34,631		900		-		125,989		272,358		10,797	283,155
Communications		886		15,130		3,158		2,817		13,118		1,081		80		47,627		83,897		5,712	89,609
Financial and professional services		-		-		3,019		355		-		-		-		40,532		43,906		25,762	69,668
Equipment and supplies		159		-		-		-		718		-		-		75,105		75,982		1,281	77,263
Other		-		10,943		4,575		4,014		1,047		-		1,100		28,946		50,625		4,738	55,363
Insurance		-		-		-		-		-		-		-		48,366		48,366		-	48,366
Overhead allocation		20,387		135,836		9,943	_	100,542	_	198,572	_	32,243	_	10,435		(208,704)		299,254		(299,254)	 
Total	\$	91,721	\$	429,180	\$	133,156	\$	285,140	\$	681,323	\$	164,173	\$	128,123	\$	1,115,458	\$	3,028,274	\$	193,322	\$ 3,221,596

# Statements of Financial Position

	Decem	nber	31,
	 2013		2012
Assets			
Cash and cash equivalents	\$ 596,961	\$	820,651
Investments	11,976,397		11,715,928
Accounts and grants receivable, net	320,760		254,561
Contributions receivable	321,866		801,500
Prepaid expenses and other assets	11,682		257
Property and equipment, net	406,096		65,183
Deposit held by ILSI	 40,000		40,000
Total assets	\$ 13,673,762	\$	13,698,080
Liabilities and net assets			
Liabilities:			
Accounts payable	\$ 154,273	\$	163,725
Accrued expenses	90,687		78,009
Deferred revenue	75,609		170,155
Amounts due to affiliates	73,644		58,164
Rent payable under shared services agreement	 93,242		95,074
Total liabilities	487,455		565,127
Net assets:			
Unrestricted:			
Undesignated	100,951		84,923
Board-designated	 11,112,367		11,068,124
Total unrestricted net assets	11,213,318		11,153,047
Temporarily restricted net assets	 1,972,989		1,979,906
Total net assets	 13,186,307		13,132,953
Total liabilities and net assets	\$ 13,673,762	\$	13,698,080

# Statement of Activities

## Year ended December 31, 2013

		Temporarily	
	<u>Unrestricted</u>	Restricted	Total
Revenue:			
Nongovernment grants	\$ 1,331,156	\$-	\$ 1,331,156
Investment income	273,079	-	273,079
Publications	11,086	-	11,086
Government grants	127,085	-	127,085
Professional fees	10,320	-	10,320
Meeting registration fees	5,148	-	5,148
Contributions	60,000	1,066,998	1,126,998
	1,817,874	1,066,998	2,884,872
Net assets released from restriction	1,073,915	(1,073,915)	
Total revenue	2,891,789	(6,917)	2,884,872
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,680,680	-	1,680,680
Center for Risk Science Innovation and Application (RSIA)	459,696	-	459,696
Center for Nutrition and Health Promotion (CNHP)	138,332	-	138,332
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	357,916	-	357,916
Center for Safety Assessment of Food and Feed (CSAFF)	162,784	-	162,784
Annual meeting	116,520	-	116,520
Branch international activity	20,623		20,623
Total program services	2,936,551	-	2,936,551
Program development	124,345	-	124,345
General and administrative	478,112		478,112
Total expenses	3,539,008		3,539,008
Change in net assets from operations	(647,219)	(6,917)	(654,136)
Net change in fair value of investments	707,490		707,490
Change in net assets	60,271	(6,917)	53,354
Net assets, beginning of year	11,153,047	1,979,906	13,132,953
Net assets, end of year	<u>\$ 11,213,318</u>	\$ 1,972,989	\$ 13,186,307

# Statement of Activities

## Year ended December 31, 2012

		Temporarily	
	Unrestricted	Restricted	Total
Revenue:			
Nongovernment grants	\$ 899,037	\$ -	\$ 899,037
Investment income	345,148	-	345,148
Publications	28,036	-	28,036
Government grants	302,506	-	302,506
Professional fees	27,030	-	27,030
Meeting registration fees	9,573	-	9,573
Contributions	26,500	2,229,275	2,255,775
	1,637,830	2,229,275	3,867,105
Net assets released from restriction	1,377,368	(1,377,368)	
Total revenue	3,015,198	851,907	3,867,105
Expenses:			
Program services:			
Center for Environmental Risk Assessment (CERA)	1,624,464	-	1,624,464
Center for Risk Science Innovation and Application (RSIA)	646,073	-	646,073
Center for Nutrition and Health Promotion (CNHP)	211,601	-	211,601
Center for Integrated Modeling of Sustainable Agriculture			
and Nutrition Security (CIMSANS)	65,674	-	65,674
Annual meeting	88,634	-	88,634
Branch international activity	93,648		93,648
Total program services	2,730,094	-	2,730,094
Program development	56,171	-	56,171
General and administrative	396,005		396,005
Total expenses	3,182,270		3,182,270
Change in net assets from operations	(167,072)	851,907	684,835
Net change in fair value of investments	87,764		87,764
Change in net assets	(79,308)	851,907	772,599
Net assets, beginning of year	11,232,355	1,127,999	12,360,354
Net assets, end of year	<u>\$ 11,153,047</u>	<u>\$ 1,979,906</u>	<u>\$ 13,132,953</u>

# Statements of Functional Expenses

## Years ended December 31, 2013 and 2012

					Program	ı Se	rvices										
	 CERA	 RSIA	 CNHP	C	IMSANS		CSAFF		Annual Meeting	I	Branch nternational Activity	Total Program Expenses	I	Program Development	A	General and Administrative	2013 Total
Salaries and benefits	\$ 647,892	\$ 218,658	\$ 20,799	\$	137,432	\$	35,807	\$	34,678	\$	7,063	\$ 1,102,329	\$	83,000	\$	287,968 \$	\$ 1,473,297
Travel and meetings	359,496	10,283	28,746		47,625		5,845		62,982		332	515,309		3,796		5,397	524,502
Grants and research awards	104,214	43,000	67,500		130,100		80,000		-		10,000	434,814		-		-	434,814
Shared services costs	-	-	-		-		-		-		-	-		-		334,682	334,682
Consultants	208,379	70,391	4,887		33,481		5,430		-		-	322,568		-		-	322,568
ILSI assessment	-	-	-		-		-		-		-	-		-		140,000	140,000
Rent	-	-	-		-		-		-		-	-		-		136,131	136,131
Communications	26,567	8,062	2,375		1,399		2,663		544		50	41,660		200		1,382	43,242
Other	19,731	3,077	1,224		-		390		1,288		-	25,710		-		13,487	39,197
Financial and professional services	388	-	-		35		-		-		-	423		-		38,365	38,788
Publications	12,615	7,830	442		-		13,763		1,514		-	36,164		-		-	36,164
Depreciation	9,850	-	3,000		-		2,773		-		-	15,623		-		-	15,623
Overhead allocation	 291,548	 98,395	 9,359		7,844	_	16,113	_	15,514		3,178	 441,951		37,349	_	(479,300)	-
Total	\$ 1,680,680	\$ 459,696	\$ 138,332	\$	357,916	\$	162,784	\$	116,520	\$	20,623	\$ 2,936,551	\$	124,345	\$	478,112 \$	\$ 3,539,008

					<b>Program Service</b>	s								
	 CERA		RSIA	 CNHP	CIMSANS		Annual Meeting	I	Branch International Activity	Total Program Expenses	 Program Development	A	General and dministrative	 2012 Total
Salaries and benefits	\$ 562,233	\$	305,490	\$ 23,726	\$ 52,899	\$	31,733	\$	29,111	\$ 1,005,192	\$ 38,356	\$	202,431	\$ 1,245,979
Travel and meetings	462,252		68,698	2,381	6,664		37,828		5,705	583,528	362		1,340	585,230
Grants and research awards	94,065		50,000	148,590	-		-		43,500	336,155	-		-	336,155
Shared services costs	-		-	-	-		-		-	-	-		292,313	292,313
Consultants	212,674		66,255	10,996	-		145		650	290,720	-		300	291,020
ILSI assessment	-		-	-	-		-		-	-	-		140,000	140,000
Rent	-		-	-	-		-		-	-	-		129,797	129,797
Communications	17,506		13,097	526	307		1,499		1,190	34,125	183		1,103	35,411
Other	7,192		3,539	735	-		1,053		-	12,519	-		8,556	21,075
Financial and professional services	241		25	50	-		734		-	1,050	10		71,012	72,072
Publications	5,446		1,500	11,669	-		1,361		392	20,368	-		-	20,368
Depreciation	9,850		-	3,000	-		-		-	12,850	-		-	12,850
Overhead allocation	 253,005	· —	137,469	 9,928	5,804		14,281		13,100	 433,587	 17,260		(450,847)	 -
Total	\$ 1,624,464	\$	646,073	\$ 211,601	\$ 65,674	\$	88,634	\$	93,648	\$ 2,730,094	\$ 56,171	\$	396,005	\$ 3,182,270

# TAB 2



#### **Board Communications Letter**

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the consolidated financial statements of the International Life Sciences Institute and Affiliate (the "Organization") for the year ended December 31, 2013, and have issued our report thereon dated July 17, 2014.

The auditor is responsible for forming and expressing an opinion about whether the consolidated financial statements that have been prepared by management with the oversight of those charged with governance are presented fairly, in all material respects, in conformity with accounting principles generally accepted in the United States ("U.S. GAAP").

The auditor is also responsible for communicating significant matters related to the consolidated financial statement audit that are, in the auditor's professional judgment, relevant to the responsibilities of those charged with governance in overseeing the financial reporting process. Generally accepted auditing standards do not require the auditor to design procedures for the purpose of identifying other matters to communicate with those charged with governance.

Consistent with our professional standards, the policy of our firm and our personal commitments to keep the lines of communication open with you, management, and our audit team, we would like to share with you the following.

#### **Significant Accounting Policies and Their Application**

Management is responsible for the selection and use of appropriate accounting policies. As is the case with virtually all organizations, the Organization has available alternative accounting principles from which to choose. The significant accounting policies used by the Organization are described in Note A to the consolidated financial statements.

The accounting policies selected and applied by the Organization are appropriate under the circumstances and are consistent with those used by other not-for-profit organizations. No new significant accounting policies were adopted and the application of existing policies was not changed during 2013. We noted no transactions entered into by the Organization during the year for which there is a lack of authoritative guidance or consensus. We noted no significant transactions that have been recognized in the consolidated financial statements in a different period than when the transaction occurred.

#### Management's Judgments and Accounting Estimates

Financial statements require the use of accounting estimates and management judgments. Certain accounting estimates are particularly sensitive because of their significance to the consolidated financial statements and because of the possibility that future events affecting them may differ significantly from those expected. The most sensitive estimates affecting the consolidated financial statements were expense classification and the allowance for doubtful accounts. We performed procedures to gather sufficient evidence to support management's conclusions regarding these estimates and found them to be reasonable.

Certain consolidated financial statement disclosures are particularly sensitive because of management judgments involved and/or their significance to financial statement users. The most sensitive disclosures affecting the consolidated financial statements were:

- Note B: Investments and Fair Value Measurements
- Note D: Related Party Transactions
- Note E: Temporarily Restricted Net Assets
- Note G: Commitments and Contingencies

#### **Related Party Relationships and Transactions**

An objective of the audit with respect to related party relationships and transactions is to obtain an understanding of such matters sufficient to be able to recognize fraud risk factors that are relevant to the identification and assessment of the risks of material misstatement due to fraud and conclude whether the consolidated financial statements, insofar as they are affected by those relationships and transactions, achieve fair presentation. An objective of the audit also is to obtain sufficient appropriate audit evidence about whether related party relationships and transactions have been appropriately identified, accounted for and disclosed in the consolidated financial statements. Note D of the consolidated financial statements includes the disclosure of significant related party transactions.

#### Significant Difficulties in Performing the Audit

We are responsible for discussing with those charged with governance any significant difficulties encountered in dealing with management related to the performance of the audit. No significant difficulties were encountered in performing the audit.

#### **Management Representations and Uncorrected Misstatements**

We have requested certain representations from management that are included in the management representation letter dated July 17, 2014. We have included the management representation letter as an exhibit to this document. We did not identify any significant uncorrected misstatements.

#### Disagreements with Management, Including Matters Discussed and Resolved

We are responsible for discussing with those charged with governance any disagreements with management, whether or not satisfactorily resolved, about matters that individually or in the aggregate could be significant to the Organization's consolidated financial statements or the auditor's report. There were no disagreements with Management.

#### Audit and Management Post-Closing Adjustments

We did not propose any adjustments as a result of our audit.

#### Management's Consultations with Other Accountants

We are not aware of consultations with other accountants regarding audit or accounting issues.

#### Significant Issues Discussed, or Subject to Correspondence with Management

We are responsible for communicating with those charged with governance any significant issues that were discussed or were the subject of correspondence with management. We discussed the accounting and disclosure for the disbandment of the ILSI International Food Biotechnology Committee ("IFBiC").

#### **Consolidated Financial Statements Included in Client-Prepared Documents**

We are responsible for reading the information contained in client-prepared documents outside of the consolidated financial statements to determine if such information is materially consistent with the audited consolidated financial statements. We are not aware of any client-prepared documents that will contain the audited consolidated financial statements.

#### Independence

Johnson Lambert LLP is independent with respect to in accordance with the applicable independence rules.

This letter is intended solely for the information and use of you, the Board of Trustees and management and is not intended to be and should not be used by anyone other than these specified parties.

We appreciate the cooperation and courtesies extended to us by the Organization's personnel. Should you wish additional clarification of these or any other matters please ask.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

July 17, 2014

Johnson Lambert LLP 3110 Fairview Park Drive, Suite 800 Falls Church, VA 22042

Attn: Alex Murray

This representation letter is provided in connection with your audit of the consolidated financial statements of the International Life Sciences Institute (ILSI) and Affiliate ("the Organization") as of and for the years ended December 31, 2013 and 2012 for the purpose of expressing an opinion as to whether the consolidated financial statements present fairly, in all material respects, the consolidated financial position, activities, and cash flows of the Organization in accordance with accounting principles generally accepted in the United States (U.S.GAAP) and for the presentation of the supplemental information in accordance with the applicable criteria.

Certain representations in this letter are described as being limited to matters that are material. Items are considered material, regardless of size, if they involve an omission or misstatement of accounting information that, in the light of surrounding circumstances, makes it probable that the judgment of a reasonable person relying on the information would be changed or influenced by the omission or misstatement.

We confirm that, to the best of our knowledge and belief, as of the date of this letter, having made such inquiries as we considered necessary for the purpose of appropriately informing ourselves:

#### Financial Statements

- We have fulfilled our responsibilities, as set out in the terms of the audit engagement dated December 2, 2013 for the preparation and fair presentation of the consolidated financial statements in accordance with U.S. GAAP.
- We acknowledge our responsibility for the design, implementation, and maintenance of internal controls and programs relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.
- We acknowledge our responsibility to ensure that the Organization's operations are conducted in accordance with the provisions of laws and regulations, including compliance with the provisions of laws and regulations that determine the reported amounts in the Organization's consolidated financial statements.



- We acknowledge our responsibility for the design, implementation, and maintenance of internal control to prevent and detect fraud.
- Significant assumptions used by us in making accounting estimates, including those measured at fair value, are reasonable.
- All liabilities resulting from retirement obligations, deferred compensation agreements, and severance packages have been recorded in the consolidated financial statements and disclosed in the notes to the consolidated financial statements.
- Related party relationships and transactions have been appropriately accounted for and disclosed in accordance with the requirements of U.S. GAAP.
- All events subsequent to the date of the consolidated financial statements and for which U.S. GAAP requires adjustment or disclosure have been adjusted or disclosed.
- You did not bring to our attention any uncorrected audit differences during this engagement.
- The effects of all known actual or possible litigation and claims have been accounted for and disclosed in accordance with U.S. GAAP.
- Arrangements with financial institutions involving compensating balances or other arrangements involving restrictions on cash balances, line of credit, or similar arrangements have been properly disclosed.
- The Organization has no plans or intentions that may materially affect the carrying value or classification of assets and liabilities.
- Guarantees, whether written or oral, under which the Organization is contingently liable have been properly reported or disclosed in the consolidated financial statements.
- Material concentrations known to management have been properly disclosed in accordance with U.S.GAAP. Concentrations refer to volumes of business, revenues, available sources of supply, or markets or geographic areas for which events could occur that would significantly disrupt normal finances within the next year.



- The methods and significant assumptions as disclosed in the consolidated financial statements were used to determine fair values of financial instruments and result in a measure of fair value appropriate for consolidated financial statement measurement and disclosure purposes. The categorization of the Organization's investments into the hierarchical levels as defined by the accounting guidance, ASC 820, Fair Value Measurements, is based on the lowest level of significant input to the securities' valuation.
- In regards to the fact that your firm assisted us by drafting the consolidated financial statements and supplementary information, including appropriate disclosures required by U.S. GAAP, we have:
  - o Made all management decisions and performed all management functions.
  - Designated an individual, Beth-Ellen Berry, who possesses suitable skill, knowledge or experience to oversee the services.
  - Evaluated the adequacy and results of the draft preparation by reviewing and accepting the consolidated financial statements and supplementary information as complete and accurate.
  - Accepted responsibility for the consolidated financial statements and supplementary information.
- In regards to the supplemental information, we:
  - Note the methods of measurement or presentation have not changes from those used in the prior period.
  - Have notified you of any significant assumptions or interpretations underlying the measurement or presentation of the supplementary information; and
  - Note that when the supplementary information is not presented with the audited consolidated financial statements, management will make the audited consolidated financial statements readily available to the intended users of the supplementary information and the auditor's report thereon.
- The Organization has satisfactory title to all owned assets, and there are no liens or encumbrances on such assets nor has any asset been pledged as collateral.
- ILSI and the Affiliate are exempt organizations under 501(c)(3) of the Internal Revenue Code. Any activities that we are aware that would jeopardize the organizations' tax exempt status and all activities subject to tax on unrelated business income or excise tax or other tax have been disclosed to you. All required filings with tax authorities are up to date. We have not been informed of any tax reviews by federal or tax taxing authorities. There is no tax position considered to be uncertain if it was to undergo an inspection by the IRS or state authorities.



• Based on relevant information and discussion with the Board of Trustees, ILSI and the Affiliate appropriately recorded the disbandment of the IFBiC program and the recording of the temporarily restricted activity related to CSAFF resulting from this transaction.

#### Information Provided

- We have provided you with:
  - Access to all information, of which we are aware that is relevant to the preparation and fair presentation of the consolidated financial statements such as records, documentation and other matters;
  - Additional information that you have requested from us for the purpose of the audit; and
  - Unrestricted access to persons within the entity from whom you determined it necessary to obtain audit evidence.
- All transactions have been recorded in the accounting records and are reflected in the consolidated financial statements and supplementary information.
- All in-kind contributions have been reflected and disclosed appropriately in the consolidated financial statements.
- We have disclosed to you the results of our risk assessment as to how and where the consolidated financial statements may be materially misstated as a result of fraud.
- We have no knowledge of any fraud or suspected fraud that affects the entity and involves:
  - o Management;
  - o Employees who have significant roles in internal control; or
  - Others when the fraud could have a material effect on the consolidated financial statements.
- We have no knowledge of any allegations of fraud, or suspected fraud, affecting the entity's consolidated financial statements communicated by employees, former employees, analysts, regulators or others.
- We have disclosed to you all known instances of non-compliance or suspected noncompliance with laws and regulations whose effects should be considered when preparing consolidated financial statements.



- There have been no communications from regulatory agencies concerning noncompliance with or deficiencies in financial reporting that could have a material effect on the consolidated financial statements.
- We are not aware of any pending or threatened litigation and claims whose effects should be considered when preparing the consolidated financial statements.
- We have disclosed to you the identity of the entity's related parties and all the related party relationships and transactions of which we are aware.

Beth-Ellen Berry

Chief Financial Officer

Suzanne Harris Executive Director



#### Internal Control Letter

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

In planning and performing our audit of the consolidated financial statements of International Life Sciences Institute and Affiliate (the "Organization") as of and for the year ended December 31, 2013, in accordance with auditing standards generally accepted in the United States of America, we considered its internal control over financial reporting ("internal control") as a basis for designing our auditing procedures for the purpose of expressing our opinion on the consolidated financial statements, but not for the purpose of expressing our opinion on the effectiveness of the Organization's internal control. Accordingly, we do not express an opinion on the effectiveness of the Organization's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct misstatements on a timely basis. A material weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis.

Our consideration of internal control was for the limited purpose described in the first paragraph and was not designed to identify all deficiencies in internal control that might be deficiencies, significant deficiencies, or material weaknesses We did not identify any deficiencies in internal control that we consider to be material weaknesses, as defined above.

This communication is intended solely for the information and use of you, the Board of Trustees, management and others within the Organization and is not intended to be and should not be used by anyone other than these specified parties.

Johnson Jambert LLP

Falls Church, Virginia July 17, 2014

From: Sent:	Suzanne Harris < > > Monday July 21, 2014 1:11 PM		
То:	's.chang@griffith.edu.au'; '	e'; Joanne Lupton;	
Cc:	; Chelsea L. Bish	op; '	'; Beth-
	Ellen Berry; Shawn Sullivan; Beth Brueg	gemeyer	
Subject:	Agenda, briefing documents and dial-in	instructions for the ILSI Financial Ov	versight
-	Committee conference call Monday,	July 28, beginning at 9:00 am EDT	-
Attachments:	FOC 2014-07-28 agd.doc; FOC 2014-04	-29 minutes.docx; Final Survey Resul	ts and
	Summary Memo ILSI BD 6-13-14.pdf; 2	013 ILSI Consolidated Board Book.pd	lf; ILSI Ops
	Q2 2014.pdf; ILSI Financial Statements	06302014.pdf; ILSI Board Q2 2014.pd	lf

#### TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The next quarterly conference call of the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Monday**, **July 28**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour. The dial-in instructions are at the end of this message.

The proposed agenda for the call is attached here:

Agenda Item II. Draft minutes from the April 29, 2014 conference call

Agenda Item III. 2013 Consolidated Audit report

Agenda Item IV. Investment recommendations and second quarter reports (operating reserve and Board-designated reserve)

Agenda Item V. 2014 Year-to-date financial report

Please let me know if you have any questions.

#### **Dial-in Instructions**

If you are calling from:	Please dial this toll-free number
Australia	1-800-21-2361
Germany	0800-182-9571
Mexico	001-888-706-6468
United Kingdom	0808-234-3676
Spain	900-98-1198
USA	1-888-706-6468

The access code for everyone is **4498699 #**. If you are going to be in another country, please let me know so that I can send you the toll free number from that country.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on:

From: Sent: To: Subject: Joanne Lupton Wednesday, July 09, 2014 5:20 PM Courtney Gaine RE: My Personal Contact Information

Courtney:

Thank you for sending me your contact information. Please stay in touch as I have a lot of respect for your business style approach to getting things done and motivating people. I too will be doing something different in that on October 1 I will become emeritus at A&M and still have an office here able to pick projects that excite me. One that excites me still (and I'm making some progress on) is bioactives and getting a DRI-like value ofr the ones with all the science behind them! I will still keep my A&M email so do stay in touch. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Courtney Gaine Sent: Wednesday, July 09, 2014 1:31 PM To: Cc: Courtney Gaine Subject: My Personal Contact Information

Dear all,

It's with a mixture of sadness and excitement that I send this email. The sadness comes from today being my last day at ILSI North America and, therefore, I will no longer be working with you all in this capacity. However, I also am excited for a new opportunity and starting the next phase of my career.

I have immensely enjoyed getting to know you all, or know you better, over these past couple of years and will miss working together on so many exciting projects. My hope is that we stay in touch, and some of you will be forced to

I will send along my new professional contact information once I have it next month. In the meantime, I'd love to hear from you. My personal email is and cell is

Enjoy the rest of your summers and talk to you all soon,

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121 From: Sent: To: Subject: Joanne Lupton Wednesday, July 09, 2014 5:20 PM Courtney Gaine RE: My Personal Contact Information

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Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

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Enjoy the rest of your summers and talk to you all soon,

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121

From: Sent: To:	Suzanne Harris < Thursday, July 03, 2014 9:25 AM ; 's.chang@griffith.edu.au'; scohen@unmc.edu; ; mdoyle@uga.edu; adamdrew@u.washington.edu; marion@vt.edu; ; '; '; ; ; 'john.c.peters@ucdenver.edu'; ; kwallace@d.umn.edu; 'weavercm@purdue.edu'; ; Prablad Soth
	; Pranad Seth
Cc:	jbradford@unmc.edu; ; Chelsea L. Bishop; '; 'tim.goss@ucdenver.edu';
	; Burnand,Valerie,VEVEY,CT- RSA ); 'haan@purdue.edu'; ; Beth-Ellen Berry; Michael Shirreffs; Shawn Sullivan;
Subject:	Agenda and dial-in instructions for the ILSI Board of Trustees mid-year conference call Monday, July 14, 2014 at 9:00 a.m. Eastern Davlight Time
Attachments:	ILSI BOT 2014-07-14 agd.doc; 2014 Dial-in Information.doc

TO: ILSI Board of Trustees

FROM: Suzie Harris

The mid-year conference call for the ILSI Board of Trustees is scheduled for **Monday**, July 14, 2014, beginning at 9:00 a.m. Eastern Daylight Time. The call will not last longer than two hours.

The toll-free numbers by country are attached here.

The proposed agenda for the conference call is attached here.

The briefing documents for the conference call are posted on the ILSI Board portal on ILSI EXTRA. The link is: <u>https://www.ilsiextra.org/ilsi/bot/SitePages/Upcoming%20Meetings.aspx</u>. Your user name is your email address – before the @. So my user name is "sharris". The password is Password1, unless you changed the password during previous visits to this site.

Please let me know if you have any questions.

## ILSI Board of Trustees 2014 Conference Call Information 9:00 am – 10:00 am US Eastern Standard Time

Monday, July 14, 2014

#### AT&T Direct Toll Free Dial-In Country Number Number Note Australia 1-800-21-2361 FROM BRAZIL (The audio conference requires two-stage dialing. First, dial the AT&T Direct Number. Brazil 0-800-890-0288 888-706-6468 Second, dial the Toll-Free Dial-In Number.) BRAZIL OTHER (The audio conference requires two-stage dialing. First, dial the AT&T Direct Number. Brazil 0-800-888-8288 888-706-6468 Second, dial the Toll-Free Dial-In Number.) Canada 888-706-6468 China 10-800-711-0988 CHINA NETCOM GROUP USERS China 10-800-110-0916 CHINA TELECOM SOUTH USERS Germany 0800-182-9571 Greece 00-800-11-005-8221 000-117 888-706-6468 India Two-stage dialing process required. 00531-11-0061 JAPAN KDD USERS Japan 0066-33-830259 **JAPAN C&W USERS** Japan 0034-800-900351 JAPAN NTT USERS Japan

00798-1-1-005-8221

001-888-706-6468

0800-022-7141

800-110-1778 0800-83-6214 (tollfree); 0-43-5579014

(caller paid)

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888-706-6468

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Netherlands

Singapore

Switzerland

United States

United Kingdom

Mexico

# ILSI<sup>®</sup> INTERNATIONAL LIFE SCIENCES INSTITUTE

Access code for all calls is 4498699#

### ILSI Board of Trustees Mid-year Conference Call

## Monday, July 14, 2014 9:00 – 11:00 a.m. Eastern Daylight Time

## AGENDA

I.	Call to Order	Dr. Sam Cohen
II.	Approval of Minutes from the 19 January ILSI Board of Trustees Meeting	Dr. Sam Cohen
III.	President's Report	Dr. Jerry Hjelle
IV.	Progress with Implementing the One ILSI Strategy	Dr. Suzie Harris
	<ul><li>a. Communication efforts</li><li>b. Board advisory groups</li><li>c. Thematic area activities</li><li>d. Governance recommendations</li></ul>	
V.	Impact of Communications	Mr. Michael Shirreffs
VI.	Report from the Publications Committee	Dr. Connie Weaver
VII.	Report of Branch Development Committee	Dr. Michael Knowles
VIII.	Report of the Financial Oversight Committee	Dr. Liz Westring
IX.	Report from the ILSI Research Foundation	Dr. Adam Drewnowski
X.	Report from the ILSI Platform for International Partnerships	Dr. Suzie Harris
XI.	Other Business	Dr. Sam Cohen
	a. Plans for 2015 Annual Meeting	Dr. Suzie Harris
XII.	Adjournment	

From: Sent: To:	Suzanne Harris Thursday, July 03, 20 marion@vt.edu;	> )14 9:25 AM ; ' ; 's.chang@griffith.edu.au'; scohen@unmc.eu ; mdoyle@uga.edu; adamdrewo Catherine Field	du; @u.washington.edu;
	•	'john.c.peters@ucdenver.e ; kwallace@d.umn.edu; 'weavercm@pu '; Prahlad Seth	Joanne Lupton; du'; rdue.edu'; ';
Cc:	;'	'; jbradford@unm ; '; 'tim.goss@ucdenver.edu'; · Burn:	ic.edu; ; Chelsea L. Bishop; and Valerie VEVEY CT-
	RSA Beth Brueggemever	; 'haan@purdue.edu'; Beth-Ellen Berry; Michael Shi	irreffs; Shawn Sullivan;
Subject:	Agenda and dial-in i Monday, July 14, 2	nstructions for the ILSI Board of Trustees m 2014 at 9:00 a.m. Eastern Daylight Time	id-year conference call
Attachments:	ILSI BOT 2014-07-14	agd.doc; 2014 Dial-in Information.doc	

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FROM: Suzie Harris

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Please let me know if you have any questions.

From: Sent: To:	Delia Murphy Thursday, May 29, 2014 8:4 'DAllison@uab.edu'; '	7 AM	
	; 'ferg	gc@foodsci.umass.edu'; '	
	'mdoyle@uga.edu'; 'jlupton	@tamu.edu'; 'dwyerj1@o	d.nih.gov';
	'jwerdman@illinois.edu'; '		; 'james.hill@ucdenver.edu';
	, ,		': 'dblund@wisc.edu':
		,	1. /
	'. /	Shawn Sullivan;	
	1	·; ·	; Sharon Weiss;
		;	
Cc:	Eric Hentges; Alison Kretser	; Delia Murphy	
Subject:	ILSI North America Conflict of Interest & Scientific Integrity Working Group		
Attachments:	PDF of COI 29 May Call Ma	terials.pdf	3, 3,

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Agenda and Materials for 29 May Conference Call

Please find attached an updated agenda and packet of materials for the Conflict of Interest & Scientific Integrity Working Group conference call today, Thursday, 29 May from 10:00 to 11:30 am EDT. Please use our conference call number to dial in:

215-446-0193 (industry members) 888-706-6468 (others) Access code: 1277013 (all)

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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## Agenda: Working Group on Conflict of Interest & Scientific Integrity **Conference Call**

Thursday, 29 May, 2014, 10:00-11:30 am EDT

Dial-in Information: 215-446-0193 (industry members), 888-706-6468 (others) Access code: 1277013 (all)

Purpose: To update the Working Group on the Public-Private Partnership (PPP) and recent activities.

I.	Welcome and Introductions	A. Kretser
II.	Communications/Publications on PPP	A. Kretser
	a. Mid America Food Processors Association Presentation, March 2014	A. Kretser
	b. "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communi	cation
	Challenge," Nutrition Today, March 2014	
	c. Experimental Biology Reception on PPPs	E. Hentges
	d. National Nutrient Databank Conference, May 2014	A. Kretser
	e. Canadian Nutrition Society Food for Health Workshop, June 2014	E. Hentges
	f. 17th IUFoST World Congress of Food Science and Technology, August 2014	E. Hentges
	g. John Milner Memorial Symposium, 12 June, 2014	A. Kretser
III.	Proof of Concept: "Branded Food Products Database for Public Health"	
	Public-Private Partnership	A. Kretser
	a. Meeting with USDA Under Secretary on PPP Progress Report	A. Kretser
	b. Implementation Phase	A. Kretser
	i. Budget	
	ii. Beta Testing	
	iii. Outreach Strategy	
IV.	GMA's Consumer Information Transparency Initiative	E. Hentges
V.	Support of Professional Societies of COI PPP Principles	E. Hentges
VI.	GRAS Assessment	E. Hentges
VII.	Next Steps	D. Lund
VIII.	Adjournment	A. Kretser



# Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Thursday, 29 May, 2014, 10:00-11:30 am EDT

#### **Attendees**

Daryl Lund, chair Rhona Applebaum Fergus Clydesdale Kerr Dow John Erdman Rachel Goldstein **Eric Hentges** Alison Kretser **Richard Lane** Beate Lloyd Delia Murphy Juan Navia Joseph Ratliff David Thomas Jennifer van de Ligt Liz Westring

#### **Tentative**

James Hill Joanne Lupton Kari Ryan

#### **Unable to Attend**

David Allison Nelson Almeida Stephanie Atkinson Claudia Riedt Wamwari Waichungo Sharon Weiss

#### **Unconfirmed**

Michael Doyle Johanna Dwyer Debra Miller Amy Preston Steven Rizk Shawn Sullivan

University of Wisconsin, Madison Coca-Cola Company University of Massachusetts at Amherst Cargill, Incorporated University of Illinois at Urbana-Champaign Mars, Incorporated **ILSI** North America **ILSI** North America PepsiCo Inc. Coca-Cola Company **ILSI** North America McNeil Nutritionals, LLC Dr Pepper Snapple Group Dr Pepper Snapple Group Cargill, Incorporated General Mills Inc.

University of Colorado Health and Wellness Center Texas A&M University Kraft Foods Group, Inc.

University of Alabama at Birmingham Kellogg Company McMaster University Dr Pepper Snapple Group Coca-Cola Company ILSI North America

The University of Georgia NIH/Tufts University Medical Center The Hershey Company The Hershey Company Mars, Incorporated ILSI North America



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

# Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 17 December, 2013, 3:00-4:30 pm EST

Dial-in Information: 215-446-0193 (industry members), 888-706-6468 (others) Access code: 1277013 (all)

Purpose: To update the Working Group on Public-Private Partnership (PPP) activities in 2013.

#### I.

#### Welcome and Introductions

a. Ms. Alison Kretser welcomed Working Group members to the call and took attendance. She shared that the purpose of the call is to update the Working Group members on the activities that took place in 2013.

#### II. Communications/Publications on PPP

A. Kretser

A. Kretser

- a. "Principles for building public-private partnerships to benefit food safety, nutrition, and health research" *Nutrition Reviews*, October 2013
  - i. Ms. Kretser shared that the ILSI North America manuscript, "Principles for building public-private partnerships to benefit food safety, nutrition, and health research", was published in the October 2013 edition of *Nutrition Reviews*. She shared that the publication has 12 co-authors, and many of the Working Group members on the phone helped to pull the manuscript together. She noted that it was a challenging review process getting the paper accepted as the reviewers wanted a stronger methodology section.
  - ii. Ms. Kretser shared the 12 principles.

#### b. Third World Congress on Research Integrity

 The Third World Congress on Research Integrity took place in May 2013 in Montreal, Canada. The USDA Under Secretary Dr. Catherine Woteki and Ms. Sylvia Rowe participated in a panel discussion on public-private partnerships and research integrity. Ms. Rowe shared the work of ILSI North America and the Guiding Principles and Dr.



Woteki announced the formation of the "Branded Food Products Database for Public Health" Public-Private Partnership, the first public announcement of the initiative.

- ii. Emerging from the Third World Congress on Research Integrity, the Montreal Statement on Research Integrity has been released. It lays out the responsibilities of Individual and Institutional Partners in Cross-Boundary Research Collaborations. The Montreal Statement aligns with our public-private partnership principles.
- iii. Proceedings from the Conference are being submitted as a manuscript to be published in early 2014.

#### c. National Academies' Government-University-Industry Research Roundtable (GUIRR) Webinar

- Ms. Kretser shared information about the webinar the "Branded Food Products Database for Public Health" Public-Private Partnership held with the National Academies' Government-University-Industry Research Roundtable (GUIRR) on 23 July 2013. GUIRR reached out to the ATIP Foundation to hold a webinar to share more information about its work and, in particular, the work of the "Branded Food Products Database for Public Health" Public-Private Partnership.
- The webinar had just fewer than 100 participants and was a wonderful opportunity for academia, the research community, and the federal agencies to learn more about the Public-Private Partnership.
- iii. The GUIRR webinar was the first time the 3 partners collaborated on a presentation together on the Public-Private Partnership.

#### d. Nutrition Today, March 2014

i. Ms. Kretser shared that we are anticipating the publication of an article in the March 2014 issue of *Nutrition Today* authored by Ms. Rowe and Mr. Nick Alexander. The publication focuses on public-private partnerships and will cite the ILSI North America paper on the guiding principles and the "Branded Food Products Database for Public Health" Public-Private Partnership as a case study. The publication will be a second harvest for ILSI North America and will continue to push the importance of the principles and the framework for successful public-private partnerships.


- *e.* "Public-Private Partnerships: The Evolving Role of Industry Funding in Nutrition Research", *Advances in Nutrition*, September 2013
  - *i.* Dr. Eric Hentges co-moderated the "Public-Private Partnerships: The Evolving Role of Industry Funding in Nutrition Research" session at Experimental Biology 2013 where he highlighted the guiding principles. Ms. Kretser noted that Dr. Jim Hill and Dr. Richard Black also participated in the session.
  - *ii.* A manuscript from the session was published in September 2013.
  - iii. Dr. Daryl Lund asked if the manuscript and the idea of building proceedings around a symposium have been shared with the Institute of Food Technology (IFT) with the suggestion that the same type of thing could be done around Food Science and Technology.
    - Dr. Hentges shared that ILSI North America has not yet met with IFT. The ILSI North America activities centered on public-private partnerships have peaked others' interest and the American Society for Nutrition (ASN) approached ILSI North America to collaborate. Dr. Hentges noted that this would be good to discuss further at Annual Meeting.

# III.Proof of Concept: "Branded Food Products Database for Public Health"Public-Private Partnership

### E. Hentges

- a. Dr. Hentges shared how the "Branded Food Products Database for Public Health" Public-Private Partnership came into being, the plans to publish the "Principles for building public-private partnerships to benefit food safety, nutrition, and health research" manuscript and then do a proof of concept project to use the principles. The USDA Under Secretary Woteki contacted ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information and use the Partnership as the proof of concept.
- b. This Public-Private Partnership with USDA and the ATIP Foundation is a case study for ILSI North America. Ms. Rowe and Mr. Alexander we will be chronicling all the activities to relate them back to the principles and will publish a manuscript on the process.
- a. Development Phase



#### i. Organizational Chart

- 1. Dr. Hentges shared the organizational chart of the Public-Private Partnership with the Working Group. He noted that one of the principles focuses on the importance of good governance, clear roles and responsibilities. Through the organizational chart, it is clear that the "Branded Food Products Database for Public Health" Public-Private Partnership was set up with this principle in mind.
- 2. The Steering Committee is comprised of individuals from the ATIP Foundation, USDA/ARS and ILSI North America and was formed in early 2013. The Steering Committee has final approval of all decisions and activities of the Public-Private Partnership. Recommendations are brought forth by four groups established by the Steering Committee; the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.

#### ii. Timeline of Activities

- Dr. Hentges shared the 2013 Timeline of activities for the "Branded Food Products Database for Public Health" Public-Private Partnership.
- 2. Dr. Hentges noted that the three Partners hold a standing weekly conference call so that communication and transparency are constant.
- 3. After the Criteria Group laid out what information needs to be in the database to make it stronger, the Partnership held listening sessions in the fall of 2013 to inform potential stakeholders about the project and to receive input on the criteria that the Criteria Group developed.
- 4. The Partnership held IT Infrastructure Group meetings that led to meeting with GS1. GS1 is a 501c3 standards organization that has members. It is the standards for the old UPC code which has now been replaced by the Global Trade Item Number or GTIN number, a unique identifier for a branded food. GS1's global system of standards is used in multiple sectors and industries, not limited to Consumer Packaged Goods (CPGs). GS1 collects data through the retailers and manufacturers who are part of their member organizations which are present in over 100 countries. This data has primarily focused on logistical



information that is valuable along the supply chain and business to business, but is now beginning to include nutrition and ingredient information relative to the consumer.

- 5. At this point, the Partnership believes the Development Phase of this project has been completed. The Partners will develop a Progress Report for the USDA Under Secretary that will lay out what has been accomplished and recommendations and plans for the Implementation Phase.
- 6. Dr. Joanne Lupton noted that at the most recent Food and Nutrition Board Meeting, the topic of public-private partnerships came up and no one present was aware of the "Branded Food Products Database for Public Health" Public-Private Partnership. She also shared that Dr. Suzanne Murphy, IOM, is interested in the Partnership. Ms. Kretser shared that Ms. Leslie Sim, IOM, participated in the 14 November Listening Session on the Partnership.
- Dr. Johanna Dwyer inquired whether the Partners have ensured the safety or confidentiality of the data that will go into the enhanced USDA National Nutrient Database.
  - a. Dr. Hentges shared that the ATIP Foundation is important because they will act as the neutral third party and provides a firewall where confidential data can be housed. The data will not be accessible through a FOIA process. The Partnership is building the IT Infrastructure to accommodate confidential information as needed in the future.
- 8. Dr. Dwyer asked what FDA, CDC, NIH and other federal agencies are contributing to the Partnership.
  - a. It was noted that the list of participants in all the Partnership groups (the Steering Committee, the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group) are included in the conference call meeting materials packet so Working Group members can see which individuals, including federal agencies, are actively participating in the Partnership. The Partnership



has selected subject matter experts and stakeholders who have a vested interest in the success of the Partnership to participate in the groups.

- b. The Partnership is committed to remaining inclusive and transparent so that all stakeholders and interested parties are aware of what is going on in the Partnership and how they can participate.
- c. Dr. Dwyer noted that someone from the Food and Nutrition Board, perhaps Dr. Suzanne Murphy, should be participating in the Partnership.
- d. Dr. Claudia Riedt posed a question about whether the Partnership has done an assessment of what companies have already agreed to share proprietary data. She also asked if the submission of data into the enhanced USDA National Nutrient Database is voluntary.
  - Dr. Hentges shared that a number of companies have already become involved. He also noted that participation is completely voluntary.

#### c. Progress Report to USDA Under Secretary

i. Dr. Hentges noted that the Partnership will create a Progress Report for the USDA Under Secretary that describes the formation of the Partnership and the activities of the Development Phase. The Progress Report will also include recommendations and plans for the Implementation Phase.

#### d. Implementation Phase

i. Dr. Hentges noted that the Partnership has heard time and time again from industry that the value of this enhanced database is the single submission of data, or "one and done." When companies create a new product or reformulate, which happens constantly, the data can be submitted once and will be publically available. The constant requests for data and information that companies receive from retailers and suppliers will all be directed to the enhanced USDA National Nutrient Database. The enhanced USDA National Nutrient Database will be a robust, sanctioned, validated USDA government database with quality control where manufacturers' data can be submitted.



- ii. GS1 has the infrastructure capability to do this and the Partnership hopes to work with them on this initiative. The Partnership has heard from FDA, GMA, ILSI North America members and listening session participants that the Partners need to work with GS1.
- iii. Many companies are already populating the GS1 system with their food service data because of the Affordable Care Act (ACA) which requires mandatory menu labeling. The data these companies are already submitting includes the majority of the criteria the Partnership has identified to collect.
- iv. There is a pilot project currently going on in the EU with GS1 collecting data in the same manner as the Partnership plans to.
  - 1. Dr. Dwyer suggested the Partnership reach out to an individual from the EU to function as an observer of the Partnership and offer comments.
  - 2. At the request of USDA ARS, Dr. Paul Fineglas, Institute of Food Research, participated on the IT Infrastructure Group call in November and was extremely supportive of the initiative. Dr. Hentges noted that the Partnership will be talking with ILSI Europe about the initiative.
- v. Participation in the "Branded Food Products Database for Public Health" Public-Private Partnership will not be exclusive to members of GS1. The Partnership is designing a mechanism for small companies and non-GS1 members to submit their data into the system. The IT Infrastructure is being built to have a portal and a format for the data so non-GS1 members will not have to pay a fee to submit their data. This will be a unique feature the Partnership will build into the project.
- vi. One of the first steps in the Implementation Phase will be a beta test. The Partnership will be looking for a small number of ILSI North America member companies to supply some data to test the flow through the system.
- vii. The Implementation Phase will include outreach and communication with potential sustaining members and stakeholders.
- viii. The Partnership has reached out to several proprietary databases to discuss the initiative. So far, the Partners have received positive comments from the proprietary



databases and all have shared that they do not view the initiative as competition. Several have offered to collaborate with the Partnership.

- ix. Dr. Hentges shared that an important aspect of this initiative is explaining how food product labeling is determined. The Partnership will plan to do a white paper that lays out exactly how labeling occurs, why the data is what it is, and why we believe the appropriate quality checks can exist. It was noted that NIH has already expressed interest in participating in this white paper. The Partners will plan to also reach out to IFT to work on this white paper.
- x. Dr. Daryl Lund noted that in November, there was the Conference in Chicago on Implementation of Food Safety Modernization Act (FSMA). The principles for public private partnerships could be useful for their efforts in the implementation of a food safety system etc. Dr. Bob Brackett should be kept informed about the Partnership.
- xi. It was suggested that the Nutrition Coordinating Committee become involved to aid in better communication of the initiative within the federal agencies. Ms. Kretser noted at the invitation of Dr. Pamela Starke Reed, NIH, she presented to the Nutrition Coordinating Committee on the Partnership in September which provided the opportunity to inform a broader group of HHS staff from various NIH institutes and HHS agencies, i.e., FDA and CDC.
- xii. The Partnership will put together an estimate of the resources that have been put into the initiative thus far.
- xiii. The Communications Group will create a document on the value proposition of the initiative to share with stakeholders.
- xiv. Dr. Hentges noted that anyone who wishes to get more involved is welcome.

#### IV. Concept of Conclave on PPP and GRAS Assessments E. Hentges/ R. Lane

#### a. Conclave on Public-Private Partnerships

 The concept of a Conclave on public-private partnerships was discussed at Annual Meeting in 2013. ILSI North America has had discussions with the IFT, ASN, Academy of Nutrition and Dietetics (AND), and the Canadian Nutrition Society (CNS) on holding a



conclave to talk about conflicts of interest around research and around the principles for public funding of research. The goals of the Conclave would be as follows:

- To achieve the acceptance of and commitment to the published principles addressing conflict of interest and public-private partnerships in funding scientific research, "Funding food science and nutrition research: financial conflicts and scientific integrity" and "Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research."
- To issue a Declaration (similar to the Montreal Statement) to provide a transparent and actionable framework for interested public and private organizations that will minimize external criticism.
- 3. To secure the promise of sustained endorsement and updating of the Statement every 2 years.
- ii. The Conflict of Interest & Scientific Integrity Working Group will create a proposal about the Conclave.
- iii. It was suggested that a one page document on the concept of the Conclave be created for the Annual Meeting to garner support.
- iv. It was noted that both AND and ASN have offered to host the Conclave. ILSI North America will have to work with both societies on how to move forward with the concept and develop institutional support for the concept from key scientific societies, relevant government agencies, the National Academy of Sciences and others.

#### b. GRAS Assessments

- i. Dr. Hentges noted that the Conflict of Interest & Scientific Integrity Working Group is exploring potential activities on GRAS Assessments.
- ii. A Feasibility Roundtable took place on 29 May 2013 that looked at several potential researchable activities. Ultimately, an idea was developed:
  - A 101 course on the definition of GRAS. The world of GRAS Assessment is handled by a small group in the regulatory realm and within the federal agencies so it is a mystery to many people. It would be beneficial to have a course that explains the process.



- a. IFT has been consulted and Fred Degnan, who has expertise in food law, is willing to contribute.
- There is a consensus to create this course; however, resources are preventing ILSI North America from taking this project on right now.
- 2. Dr. Jennifer Van de Ligt shared that the Pew Foundation has concerns about transparency around GRAS substances and on conflicts of interest, specifically that companies and external toxicological experts used for GRAS Assessments are put in a conflict of interest situation in order to render a scientific opinion.
- 3. The question was raised how a GRAS 101 course would address conflicts of interest specifically. GRAS best practices or standards should be the focus, not just GRAS 101. How does one set up a sufficiently independent panel with oversight?
  - a. There is still a need to explain how GRAS Assessment happens and a greater dissemination of that information, but the main need is to include the information on conflict of interest.
- Dr. Dwyer suggested a one page document be created on the GRAS 101 course for Annual Meeting 2014.
- 5. Dr. Fergus Clydesdale noted that it is important to not only discuss what is being done now in GRAS Assessment but the course should also include discussion on proactively developing a better way to design the GRAS Assessment process. Dr. Clydesdale suggested that a manuscript, similar to what was done on publicprivate partnerships, could be developed that includes a set of principles or best practices in GRAS Assessment.
  - a. Dr. Lund shared that GRAS Assessment is typically avoided because people do not understand it so the GRAS 101 course should include information about the 101 basics first and foremost. Then, the course could segue into a "group think" about how the GRAS approval process can be improved. The discussion could include questions about



operating within the guidelines in a way that is verifiable and transparent.

- 6. The Working Group agreed that this is an important project to pursue.
- 7. It was suggested that ILSI North America contact Dr. Clydesdale for further discussion on the GRAS 101 course and the potential for Dr. Clydesdale's graduate students to play a role. Dr. Richard Lane and Dr. Van de Ligt could also be involved in the planning of the 101 course. It was noted that ASN may want to be involved.

#### Next Steps

V.

#### D. Lund

- Provide the Progress report on the "Branded Food Products Database for Public Health" Public-Private Partnership to the USDA Under Secretary on the Development Phase and lay out concepts for the Implementation Phase (completed).
- b. Share more information about the Conclave and the GRAS assessment ideas. Include information about the two concepts in the Board Book for Annual Meeting (completed.)
- c. Create a one page document on the concept of the Conclave for the 2014 Annual Meeting (completed.)
- d. Create a one page document on the GRAS 101 course for the 2014 Annual Meeting (completed.)
- e. Proof of principles report should be written.
- f. Consider a new project for the ILSI North America COI & Scientific Integrity Working Group to undertake in collaboration with the IOM Food and Nutrition Board and ASN on the evaluation process of establishing DRI values for bioactives. Currently, the IOM is at an impasse due to COI issues. The establishment of a PPP may be needed to move it forward. It may be helpful to reach out to a number of past presidents of ASN who are on the ILSI North America board that could serve as thought leaders for this new initiative.

#### VI. Adjournment

A. Kretser



### Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

#### **Attendees**

Daryl Lund, chair Fergus Clydesdale Johanna Dwyer John Erdman **Eric Hentges** Alison Kretser Karl Kramer **Richard Lane** Joanne Lupton Debra Miller Delia Murphy Juan Navia Joseph Ratliff Claudia Riedt Kari Ryan Shawn Sullivan **David Thomas** Jennifer van de Ligt Sharon Weiss

#### Unable to Attend

David Allison Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle **Thomas Ells** Rachel Goldstein Steve Hermansky James Hill Susan Offutt **Amy Preston** Steven Rizk **Doris Tancredi Connie Weaver** Liz Westring

University of Wisconsin, Madison University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign **ILSI North America ILSI North America** Tate & Lyle PepsiCo Inc. Texas A&M University The Hershey Company **ILSI North America** McNeil Nutritionals, LLC Dr Pepper Snapple Group **Dr Pepper Snapple Group** Kraft Foods Group, Inc. **ILSI North America Dr Pepper Snapple Group** Cargill, Incorporated **ILSI North America** 

University of Alabama at Birmingham Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia McNeil Nutritionals, LLC Mars, Incorporated ConAgra Foods, Inc. University of Colorado Health and Wellness Center **U.S. Government Accountability Office** The Hershey Company Mars, Incorporated Mondelez International **Purdue University** General Mills Inc.





Foundation website www.atipfoundation.com

# **Public-Private Partnership "Branded Food Products Database for Public Health"**









Agricultural Research Service



# **ILSI North America**

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply. The organization carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.

# **USDA-ARS**

Founded in 1862, the United States Department of Agriculture (USDA) is the U.S. federal executive department that provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management. The USDA funds/manages many internal and external programs that conduct research, set public policy and disseminate information regarding food, nutrition, healthy eating and the relationship between agricultural production and optimal nutrition.

# More details and FAQs about the Public-Private **Partnership can be found on the ATIP Foundation** website: www.atipfoundation.com

### **Public-Private Partnership Timeline of Key Events** 3<sup>rd</sup> World Congress on and ILSI Criteria Research NA GUIRR Group Integrit MOU Webinar Meeting Session Listening Data Session, IT Infra-Listening Quality Steering NAS/GUIRR structure Session Subgroup Committee Washington Cleveland Group Meeting Meeting Meeting OH Mid America National Food Partnership Nutrient Processors Meeting w/ Databank Assoc. Annua USDA Under Communications Conference Meeting Group Meeting Secretary Session Session 2014 May

The ATIP Foundation, LLC is a 501(c)(3) non-profit entity with its corporate office in Arlington, Texas and member offices in eight states. It is governed by members comprised of technology based economic development entities that serve as Federal Partnership Intermediaries to the U.S. **Department of Agriculture.** The Foundation engages with the USDA through USDA's 7-member Liaison Committee. The ATIP Foundation members include the California Association for Local Economic Development; the Center for Innovation at Arlington, LLC (Texas); the Center for Innovative Food Technology (CIFT) in Toledo, Ohio; the Georgia Research Alliance, Inc.; Innovate Mississippi; the Kansas Bioscience Authority; Maryland Technology Development Corporation (TEDCO); Ben Franklin Technology Development Authority, Pennsylvania Department of **Community & Economic Development; and the Wisconsin Security Research Consortium.** 

#### Public-Private Partnership "Branded Food Products Database for Public Health"







#### **Executive Summary**

The ATIP Foundation, ILSI North America, and USDA/ARS established the "Branded Food Products Database for Public Health" Public-Private Partnership (PPP) in first quarter of 2013 to enhance the public's health, which is significantly dependent on diet, through increased knowledge of the nutritional content of the nation's food supply. This will be accomplished by obtaining comprehensive food composition data from the food industry and making it available to government, industry, the scientific community and the general public through an enhanced USDA National Nutrient Database, developed and maintained by the USDA-ARS Nutrient Data Laboratory in Beltsville, MD.

This Progress Report describes the formation of the Partnership and the activities of the Development Phase. The Report signifies the transition into the Implementation Phase in the first quarter of 2014.

The Partners have modeled the governance and operations of the Partnership on an ILSI North America publication on twelve principles for the establishment and operations of research public-private partnerships. Alison Kretser, ILSI North America, serves as the Project Director. The ATIP Foundation is the neutral third party within the Partnership and has the capability to maintain proprietary information if needed. The Steering Committee has final approval of all decisions and activities of the Public-Private Partnership. Recommendations are brought forth by four groups established by the Steering Committee; the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.

#### **Criteria Group Recommendations**

The Criteria Group established the short term and long term scope of nutrient and non-nutrient data based on their work and additional input from a broad base of stakeholders participating in listening sessions on the project. These recommendations were approved by the Steering Committee and include long term recommendations for expansion of the enhanced database beyond what is initially envisioned. A fundamental change in the enhanced USDA National Nutrient Database will be historical data on branded and private label food products. The data criteria (attributes) that follow are consistent with the information required under current labeling law.

#### Proposed Phase 1 Attributes

- 1. Parent Company (manufacturer, subsidiary, signature line) or Private Label (signature line)
- 2. Product Name and Generic Descriptor
- 3. Global Trade Item Number (GTIN)
- 4. Ingredient List and Sub-List (hierarchical and in descending order)
- 5. Weights and Measures (net weight/volume of package)
- 6. Serving Size and Servings per Package
- 7. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)
  - a. (as packaged and as prepared with added ingredients)

8. Date Stamp associated with most current formulation (effective date of change/introduction)

#### Proposed Phase 2 Attributes

1. Food Group Classification based on the Dietary Guidelines for Americans

#### TBD Proposed Future Attributes

- 1. Target Moisture and Ash
- 2. Expanded Nutrient Profile
  - a. Begin with the goal to include 33 nutrients included in the USDA/CNPP SuperTracker and expand as appropriate to all possible nutrients
- 3. Non-Nutritive Components like Caffeine
- 4. Analytical (Unrounded) Data behind NFP
- 5. Nutrient Content Claims
- 6. Bioactive Components
- 7. Label Images- visual picture of the food
- 8. Preparation Instructions
- 9. Top 8 Allergens
  - a. Include cross contact allergens if it is labeled.
  - b. Tabled for further consideration on whether this type of information is appropriate.
- 10. Gluten Free Statement
  - a. Tabled for further consideration on whether this type of information is appropriate.

#### Data Quality System Recommendations

- 1. The QC allowed for compliance within Nutrition Labeling and Education Act (NLEA) should be used as the data quality system.
- 2. Major manufacturers all have documented QC programs for NLEA compliance.
- 3. Build an automated QC check list into the Data Submission Process
  - a. Mechanism to flag "out-of-bounds" data
  - b. Set expected ranges
  - c. Confirmation that the primary constituents listed on the NFP actually add up to the serving size
- 4. All food products would be accepted, no requirement for a time metric in the marketplace, i.e. one year
- 5. Align on a standardized, validated algorithm that will be used across all food products to determine food groups.
- 6. Key Recommendation: The PPP should capture the data acquisition and quality system in a white paper to demonstrate the rigor behind the system for the enhanced USDA National Nutrient Database.

The USDA-stated seal of approval on the quality of the data submitted to the enhanced National Nutrient Database will be an important feature for financial support of the project and an incentive for the voluntary participation of food manufacturers.

With the identification of the GS1 IT infrastructure for the enhanced USDA National Nutrient Database, the Partnership will be able to collect nutrient information in real time on branded and private label products, removing the need to prioritize data submission by product categories.

#### Communications

The Communications Group was responsible for the development of the FAQ document on the Public-Private Partnership that highlights the purpose and goals of the initiative. The document is hosted on the ATIP Foundation website at <u>www.ATIPFoundation.com</u> along with other communications on the Partnership. The Communications Group also spearheaded the development of the materials and format for the listening sessions on the Partnership.

#### Listening Sessions

The Steering Committee requested that the Partnership convene a series of listening sessions to engage a broader group of stakeholders. The purpose of the listening sessions was to communicate about the Partnership, gather input regarding current and potential usage, and opinions on the addition of products and proposed nutrient data to the USDA National Nutrient Database, specifically from existing user groups and food manufacturers. Two listening sessions were convened in Cleveland, OH (October 10) and Washington, D.C. (November 14), the latter co-sponsored and hosted by the National Academies' Government-University-Industry Research Roundtable (GUIRR). Participants were uniformly grateful to be included in the listening sessions, supportive of the Public-Private Partnership effort, and related that success in this initiative would greatly benefit their specific needs and enhance their related programs / projects.

#### **IT Infrastructure Group Recommendations**

The IT Infrastructure Group was formed to identify options for the infrastructure of the enhanced USDA National Nutrient Database. It was very important to the Partnership that we established a robust outreach effort to be as inclusive as possible with entities involved in nutrient databases as well as other types of large databases so we did not discover further into the project that we should have included something else. The recommendations from the Public-Private Partnership on the IT Infrastructure are as follows.

- 1. The ATIP Foundation will enter into a contract with a GS1 certified data pool service provider.
- 2. The IT infrastructure will be built to have a portal and a format for the data so non-GS1 members will have a mechanism to submit data without cost.
- 3. The ATIP Foundation is prepared, if needed, to provide services for analysis of data with approved algorithms, i.e. standardized, validated algorithm for determination of food groups and imputing missing nutrients for a food product.
- 4. The ATIP Foundation will be able to publish data to the USDA National Nutrient Database.
- 5. The ATIP Foundation will develop the IT Infrastructure in a manner that it can be used as a contingency plan for the USDA National Nutrient Database in the event public need cannot be met during the upgrading of the same.

GS1 provides the Partnership with an extremely strong and credible IT Infrastructure to realize the goal of the Partnership to establish an enhanced USDA National Nutrient Database. GS1 is an established 501c3 standards organization used for Business to Business and supply chain management by the largest market share of the branded food manufacturers.

### Public-Private Partnership "Branded Food Products Database for Public Health"





#### SDA Ocs Agricultural Research Service

### <u>Value Proposition of the "Branded Food Products Database for Public</u> <u>Health" Public-Private Partnership</u>

#### Story of the Partnership

Assessing the nutritional health of the American people depends on accurate and comprehensive data regarding the nutrient composition of commonly consumed foods. USDA's Agricultural Research Service (ARS) maintains a National Nutrient Database of the composition of such foods, and although the food industry has compositional data for their own products, very little of that data is publicly available through the database. As part of USDA's response to the Presidential Memorandum in October 2011, ARS approached ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information. Previous efforts by USDA/ARS on their own had seen limited success which is not unexpected given the volume and fluidity of branded food products in the U.S. marketplace.

Accordingly, the USDA/ARS, the International Life Sciences Institute (ILSI) North America and the ATIP Foundation (Agricultural Technology Innovation Partnership) have formed a Public-Private Partnership to enhance public health by augmenting the USDA National Nutrient Database with "nutrient composition of branded foods and private label" data provided by the food industry. This Partnership will ensure this information will be made publically available to those who utilize such data including the federal agencies, the research community, proprietary databases and end users, and the food industry.

The Partnership has established expert groups whose representation is made up of federal government agencies, academic nutrition researchers, a non-government organization (NGO), and ILSI North America member scientists. These expert groups, with additional input from two listening sessions, submitted recommendations for approval by the Steering Committee and, ultimately, these were approved by Dr. Catherine Woteki, USDA Under Secretary for Research, Education, and Economics (REE) and Chief Scientist. These recommendations included specific attributes that will be submitted to the enhanced USDA National Nutrient Database. More work remains to be done and supporters will have the opportunity to participate in these discussions.

Enhancement of the USDA/ARS database through this Public-Private Partnership will be conducted in phases, with information from the Nutrition Facts Panel being obtained first and other, more detailed information being obtained at later stages. The database enhancement is also tied to changes in the infrastructure of the USDA/ARS database that will allow the data to be accessed and utilized more efficiently. The changes brought about by this Public-Private Partnership will ensure that USDA ARS nutrient composition data will remain the "Gold Standard" for the next decade and beyond.

A public-private partnership provides the framework to convene the expertise to compile nutrient data on branded and private label products, secure the private sector engagement in providing this information, as well as the broad-based constituent funding necessary to maximize content and provide timely

information for nutrition, agricultural and diet-related health policy on the nutrient composition of the U.S. food supply.

#### What are the Benefits to Participating in the Partnership?

Corporations and organizations can participate either as providers of branded or private label food product nutrition data, or as financial contributors to support the development and sustainability of the enhanced USDA National Nutrient Database. The ATIP Foundation will acknowledge participants on the Foundation website pages under the Partnership logo. The listing of participants verifies the commitment of professional societies, organizations, and corporations that support this important initiative. A "Sustaining Members Council" will be established with a subset of participants, and the existing Criteria Group of the Partnership. The "Sustaining Members Council" will function in an advisory capacity with the Partnership, making recommendations to promote public health by sustaining this broadly available database.

#### How will Success be Measured?

There are many indicators of success for this initiative. For example, the Partnership will have achieved success when thousands of branded and private label products are integrated in real time into the enhanced National Nutrient Database and timely updates are routine. Success will have been achieved when the database is viewed as the most comprehensive nutrient database. Success can be measured by the breadth of manufacturers- large, medium, and small- who are voluntarily participating. Other goals for measuring success will be met when information provided on an individual food product also includes imputed nutrient data and food groups, and the source of the nutrient values is transparent. USDA ARS will issue comprehensive reports on the nutritional composition of the food supply. Success will also be measured by the presence of a vibrant group of sustaining members who support the long term viability of the enhanced USDA National Nutrient Database. Achievement will be measured by other countries adopting our system.

#### Value of Initiative

- Historical data on branded and private label food products will become available. The nutrition research community will benefit enormously from having this information for tracking dietary trends.
- The value of this initiative is in the governing structure that has established key groups to meet the challenges and achieve the goals set by the Partnership: the Operation and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.
  - For example, the Criteria Group brings expertise across a broad range of nutrition professionals who developed the data quality system sanctioned by the USDA.
  - The IT infrastructure has been designed to be nimble and to accommodate future needs for years to come.
- The 12 principles for establishing and operating a public-private partnership are clearly visible within the Partnership.
- Sustaining members will become integral participants in the Partnership.

#### Key Value for Government

An expanded database will contain much more information on individual food items allowing for research and policy to be based on a true assessment of the extent and fluidity of the food system.

"The composition of the food supply and consumer dietary choices are key inputs for agricultural and food policy decisions. Comprehensive data can inform these decisions, but the volume and fluidity of branded food products in the U.S. marketplace are key challenges. USDA has concluded that this is best pursued through a public-private partnership led by the ATIP Foundation and ILSI North America that is transparent and inclusive of all facets of the diverse food system in North America."

--- Dr. Catherine Woteki, Chief Scientist and USDA Under Secretary for Research, Education, and Economics

"The American diet is diverse. The addition of nutrition information from branded foods will be a tremendous asset to monitoring the American diet and achievements of industry to make healthier products."

--- Dr. Barbara Bowman, CDC

"Having data on branded food products to supplement the USDA National Nutrient Database will be extremely helpful to FDA in tracking the composition of the food supply and making food policy decisions to promote public health," said Jessica Leighton, PhD, senior nutrition science and policy advisor in FDA's Office of Foods and Veterinary Medicine. "The more accurate picture we have of the nutrient content of the food supply, the better informed our decisions on labeling requirements and encouraging food product reformulation will be."

--- Dr. Jessica Leighton, FDA

#### Key Value for Nutrition Researchers

Additional data in the USDA National Nutrient Database will greatly benefit the NHANES survey by allowing for more specific assessment of foods eaten. For example, if a person reports having eaten an item such as "vegetable soup", instead of the nutritional value being based on an averaged and generic database value, it would be based on the actual brand item consumed, and nutrient composition would be that supplied by the company.

"As a frequent user of the National Nutrient Database, it is with extreme pleasure to hear that the Public-Private Partnership is moving forward. The Harvard School of Public Health maintains a nutrient database for the analysis of semi-quantitative food frequency questionnaires. This database requires accurate and up to date brand data for cereals, margarines, oils, and fortified foods. The Public-Private Partnership would provide a more efficient means for us to maintain this accurate time specific brand data in our system."

--- Laura Sampson Kent, Harvard School of Public Health

#### Key Value for Proprietary End Users

The enhanced USDA National Nutrient Database will increase the number of food products for end users who develop applications for consumers and health professionals. By expanding the data available for use in private applications, consumers seeking to eat more healthy diets and dieticians with the responsibility of developing specific diets are the beneficiaries of this information.

"The Branded Food Products Database for Public Health will be a valuable resource to the University of Minnesota Nutrition Coordinating Center. It will allow us to improve the currency and completeness of our food and nutrient database, which will benefit nutrition researchers across the country who rely on it to carry out nutrition-related studies."

--- Lisa Harnack, University of Minnesota Nutrition Coordinating Center

#### Key Value for Professional Societies

- The professional society members rely on the comprehensiveness of the USDA National Nutrient Database for their effort to tease out dietary patterns and nutrient inter-relationships with chronic disease/s.
- The enhanced database will provide more accurate information about what their clients are truly eating.

"The USDA's Nutrient Database is the basis for the science and evidence-based practice of nutrition and dietetics. This important resource helps clinicians counsel patients, researchers plan projects, and food production experts create menus and products. This unique public-private partnership to expand the database and make it more comprehensively reflect the food supply available to consumers is crucial. We believe that ultimately this database expansion will improve the public's health, aligning with our mission."

--- Sonja L. Connor, MS, RDN, LD, President-elect 2013-2014, Academy of Nutrition and Dietetics

### Key Value for Industry

- The enhanced USDA National Nutrient Database will become the single source of truth for nutrition data on branded and private label products.
  - Manufacturers will no longer have to respond to multiple requests from retailers and others and instead direct them to the Database.
- Recognizing that participation in this initiative will be resource-intensive for manufacturers, the Partnership has leveraged the existing GS1 community to ensure alignment with current industry practices.
  - Companies are already submitting product information into the GS1 network.
  - Trust has already been established that the system is secure and manufacturers can assure the accuracy of their shared data.
- Manufacturers recognize that more customers and consumers want virtual nutrition product information and the demand for this information will only intensify in the future.
  - Participation will ensure that your data is included in existing and newly developed nutrition apps that will draw from the augmented Database.
  - Participation will ensure improved customer service for the growing trend in online grocery sales and food delivery systems, such as Amazon, require virtual nutrition information.

Manufacturers provide extensive recipes on their own websites and would benefit from having more accurate nutrient information on ingredients used in these recipes.

"General Mills is interested in continuing to work with the Public-Private Partnership to eventually provide our customers and consumers with a single source of accurate, up-to-date label information, available electronically through USDA"

--- Elizabeth Westring, General Mills Inc.

"This Partnership seeks to expand the USDA Standard Reference to include up-to-date branded manufacture data. It is critical that this data be available to researchers utilizing intake data, and others monitoring the food supply, in order to accurately represent the nutrition of our products in the marketplace and responsibly inform public policy."

--- Patricia Zecca, Campbell Soup Company

### Public-Private Partnership "Branded Food Products Database for Public Health"







#### Features of the Enhanced USDA National Nutrient Database

The goal of the Public-Private Partnership is to expand the current nutrient data by obtaining compositional data directly from the food industry. An expanded database will contain much more information on individual food items allowing for research and policy to be based on a true assessment of the extent and fluidity of the food system.

Nutrition Fa           Serving Size 2/3 cup (55g)           Servings Per Container About 8           Amount Per Serving           Calories 230         Calories fr	rom Fat 40	1.	<ul> <li>Parent Company (Manufacturer, Subsidiary, signature line) or Private Label (signature line)</li> <li>Enhanced database will allow for more specific data collection and analysis in NHANES; allowing for more specific assessment of foods eaten by the population.</li> </ul>
% D Total Fat 8g Saturated Fat 1g <i>Trans</i> Fat 0g Cholesterol 0mg Sodium 160mg Total Carbohydrate 37g Dietary Fiber 4g Sugar 10	aily Value* 12% 5% 0% 7% 12% 16%	2.	<ul> <li>Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)</li> <li>Information available "as packaged" and "as prepared", with added ingredients</li> <li>No longer will a nutritional value be based on an averaged or generic database value.</li> </ul>
Vitamin A Calcium	10% 8% 20% 45%	3. 4. 5.	Product name and generic descriptor Weights and measures Serving size and servings per package
Percent Daily Values are based on a 2,000     Your daily value may be higher or lower deg your calorie needs.     Calories: 2,000     Total Fat Less than 65g     Sat Fat Less than 20g     Cholesterol Less than 300mg     Sodium Less than 2,400m     Total Carbohydrate 300g     Dietary Fiber 25g	0 calorie diet. bending on 2,500 80g 25g 300mg 92,400mg 375g 30g	6. 7.	<ul> <li>Date Stamp associated with most current formulation (effective date of change/introduction)</li> <li>Historical data on food products will allow for tracking dietary trends.</li> <li>Ingredient list and sub-list (hierarchical and in descending order)</li> </ul>
INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR NIACH IROU, THAININ MIXINITRATE (VITAMIN 51, RIDRFAVIN) FOLD, ADD, COPN, SYNLP, SUBAR, SOMERN AND PLAKI ON FOR FRESHNESS, COMN SYNLP, SUBAR, SOMERN AND PLAKI ON FOR FRESHNESS, COMN SYNLP, SUBAR, SOMERN AND PLAKI ON ENDER STRUP, FRUITOSE, BLYCERIE, CONTROLS, MINE SODA, SOCIUM ADD, PROPHOSTRATE, MONORAL COMN DEIED CREAM, CALCUM ADR ADDRIVENTS, AND ADDRIE SODA, SOCIUM ADD, PROPHOSTANET, MONORAL CALCUM CALCUM SULFATE, DISTULLED MONORALYSPECTS, HTMODO GATHEL, DALER, ANALUSA, AND ARTIFICAL RANDO, KAN CHALLIAN KA, XARTINA GUN, ALARTIARE, FLE RED 440 LAKE, CARANEL, COLOR, NACHANATE, RUTA, KAN ENNIN, MITAMIN B, MININI HTRODOLDOBE (VITAMIN B, FUN, NILLIAN B, MININI HTRODOLDOBE (VITAMIN B, FUN, NILLIAN B, BL, MININI HTRODOLDOBE (VITAMIN B, FUN, NILLIAN B, BL, MININI HTRODOLDOBE (VITAMIN B, FUN, MININI MININI B, MININI HTRODOLDOBE (VITAMIN B), FUN, CALO, REAM, FILLION R, SULER A, BLE A, BLE	N. REDUCED VITAMIN B91. (WTH TBHG H FRUCTOSE SS OF COCOA SSAPCH SAIT. NING FBANING FWOSPHATE. SAUTE ADDED. SOV LLA EXTRACT, LOW AS LAKE. KE. REDUCED AM 80, ROD- CITIGE CACD, A	8.	<ul> <li>This information has never been captured before in the National Nutrient Database. Having this information available will allow for analysis that has never been done.</li> <li>GTIN Number</li> <li>Specific nutrient composition directly from the food product, correlated to this number, will be available.</li> </ul>
5 901234 1234	57 >	s f f	'Food composition databases are central to the conduct of nutrition research, as they standardize how foods can be characterized in terms of nutrients, dietary guidance-based food groups and other relevant dietary constituents. The Branded Food Products Database for Public Health will provide researchers the first-ever completely free and publicly available database on the composition of foods by brand name. This will enable greater

specificity in all types of nutrition studies of individual's diets and food environments." - Dr. Susan Krebs-Smith, National Institutes of Health



# Acceptance of Financial Support from Industry for Research, Education & Consulting

#### AUTHORS

Emily J. Dhurandhar, PhD, The Obesity Society Advocacy Chair Ted Kyle, RPh, The Obesity Society Advocacy Consultant Martin Binks, PhD, The Obesity Society Secretary Treasurer Nikhil Dhurandhar, PhD, The Obesity Society President-Elect

#### **TOS POSITION**

Scientists and industry should be encouraged to collaborate in the interest of scientific discovery and public health, without fear of reprisal based solely on the collaboration. In itself, a transparent relationship between scientists and industry with full disclosure should not be used to insinuate compromised integrity of a researcher. Attempting to discredit scientific opinions or individuals solely on the basis of collaborative relationships and/or funding sources has no place in the scientific process.

#### **BACKGROUND & STATEMENT OF THE PROBLEM**

Nutrition and obesity researchers have frequently endured *ad hominem* attacks based on relationships with various industries (e.g., food and pharmaceutical) in recent years. Interactions between scientists and industry are a natural and important process reflecting the need to critically evaluate the available evidence that exists on any particular question with scientific rigor. Innuendo and suggestions of wrongdoing in the absence of any objective indication of impropriety have led to public attacks on the credibility of scientists funded by these industries either directly or through their institutions, has been frequently discredited solely on these fully transparent financial relationships without any reference to the evidence on the scientific question at hand. The Obesity Society considers this response inappropriate for several reasons.

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For this reason, many policies are in place from both advisory panels and scientific publication outlets to ensure transparency and disclosure of *all* potential sources of bias. It is common practice for scientific entities to disclose their source of funding for a study, and to develop clear stipulations that outline the ethical use of funds and commitment to non-influence of the funding source over the design, analysis, interpretation, and publication of the scientific process. Such policies and practices allow any discrepancies to be addressed through scientific rigor and full disclosure. For example, The Obesity

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The ability of scientists to do their work, engage in free and open dialogue, offer expert opinion, and conduct meaningful research is crucial to advancing public health. *Funding source is not a sufficient basis upon which to discount otherwise sound scientific evidence.* 

#### RECOMMENDATIONS

Dismissing the contributions of individual scientists and attempting to discredit individuals based on funding source should not be practiced. Collaborations between scientists and industry and/or funding for such collaborations should be transparent with full disclosure.

#### REFERENCES

1. Cope MB, Allison DB. White hat bias: examples of its presence in obesity research and a call for renewed commitment to faithfulness in research reporting. Int J Obesity 2010;34:84-8.

2. The Obesity Society (TOS) Guidelines for Accepting Funds from External Sources. The Obesity Society, 2013. (Accessed January 30, 2014, <u>here</u>)

The Obesity Society

8757 Georgia Avenue, Suite 1320, Silver Spring, MD 20910 | Phone (301) 563-6526 | Fax (301) 563-6595

From: **Delia Murphy** Thursday, May 29, 2014 8:47 AM Sent: 'DAllison@uab.edu'; ' To: '; fergc@foodsci.umass.edu'; 'mdoyle@uga.edu'; 'jlupton@tamu.edu'; 'dwyerj1@od.nih.gov'; 'jwerdman@illinois.edu'; '; 'james.hill@ucdenver.edu'; '; 'dblund@wisc.edu'; ī. '; Sharon Weiss; ;' Cc: Eric Hentges; Alison Kretser; Delia Murphy

Subject: Attachments: Eric Hentges; Alison Kretser; Delia Murphy ILSI North America Conflict of Interest & Scientific Integrity Working Group PDF of COI 29 May Call Materials.pdf

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Agenda and Materials for 29 May Conference Call

Please find attached an updated agenda and packet of materials for the Conflict of Interest & Scientific Integrity Working Group conference call today, Thursday, 29 May from 10:00 to 11:30 am EDT. Please use our conference call number to dial in:

215-446-0193 (industry members) 888-706-6468 (others) Access code: 1277013 (all)

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America: From: Sent: To: Delia Murphy > Tuesday, May 27, 2014 11:41 AM 'DAllison@uab.edu'; ' 'mdoyle@uga.edu'; 'jlupton@tamu.edu'; 'dwyerj1@od.nih.gov'; 'jwerdman@illinois.edu'; ' ', 'dblund@wisc.edu'; '

Sharon Weiss;

Cc:Eric Hentges; Alison Kretser; Delia MurphySubject:ILSI North America Conflict of Interest & Scientific Integrity Working GroupAttachments:COI 29 May Call Agenda.doc; Meeting Minutes\_17 Dec COI Call.doc; Progress ReportExecutive Summary.docx; Obesity Society-Acceptance of Financial Support from<br/>Industry for Research.docx

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Please use our conference call number to dial in:

215-446-0193 (industry members) 888-706-6468 (others) Access code: 1277013 (all)

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#### Public-Private Partnership "Branded Food Products Database for Public Health"







#### **Executive Summary**

The ATIP Foundation, ILSI North America, and USDA/ARS established the "Branded Food Products Database for Public Health" Public-Private Partnership (PPP) in first quarter of 2013 to enhance the public's health, which is significantly dependent on diet, through increased knowledge of the nutritional content of the nation's food supply. This will be accomplished by obtaining comprehensive food composition data from the food industry and making it available to government, industry, the scientific community and the general public through an enhanced USDA National Nutrient Database, developed and maintained by the USDA-ARS Nutrient Data Laboratory in Beltsville, MD.

This Progress Report describes the formation of the Partnership and the activities of the Development Phase. The Report signifies the transition into the Implementation Phase in the first quarter of 2014.

The Partners have modeled the governance and operations of the Partnership on an ILSI North America publication on twelve principles for the establishment and operations of research public-private partnerships. Alison Kretser, ILSI North America, serves as the Project Director. The ATIP Foundation is the neutral third party within the Partnership and has the capability to maintain proprietary information if needed. The Steering Committee has final approval of all decisions and activities of the Public-Private Partnership. Recommendations are brought forth by four groups established by the Steering Committee; the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.

#### **Criteria Group Recommendations**

The Criteria Group established the short term and long term scope of nutrient and non-nutrient data based on their work and additional input from a broad base of stakeholders participating in listening sessions on the project. These recommendations were approved by the Steering Committee and include long term recommendations for expansion of the enhanced database beyond what is initially envisioned. A fundamental change in the enhanced USDA National Nutrient Database will be historical data on branded and private label food products. The data criteria (attributes) that follow are consistent with the information required under current labeling law.

#### Proposed Phase 1 Attributes

- 1. Parent Company (manufacturer, subsidiary, signature line) or Private Label (signature line)
- 2. Product Name and Generic Descriptor
- 3. Global Trade Item Number (GTIN)
- 4. Ingredient List and Sub-List (hierarchical and in descending order)
- 5. Weights and Measures (net weight/volume of package)
- 6. Serving Size and Servings per Package
- 7. Nutrition Facts Panel (NFP) and Expanded Facts Panel (when available)
  - a. (as packaged and as prepared with added ingredients)

8. Date Stamp associated with most current formulation (effective date of change/introduction)

#### Proposed Phase 2 Attributes

1. Food Group Classification based on the Dietary Guidelines for Americans

#### TBD Proposed Future Attributes

- 1. Target Moisture and Ash
- 2. Expanded Nutrient Profile
  - a. Begin with the goal to include 33 nutrients included in the USDA/CNPP SuperTracker and expand as appropriate to all possible nutrients
- 3. Non-Nutritive Components like Caffeine
- 4. Analytical (Unrounded) Data behind NFP
- 5. Nutrient Content Claims
- 6. Bioactive Components
- 7. Label Images- visual picture of the food
- 8. Preparation Instructions
- 9. Top 8 Allergens
  - a. Include cross contact allergens if it is labeled.
  - b. Tabled for further consideration on whether this type of information is appropriate.
- 10. Gluten Free Statement
  - a. Tabled for further consideration on whether this type of information is appropriate.

#### Data Quality System Recommendations

- 1. The QC allowed for compliance within Nutrition Labeling and Education Act (NLEA) should be used as the data quality system.
- 2. Major manufacturers all have documented QC programs for NLEA compliance.
- 3. Build an automated QC check list into the Data Submission Process
  - a. Mechanism to flag "out-of-bounds" data
  - b. Set expected ranges
  - c. Confirmation that the primary constituents listed on the NFP actually add up to the serving size
- 4. All food products would be accepted, no requirement for a time metric in the marketplace, i.e. one year
- 5. Align on a standardized, validated algorithm that will be used across all food products to determine food groups.
- 6. Key Recommendation: The PPP should capture the data acquisition and quality system in a white paper to demonstrate the rigor behind the system for the enhanced USDA National Nutrient Database.

The USDA-stated seal of approval on the quality of the data submitted to the enhanced National Nutrient Database will be an important feature for financial support of the project and an incentive for the voluntary participation of food manufacturers.

With the identification of the GS1 IT infrastructure for the enhanced USDA National Nutrient Database, the Partnership will be able to collect nutrient information in real time on branded and private label products, removing the need to prioritize data submission by product categories.

#### Communications

The Communications Group was responsible for the development of the FAQ document on the Public-Private Partnership that highlights the purpose and goals of the initiative. The document is hosted on the ATIP Foundation website at <u>www.ATIPFoundation.com</u> along with other communications on the Partnership. The Communications Group also spearheaded the development of the materials and format for the listening sessions on the Partnership.

#### Listening Sessions

The Steering Committee requested that the Partnership convene a series of listening sessions to engage a broader group of stakeholders. The purpose of the listening sessions was to communicate about the Partnership, gather input regarding current and potential usage, and opinions on the addition of products and proposed nutrient data to the USDA National Nutrient Database, specifically from existing user groups and food manufacturers. Two listening sessions were convened in Cleveland, OH (October 10) and Washington, D.C. (November 14), the latter co-sponsored and hosted by the National Academies' Government-University-Industry Research Roundtable (GUIRR). Participants were uniformly grateful to be included in the listening sessions, supportive of the Public-Private Partnership effort, and related that success in this initiative would greatly benefit their specific needs and enhance their related programs / projects.

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- 1. The ATIP Foundation will enter into a contract with a GS1 certified data pool service provider.
- 2. The IT infrastructure will be built to have a portal and a format for the data so non-GS1 members will have a mechanism to submit data without cost.
- 3. The ATIP Foundation is prepared, if needed, to provide services for analysis of data with approved algorithms, i.e. standardized, validated algorithm for determination of food groups and imputing missing nutrients for a food product.
- 4. The ATIP Foundation will be able to publish data to the USDA National Nutrient Database.
- 5. The ATIP Foundation will develop the IT Infrastructure in a manner that it can be used as a contingency plan for the USDA National Nutrient Database in the event public need cannot be met during the upgrading of the same.

GS1 provides the Partnership with an extremely strong and credible IT Infrastructure to realize the goal of the Partnership to establish an enhanced USDA National Nutrient Database. GS1 is an established 501c3 standards organization used for Business to Business and supply chain management by the largest market share of the branded food manufacturers.



1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

## Meeting Minutes: Working Group on Conflict of Interest & Scientific Integrity Conference Call

Tuesday, 17 December, 2013, 3:00-4:30 pm EST

Dial-in Information: 215-446-0193 (industry members), 888-706-6468 (others) Access code: 1277013 (all)

Purpose: To update the Working Group on Public-Private Partnership (PPP) activities in 2013.

#### Ι.

#### Welcome and Introductions

a. Ms. Alison Kretser welcomed Working Group members to the call and took attendance. She shared that the purpose of the call is to update the Working Group members on the activities that took place in 2013.

#### II. Communications/Publications on PPP

A. Kretser

A. Kretser

- a. "Principles for building public-private partnerships to benefit food safety, nutrition, and health research" *Nutrition Reviews*, October 2013
  - i. Ms. Kretser shared that the ILSI North America manuscript, "Principles for building public-private partnerships to benefit food safety, nutrition, and health research", was published in the October 2013 edition of *Nutrition Reviews*. She shared that the publication has 12 co-authors, and many of the Working Group members on the phone helped to pull the manuscript together. She noted that it was a challenging review process getting the paper accepted as the reviewers wanted a stronger methodology section.
  - ii. Ms. Kretser shared the 12 principles.

#### b. Third World Congress on Research Integrity

 The Third World Congress on Research Integrity took place in May 2013 in Montreal, Canada. The USDA Under Secretary Dr. Catherine Woteki and Ms. Sylvia Rowe participated in a panel discussion on public-private partnerships and research integrity. Ms. Rowe shared the work of ILSI North America and the Guiding Principles and Dr.



Woteki announced the formation of the "Branded Food Products Database for Public Health" Public-Private Partnership, the first public announcement of the initiative.

- ii. Emerging from the Third World Congress on Research Integrity, the Montreal Statement on Research Integrity has been released. It lays out the responsibilities of Individual and Institutional Partners in Cross-Boundary Research Collaborations. The Montreal Statement aligns with our public-private partnership principles.
- iii. Proceedings from the Conference are being submitted as a manuscript to be published in early 2014.

#### c. National Academies' Government-University-Industry Research Roundtable (GUIRR) Webinar

- Ms. Kretser shared information about the webinar the "Branded Food Products Database for Public Health" Public-Private Partnership held with the National Academies' Government-University-Industry Research Roundtable (GUIRR) on 23 July 2013. GUIRR reached out to the ATIP Foundation to hold a webinar to share more information about its work and, in particular, the work of the "Branded Food Products Database for Public Health" Public-Private Partnership.
- The webinar had just fewer than 100 participants and was a wonderful opportunity for academia, the research community, and the federal agencies to learn more about the Public-Private Partnership.
- iii. The GUIRR webinar was the first time the 3 partners collaborated on a presentation together on the Public-Private Partnership.

#### d. Nutrition Today, March 2014

i. Ms. Kretser shared that we are anticipating the publication of an article in the March 2014 issue of *Nutrition Today* authored by Ms. Rowe and Mr. Nick Alexander. The publication focuses on public-private partnerships and will cite the ILSI North America paper on the guiding principles and the "Branded Food Products Database for Public Health" Public-Private Partnership as a case study. The publication will be a second harvest for ILSI North America and will continue to push the importance of the principles and the framework for successful public-private partnerships.



- *e.* "Public-Private Partnerships: The Evolving Role of Industry Funding in Nutrition Research", *Advances in Nutrition*, September 2013
  - *i.* Dr. Eric Hentges co-moderated the "Public-Private Partnerships: The Evolving Role of Industry Funding in Nutrition Research" session at Experimental Biology 2013 where he highlighted the guiding principles. Ms. Kretser noted that Dr. Jim Hill and Dr. Richard Black also participated in the session.
  - *ii.* A manuscript from the session was published in September 2013.
  - iii. Dr. Daryl Lund asked if the manuscript and the idea of building proceedings around a symposium have been shared with the Institute of Food Technology (IFT) with the suggestion that the same type of thing could be done around Food Science and Technology.
    - Dr. Hentges shared that ILSI North America has not yet met with IFT. The ILSI North America activities centered on public-private partnerships have peaked others' interest and the American Society for Nutrition (ASN) approached ILSI North America to collaborate. Dr. Hentges noted that this would be good to discuss further at Annual Meeting.

# III.Proof of Concept: "Branded Food Products Database for Public Health"Public-Private Partnership

### E. Hentges

- a. Dr. Hentges shared how the "Branded Food Products Database for Public Health" Public-Private Partnership came into being, the plans to publish the "Principles for building public-private partnerships to benefit food safety, nutrition, and health research" manuscript and then do a proof of concept project to use the principles. The USDA Under Secretary Woteki contacted ILSI North America to see if the organization would join with the Agency in enhancing the USDA National Nutrient Database with branded food products nutrition information and use the Partnership as the proof of concept.
- b. This Public-Private Partnership with USDA and the ATIP Foundation is a case study for ILSI North America. Ms. Rowe and Mr. Alexander we will be chronicling all the activities to relate them back to the principles and will publish a manuscript on the process.
- a. Development Phase



#### i. Organizational Chart

- 1. Dr. Hentges shared the organizational chart of the Public-Private Partnership with the Working Group. He noted that one of the principles focuses on the importance of good governance, clear roles and responsibilities. Through the organizational chart, it is clear that the "Branded Food Products Database for Public Health" Public-Private Partnership was set up with this principle in mind.
- 2. The Steering Committee is comprised of individuals from the ATIP Foundation, USDA/ARS and ILSI North America and was formed in early 2013. The Steering Committee has final approval of all decisions and activities of the Public-Private Partnership. Recommendations are brought forth by four groups established by the Steering Committee; the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group.

#### ii. Timeline of Activities

- Dr. Hentges shared the 2013 Timeline of activities for the "Branded Food Products Database for Public Health" Public-Private Partnership.
- 2. Dr. Hentges noted that the three Partners hold a standing weekly conference call so that communication and transparency are constant.
- 3. After the Criteria Group laid out what information needs to be in the database to make it stronger, the Partnership held listening sessions in the fall of 2013 to inform potential stakeholders about the project and to receive input on the criteria that the Criteria Group developed.
- 4. The Partnership held IT Infrastructure Group meetings that led to meeting with GS1. GS1 is a 501c3 standards organization that has members. It is the standards for the old UPC code which has now been replaced by the Global Trade Item Number or GTIN number, a unique identifier for a branded food. GS1's global system of standards is used in multiple sectors and industries, not limited to Consumer Packaged Goods (CPGs). GS1 collects data through the retailers and manufacturers who are part of their member organizations which are present in over 100 countries. This data has primarily focused on logistical



information that is valuable along the supply chain and business to business, but is now beginning to include nutrition and ingredient information relative to the consumer.

- 5. At this point, the Partnership believes the Development Phase of this project has been completed. The Partners will develop a Progress Report for the USDA Under Secretary that will lay out what has been accomplished and recommendations and plans for the Implementation Phase.
- 6. Dr. Joanne Lupton noted that at the most recent Food and Nutrition Board Meeting, the topic of public-private partnerships came up and no one present was aware of the "Branded Food Products Database for Public Health" Public-Private Partnership. She also shared that Dr. Suzanne Murphy, IOM, is interested in the Partnership. Ms. Kretser shared that Ms. Leslie Sim, IOM, participated in the 14 November Listening Session on the Partnership.
- Dr. Johanna Dwyer inquired whether the Partners have ensured the safety or confidentiality of the data that will go into the enhanced USDA National Nutrient Database.
  - a. Dr. Hentges shared that the ATIP Foundation is important because they will act as the neutral third party and provides a firewall where confidential data can be housed. The data will not be accessible through a FOIA process. The Partnership is building the IT Infrastructure to accommodate confidential information as needed in the future.
- 8. Dr. Dwyer asked what FDA, CDC, NIH and other federal agencies are contributing to the Partnership.
  - a. It was noted that the list of participants in all the Partnership groups (the Steering Committee, the Operations and Management Group, the Criteria Group, the IT Infrastructure Group, and the Communications Group) are included in the conference call meeting materials packet so Working Group members can see which individuals, including federal agencies, are actively participating in the Partnership. The Partnership


has selected subject matter experts and stakeholders who have a vested interest in the success of the Partnership to participate in the groups.

- b. The Partnership is committed to remaining inclusive and transparent so that all stakeholders and interested parties are aware of what is going on in the Partnership and how they can participate.
- c. Dr. Dwyer noted that someone from the Food and Nutrition Board, perhaps Dr. Suzanne Murphy, should be participating in the Partnership.
- d. Dr. Claudia Riedt posed a question about whether the Partnership has done an assessment of what companies have already agreed to share proprietary data. She also asked if the submission of data into the enhanced USDA National Nutrient Database is voluntary.
  - Dr. Hentges shared that a number of companies have already become involved. He also noted that participation is completely voluntary.

#### c. Progress Report to USDA Under Secretary

i. Dr. Hentges noted that the Partnership will create a Progress Report for the USDA Under Secretary that describes the formation of the Partnership and the activities of the Development Phase. The Progress Report will also include recommendations and plans for the Implementation Phase.

#### d. Implementation Phase

i. Dr. Hentges noted that the Partnership has heard time and time again from industry that the value of this enhanced database is the single submission of data, or "one and done." When companies create a new product or reformulate, which happens constantly, the data can be submitted once and will be publically available. The constant requests for data and information that companies receive from retailers and suppliers will all be directed to the enhanced USDA National Nutrient Database. The enhanced USDA National Nutrient Database will be a robust, sanctioned, validated USDA government database with quality control where manufacturers' data can be submitted.



- ii. GS1 has the infrastructure capability to do this and the Partnership hopes to work with them on this initiative. The Partnership has heard from FDA, GMA, ILSI North America members and listening session participants that the Partners need to work with GS1.
- iii. Many companies are already populating the GS1 system with their food service data because of the Affordable Care Act (ACA) which requires mandatory menu labeling. The data these companies are already submitting includes the majority of the criteria the Partnership has identified to collect.
- iv. There is a pilot project currently going on in the EU with GS1 collecting data in the same manner as the Partnership plans to.
  - 1. Dr. Dwyer suggested the Partnership reach out to an individual from the EU to function as an observer of the Partnership and offer comments.
  - 2. At the request of USDA ARS, Dr. Paul Fineglas, Institute of Food Research, participated on the IT Infrastructure Group call in November and was extremely supportive of the initiative. Dr. Hentges noted that the Partnership will be talking with ILSI Europe about the initiative.
- v. Participation in the "Branded Food Products Database for Public Health" Public-Private Partnership will not be exclusive to members of GS1. The Partnership is designing a mechanism for small companies and non-GS1 members to submit their data into the system. The IT Infrastructure is being built to have a portal and a format for the data so non-GS1 members will not have to pay a fee to submit their data. This will be a unique feature the Partnership will build into the project.
- vi. One of the first steps in the Implementation Phase will be a beta test. The Partnership will be looking for a small number of ILSI North America member companies to supply some data to test the flow through the system.
- vii. The Implementation Phase will include outreach and communication with potential sustaining members and stakeholders.
- viii. The Partnership has reached out to several proprietary databases to discuss the initiative. So far, the Partners have received positive comments from the proprietary



databases and all have shared that they do not view the initiative as competition. Several have offered to collaborate with the Partnership.

- ix. Dr. Hentges shared that an important aspect of this initiative is explaining how food product labeling is determined. The Partnership will plan to do a white paper that lays out exactly how labeling occurs, why the data is what it is, and why we believe the appropriate quality checks can exist. It was noted that NIH has already expressed interest in participating in this white paper. The Partners will plan to also reach out to IFT to work on this white paper.
- x. Dr. Daryl Lund noted that in November, there was the Conference in Chicago on Implementation of Food Safety Modernization Act (FSMA). The principles for public private partnerships could be useful for their efforts in the implementation of a food safety system etc. Dr. Bob Brackett should be kept informed about the Partnership.
- xi. It was suggested that the Nutrition Coordinating Committee become involved to aid in better communication of the initiative within the federal agencies. Ms. Kretser noted at the invitation of Dr. Pamela Starke Reed, NIH, she presented to the Nutrition Coordinating Committee on the Partnership in September which provided the opportunity to inform a broader group of HHS staff from various NIH institutes and HHS agencies, i.e., FDA and CDC.
- xii. The Partnership will put together an estimate of the resources that have been put into the initiative thus far.
- xiii. The Communications Group will create a document on the value proposition of the initiative to share with stakeholders.
- xiv. Dr. Hentges noted that anyone who wishes to get more involved is welcome.

#### IV. Concept of Conclave on PPP and GRAS Assessments E. Hentges/ R. Lane

#### a. Conclave on Public-Private Partnerships

 The concept of a Conclave on public-private partnerships was discussed at Annual Meeting in 2013. ILSI North America has had discussions with the IFT, ASN, Academy of Nutrition and Dietetics (AND), and the Canadian Nutrition Society (CNS) on holding a



conclave to talk about conflicts of interest around research and around the principles for public funding of research. The goals of the Conclave would be as follows:

- To achieve the acceptance of and commitment to the published principles addressing conflict of interest and public-private partnerships in funding scientific research, "Funding food science and nutrition research: financial conflicts and scientific integrity" and "Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research."
- 2. To issue a Declaration (similar to the Montreal Statement) to provide a transparent and actionable framework for interested public and private organizations that will minimize external criticism.
- 3. To secure the promise of sustained endorsement and updating of the Statement every 2 years.
- ii. The Conflict of Interest & Scientific Integrity Working Group will create a proposal about the Conclave.
- iii. It was suggested that a one page document on the concept of the Conclave be created for the Annual Meeting to garner support.
- iv. It was noted that both AND and ASN have offered to host the Conclave. ILSI North America will have to work with both societies on how to move forward with the concept and develop institutional support for the concept from key scientific societies, relevant government agencies, the National Academy of Sciences and others.

#### b. GRAS Assessments

- i. Dr. Hentges noted that the Conflict of Interest & Scientific Integrity Working Group is exploring potential activities on GRAS Assessments.
- ii. A Feasibility Roundtable took place on 29 May 2013 that looked at several potential researchable activities. Ultimately, an idea was developed:
  - A 101 course on the definition of GRAS. The world of GRAS Assessment is handled by a small group in the regulatory realm and within the federal agencies so it is a mystery to many people. It would be beneficial to have a course that explains the process.



- a. IFT has been consulted and Fred Degnan, who has expertise in food law, is willing to contribute.
- b. There is a consensus to create this course; however, resources are preventing ILSI North America from taking this project on right now.
- 2. Dr. Jennifer Van de Ligt shared that the Pew Foundation has concerns about transparency around GRAS substances and on conflicts of interest, specifically that companies and external toxicological experts used for GRAS Assessments are put in a conflict of interest situation in order to render a scientific opinion.
- 3. The question was raised how a GRAS 101 course would address conflicts of interest specifically. GRAS best practices or standards should be the focus, not just GRAS 101. How does one set up a sufficiently independent panel with oversight?
  - a. There is still a need to explain how GRAS Assessment happens and a greater dissemination of that information, but the main need is to include the information on conflict of interest.
- Dr. Dwyer suggested a one page document be created on the GRAS 101 course for Annual Meeting 2014.
- 5. Dr. Fergus Clydesdale noted that it is important to not only discuss what is being done now in GRAS Assessment but the course should also include discussion on proactively developing a better way to design the GRAS Assessment process. Dr. Clydesdale suggested that a manuscript, similar to what was done on publicprivate partnerships, could be developed that includes a set of principles or best practices in GRAS Assessment.
  - a. Dr. Lund shared that GRAS Assessment is typically avoided because people do not understand it so the GRAS 101 course should include information about the 101 basics first and foremost. Then, the course could segue into a "group think" about how the GRAS approval process can be improved. The discussion could include questions about



operating within the guidelines in a way that is verifiable and transparent.

- 6. The Working Group agreed that this is an important project to pursue.
- 7. It was suggested that ILSI North America contact Dr. Clydesdale for further discussion on the GRAS 101 course and the potential for Dr. Clydesdale's graduate students to play a role. Dr. Richard Lane and Dr. Van de Ligt could also be involved in the planning of the 101 course. It was noted that ASN may want to be involved.

#### Next Steps

V.

#### D. Lund

- Provide the Progress report on the "Branded Food Products Database for Public Health" Public-Private Partnership to the USDA Under Secretary on the Development Phase and lay out concepts for the Implementation Phase (completed).
- b. Share more information about the Conclave and the GRAS assessment ideas. Include information about the two concepts in the Board Book for Annual Meeting (completed.)
- c. Create a one page document on the concept of the Conclave for the 2014 Annual Meeting (completed.)
- d. Create a one page document on the GRAS 101 course for the 2014 Annual Meeting (completed.)
- e. Proof of principles report should be written.
- f. Consider a new project for the ILSI North America COI & Scientific Integrity Working Group to undertake in collaboration with the IOM Food and Nutrition Board and ASN on the evaluation process of establishing DRI values for bioactives. Currently, the IOM is at an impasse due to COI issues. The establishment of a PPP may be needed to move it forward. It may be helpful to reach out to a number of past presidents of ASN who are on the ILSI North America board that could serve as thought leaders for this new initiative.

### VI. Adjournment

A. Kretser



## Attendance: Working Group on Conflict of Interest & Scientific Integrity Conference Call

#### **Attendees**

Daryl Lund, chair Fergus Clydesdale Johanna Dwyer John Erdman **Eric Hentges** Alison Kretser Karl Kramer **Richard Lane** Joanne Lupton Debra Miller Delia Murphy Juan Navia Joseph Ratliff Claudia Riedt Kari Ryan Shawn Sullivan **David Thomas** Jennifer van de Ligt Sharon Weiss

#### Unable to Attend

David Allison Nelson Almeida Rhona Applebaum Stephanie Atkinson Kerr Dow Michael Doyle **Thomas Ells** Rachel Goldstein Steve Hermansky James Hill Susan Offutt **Amy Preston** Steven Rizk **Doris Tancredi Connie Weaver** Liz Westring

University of Wisconsin, Madison University of Massachusetts at Amherst NIH/Tufts University Medical Center University of Illinois at Urbana-Champaign **ILSI North America ILSI North America** Tate & Lyle PepsiCo Inc. Texas A&M University The Hershey Company **ILSI North America** McNeil Nutritionals, LLC Dr Pepper Snapple Group **Dr Pepper Snapple Group** Kraft Foods Group, Inc. **ILSI North America Dr Pepper Snapple Group** Cargill, Incorporated **ILSI North America** 

University of Alabama at Birmingham Kellogg Company Coca-Cola Company McMaster University Cargill, Incorporated The University of Georgia McNeil Nutritionals, LLC Mars, Incorporated ConAgra Foods, Inc. University of Colorado Health and Wellness Center **U.S. Government Accountability Office** The Hershey Company Mars, Incorporated Mondelez International **Purdue University** General Mills Inc.



## Agenda: Working Group on Conflict of Interest & Scientific Integrity **Conference Call**

Thursday, 29 May, 2014, 10:00-11:30 am EDT

Dial-in Information: 215-446-0193 (industry members), 888-706-6468 (others) Access code: 1277013 (all)

### Purpose: To update the Working Group on the Public-Private Partnership (PPP) and recent activities.

I.	Welcome and Introductions	A. Kretser
II.	Communications/Publications on PPP	A. Kretser
	a. Mid America Food Processors Association Presentation, March 2014	A. Kretser
	b. "Public-Private Partnerships in Nutrition: Meeting the Public-Private Communi	cation
	Challenge," Nutrition Today, March 2014	
	c. Experimental Biology Reception on PPPs	E. Hentges
	d. National Nutrient Databank Conference, May 2014	A. Kretser
	e. Canadian Nutrition Society Food for Health Workshop, June 2014	E. Hentges
	f. 17th IUFoST World Congress of Food Science and Technology, August 2014	E. Hentges
III.	Proof of Concept: "Branded Food Products Database for Public Health"	
	Public-Private Partnership	A. Kretser
	a. Meeting with USDA Under Secretary on PPP Progress Report	A. Kretser
	b. Implementation Phase	A. Kretser
	i. Budget	
	ii. Beta Testing	
	iii. Outreach Strategy	
IV.	GMA's Consumer Information Transparency Initiative	E. Hentges
V.	Support of Professional Societies of COI PPP Principles	E. Hentges
VI.	GRAS Assessment	E. Hentges
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VIII.	Adjournment	A. Kretser



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#### **Unconfirmed**

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University of Colorado Health and Wellness Center Texas A&M University

University of Alabama at Birmingham McMaster University Dr Pepper Snapple Group Coca-Cola Company ILSI North America

Kellogg Company University of Massachusetts at Amherst The University of Georgia NIH/Tufts University Medical Center Coca-Cola Company The Hershey Company The Hershey Company Mars, Incorporated Kraft Foods Group, Inc. ILSI North America

From: Sent: To:	Delia Murphy Tuesday, May 27, 2014 11:41 AM 'DAllison@uab.edu'; ' ; 'fergc@foodsci.um 'mdoyle@uga.edu'; 'jlupton@tamu.edu'; 'c 'jwerdman@illinois.edu';	m'; hass.edu'; łwyerj1@od.nih.gov'; '; 'james.hill@ucdenver.edu';
		'; 'dblund@wisc.edu';
	Shawn Sullivar	ı; '               ; '; Sharon Weiss;
Cc: Subject: Attachments:	Eric Hentges; Alison Kretser; Delia Murphy ILSI North America Conflict of Interest & S COI 29 May Call Agenda.doc; Meeting Min Executive Summary.docx; Obesity Society- Industry for Research.docx	cientific Integrity Working Group utes_17 Dec COI Call.doc; Progress Report Acceptance of Financial Support from

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Agenda and Materials for 29 May Conference Call

Please find attached the agenda for the America Conflict of Interest & Scientific Integrity Working Group conference call on Thursday, 29 May from 10:00 to 11:30 am EDT. Also attached are the meeting materials, which include: the meeting minutes from the 17 December Conflict of Interest & Scientific Integrity Working Group conference call, the Executive Summary from the Progress Report submitted to USDA Under Secretary Woteki on the "Branded Food Products Database for Public Health" Public-Private Partnership, and a statement on the "Acceptance of Financial Support from Industry for Research, Education, and Consulting" from the Obesity Society.

Please use our conference call number to dial in:

215-446-0193 (industry members) 888-706-6468 (others) Access code: 1277013 (all)

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

www.ILSINA.org Follow ILSI North America:

From: Sent: To: Delia Murphy > Wednesday, May 21, 2014 7:49 AM DAllison@uab.edu; ; fergc@foodsci.umass.edu; mdoyle@uga.edu; Joanne Lupton; dwyerj1@od.nih.gov; jwerdman@illinois.edu; Eric Hentges; james.hill@ucdenver.edu; ; dblund@wisc.edu; ; ; Shawn Sullivan; ; ; Sharon Weiss;

Cc:Alison Kretser; Delia MurphySubject:ILSI North America Conflict of Interest & Scientific Integrity Working GroupAttachments:COI 29 May Call Agenda.doc

To: ILSI North America Conflict of Interest & Scientific Integrity Working Group Re: Agenda for 29 May Conference Call

Please find attached the agenda for the America Conflict of Interest & Scientific Integrity Working Group conference call on Thursday, 29 May from 10:00 to 11:30 am EDT. Additional meeting materials will be sent early next week.

Please use our conference call number to dial in:

215-446-0193 (industry members) 888-706-6468 (others) Access code: 1277013 (all)

Best, Delia

Delia Murphy Science Program Associate ILSI North America 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 202.659.0074 ext. 135

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University of Colorado Health and Wellness Center Texas A&M University

University of Alabama at Birmingham Coca-Cola Company ILSI North America

Kellogg Company University of Massachusetts at Amherst The University of Georgia NIH/Tufts University Medical Center Coca-Cola Company The Hershey Company The Hershey Company Mars, Incorporated Kraft Foods Group, Inc. ILSI North America

From: Sent: To:	Suzanne Harris Wednesday, May 07,	2014 8:18 AM					
	marion@vt.edu;	, chang@griffith.edu.au; Cohen, Samuel M (scohen@unmc.e. mdoyle@uga.edu; adamdrew@u.washington.edu Catherine Field					
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		; john.c.peters@uc	denver.edu;				
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Subject:	Letter from the ILSI F	President					
Attachments:	Pres letter 2014-05.p	df; ILSI Financial Statements 0331	2014.pdf				
τo	II SI Board of Trustees						

IO: ILSI Board of Trustees

FROM: Suzie Harris

I am sending you a letter from Dr. Jerry Hjelle, ILSI President, and the first quarter financial statement for ILSI. Please let Jerry or me know if you have any questions about either document.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	3/3	31/2014 <sup>(1)</sup>	1	2/31/2013 <sup>(2)</sup>		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	628 466	\$	229 754	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ŷ	613.343	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		77,550		104,586		169,244		119,954		257,151
Due From ILSI Entities for Shared Services & AM		311,716		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		3,803		27,895		16,979		24,342		31,626
Total Current Assets		1,634,878		1,494,414		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		349,931		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		570,178		566,504		269,608		268,446		264,897
Total Other Assets		920,109		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		372,213		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		450,818		441,818		759,904		820,069		120,324
Total Assets	\$	3,005,805	\$	2,860,299	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	350,135	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		108,311		104,768		103,744		80,695		79,435
Deferred Revenue		14,315		77,059		102,343		86,498		94,645
Total Current Liabilities		472,761		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		750,104		758,181		833,414		891,432		932,650
l otal Long-Term Liabilities		996,104		1,004,181		1,079,414		1,137,432		1,178,650
Total Liabilities		1,468,865		1,270,328		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		(53,030)		(217,562)		(130,090)		323,092		453,081
Total Net Assets		1,536,941		1,589,971		1,807,533		1,937,623		1,614,532
Total Liabilities and Net Assets	\$	3,005,805	\$	2,860,299	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	258.403	\$	471.248	\$	681.148	\$	559.848	\$	418.355
Board-Designated Reserve Fund	Ŧ	570,178	Ŧ	566,504	Ŧ	269,608	Ŧ	268,446	Ŧ	264,897
Strategic Planning Resources		36,504		43,411		-				-
Restricted Programs (PIP, GTF, Africa, Other)		526,863		360,036		107,907		151,425		38,850
International Committees (Pre 09/2013)/Branches		144,992		148,772		748,871		957,905		892,430
Total Net Assets	\$	1,536,941	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
(2)							ć			
Current Assets Minus Current Liabilities (Liquidity) <sup>(3)</sup>	\$	1,162,117	\$	1,226,993	\$	1,493,287	\$	1,629,792	\$	1,467,396
		3.40		6.09		0.18		o.29		0.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> Preliminary 2013 balances pending audit completion.

<sup>(3)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratios vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

#### Internal Financial Statement

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			COM	MUNICATION	s	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>		
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/
For the Three Months Ended March 31, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
		740.000	0%			NI/A			NI/A		740.000	0%
CONFEDENCE/ DECISTRATION EEES	30.034	35,000	86%	-	-	N/A	-	-	N/A	30.034	35,000	86%
CONTRIBUTIONS	30,034	33,000	00 /0 N/Δ			N/Δ	_		N/A	30,034	55,000	N/A
EEE FOR SERVICES	24 036	87 068	28%		-	N/A	_	_	N/A	24 036	87 068	28%
SHARED SERVICES REIMBURSEMENT			N/A	-	-	N/A	-	-	N/A		-	N/A
INVESTMENT AND OTHER INCOME	8.050	-	N/A	-	-	N/A	-	-	N/A	8.050	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	142.925	327.852	44%	142,925	327.852	44%
TOTAL REVENUE	62,120	862,068	7%	-	-	N/A	142,925	327,852	44%	205,045	1,189,920	17%
EXPENSES												
COMMUNICATIONS	3 624	6 640	55%	6.304	14 300	44%	227	2 350	10%	10 154	23 290	44%
	0,021	0,040	0070	0,004	14,000	4470		2,000	1070	10,104		-1-170
FINANCIAL/PROFESSIONAL FEES	4,239	31,900	13%	-	-	N/A	-	-	N/A	4,239	31,900	13%
											-	
GENERAL & ADMINISTRATIVE	22 740	107.000	260/			N1/A			NI/A	22 740	-	260/
Shared Services Overhead	32,749	127,000	20%	-	-	IN/A	-	-	IN/A	32,749	127,000	20%
Rent	12,303	47,140	20%	-	-	IN/A	-	-	IN/A	12,303	47,140	20%
Depreciation	-	24,621	0%	- 0.770	-	N/A	-	4 500	N/A	4 504	24,621	0%
Other Indirect Deimburgement	1,207	9,520	13%	2,770	6,000	40%	523	4,580	11%	4,501	20,100	23%
Indirect Reimbursement	(00,455)	(290,906)	24%	36,034	145,905	20%	27,107	109,142	23%	(3,234)	(35,001)	9%
STAFFING											_	
Salaries	70.565	249.744	28%	34.639	130,739	26%	24.760	97.797	25%	129,964	478.280	27%
Benefits	15,784	59,938	26%	7.621	31.377	24%	5,447	23,471	23%	28,852	114,787	25%
Outside Services	2,561	1,400	183%		-	N/A			N/A	2,561	1,400	183%
	-										-	
CONSULTANTS	6,000	10,550	57%	10,691	36,500	29%	600	-	N/A	17,291	47,050	37%
IT SUPPORT SERVICES	-	-	N/A	17,850	50,000	36%	-	-	N/A	17,850	- 50,000	36%
											-	
PUBLICATIONS	4,578	4,750	96%	4,024	15,000	27%	8,402	66,100	13%	17,004	85,850	20%
MEETINGS											-	
Travel - Board	45,912	46,000	100%	-	-	N/A	-	-	N/A	45,912	46,000	100%
Travel - Staff	4,642	1,122	414%	1,531	4,000	38%	1,916	9,605	20%	8,089	14,727	55%
Travel - Advisors/Speakers/Invitees	8,676	14,484	60%	-	-	N/A	1,941	2,568	76%	10,617	17,052	62%
Travel - Credits	(25,614)	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A
Group Functions/Business Meals	67,062	82,325	81%	-	1,000	0%	-	750	0%	67,062	84,075	80%
Other Expenses (Audiovisual/Mgmt Fee)	39,763	47,650	83%	939	-	N/A	-	-	N/A	40,703	47,650	85%
SUBTOTAL MEETINGS	140,441	191,581	73%	2,470	5,000	49%	3,858	12,923	30%	146,769	209,504	70%
OTHER PROGRAM EXPENSES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A
TOTAL EXPENSES	225,716	473,882	48%	124,403	434,821	29%	71,004	316,363	22%	421,123	1,225,066	34%
CHANGE IN NET ASSETS	(163,597)	388,187		(124,403)	(434,821)		71,921	11,489		(216,079)	(35,146)	
NET ASSETS, BEGINNING OF PERIOD	1,812,896	1,812,896		(1,806,780)	(1,806,780)		1,075,046	1,075,046		- 1,081,163	- 1,081,163	
NET ASSETS, END OF PERIOD	1,649,299	2,201,083		(1,931,183)	(2,241,601)		1,146,968	1,086,535		865,084	1,046,017	

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTRICTED PROGRAMS			INT'L BRANCH ACTIVITY			SHAR	ED SERVICE	S	TOTAL		
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2013	2014	% YTD/	2014	2014	% YTD/
For the Three Months Ended March 31, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
			NI/A			NI/A			NI/A		740.000	0%
DRAINGH/INSTITUTE ASSESSMENT	-	-	IN/A	-	-	IN/A	-	-	IN/A	20.024	740,000	0%
CONTRIBUTIONS	200.656	-	110%	- 13 167	12 600	105%	-	-	N/A	213 823	180 600	118%
EFE FOR SERVICES	200,030	100,000	N/A	13,107	12,000	N/Δ	-	_	N/Δ	213,025	87.068	28%
SHARED SERVICES REIMBURSEMENT	_	_	N/A	_	_	N/A	374 429	1 494 100	25%	374 429	1 494 100	25%
INVESTMENT AND OTHER INCOME	-	-	N/A	-	-	N/A		-	N/A	8 050	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	142,925	327,852	44%
TOTAL REVENUE	200,656	168,000	119%	13,167	12,600	N/A	374,429	1,494,100	25%	793,298	2,864,620	28%
EXPENSES												
COMMUNICATIONS	13	1 555	1%	63	160	40%	9 074	42 000	22%	19 304	67 005	29%
	10	1,000	170		100		0,011	,000	/0	10,001	01,000	2070
FINANCIAL/PROFESSIONAL FEES	-	-	N/A	-	-	N/A	11,495	56,700	20%	15,734	88,600	18%
Shared Services Overhead	-	_	N/A	-	_	N/A	-	-	N/A	32 749	127 000	26%
Rent	-	_	N/A	-	-	N/A	36 364	143 700	25%	48 728	190 846	26%
Depreciation	-	-	N/A	-	-	N/A		18 000	_0%		42 621	20%
Other	-	-	N/A	-	-	N/A	32,711	165.000	20%	37.272	185,100	20%
Indirect Reimbursement	1,961	30,539	6%	1,273	5,323	24%	-	-	N/A		-	N/A
	,											
STAFFING												
Salaries	1,786	27,364	7%	1,160	4,770	24%	226,190	840,000	27%	359,100	1,350,414	27%
Benefits	393	6,567	6%	255	1,145	22%	49,762	202,000	25%	79,261	324,499	24%
Outside Services	-	-	N/A	-	-	N/A	-	-	N/A	2,561	1,400	183%
CONSULTANTS	-	-	N/A	-	-	N/A	-	-	N/A	17,291	47,050	37%
			NI/A			NI/A	250	0.000	20/	18 100	50.000	210/
II SUPPORT SERVICES	-	-	N/A	-	-	N/A	250	9,000	3%	18,100	59,000	31%
PUBLICATIONS	-	-	N/A	-	-	N/A	-	-	N/A	17,004	85,850	20%
MEETINGS												
MEETINGS Travel Board			NI/A			NI/A			NI/A	45 012	46.000	100%
Travel - Staff		5 000	0%	5 502	7 800	71%	8 566	10.000	86%	22 156	37 527	59%
Travel - Advisors/Speakers/Invitees	657	2 200	30%	5,502	25,000	0%	0,000	-	N/A	11 274	44 252	25%
Travel - Credits		2,200	N/A	_	23,000	N/A	_	_	N/A	(25.614)		N/A
Group Functions/Business Meals	1 232	1 300	95%	5 4 1 1	8 900	61%	18	7 700	0%	73 723	101 975	72%
Other Expenses (Audiovisual/Mamt Fee)	2 453	1,000	204%	3 283	2 860	115%	-	-	N/A	46 438	51 710	90%
SUBTOTAL MEETINGS	4,342	9,700	45%	14,196	44,560	32%	8,584	17,700	48%	173,891	281,464	62%
OTHER PROGRAM EXPENSES	25,334	5,000	507%	-	13,500	0%	-	-	N/A	25,334	18,500	137%
TOTAL EXPENSES	33 829	80 725	42%	16 947	69 458	24%	374 429	1 494 100	25%	846 330	2 869 348	29%
			-12/0			2-170			2070		_,000,040	2070
CHANGE IN NET ASSETS	166,827	87,275		(3,780)	(56,858)		-	-		(53,030)	(4,728)	
NET ASSETS, BEGINNING OF PERIOD	360,036	360,036		148,772	148,772		-	-		1,589,971	1,589,971	
NET ASSETS, END OF PERIOD	526,863	447,311		144,992	91,914		-			1,536,941	1,585,243	
					_22222222							



International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

May 6, 2014

Dear ILSI Trustees,

The first quarter of 2014 has been an exciting time with the very successful 2014 ILSI Annual Meeting in Bermuda, the approval of another new ILSI branch – ILSI Mesoamerica, and the implementation of the One ILSI strategy following the meeting. I thoroughly enjoyed visiting both ILSI Southeast Asia Region and ILSI Taiwan for their branch annual meetings in April. Both of these branches are excellent examples of the power and value of ILSI's global network and tripartite approach. ILSI Southeast Asia Region has a very impressive array of ongoing activities in the four thematic areas, many of which are done in cooperation and collaboration with other ILSI branches in Asia or elsewhere. ILSI Taiwan truly demonstrated their commitment to the tripartite approach by having a number of very high-level national and local government leaders actively engaged in their meeting. Congratulations to Geoff Smith and Boon Yee Yeong for ILSI Southeast Asia's great example and to Lucy Hwang and Jenny Chang for building ILSI Taiwan so quickly into another very strong ILSI branch.

<u>One ILSI Implementation</u> – We are still in the early days of implementing the new One ILSI strategy, but I am pleased with the progress to date. The four thematic area teams (food and water safety; toxicology and risk science; nutrition, health and well-being; and agriculture sustainability/nutrition security) are moving forward with plans for specific, cross-branch collaborations in 2014-15. I encourage you to visit the ILSI website – the thematic area pages (under the Science and Research tab) -- to learn more about what is currently being done by the branches in each of the four areas. A section of each quarterly *ILSI News* will be devoted to the new cross-branch activities.

Thank you to those trustees who volunteered to participate in one of the two board advisory groups – Science and Value/Stakeholders. The Science Board Advisory Group is led by Alan Boobis and Peter van Bladeren. Mike Doyle, Catherine Field, Lewis Smith, Sara Valdés, Connie Weaver and Flávio Zambrone volunteered for this group. Their first conference call was yesterday, May 5, and proved to be very productive. Todd Abraham, Sam Cohen and Geoff Smith lead the Value/Stakeholder Board Advisory Group and Rhona Applebaum joined this advisory group. They are meeting regularly with Michael Shirreffs, ILSI Director of Communications. If you would like to participate in one of these two groups, please let me or Suzie Harris know.

A working group of the ILSI Board of Trustees Executive Committee is addressing the One ILSI governance recommendations. I am chairing this group and very much appreciate having Alan Boobis, Sam Cohen, John O'Brien, and Geoff Smith actively engaged in this very important group. The members of the Transition Team/Governance Sub-team – Lewis Smith, Gert Meijer, Morven McLean and Shawn Sullivan – are also involved.

Suzie Harris and Michael Shirreffs are hosting a series of regional webinars to share more information about the One ILSI strategy with the branches. To date, two such webinars have been held – one for the Asian branches and another for the Latin American branches. Branch staff, branch trustees and branch member representatives are encouraged to participate and to ask questions. If you would like to participate in a future webinar, please let Suzie Harris know.

<u>ILSI Publications Committee</u> – I am very pleased that Connie Weaver accepted my invitation to chair the ILSI Board of Trustees Publications Committee. This group is also looking at how ILSI can contribute to the current interest in open data.

<u>Branch Status</u> – ILSI Mesoamerica is up and going with eight founding members. Dr. Diána Bánáti, Executive and Scientific Director, ILSI Europe, participated in one of their very first meetings. Ms. Gisela Kopper is the executive director of the new branch and has been very active within the branch network.

I also want to inform you that at the request of the ILSI Board of Trustees Executive Committee, Suzie Harris informed ILSI North Africa and Gulf Region that ILSI was terminating the charter agreement with them as they have not been able to function as a branch for more than three years. Discussions are still ongoing with ILSI members who are active in the Middle East and Gulf States about establishing a new branch. When this happens, the companies that belonged to the North African branch will be invited to join the new branch. This is the first time that an ILSI branch has been terminated. If you have any questions about the decision and how it was implemented, please contact me or Suzie.

<u>ILSI Research Foundation</u> – As you heard during the ILSI Assembly of Members, Dr. Adam Drewnowski is now the Chair of the ILSI Research Foundation Board of Trustees. He is a very active chair and will help expand the foundation's activities in the coming months and years. A search is underway for the executive director of the Research Foundation. If you have suggestions for possible candidates, please let Peter van Bladeren know. He is chairing the search committee.

<u>First Quarter Financial Report</u> – The report is attached and I am pleased that ILSI is in a good position financially. Please contact Liz Westring, ILSI Treasurer, or Beth-Ellen Berry if you have any comments or questions about the report.

I am looking forward to the board's mid-year call in late July or early August. I welcome your questions and comments between now and then.

Best regards,

Jery Helle

Jerry Hjelle President

From: Sent: To:	Suzanne Harris Thursday, April 24, 2014 8:37 AM						
	; marion@vt.edu;	s.chang@griffith.edu.au; Co ; mdoyle@uga.ec ; Catherin	hen, Samuel M (scohen@unmc.edu); lu; adamdrew@u.washington.edu; e Field				
		john.c.peters@	; Joanne Lupton; @ucdenver.edu;				
		; Rodriguez, Felipe {PI}					
	; G	eoff	; thompson@rustichouseltd.eu; m; kwallace@d.umn.edu;				
	weavercm@purdue.ec	lu;	; Flavio Zambrone; LEWIS SMITH				
Cc:	;		S				
		Usui-Etsuko(?? ?	?)				
	Chelsea L. Bishop; c		; tim.goss@ucdenver.edu; m; Burnand,Valerie,VEVEY,CT-				
	RSA	); haan@purdue	e.edu; Christine Lagerquist				
Subject: Attachments:	Polling for date for the 2014 ILSI BOT Calenda	) e mid-year ILSI Board of Tru: ar Poll v2.docx	stees conference call				

TO: ILSI Board of Trustees

FROM: Suzie Harris

The ILSI Board of Trustees meets by conference call at mid-year. Please use the attached calendar to indicate when you are available for a two hour conference call beginning at 9:00 a.m. Eastern Daylight Time.

Please return the attachment with your availability marked by **Friday, May 9.** Let me know if you have any questions about my request.

Thank you for taking time to respond to this request.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

### 2014 ILSI BOARD OF TRUSTEES Mid-Year Conference Call Poll

July 2014									
Monday	Tuesday	Wednesday	Thursday	Friday					
14	15	16	17	18					
28	29	30	31						
		August 2014							
Monday	Tuosday	Wednesday	Thursday	Friday					
monday	Tuesuay	weunesuay	marsaay	ппау					
	Tuesday	weunesday	maisaciy	1					
4	5	6	7	1 8					

Please return to Suzie Harris (<u>sharris@ilsi.org</u>) by Friday, May 9, 2014.

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From: Sent: To:	Suzanne Harris Thursday, April 24, 2014 7:53 AM ; s.chang@griffith.edu.au; e e; Joanne Lupton; Rodriguez, Felipe {PI} ; LEWIS SMITH					
Cc:	Christine Lagerquist ; Cholsea L. Bishon: Both-Ellon Borny: Shawn Sullivan: Both					
	Brueggemever					
Subject:	Agenda, briefing materials and dial-in instructions for the ILSI Financial Oversight Committee conference call Tuesday, April 29, 2014 at 9:00 am EDT					
Attachments:	FOC 2014-04-29 agd.doc; FOC 2013-11-05 minutes.docx; ILSI Financial Statements 03312014.pdf; ILSI Ops Q1 2014.pdf; ILSI Board Q1 2014.pdf					

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The ILSI Board of Trustees Financial Oversight Committee is scheduled to have a conference call on **Tuesday, April 29**, **2014, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than one hour. The dial-in instructions are at the end of this message.

The proposed agenda for the conference call is attached here:

Agenda Item II. Draft minutes from the November 5, 2013 conference call

Agenda Item III. Reports from Raffa Wealth Management

Agenda Item IV. Year-to-date financial report

Please let me know if you have questions prior to the conference call

#### **Dial-in Instructions**

If you are calling from:	Please dial this toll-free number
Australia	1-800-21-2361
Germany	0800-182-9571
Mexico	001-888-706-6468
United Kingdom	0808-234-3676
Spain	900-98-1198
USA	1-888-706-6468

The access code for everyone is **4498699 #**. If you are going to be in another country, please let me know so that I can send you the toll free number from that country.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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# **Portfolio Review**

### **ILSI - Board Designated Reserve**

1156 15th Street, NW Washington, DC 20005

Prepared By: Raffa Wealth Management LLC

March 31, 2014

Wealth Management, LLC



## **Market Commentary**

**ILSI - Board Designated Reserve** 

### **Overview**

After an up and down month stocks ended in positive territory. Concerns over the Crimea region's secession and recent meager economic numbers, were countered with more signals pointing to the recent economic slowdown being driven by poor winter weather with expectations for improved growth in the second quarter. While hindered by weather consumer spending, factory output, the jobs report, and retail sales all posted growth. A record number of firms went public over the first quarter and a heavy amount of merger activity continued in March to help drive markets. US stocks rose 0.53% in March and gained 1.97% for the first quarter.

Foreign stocks edged up in March as the likelihood of action by the ECB increased. While, the political situation in Ukraine on Europe's doorstep made investors uneasy, ECB policy makers sated they were prepared to make more aggressive moves to fight low inflation in Europe. Euro zone business activity improved, retail sales rose and consumer confidence reached levels last seen in 2007. Japan appeared on shakier footing as their 4Q GDP was revised down to 0.7%. China posted weaker industrial output and manufacturing and reduced exports showing the country continues to have growth issues. The numbers spurred talk of additional stimulus measures being undertaken in the country. In a break from the recent trend emerging markets vastly outpaced developed markets for the month. International stocks ticked up 0.40% for the month helping to drive the 0.57% quarterly return.

Fixed income edged down in March after Fed Chairwoman Yellen's first post FOMC meeting press conference where she made comments that made investors believe interest rate increases could occur sooner than previously thought. However, for the quarter bonds generally performed well as interest rates sank in January over global growth concerns. The 10 year Treasury yield edged up slightly in March, but has sank from 3.04% to end 2013 to 2.73%. Munis and corporates were the top performing sectors with long and short term bonds outperforming intermediate term bonds. The broad bond market sank 0.17% in March reducing first quarter performance to 1.84%.

Index Performance	March	YTD	Trl 1 yr.
US Stock (Russell 3000)	0.53%	1.97%	22.61%
Foreign Stock (FTSE AW ex US)	0.40%	0.57%	12.81%
Total US Bond Mkt. (BarCap Aggregate)	-0.17%	1.84%	-0.10%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.29%	0.25%	-0.03%
Municipal Bonds (BarCap 1-10yr Muni)	-0.37%	1.60%	0.78%
Cash (ML 3Month T-Bill)	0.00%	0.01%	0.07%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.



# Actual vs. Target Allocation

#### ILSI - Board Designated Reserve

Period Ending: 3/31/2014 Portfolio Inception Date: 9/30/2012

Actual Allocation



Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	30.04%	\$171,304.53	30.00%	\$171,053.36	(0.04%)	(\$251.18)
Short Bond	65.19%	\$371,678.10	65.00%	\$370,615.60	(0.19%)	(\$1,062.50)
Cash	4.77%	\$27,195.22	5.00%	\$28,508.89	0.23%	\$1,313.67
TOTAL		\$570,177.85		\$570,177.85		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



## **Performance Summary**

**ILSI - Board Designated Reserve** 

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

## **Portfolio Activity**

	Last 3 Months	Last 1 Year	Since Inception
BEGINNING VALUE	566,503.83	570,516.49	269,574.23
Net Contributions	0.00	0.00	300,140.66
Capital Appreciation	2,858.18	(5,416.53)	(6,040.57)
Income	1,030.82	5,929.39	7,565.12
Management Fees	(214.98)	(851.50)	(1,061.59)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	570,177.85	570,177.85	570,177.85
INVESTMENT GAIN	3,674.02	(338.64)	462.96

## **Portfolio Returns**

	Last 3 Months	Last 1 Year	Since Inception
Your Portfolio	0.6%	(0.1%)	0.0%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5), the Ministrate Borne benchmark (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 3/31/2014 Portfolio Inception Date: 9/30/2012

**ILSI - Board Designated Reserve** 



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# **Asset Class Performance Summary**

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Board Designated Reserve**

Asset Class Description	Inception Date	Current Value	Last 3 Months	Last 1 Year	Since Inception
Intermediate Bond	9/30/2012	171,305	1.85%	(0.21%)	(0.20%)
BarCap US Agg.			1.84%	(0.10%)	0.00%
Short Bond	9/30/2012	371,678	0.21%	0.23%	0.30%
BarCap 1-5 Yr Gov			0.25%	(0.03%)	0.12%
Cash	9/30/2012	27,195	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.07%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	570,178	0.69%	0.09%	0.14%
Total Portfolio (Net of Fees)	9/30/2012	570,178	0.65%	(0.06%)	(0.02%)
Portfolio Benchmark			0.62%	0.17%	0.20%

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Board Designated Reserve**

Description	3/31/2013 Value	Net Flows	Capital Appreciation	Income Expenses	3/31/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	570,516	0	(5,417)	5,078	570,178	(0.1%)	(0.1%)
Intermediate Bond	171,662	0	(4,625)	4,268	171,305	(0.2%)	(0.2%)
Vanguard Total Bond Market Fund	171,662	0	(4,625)	4,268	171,305	(0.2%)	(0.2%)
Short Bond	370,812	0	(791)	1,658	371,678	0.2%	0.2%
DFA One Year Fixed	256,535	0	(49)	901	257,387	0.3%	0.3%
Vanguard Short-Term	114,276	0	(742)	756	114,291	0.0%	0.0%
Cash	28,043	0	0	(848)	27,195		
Sch Adv Cash Resrv Prem	28,043	0	0	(848)	27,195		

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# Disclaimers

**ILSI - Board Designated Reserve** 

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# **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

The total value of all investments in your portfolio at the beginning or ending of the period or on a specific date. This value includes the market value of securities, cash and money funds, and accrued interest on bonds.

#### **Capital Flows**

Deposits and withdrawals of cash and securities. Capital flows include receipts and transfers of securities as well as cash deposits and withdrawals.

#### **Cost Basis**

Original price of an asset, used in determining capital gains. Cost Basis is usually the purchase price including all fees.

#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

# **Portfolio Review**

ILSI - Operating Reserve 1156 15th Street, NW

Washingon, DC 20005

Prepared By: Raffa Wealth Management LLC

March 31, 2014

Wealth Management, LLC



# **Market Commentary**

**ILSI - Operating Reserve** 

# **Overview**

After an up and down month stocks ended in positive territory. Concerns over the Crimea region's secession and recent meager economic numbers, were countered with more signals pointing to the recent economic slowdown being driven by poor winter weather with expectations for improved growth in the second quarter. While hindered by weather consumer spending, factory output, the jobs report, and retail sales all posted growth. A record number of firms went public over the first quarter and a heavy amount of merger activity continued in March to help drive markets. US stocks rose 0.53% in March and gained 1.97% for the first quarter.

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March	YTD	Trl 1 yr.
0.53%	1.97%	22.61%
0.40%	0.57%	12.81%
-0.17%	1.84%	-0.10%
-0.29%	0.25%	-0.03%
-0.37%	1.60%	0.78%
0.00%	0.01%	0.07%
	March 0.53% 0.40% -0.17% -0.29% -0.37% 0.00%	MarchYTD0.53%1.97%0.40%0.57%-0.17%1.84%-0.29%0.25%-0.37%1.60%0.00%0.01%

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**Actual Allocation** 

Period Ending: 3/31/2014 Portfolio Inception Date: 9/30/2012



**Target Allocation** 

Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	29.82%	\$182,899.44	30.00%	\$184,003.04	0.18%	\$1,103.60
Short Bond	65.46%	\$401,510.09	65.00%	\$398,673.26	(0.46%)	(\$2,836.83)
Cash	4.72%	\$28,933.94	5.00%	\$30,667.17	0.28%	\$1,733.23
TOTAL		\$613,343.47		\$613,343.47		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

#### **ILSI - Operating Reserve**

# **Portfolio Activity**

	Last 3 Months	Last 1 Year	Since Inception
BEGINNING VALUE	609,413.54	613,700.35	914,179.08
Net Contributions	0.00	0.00	(300,135.84)
Capital Appreciation	3,057.20	(5,791.36)	(9,861.80)
Income	1,104.00	6,350.48	10,790.49
Management Fees	(231.27)	(916.00)	(1,628.46)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	613,343.47	613,343.47	613,343.47
INVESTMENT GAIN	3,929.93	(356.88)	(699.77)

# **Portfolio Returns**

	Last 3 Months	Last 1 Year	Since Inception
Your Portfolio	0.6%	(0.1%)	0.0%

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 



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# **Asset Class Performance Summary**

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Asset Class Description	Inception Date	Current Value	Last 3 Months	Last 1 Year	Since Inception
Intermediate Bond	9/30/2012	182,899	1.85%	(0.21%)	(0.20%)
BarCap US Agg.			1.84%	(0.10%)	0.00%
Short Bond	9/30/2012	401,510	0.21%	0.23%	0.30%
BarCap 1-5 Yr Gov			0.25%	(0.03%)	0.12%
Cash	9/30/2012	28,934	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.01%	0.07%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	613,343	0.68%	0.09%	0.14%
Total Portfolio (Net of Fees)	9/30/2012	613,343	0.64%	(0.06%)	(0.01%)
Portfolio Benchmark			0.62%	0.17%	0.20%

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# **Position Performance Summary**

Period Ending: 3/31/2014

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Description	3/31/2013 Value	Net Flows	Capital Appreciation	Income Expenses	3/31/2014 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	613,700	0	(5,791)	5,434	613,343	(0.1%)	(0.1%)
Intermediate Bond	183,281	0	(4,939)	4,557	182,899	(0.2%)	(0.2%)
Vanguard Total Bond Market Fund	183,281	0	(4,939)	4,557	182,899	(0.2%)	(0.2%)
Short Bond	400,573	0	(853)	1,790	401,510	0.2%	0.2%
DFA One Year Fixed	277,404	0	(53)	975	278,326	0.3%	0.3%
Vanguard Short-Term	123,169	0	(799)	815	123,185	0.0%	0.0%
Cash	29,846	0	0	(912)	28,934		
Sch Adv Cash Resrv Prem	29,846	0	0	(912)	28,934		



# Disclaimers

**ILSI - Operating Reserve** 

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#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	3/3	31/2014 <sup>(1)</sup>	1	2/31/2013 <sup>(2)</sup>		12/31/2012		12/31/2011		12/31/2010
Current Assets										
Cash	\$	628 466	\$	229 754	\$	509 443	\$	773 370	\$	883 041
Short-Term Investments	Ŷ	613.343	Ψ	609.414	Ψ	914.298	Ψ	911.040	Ψ	401.663
Accounts Receivable		77,550		104,586		169,244		119,954		257,151
Due From ILSI Entities for Shared Services & AM		311,716		522,765		171,782		109,126		156,341
Prepaid Expenses and Other Current Assets		3,803		27,895		16,979		24,342		31,626
Total Current Assets		1,634,878		1,494,414		1,781,746		1,937,832		1,729,822
Other Assets										
Rent Receivable under Shared Space Agreement		349,931		357,566		364,147		356,748		334,566
Board-Designated Reserve Fund		570,178		566,504		269,608		268,446		264,897
Total Other Assets		920,109		924,067		633,755		625,194		599,463
Fixed Assets										
Computer Software and Equipment		372,213		363,213		594,523		510,315		282,834
Office Furniture		114,075		114,075		114,075		114,075		116,075
		723,761		723,761		723,761		703,909		703,909
Accumulated Depreciation		(759,231)		(759,231)		(672,454)		(508,231)		(376,494)
Total Net Fixed Assets		450,818		441,818		759,904		820,069		120,324
Total Assets	\$	3,005,805	\$	2,860,299	\$	3,175,406	\$	3,383,095	\$	3,055,609
LIABILITES AND NET ASSETS										
Current Liabilities										
Accounts Payable	\$	350,135	\$	84,320	\$	82,373	\$	140,847	\$	88,347
Accrued Liabilities		108,311		104,768		103,744		80,695		79,435
Deferred Revenue		14,315		77,059		102,343		86,498		94,645
Total Current Liabilities		472,761		266,147		288,460		308,040		262,427
Long-Term Liabilities										
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000
Deferred Rent		750,104		758,181		833,414		891,432		932,650
l otal Long-Term Liabilities		996,104		1,004,181		1,079,414		1,137,432		1,178,650
Total Liabilities		1,468,865		1,270,328		1,367,873		1,445,472		1,441,077
Net Assets										
Beginning Balance		1,589,971		1,807,533		1,937,623		1,614,532		1,161,451
Current Year Change		(53,030)		(217,562)		(130,090)		323,092		453,081
Total Net Assets		1,536,941		1,589,971		1,807,533		1,937,623		1,614,532
Total Liabilities and Net Assets	\$	3,005,805	\$	2,860,299	\$	3,175,406	\$	3,383,095	\$	3,055,609
NET ASSETS - DETAIL										
Unrestricted Operations	\$	258.403	\$	471.248	\$	681.148	\$	559.848	\$	418.355
Board-Designated Reserve Fund	Ŧ	570,178	Ŧ	566,504	Ŧ	269,608	Ŧ	268,446	Ŧ	264,897
Strategic Planning Resources		36,504		43,411		-				-
Restricted Programs (PIP, GTF, Africa, Other)		526,863		360,036		107,907		151,425		38,850
International Committees (Pre 09/2013)/Branches		144,992		148,772		748,871		957,905		892,430
Total Net Assets	\$	1,536,941	\$	1,589,971	\$	1,807,533	\$	1,937,623	\$	1,614,532
(2)							ć			
Current Assets Minus Current Liabilities (Liquidity) <sup>(3)</sup>	\$	1,162,117	\$	1,226,993	\$	1,493,287	\$	1,629,792	\$	1,467,396
		3.40		6.09		0.18		o.29		0.59

<sup>(1)</sup> The 2014 balances are interim and have not been fully adjusted for all accrued revenues and expenses. All balances will be fully adjusted and reported on the 2014 financial statement audit.

<sup>(2)</sup> Preliminary 2013 balances pending audit completion.

<sup>(3)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratios vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

#### Internal Financial Statement

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC COMMUNICATIONS			s	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>				
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/	2014	2014	% YTD/
For the Three Months Ended March 31, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
		740.000	0%			NI/A			NI/A		740.000	0%
CONFEDENCE/ DECISTRATION EEES	30.034	35,000	86%	-	-	N/A	-	-	N/A	30.034	35,000	86%
CONTRIBUTIONS	30,034	33,000	00 /0 N/Δ			N/Δ	_		N/A	30,034	55,000	N/A
EEE FOR SERVICES	24 036	87 068	28%		_	N/A	_	_	N/A	24 036	87 068	28%
SHARED SERVICES REIMBURSEMENT			N/A	-	-	N/A	-	-	N/A		-	N/A
INVESTMENT AND OTHER INCOME	8.050	-	N/A	-	-	N/A	-	-	N/A	8.050	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	142.925	327.852	44%	142,925	327.852	44%
TOTAL REVENUE	62,120	862,068	7%	-	-	N/A	142,925	327,852	44%	205,045	1,189,920	17%
EXPENSES												
COMMUNICATIONS	3 624	6 640	55%	6.304	14 300	44%	227	2 350	10%	10 154	23 290	44%
	0,021	0,040	0070	0,004	14,000	4470		2,000	1070	10,104		-1-170
FINANCIAL/PROFESSIONAL FEES	4,239	31,900	13%	-	-	N/A	-	-	N/A	4,239	31,900	13%
											-	
GENERAL & ADMINISTRATIVE	22 740	107.000	260/			N1/A			NI/A	22 740	-	260/
Shared Services Overhead	32,749	127,000	20%	-	-	IN/A	-	-	IN/A	32,749	127,000	20%
Rent	12,303	47,140	20%	-	-	IN/A	-	-	IN/A	12,303	47,140	20%
Depreciation	-	24,621	0%	- 0.770	-	N/A	-	4 500	N/A	4 504	24,621	0%
Other Indirect Deimburgement	1,207	9,520	13%	2,770	6,000	40%	523	4,580	11%	4,501	20,100	23%
Indirect Reimbursement	(00,455)	(290,906)	24%	36,034	145,905	20%	27,107	109,142	23%	(3,234)	(35,001)	9%
STAFFING											_	
Salaries	70.565	249.744	28%	34.639	130,739	26%	24.760	97.797	25%	129,964	478.280	27%
Benefits	15,784	59,938	26%	7.621	31.377	24%	5,447	23,471	23%	28,852	114,787	25%
Outside Services	2,561	1,400	183%		-	N/A			N/A	2,561	1,400	183%
	-										-	
CONSULTANTS	6,000	10,550	57%	10,691	36,500	29%	600	-	N/A	17,291	47,050	37%
IT SUPPORT SERVICES	-	-	N/A	17,850	50,000	36%	-	-	N/A	17,850	- 50,000	36%
											-	
PUBLICATIONS	4,578	4,750	96%	4,024	15,000	27%	8,402	66,100	13%	17,004	85,850	20%
MEETINGS											-	
Travel - Board	45,912	46,000	100%	-	-	N/A	-	-	N/A	45,912	46,000	100%
Travel - Staff	4,642	1,122	414%	1,531	4,000	38%	1,916	9,605	20%	8,089	14,727	55%
Travel - Advisors/Speakers/Invitees	8,676	14,484	60%	-	-	N/A	1,941	2,568	76%	10,617	17,052	62%
Travel - Credits	(25,614)	-	N/A	-	-	N/A	-	-	N/A	(25,614)	-	N/A
Group Functions/Business Meals	67,062	82,325	81%	-	1,000	0%	-	750	0%	67,062	84,075	80%
Other Expenses (Audiovisual/Mgmt Fee)	39,763	47,650	83%	939	-	N/A	-	-	N/A	40,703	47,650	85%
SUBTOTAL MEETINGS	140,441	191,581	73%	2,470	5,000	49%	3,858	12,923	30%	146,769	209,504	70%
OTHER PROGRAM EXPENSES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A
TOTAL EXPENSES	225,716	473,882	48%	124,403	434,821	29%	71,004	316,363	22%	421,123	1,225,066	34%
CHANGE IN NET ASSETS	(163,597)	388,187		(124,403)	(434,821)		71,921	11,489		(216,079)	(35,146)	
NET ASSETS, BEGINNING OF PERIOD	1,812,896	1,812,896		(1,806,780)	(1,806,780)		1,075,046	1,075,046		- 1,081,163	- 1,081,163	
NET ASSETS, END OF PERIOD	1,649,299	2,201,083		(1,931,183)	(2,241,601)		1,146,968	1,086,535		865,084	1,046,017	

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTR	RESTRICTED PROGRAMS INT'L BRANCH ACTIVITY		SHAR	ED SERVICE	S	TOTAL					
FUNCTIONAL ACTIVITY STATEMENT	2014	2014	% YTD/	2014	2014	% YTD/	2013	2014	% YTD/	2014	2014	% YTD/
For the Three Months Ended March 31, 2014	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
			NI/A			NI/A			NI/A		740.000	0%
DRAINGH/INSTITUTE ASSESSMENT	-	-	IN/A	-	-	IN/A	-	-	IN/A	20.024	740,000	0%
CONTRIBUTIONS	200.656	-	110%	- 13 167	12 600	105%	-	-	N/A	213 823	180,600	118%
EFE FOR SERVICES	200,030	100,000	N/A	13,107	12,000	N/Δ	-	_	N/Δ	213,025	87.068	28%
SHARED SERVICES REIMBURSEMENT	_	_	N/A	_	_	N/A	374 429	1 494 100	25%	374 429	1 494 100	25%
INVESTMENT AND OTHER INCOME	-	-	N/A	-	-	N/A		-	N/A	8 050	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	142,925	327.852	44%
TOTAL REVENUE	200,656	168,000	119%	13,167	12,600	N/A	374,429	1,494,100	25%	793,298	2,864,620	28%
EXPENSES												
COMMUNICATIONS	13	1 555	1%	63	160	40%	9 074	42 000	22%	19 304	67 005	29%
	10	1,000	170		100		0,011	,000	/0	10,001	01,000	2070
FINANCIAL/PROFESSIONAL FEES	-	-	N/A	-	-	N/A	11,495	56,700	20%	15,734	88,600	18%
Shared Services Overhead	-	_	N/A	-	_	N/A	-	-	N/A	32 749	127 000	26%
Rent	-	_	N/A	-	-	N/A	36 364	143 700	25%	48 728	190 846	26%
Depreciation	-	-	N/A	-	-	N/A		18 000	_0%		42 621	20%
Other	-	-	N/A	-	-	N/A	32,711	165.000	20%	37.272	185,100	20%
Indirect Reimbursement	1,961	30,539	6%	1,273	5,323	24%	-	-	N/A		-	N/A
	,											
STAFFING												
Salaries	1,786	27,364	7%	1,160	4,770	24%	226,190	840,000	27%	359,100	1,350,414	27%
Benefits	393	6,567	6%	255	1,145	22%	49,762	202,000	25%	79,261	324,499	24%
Outside Services	-	-	N/A	-	-	N/A	-	-	N/A	2,561	1,400	183%
CONSULTANTS	-	-	N/A	-	-	N/A	-	-	N/A	17,291	47,050	37%
			NI/A			NI/A	250	0.000	20/	18 100	50.000	210/
II SUPPORT SERVICES	-	-	N/A	-	-	N/A	250	9,000	3%	18,100	59,000	31%
PUBLICATIONS	-	-	N/A	-	-	N/A	-	-	N/A	17,004	85,850	20%
MEETINGS												
MEETINGS Travel Board			NI/A			NI/A			NI/A	45 012	46.000	100%
Travel - Staff		5 000	0%	5 502	7 800	71%	8 566	10.000	86%	22 156	37 527	59%
Travel - Advisors/Speakers/Invitees	657	2 200	30%	5,502	25,000	0%	0,000	-	N/A	11 274	44 252	25%
Travel - Credits		2,200	N/A	_	23,000	N/A	_	_	N/A	(25.614)		N/A
Group Functions/Business Meals	1 232	1 300	95%	5 4 1 1	8 900	61%	18	7 700	0%	73 723	101 975	72%
Other Expenses (Audiovisual/Mamt Fee)	2 453	1,000	204%	3 283	2 860	115%	-	-	N/A	46 438	51 710	90%
SUBTOTAL MEETINGS	4,342	9,700	45%	14,196	44,560	32%	8,584	17,700	48%	173,891	281,464	62%
OTHER PROGRAM EXPENSES	25,334	5,000	507%	-	13,500	0%	-	-	N/A	25,334	18,500	137%
TOTAL EXPENSES	33 829	80 725	42%	16 947	69 458	24%	374 429	1 494 100	25%	846 330	2 869 348	29%
			-12/0			2-170			2070		_,000,040	2070
CHANGE IN NET ASSETS	166,827	87,275		(3,780)	(56,858)		-	-		(53,030)	(4,728)	
NET ASSETS, BEGINNING OF PERIOD	360,036	360,036		148,772	148,772		-	-		1,589,971	1,589,971	
NET ASSETS, END OF PERIOD	526,863	447,311		144,992	91,914		-			1,536,941	1,585,243	
					_22222222							

### ILSI Board of Trustees Financial Oversight Committee

### Conference Call Tuesday, November 5, 2013

### **DRAFT MINUTES**

### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began the conference call at 9:01 a.m. Eastern Standard Time. In addition to Dr. Westring, the following trustees and staff participated: Dr. Jay Goodman, Dr. Joanne Lupton, Dr. Lewis Smith, Ms. Beth-Ellen Berry, Dr. Suzie Harris and Mr. Shawn Sullivan.

The agenda for the conference call is attached.

### II. Approval of Minutes from the July 24, 2013 Conference Call

The minutes were approved as distributed.

### III. Review of 2013 Year-to-date Financial Report

Ms. Berry began with the ILSI Balance Sheet which lists assets, liabilities and net assets for a specific day, in this case September 30, 2013, as well as audited year-end figures for the past five years. Ms. Berry noted that the ILSI International Food Biotechnology Committee (IFBiC) approved the transfer of the committee's assets as of September 30, 2013. Most of these assets were transferred to the ILSI Research Foundation on October 1, 2013. The ILSI Health and Environmental Sciences Institute also received some of the IFBiC assets.

ILSI is fairly liquid with current assets of over \$1.4 million. Dr. Goodman noted that this value is less than that of the past three years. Ms. Berry agreed and noted that the next month's statement will show the cash transfer of the IFBIC assets (\$293,699). IFBIC also had significant fixed assets – software and curator tools for the Crop Composition Database. These were also transferred on October 1, 2013 to the ILSI Research Foundation.

In Ms. Berry's view all other parts of the balance sheet are in line with expectations. She called attention to the Net Assets – Detail section of the report. The Board-designated reserve is a little less than 50 percent of unrestricted annual operating expenses – the target set in the ILSI Reserve Policy. The Strategic Planning expenses are being covered by special contributions from member companies solicited by Dr. Jerry Hjelle, ILSI President. The restricted programs are presented in more detail on the following page. The International Committees line excludes IFBiC from September 30, 2013 net asset balance. What remains is primarily funds under the control of the ILSI Focal Point in China.

Ms. Berry moved on to the Functional Activity Statement which provides details on year-to-date (as of September 30, 2013) revenue and expenses by function. She noted that ILSI Governance and Coordination (GC), ILSI Communications, and ILSI Press form the unrestricted activities which are paid for by branch assessments and ILSI Press revenue. Ms. Berry stated that about 98 percent of the 2013

branch assessments had been received. In response to a question from Dr. Goodman, Ms. Berry noted that several branches still needed to pay their 2013 assessments. These included ILSI Argentina, ILSI Brasil, ILSI Focal Point in China and ILSI Mexico. All were in contact with the ILSI office about the outstanding payments. ILSI North Africa and Gulf Region is the only branch that has not paid their assessment for several years. They, like ILSI Brasil, have difficultly sending money outside of their country. Dr. Goodman asked that all future reports include a list of branches who are delinquent with their assessment payments.

Ms. Berry noted that the Contributions line for ILSI GC is made-up of contributions collected from member companies to off-set expenses associated with the strategic planning effort and remaining funds will be used to support the thematic area teams.

The expenses are as expected for ILSI GC with the exception of the strategic planning costs (January meeting and July meeting – consultant costs, plus travel for trustees and transition team members), which were not included in the 2013 budget.

The Communications function will not spend all of the IT and consultant budget for 2013. Dr. Smith expressed concern that ILSI may be "under investing" in the communications area as evidenced by the failure to spend the full budget. Ms. Berry stated that the Communications budget was increased in 2013 to cover a portion of the IT personnel costs and consultants, but the full amount budgeted was not needed. Dr. Goodman suggested that an evaluation should be carried out to determine what the branches were receiving for their assessments.

ILSI Press is running as budgeted. The guaranteed minimum has been received from Wiley and a small overage in royalty payment is expected, but the exact amount is not known at this time.

For the restricted functions, Ms. Berry briefly described the functions of each category:

- Restricted Programs include the ILSI Platform for International Partnerships (PIP), the Africa project, and the Branch Travel Grant
- International Activities include the ILSI Focal Point in China funds a combination of supporting company contributions and two fellowship programs
- IFBiC includes activity through September 30, 2013. The "Other Program Expenses" is the full amount of net assets transferred. This column will be removed in 2014.

# IV. ILSI Reserve Fund Performance Report

A report from Raffa Wealth Management, LLC was circulated to the committee prior to the conference call. There are two separate accounts, one for the reserve fund and one for the excess operating cash. Both are invested in short term bond funds. The value of such funds has declined recently due to the change in interest rates. The decline is expected to be temporary because as bond funds mature the principle will be re-invested in higher yielding bonds. Ms. Berry said that the Raffa Wealth Management expects the funds to break even by the end of 2013. To date there has been a 0.5 percent decline in the reserve fund value, which is in line with the benchmark.

# V. Review of 2013 Year-end Projection and Proposed 2014 Budget

The draft 2013 year-end projections and proposed 2014 budget were distributed to the committee prior to the conference call. Ms. Berry noted that the expected total branch assessment for 2013 may exceed \$750,000. The 2014 budget includes a slightly lower figure -- \$740,000 (same as shown as the 2013 year-end projection). The projected contributions for the ILSI strategic planning activities total \$95,000, which is \$30,000 more that shown in the September 30, 2013 statement. Ms. Berry noted that the shared services overhead for ILSI is budgeted in ILSI GC along with the rent, based on full-time equivalents. The projected amount of \$197,000 includes the loss of IFBiC's 2.4 full-time equivalents transferred to the ILSI Research Foundation. These positions are not included in the 2014 budget either. The Indirect Reimbursement is also less, reflecting the loss of IFBiC.

The consultant expenses in 2013 exceeded the budget as the costs for Tim Fallon's services for strategic planning were not budgeted. His costs for participating in the 2014 ILSI Annual Meeting are included in the 2014 budget. The annual meeting costs for 2014 are higher than 2013 as the venue is more expensive.

The closing of IFBiC affects ILSI CG in two ways. First, there will be less total cash available for cash flow. Second, IFBiC was covering a portion of the general ILSI expenses (executive director's salary/benefits and ILSI Board of Trustees expenses). The total financial impact is about \$80,000. To compensate for the second impact, only 1 full-time equivalent (FTE) is budgeted for ILSI Communications in 2014. The extra 0.4 FTE will be shifted to the Shared Services Group. This change is not expected to have a significant negative impact on ILSI Communications. The shift, valued at \$60,000, is appropriate as the four entities based at the Washington office are receiving more IT services in the form of off-site meeting support.

The ILSI Press 2014 budget includes about \$18,000 in additional royalties over the guaranteed amount. There is also a 5 percent increase in expenses to cover additional copyediting support. The publishing contract with Wiley will be in its fifth and final year in 2014. ILSI will need to notify them before the end of 2013, if ILSI does not wish to renew the contract.

For the restricted functions, Ms. Berry noted that \$10,000 is budgeted for the Africa plan. She also noted that the ILSI PIP will end 2013 below the net asset level. However, PIP expects to receive new funding in 2014 from the Industry Council for Development (ICD). The ILSI Focal Point in China will support new fellowships in 2014, shown in the International Branch Activity function. The IFBiC Committee function is zero in 2014 as the committee no longer exists. The Shared Services function is budgeted with a 4 percent increase in 2014.

In terms of the Unrestricted Subtotal, ILSI is expected to end 2013 with a surplus of \$70,000 as opposed to the \$81,000 deficit that was budgeted. The 2014 budget shows a \$56,000 deficit, but Ms. Berry promised the committee that staff would manage the unrestricted accounts carefully.

**Action:** The ILSI Financial Oversight Committee agreed to move the proposed 2014 budget forward to the ILSI Board of Trustees for approval.

Ms. Berry reminded the committee that minor adjustments would be made to reflect the true situation at the end of 2013. Dr. Smith asked that Dr. Westring's report to the ILSI Board include a slide describing the impact of the dissolution of IFBiC on the ILSI GC budget. Ms. Berry agreed noting that the 2014 budget was conservative and the actual decline in net assets may not be as great as shown.

#### VI. New Business

**Selection of auditors for 2013** – Ms. Berry stated that the current audit firm – Johnson and Lambert – has been very effective. 2013 will be the third year ILSI has used them.

**Action:** The ILSI Financial Oversight Committee approved Johnson and Lambert as the audit firm for the 2013 audit.

**Format of the ILSI audit statement** – In 2012, Johnson and Lambert noted that ILSI should not have an audit statement that does not include the ILSI Research Foundation, as the foundation is a supporting organization to ILSI. The options for 2013 are to maintain the current format – ILSI stand-alone audit, ILSI Research Foundation stand-alone audit and a combined audit – or to have a single statement (consolidated audit) with supplementary stand-alone reports.

**Action:** The ILSI Financial Oversight Committee approved the second option – consolidated report with supplementary stand-alone reports.

Dr. Smith questioned why an audit of the entire organization – ILSI, plus branches and Research Foundation – was not conducted. Mr. Sullivan pointed out that the legal relationship between the branches and ILSI is not the same as ILSI has with the ILSI Research Foundation. Under the charter agreement that each branch signed with ILSI, there is no financial liability for ILSI from any branch.

**Joint meeting of the Washington-based finance committees** – Ms. Berry asked if the ILSI Financial Oversight Committee wanted to have a joint finance committee meeting with ILSI HESI, ILSI North America and ILSI Research Foundation during the 2014 ILSI Annual Meeting. These entities all share the same Chief Financial Officer, audit firm and investment firm. No issues for discussion were identified, thus no meeting was deemed necessary.

### VII. Next Steps

- Future financial reports will include information about which branches are behind in paying their annual ILSI assessment.
- The financial report to the ILSI Board of Trustees in January will include a slide showing the impact of the closing down of ILSI IFBiC on the ILSI GC financial position.

### VIII. Adjournment

As there was no further business, Dr. Westring ended the conference call at 10:01 a.m. Eastern Standard Time.

Signed:	Date:
	Date

### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

### Tuesday, November 5, 2013 9:00 – 10:30 am Eastern Standard Time

### AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the July 24, 2013 Conference Call
- III. Review of 2013 Year-to-date Financial Report
- IV. ILSI Reserve Fund Performance Report Raffa Wealth Management
- V. Review of 2013 Year-end Projection and Proposed 2014 Budget
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

# ILSI Board of Trustees Financial Oversight Committee

# **Conference Call**

# Tuesday, April 29, 2014 9:00 – 10:00 am Eastern Daylight Time

### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the November 5, 2013 Conference Call
- III. ILSI Reserve Fund Performance Report Raffa Wealth Management
- IV. Review of 2014 Year-to-date Financial Report
- V. New Business
- VI. Next Steps
- VII. Adjournment

From: Sent: To: Cc: Subject: Courtney McComber < Monday, April 21, 2014 8:41 AM Courtney McComber Courtney Gaine; Ashley Jarvis Don't Miss It - EB 2014 - ILSI North America Calendar of Events



If you are planning to attend Experimental Biology 2014 in San Diego, then don't miss ILSI North America's calendar of events beginning with our annual Saturday morning symposium. This year's session is titled "Fortification and Health: Opportunities and Challenges."

# ILSI North America's Calendar of Events

### Saturday, 26 April

ILSI North America/ASN Symposium Honoring John A. Milner Fortification and Health: Opportunities and Challenges Saturday, 26 April 2014, 8:30am – 12:30am, Ballroom 20D Tribute to John A. Milner – David Allison, University of Alabama at Birmingham Session Chairs: Johanna Dwyer, Tufts Medical Center and Kathryn Wiemer, General Mills, Inc. Speakers: Janet King, Children's Hospital Oakland Research Institute; Regan Bailey, NIH ODS; Valerie Tarasuk, University of Toronto; Christine Taylor, NIH ODS; Carl Keen, University of California at Davis; Martin Philbert, University of Michigan; Omar Dary, USAID; Kevin Miller, General Mills, Inc. Session program can be found here

### Sunday, 27 April

**Poster: Sugars and Health: Applying Evidence Mapping Methods to Assess the Evidence** Sunday, 27 April 2014, 1:45pm - 2:45pm, Poster Board Number C169 Presenter: Samantha Berger, Tufts University

### Monday, 28 April

Symposium: Neurocognition: The Food-Brain Connection (Sponsored by ASN)

Monday, 28 April 2014, 8:30am – 12:30am, Ballroom 20D Speakers: James Hill, University of Colorado; Kent Berridge, University of Michigan; Nicole Avena, University of Florida; Hisham Ziauddeen, University of Cambridge; Miguel Alonso-Alonso, Harvard University; David Allison, University of Alabama at Birmingham

Session program can be found here

#### Tuesday, 29 April

**Oral Presentation: Sodium to Potassium Ratio and Food Choices of U.S. Adults** Tuesday, 29 April 2014 12:00pm - 12:15pm, San Diego Convention Center, Room 29D Presenter: Donna Rhodes, USDA Food Surveys Research Group

# Oral Presentation: Low-Calorie Sweeteners and Body Weight and Composition: a Meta-Analysis of Randomized Controlled Trials and Prospective Cohorts

Tuesday, 29 April 2014 3:00pm - 3:15pm, San Diego Convention Center, Room 30C Presenter: Vanessa Perez, Exponent, Inc.

#### Reception: Nutrition Science Public/Private Partnership Update & Reception

Tuesday, 29 April 2014, 5:00pm – 7:00pm, San Diego Hilton Bayfront, Cobalt Room 501B

Safe travels and hope to see you in sunny San Diego!

Courtney Kelly McComber ILSI North America Program and Conference Manager 1156 Fifteenth Street NW Suite 200 Washington, DC 20005 202-659-0074 ext. 143 202-659-3859 (fax) From:onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of<br/>nutritionreviews@ilsi.orgSent:Monday, April 21, 2014 2:01 AMTo:Joanne LuptonCc:sdonovan@illinois.eduSubject:Second reminder: Request to review

21-Apr-2014

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited by Dr. Sharon Donovan to review a manuscript entitled "Linking Flavonoid Intakes to Health Outcomes with Better Food Composition Tables" [Manuscript ID NUTR-REV-063-ES-04-2014]. A follow-up to that invitation was also sent, but we do not seem to have received a response.

In order to ensure your preference with regard to this invitation is recorded, and to avoid any undue delay in the processing of the submission, we would be grateful if you could indicate your ability to assist by clicking on the appropriate link below:

Agreed: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=250a5af5a6694393984ed81d220a13e5

Declined: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=825e3fb314d346aa993fbbfb4c90f9cb

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Your opinion on the suitability of this submission for possible publication in Nutrition Reviews will be highly valued by the editors. Please let us know if your schedule will permit you to accept.

Kind regards,

**Nutrition Reviews** 

Impact Factor 4.597 www.nutritionreviewsjournal.com, Nutrition Reviews nutritionreviews@ilsi.org

Impact Factor: 4.597 www.nutritionreviewsjournal.com

cc. Dr. Sharon Donovan [email ref: SE-33-a] From:onbehalfof+nutritionreviews+ilsi.org@manuscriptcentral.com on behalf of<br/>nutritionreviews@ilsi.orgSent:Saturday, April 19, 2014 1:49 AMTo:Joanne LuptonCc:Subject:Subject:Reminder: Request to review

19-Apr-2014

\*\*\*This is an automatically-generated reminder/notification\*\*\*

Dear Dr. Lupton:

Recently, you were invited to review a manuscript entitled "Linking Flavonoid Intakes to Health Outcomes with Better Food Composition Tables" [Manuscript ID NUTR-REV-063-ES-04-2014] for Nutrition Reviews, but a response to that invitation has not yet been received.

In order to ensure the review process proceeds in a timely fashion, this invitation is being extended again. To automatically register your response, please click on the appropriate link below:

Agreed: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=a1e4692a64d143c9972827e907724044

Declined: http://mc.manuscriptcentral.com/nutr-rev?URL\_MASK=2f82d614c22844d59421d326a8539827

You may also respond to this message directly via e-mail.

If you are unable to review at this time, it would be very helpful if you could provide the name and e-mail address of another qualified expert who may be able to assist.

Thank you for considering this invitation. I hope your schedule will allow you to accept.

Sincerely,

Sharon Donovan Associate Editor Nutrition Reviews Impact Factor 4.597 www.nutritionreviewsjournal.com

[email ref: SE-32-a]

From: Sent: To: Cc: Subject:

Courtney McComber < Wednesday, April 02, 2014 12:53 PM Courtney McComber Heather Steele SAVE the DATE: ILSI North America FNSP Mtg – 23 July 2014 in Washington DC



# SAVE THE DATE! ILSI North America Food, Nutrition & Safety Program (FNSP) Mid-Year Meeting Wednesday, 23 July 2014 Washington, DC

Dear ILSI North America Colleagues and Friends:

**Please save the date of Wednesday, 23 July**, to join us for the Mid-Year Meeting of the ILSI North America Food, Nutrition and Safety Program (FNSP) in Washington, DC. The meeting will be held at the Madison Hotel in downtown Washington, DC, and will combine presentations on topics of current interest with reports on the progress of new and ongoing projects since the annual meeting in January. More information COMING SOON on the program, speakers and registration details.

In the meantime, please mark the date on your calendar; we look forward to seeing you this summer.

Some of the specific topics we expect to include are:

- Microbiota and Health: an update on the latest research in this field
- Cause and Effect and the Attribution of Food-borne Outbreaks
- Food Patterns Associated with Outcomes
- Rapid detection technologies for the improved safety and quality of foods
- Aging and Nutrition
- Reports from EB 2014 workshops including Fortification and Health, and Neurocognition: the Food-Brain Connection

\*\*Special Pre-meeting workshop on "The Role and Use of Nutritional Studies in Evaluating the Safety of a Food or Ingredient" – is scheduled for Tuesday, 22 July 2014, at the Madison Hotel in Washington, DC. Additional information,

including details for special registration, is coming soon; please contact Ms. Heather Steele at ILSI North America ) with any questions.

Courtney Kelly McComber ILSI North America Program and Conference Manager 1156 Fifteenth Street NW Suite 200 Washington, DC 20005 202-659-0074 ext. 143 202-659-3859 (fax)

From:	Joanne Lupton		
Sent:	Wednesday, March 12, 2014 7:19 PM		
То:	; Hagen Schroeter;		
Cc:	Erdman, John W; Courtney Gaine		
Subject:	FW: 2014-03-07; CRN-International Scientific Symposium; Proceedings		
Attachments:	Letter to Attendees of the 2013 CRN-I Scientific Symposium.pdf; 2014 CRN-I PROCEEDINGS EJN LUPTON ET AL.pdf		

Hello all:

I have mentioned to each of you that I would send you the article on developing a DRI-like process for bioactives that was the result of a CRN symposium. Here is the article. It isn't perfect but I think it raises all the major issues that stand in the way of having DRI values for bioactives – and suggests solutions to those issues. Any comments are very welcome. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: James C. Griffiths [mailto:]Sent: Friday, March 07, 2014 7:51 AM]To: James C. Griffiths]Cc: CRNStaff]Subject: 2014-03-07; CRN-International Scientific Symposium; Proceedings



7 March 2014

Dear Attendee:

CRN-I is delighted to inform you that we have available the journal publication resulting from our scientific symposium, **Bioactives: Qualitative Nutrient Reference Values for Life-stage Groups?** held in Kronberg im Taunus, Germany on 1 November 2013.

Published in the *European Journal of Nutrition*, "Exploring the benefits and challenges of establishing a DRI-like process for bioactives" is an open-access article. Please feel free to share the article with your colleagues and others interested in nutrition, dietary reference intakes, essential and non-essential nutrients, adequate intake and bioactives. CRN-I hopes the symposium and subsequent journal article encourage regulatory agencies and the research communities to examine the science surrounding bioactive compounds more diligently and foster understanding of the potential benefits.

**Exploring the benefits and challenges of establishing a DRI-like process for bioactives** Lupton JR, Atkinson SA, Chang N, et al. Eur J Nutr. 2014 Feb 25. [Epub ahead of print] Available at: <u>http://link.springer.com/article/10.1007/s00394-014-0666-3</u>

We look forward to seeing you again at future CRN-I scientific events. Visit the CRN-I website at <u>www.crn-i.ch</u> for updates or join our e-mailing list by contacting Haiuyen Nguyen at

Best regards,

James C Griffiths, PhD Vice President, Scientific & International Affairs Council for Responsible Nutrition-International Tel: +1-202-204-7662 Mobile: +1-301-789-8830 Fax: +1-202-204-7701 E-mail:

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SUPPLEMENT

# Exploring the benefits and challenges of establishing a DRI-like process for *bioactives*

Joanne R. Lupton · Stephanie A. Atkinson · Namsoo Chang · Cesar G. Fraga · Joseph Levy · Mark Messina · David P. Richardson · Ben van Ommen · Yuexin Yang · James C. Griffiths · John Hathcock

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**Abstract** *Bioactives* can be defined as: "Constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs, which are responsible for changes in health status" (Office of Disease Prevention and Health Promotion, Office of Public Health and Science, Department of Health and Human Services in Fed Reg 69:55821–55822, 2004). Although traditional nutrients, such as vitamins, minerals, protein, essential fatty acids and essential amino acids, have dietary reference intake (DRI) values, there is no such evaluative process for *bioactives*. For certain classes of *bioactives*, substantial scientific evidence exists to validate a relationship between their intake and enhanced health conditions or reduced risk of disease. In addition, the study of *bioactives* and their relationship to disease risk is a growing area of research supported by

This is the fourth CRN-International conference report. Previous conference reports were published in Regulatory Toxicology and Pharmacology, European Journal of Nutrition, and European Journal of Nutrition, respectively.

J. R. Lupton Texas A&M University, College Station, TX, USA

S. A. Atkinson McMaster University, Hamilton, ON, Canada

N. Chang Ewha Womans University, Seoul, Korea

C. G. Fraga University of Buenos Aires, Buenos Aires, Argentina

J. Levy Ben-Gurion University of the Negev and Soroka Medical Center, Beer-Sheva, Israel

M. Messina Nutrition Matters, Inc., Port Townsend, WA, USA government, academic institutions, and food and supplement manufacturers. Importantly, consumers are purchasing foods containing *bioactives*, yet there is no evaluative process in place to let the public know how strong the science is behind the benefits or the quantitative amounts needed to achieve these beneficial health effects. This conference, *Bioactives: Qualitative Nutrient Reference Values for Life-stage Groups?*, explored why it is important to have a DRI-like process for *bioactives* and challenges for establishing such a process.

**Keywords** *Bioactives* · Dietary reference intakes · Non-essential nutrients · Adequate intake

#### Why it is important to have a DRI-like process for the evaluation of *bioactives*

Bioactives are important to human health, they are an active area of research, and consumers are purposefully purchasing foods containing them. Substantial evidence

D. P. Richardson DPR Nutrition Ltd, Surrey, UK

D. P. Richardson School of Chemistry, Food and Pharmacy, University of Reading, Reading, UK

B. van Ommen TNO, Zeist, The Netherlands

Y. Yang China CDC, Beijing, China

J. C. Griffiths · J. Hathcock (⊠) Council for Responsible Nutrition, Washington, DC, USA e-mail: info@johnhathcockconsulting.com exists that specific bioactives beneficially affect health. This conference heard from three experts on bioactives: Dr. Cesar G. Fraga on flavanols; Dr. Joseph Levy on lycopene and other tomato carotenoids; and Dr. Mark Messina on soybean isoflavones. A few of their major points are discussed here, since the overall goal of the conference was to discuss the feasibility of applying a dietary reference intake (DRI)-like process to the evaluation of bioactives rather than a scientific discussion on bioactives themselves, the reader is referred to a number of key papers for more information in support of a specific bioactive and decreased risk of a disease or other health-related condition. There is strong evidence for the effect of flavanols on decreased risk of cardiovascular disease and associated risk factors. This evidence includes demographic data and human interventions, and it is mechanistically supported by animal and ex vivo studies [10]. (-)-Epicatechin is the compound better studied [24]; however, other flavanols and flavonoids could share these protective actions [30]. Another important class of bioactives is isoflavones derived from soybean. Although it is not possible to infer a direct causal relationship, case-control and prospective epidemiologic studies show isoflavone intake via soyfoods is associated with a lower risk of several chronic diseases including breast [32] and prostate [33] cancer, and among women, coronary heart disease (CHD) [18] and osteoporosis [17, 34]. Furthermore, there is relatively solid evidence that isoflavones increase flow-mediated dilation in post-menopausal women with impaired endothelial function [6] and there is suggestive, but limited evidence, that isoflavones reduce carotid intima media thickness [12]. The most impressive clinical data exist for the alleviation of menopausal hot flashes [27]. Lycopene and other tomato carotenoids have been found to decrease blood pressure in pre-hypertensive patients as well as reduce post-prandial blood-oxidized low-density lipoproteins [5, 7, 16, 22].

Research on bioactives is a significant portion of diet, nutrition and disease portfolios of governments, at universities, and at food manufacturers. Consumers are interested in optimal health and are purposefully purchasing foods containing bioactives. However, there is no evaluative process in place to inform the public about the strength of the science behind the purported benefits of a specific bioactive of interest, nor is there information on how much of a particular bioactive is necessary to be of benefit. If there were a process to evaluate the strength of the science behind the intake of a *bioactive* and decreased risk of disease (or other health condition), standards would be set for this research, studies could be compared across laboratories, and consumers and health professionals could have more confidence in what they were eating; and the field could move forward more quickly. If that science base were combined with a recommended intake value, assessments could be made as to whether or not populations or specific age groups were meeting that recommendation and consumers would know the overall contribution of a food product to the recommended amount.

Having a DRI value increases the status of a bioactive and makes it part of nutrition public policy. Without a DRI value, it is unlikely that bioactive information will be incorporated into national nutrition intake surveys such as NHANES (National Health and Nutrition Examination Survey) in the US. National nutrition surveys describe the amount of nutrients being consumed by representative populations, and then those intake values are compared to a DRI to determine whether the population is eating too much or too little of that substance. If too little, the substance might be called an "at risk" nutrient, and education campaigns to improve people's intakes (within one's calorie allotment) could be implemented. Thus, not having reference intake values limits the ability to develop messaging to the public regarding bioactives for which there is solid scientific evidence of their health-enhancing effects. Importantly, health professionals (such as physicians, physician assistants, nurses, and dietitians) who may offer advice to clients on what they should be eating, would be more comfortable recommending bioactives if they have gone through a rigorous evaluation process. In most countries, the overall nutrition policy is called "dietary guidance". Although this guidance is food rather than nutrient based, the food recommendations are derived from the DRI values for the nutrients. For example, the philosophy of the US Dietary Guidelines is that if one follows the recommendations of the guidelines, one will automatically meet the DRI values for all nutrients [20]. Thus, dietary guidance is another important way that information on bioactives with substantial science behind their efficacy could be transmitted to consumers. For a summary of the advantages of having a DRI-like process for the evaluation of bioactives, see Table 1.

Dietary fiber is an example of a bioactive with a DRI value. Although dietary fiber is a non-essential nutrient, it does have an officially recommended intake value [14]. This means that the amount of fiber in a food product is on most fact-based food labels throughout the world. It is also generally included in the questionnaires on national food intake surveys so that information is available as to whether or not the DRI value for fiber is being met. It also means that it is considered and promoted in dietary guidance. Dietary fiber is thus of concern to consumers who are looking to increase it in their diets.

#### What are the challenges to establishing such a system and how can those challenges be met

The process for determining nutrient reference values in the US and Canada changed significantly in 1994 when several

Importance	Example	Benefit for having a DRI-like value		
<i>Bioactives</i> are important to human health	For example, there is strong science behind the relationship between flavanols and decreased risk of cardiovascular disease [10, 15]; isoflavones and lower risk of several chronic diseases [18, 27, 32]; and lycopene and other tomato carotenoids and decreased blood pressure [5, 7, 16, 22]	A major benefit would be that they would be recognized as being important to health and evaluated accordingly. Investigators, regulatory agencies, consumers would all know how strong the science was behind science messaging on these compounds		
<i>Bioactives</i> are a significant portion of diet and disease research portfolios	Governments, Universities, and Food Manufacturers are supporting studies on <i>bioactives</i>	Standards would be set so that studies could be compared across laboratories		
Consumers are interested in optimal health and are purposefully purchasing foods containing <i>bioactives</i>	This was part of the rationale for setting DRI values for <i>bioactives</i> in China	Consumers would benefit from strengthened knowledge that they were making decisions based on science and they would also have a target to aim for in terms of intake		
Having a DRI value increases the status of a bioactive and makes it part of nutrition public policy	Substances that have DRI values are regularly evaluated in populations to see if that population is meeting established DRI values	If the bioactive is part of the intake assessment of nutrients/foods, then we will learn whether or not that population is actually meeting the DRI value, or if it is an "at risk" nutrient		
The process by which a bioactive is evaluated would set standards which would raise the level of science	Such requirements as having a formal definition, and an approved method of analysis would help comparing studies across laboratories	Using common methods of analysis and a common definition would allow studies to build on each other and advance the science more rapidly		
With a transparent process for evaluation, the results would provide science-based recommendations for improving diets	Health professionals such as doctors, dietitians, and educators would be more comfortable making diet recommendations	Messaging on intake of <i>bioactives</i> would be science based		
Having an intake value would set a goal for incorporating <i>bioactives</i> into diets	Consumers would know whether a food was a good source of that bioactive, or how much one would need to eat in order to reach the intake value	Having a target intake value would discourage messaging on products that suggest they are a good source of a specific bioactive when they only contain a negligible amount		

Table 1 Why it is important to have a DRI-like process for the evaluation of bioactives

kinds of reference values were introduced and articulated in the 1994 publication, How Should The Recommended Dietary Allowances Be Revised [9]. There were two major changes: (1) that values could be based on reduced risk of a disease and (2) that there were additional values other than the recommended dietary allowance (RDA), i.e., estimated average requirement, adequate intake (AI), and upper level (UL). A conclusion of this report was that the "reduction in risk of chronic disease is a concept that should be included in the formulation of future RDAs where sufficient data for efficacy and safety exist [9] ". This conclusion represented a "new paradigm" from what had previously existed. Using these criteria, four DRI values have since been set based on chronic disease: osteoporosis and fractures for calcium and vitamin D, dental caries for fluoride, CHD for fiber, and a combination of endpoints including salt sensitivity, kidney stones, and blood pressure for potassium [28]. Thus, this suggests that bioactives could qualify for a DRI value if they could show strong science behind reduced risk of disease.

Demonstrating reduced risk of disease with a bioactive is more difficult than it is to show prevention of a deficiency outcome with an essential nutrient. A major difference between bioactives and essential nutrients (i.e., vitamins, minerals, essential fatty acids, and essential amino acids) is that the absence of bioactives in the diet does not result in a deficiency disease, whereas the absence of an essential nutrient eventually results in deficiency symptoms (e.g., lack of vitamin C and scurvy, thiamin and beriberi, iron and anemia). This difference means that a DRI value would have to be based on an endpoint other than a deficiency disease. As shown above, this could be decreased risk of a chronic disease, but showing cause and effect with a bioactive and chronic disease is more difficult than when the disease is specific nutrient related. In other words, if vitamin C intake is inadequate, 100 % of the deficient people will eventually get scurvy. This is not the case for chronic disease which is affected by multiple nutrients, and is also impacted by other non-nutrient factors (e.g., gender, age, and genetics) [28].

Dr. Ben van Ommen challenged the concept of relating health to just decreased risk of disease and suggested that in quantifying the health effects of *bioactives* "we might need to consider in greater depth what health is, what mechanisms are involved in maintaining health, and how to best quantify these". A pioneer in this new area of "optimal health," he considers health to be appropriate adaptation to a continuously changing environment—and food

is a key part of that changing environment. He calls this adaptive capacity "phenotypic flexibility" and states that it is key to maintenance of overall homeostasis "and thus to a healthy life". He and his research group have also developed ways to test for "phenotypic flexibility" by stressing specific components of the system that maintain homeostasis and evaluating the stress response reactions. These response reactions usually appear to be more informative and sensitive than their homeostatic counterpart. A classic example is the oral glucose tolerance test versus fasting glucose, and numerous other comparable "challenge biomarkers" that are now being developed [23, 29]. If accepting decreased risk of disease as an endpoint for a DRI value was a paradigm shift, Dr. van Ommen's emphasis on "phenotypic flexibility" is definitely a new paradigm shift which should become more widely accepted as an evaluation of efficacy for a bioactive as the research to measure this flexibility is validated.

Issues regarding the setting of life-stage DRI values for bioactives

Dr. Stephanie Atkinson discussed possible approaches for determining life-stage DRI values for bioactives using information from previous DRI recommendations developed for infants, children, and youth as an example [1]. She suggested using three age groupings to establish DRI values for bioactives: (1) infants to 1 year of age; (2) children 1-8 years; and (3) individuals over 8 years. For Infants to 1 year of age, she suggested using human milk as a "reference". For children 1-8 years, in the absence of clinical trials, it was suggested that AI values be derived from population-based intake data associated with health outcomes. For those over age eight, the suggestion was to derive the value from existing data on biomarkers of chronic disease or extrapolation from adults. The rationale and the cautions for each of these recommendations were provided. Issues in establishing life-stage DRIs for bioactives vary greatly from one substance to another. For example, in infants, intakes from human milk bioactive substances such as nucleotides [25], carnitine [2], lutein [3], and glycoconjugate sugars [19, 26] have been used to derive safe levels of addition of such compounds to infant formulas. Evidence of the biological benefit of addition of these substances to the health of formula-fed infants is inconsistent, but no adverse effects have been identified. A lack of response to addition of a *bioactive* to formula may relate to the variable bioavailability of a bioactive depending on whether it is found in breast milk or added to formula. For example, approximately four times more lutein is needed in infant formula than is naturally present in human milk to achieve similar infant serum lutein concentrations [3]. For the case of dietary fiber, using human milk as a reference for infants 7–12 months of age cannot be done because of the absence of this substance in milk. Remaining challenges include selection of the best model (approach): For example, objectively differentiating between the various age groups on a basis other than age itself seems logical, if difficult. Also, the development of recommended intakes or maximal effect ranges is another choice.

Establishing safety of *bioactives* and adjusting for different population groups may not be the same as it is for essential nutrients

Dr. David Richardson discussed the process of establishing the safety of bioactives. For nutrients and other dietary ingredients, the limitations on safety are commonly set through identifying a "Tolerable Safe UL". This is done by identifying any "hazard" associated with high intakes, establishing a dose-response relationship, evaluating the uncertainty and selecting a composite "safety factor," and then calculating an UL value. This procedure cannot be applied when no hazard can be identified (as with many bioactives). However, there is an alternative risk assessment approach that is based on the highest observed intake (HOI) method developed by FAO/WHO [8] and included in Codex Guidelines [6]. The HOI is defined as the highest level of intake observed with the available data of acceptable quality, showing an absence of adverse effects. Since most bioactives have no known hazard, the HOI is an important alternative approach to setting quantitative value limits on the amounts of bioactives that may be considered safe.

Even if there is agreement on this general approach, the problem remains that most safety data are derived from studies on adult subjects designed to look for benefit rather than harm. Scaling the healthy adult values to give confident estimates of the amounts to be deemed safe in subpopulation groups is difficult. Nonetheless, an adult UL or HOI value is needed to give an appropriate basis for policies directed to other population groups. Most DRI values fall well below the ULs/safe ULs, but some high intakes can approach or exceed the safe UL. A narrow range between a DRI and upper safe level may be unjustified when there is a lack of evidence of a demonstrable adverse effect/toxicity at current levels above an upper safe level. If intakes exceed the UL/HOI, the significant uncertainties about the safe level are more likely to indicate that the intake is not the problem but rather the application of a safe level based on inadequate data. In practical terms, adverse effects are more often observed with inadequate intakes rather than excessive intakes. Clearly, care and scientific judgment must be taken in the use of a safe UL as the benchmark in the selection of ULs/HOIs for bioactives.

A sustainable approach is needed for the evaluation of efficacy and intake recommendations for *bioactives* 

#### Lessons learned from South Korea

There is growing interest in establishing a DRI-like system for setting intake values for *bioactives* [4, 11]. Although South Korea does not have a DRI system for establishing intake values for *bioactives*, they do have an evaluative process together with a process to determine intake values. Dr. Namsoo Chang explained this process for South Korea. The Health Functional Food (HFF) Act was enacted in 2004 with the goal of ensuring the safety of HFF with certain health claims for consumer information. At its inception the HFF covered products in the form of tablets, capsules, powders, granules, pastes, gels, jellies, and bars that were intended to enhance and preserve human health and contained one or more functional ingredients or constituents. In 2008, the scope was extended to include conventional foods and other diet supplements.

What is unique about the HFF act in South Korea is that unlike other countries, the government of South Korea is endorsing a particular product with a HFF "seal". There are two types of HFF, generic and product-specific. The generic type (shown in Table 2) contains both 28 essential nutrients and 55 non-nutrients. Both the nutrients and nonnutrients are considered to have substantial efficacy and safety data to have been considered for the generic category. All of these substances listed on the generic health/ Functional Food Code include health claims and intake recommendations. This generic type HFF is most analogous to establishing a process for evaluation of efficacy and intake values for DRIs, although they are not called DRIs by the South Korean Government.

If the *bioactive* is not on the generic type list of functional ingredients, then it needs to follow a process and receive approval. Manufacturers submit a dossier for comprehensive scientific evaluation of safety and efficacy, which is reviewed by the Government and Advisory Committees. The application must consist of any data on the history of safe use, manufacturing processes, recommend intake levels, toxicological data, clinical data, nutritional evaluation data, and bioavailability data.

Soy isoflavones (discussed in this conference) have a generic health claim which is that they help to maintain bone health. The isoflavone content of common soybean products in Korea is known, as is the isoflavone intake in South Korea. Although no safety data were available in Korea, the safe intake level for isoflavones was adopted from the Japanese standards. A recommended intake is set at 24–27 mg/day as aglycone soybean isoflavones. Notably, a caution is stated for infants, children, pregnant and lactating women, and individuals who have an allergy to

Table 2
Functional ingredients listed in the South Korean Health/

Functional Food Code (Generic Type)
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Nutrients	Non-nutrients				
Vitamin A	Alkoxyglycerol	Banaba leaf extract			
Vitamin D	Aloe gel	Evening primrose seed extract			
Vitamin E	Aloe whole leaf	Ganodermalucidun fruit body extracts			
Vitamin K	Chitosan/ chitooligosaccharide	Garciniacambogia extract			
Beta carotene	Chlorella	Ginko leaf extract			
Vitamin B1	CLA	Green tea extracts			
Vitamin B2	Coenzyme Q10	Guava leaf extract			
Vitamin B6	Fructooligosaccharide	Haematococcus extract			
Vitamin B12	Gamma-linoleic acid	Japanese apricot extract			
Niacin	Ginseng	Milk thistle extract			
Vitamin C	Glucosamine	Propolis extract			
Pantothenic acid	L-theanine	Saw palmetto extract			
Folic acid	Lecithin	Functional fiber			
Biotin	Lutein	Guar gum/hydrolyzates			
Calcium	MSM	Glucomannan			
Magnesium	Mucopolysaccharide	Indigestible maltodextrin			
Potassium	N-acetylglucosamine	Oat fiber			
Zinc	Octacosanol	Soy fiber			
Copper	Omega-3 fatty acids	Tree ear			
Selenium	Phosphatidylserine	Wheat fiber			
Manganese	Phytosterol ester	Barley fiber			
Iron	Plants containing chlorophyll	Arabic gum			
Iodine	Probiotics	Corn bran			
Molybdenum	Red ginseng	Inulin			
Chrome	Red yeast rice	Psyllium husk			
Dietary fiber	Soy isoflavone	Polydextrose			
Essential fatty acids	Soy protein	Fenugreek seed			
Protein	Spirulina				
	Squalene				

soybean, and individuals who are sensitive to estrogen. A generic claim for lutein (a *bioactive* found in tomatoes) also exists. The health claim is, "helps eye health by maintaining the density of macular pigments which can be decreased by aging". Based on review of existing literature, the intake recommendation was set at 10–20 mg lutein/day with a warning for yellowing of skin if taken at excessive amounts. In addition, a recommendation for intake of all-*trans* lycopene at 5.7–15 mg/day is provided based on the health claim for tomato extracts as an antioxidant. This recommendation is accompanied by a caution for pregnant and lactating women and for children. Flavonoids and lycopene are listed in the product-specific

category, rather than the generic category. A flavonoid database is available for commonly consumed food by Koreans based on the USDA and Japanese flavonoid databases, which were developed in 2009. Flavonoids have been linked to reduced risk for chronic diseases and improved health outcomes, and six subclasses of flavonoids are identified by structure.

Currently, the Ministry of Health and Welfare is revising the South Korean DRIs and plans to release the revised version in 2015. Although it was recently decided that bioactive substances will not be included in the 2015 version of the DRIs, the need to establish DRIs for bioactive substances was raised. If there were to be a DRI value for bioactives, it would most likely be the AI value. The AI is defined as "The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate-used when an RDA cannot be determined" [13]. Importantly, South Korea may be able to contribute to establishing ULs for bioactives, since they have a postmarket surveillance system on health/functional foods. They are operating an online system for adverse events data collection from consumers, manufacturers, and healthcare professionals. They have the integrated database on products and safety data and are in the process of doing statistical modeling to determine a cause effect relationship of any adverse event.

#### Setting specific proposed levels for bioactive compounds: Recent experiences in China

Professor Yang Yuexin described the process for setting a special category of DRIs (called specific proposed level; SPL) in China. This new category is used to evaluate and assign an intake value for bioactives. This is the only country, of which we are aware, that has actually established DRI values for bioactives. The China Nutrition Society, similar to the Institute of Medicine in the US, changed their intake evaluation process for nutrients from only RDAs to DRIs. This change was initiated in 2000 and resulted in 32 DRI values for nutrients. In 2010, they initiated the incorporation of a SPL for non-nutrients and a proposed Intake that is based on reducing the risk of noncommunicable chronic disease and improving optimal health. Their stated rationale as to why they consider the SPL a DRI value is that both traditional medicine and modern nutrition research have deepened the understanding of plant compounds; and also because consumers are widely consuming these bioactive substances in China. In 2010, they had seven different expert review panels containing a total of 87 experts develope the DRIs for China to be released in 2014. One of the seven panels was on "non-

Table 3 "Non-nutrients" that were evaluated by the Chinese DRI Process

Non-nutrient substances	
Water	Lycopene
Dietary fiber	Proanthocyanidines
FOS anthocyanin	Isoflavones
Resveratrol	Phytosterols
Catechol	Isothiocyanates
Quercetin	Allicin, gallic
Curcumin	Glucosamine
Chlorogenic acid	GABA
Lutein/zeaxanthin	Alpha lipoic acid (LA)
	<i>L</i> -carnitine

nutrients," and 21 experts were involved in this panel. The goal of this panel was to develop DRI values for water, fiber, and 18 phytochemicals (SPLs). The SPLs reflect the current state of scientific knowledge and are published as a series of reports by the Chinese Nutrition Society. Both SPLs and ULs are set for *bioactives*. Table 3 shows the "non-nutrients" that were evaluated by the Chinese DRI process.

The Chinese Nutrition Society has acknowledged that there are some *bioactives* that "like some other nutrients, are essential for reaching the full (genetically-determined) lifespan". They have termed these nutrients as "life span essential" [31]. The Chinese experience in establishing DRI-like values for *bioactives* should be followed closely, and they should be acknowledged as being the pioneers in this area.

Setting a high bar for entrance into the evaluation system

One issue with setting up a DRI-like process for the evaluation of bioactives is the very wide range of the strength of the science behind the intake of a bioactive and a purported reduced risk of disease. For some *bioactives*, little research has been conducted, whereas for others there are 20-30 years of research in support of a protective effect. A concern is that the evaluators would have to be dealing with requests when there was insufficient information to apply the process. One suggestion to offset this challenge is to set a high standard for "entrance into the evaluative process". Dr. Joanne Lupton discussed potential entrance criteria as necessary information before a bioactive could be considered for a DRI-like evaluation process (see Table 4). Setting these nine criteria as essential for consideration for evaluation serves several goals: It minimizes the effort of the evaluator; and importantly, it sets a standard, if met, that investigators and funding sources

Table 4	Proposed	criteria	for a	bioactive	to	qualify	for e	valuation
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Criterion	Additional information	Rationale for criterion		
A definition of the substance which is commonly accepted	Definition should match the method of analysis	Makes it easier to build a database of efficacy of bioactive if substances with the same definition are compared		
A method of analyzing the substance which is consistent with the definition	Preferably backed up by a multi-center analysis such as an AOAC method	Facilitates comparing studies across laboratories. Need a definition and an approved method of measuring so that intake values can be determined, and if populations are meeting recommended intake values		
Database of the amount of the bioactive in foods	Preferably global and updated on a regular basis as new foods come on the market	To determine the amount of this bioactive currently in the food supply and enable determining how much people are consuming. Also necessary for baseline data for clinical trials and input into epidemiological studies		
Prospective cohort studies	Both sexes, showing decreased risk of a disease such as CVD with increased intake of the bioactive. Must be able to isolate the specific bioactive versus other <i>bioactives</i> . Best if the bioactive is also measured in blood/urine, etc. in subset of population and supports food intake data. Relationship to the disease should be consistent with clinical trials	Dose–response data or at least highest quintile versus lowest quintile for the bioactive will help to set level of efficacy		
Clinical trials on digestion, absorption, activation, transport, excretion of the substance	Important to understand the level of absorption and what substances interfere with that absorption, also what the active molecule is and how long it stays in the blood	This information is useful for determining intake and factors that affect intake, transport, activation, etc		
Clinical trials on efficacy and dose–response data	Conducted in healthy populations. Bioactive must be measured. Accepted endpoint linked to decreased risk of the particular disease. If surrogate marker, must be "accepted" by regulatory agencies	Need dose–response data to determine the efficaciou level, and determine intake values		
Safety data at the level of intake that might be anticipated	Ideally would include safety data for special populations such as children, pregnant or lactating women	Need this information even if the bioactive is considered generally regarded as safe (GRAS). GRAS means "safe for intended use"		
Systematic Reviews and/or meta analyses showing efficacy	In the US, the Institute of Medicine now requires systematic reviews for setting DRI values (most recent was calcium and vitamin D). The US Dietary Guidelines now requires these also	Having a systematic review that shows efficacy is a real plus and may be necessary, e.g., a Cochrane review. These reinforce the need to have major prospective epidemiological studies and randomized clinical trials		
A plausible biological explanation for efficacy	This is not required but is a very large plus if it is available	Scientists/evaluators of the research are more comfortable if there is an explanation, particularly if that explanation is accepted by the scientific community		

could design their research to meet, knowing that there would be a certain level of credibility if they were to do so.

#### Summary, conclusion, and next steps

The speakers were in consensus that providing a framework for the evaluation of *bioactives* could be of benefit to scientists working in this field, to funders of the research, to governments, and importantly to consumers. However, they were also aware of the potential challenges to establishing such a framework. Clearly, there is a difference between determining intake values for essential nutrients and *bioactives*, and thus the basis of the intake value cannot be on a single-nutrient deficiency disease. Nonetheless, other endpoints such as reduced risk of disease may be applicable. Basing a DRI value on reduced risk of disease has been used for four nutrients that have DRI values. Alternatively, the AI value was considered by some to be an appropriate value for consideration as by definition it can reflect the current intake of specific healthy populations. Setting life-stage values for *bioactives* is also a challenge, but Dr. Atkinson suggested a different model for consideration. Instead of concentrating on the *bioactive*, per se, she suggested establishing goals for life stages. For example, for early life, it might be "optimal development" and markers for that could be body composition, or

cognitive/behavioral outcomes. For child/adolescent, the DRI value could be based on early biomarkers that are sensitive indicators of chronic disease risk. Then, bioactives that were shown to affect those outcomes could receive intake values for that life stage. This model warrants development and consideration. Another challenge is establishing an UL value for bioactives in the absence of any evidence of toxicological effects. Here, it appears that there is an extensive literature on risk/benefit systems which should be considered for application to bioactives. Finally, the logistics of how to set the framework, who is the "keeper" of the system, and what it would take for a bioactive to be considered in this framework requires serious consideration. A proposed next step would be a workshop with representation from all key stakeholders to discuss the challenges to having a framework for the evaluation of bioactives and how those challenges may be overcome.

Conflict of interest J. R. Lupton, S. A. Atkinson, N. Chang, C. F. Fraga, J. Levy, M. Messina, D. P. Richardson, B. v. Ommen, Y. Yuexin and J. C. Griffiths had their travel expenses reimbursed by CNR-I. J. R. Lupton consults to Mars, Inc. S. A. Atkinson is a member of the Board of Trustees of the International Life Sciences Institute for North America. M. Messina regularly consults for companies and organizations that sell and/or manufacture soyfoods and/or soy isoflavone supplements. J. Levy consults to LycoRed. D. P. Richardson is a Scientific Adviser to the UK Council for Responsible Nutrition (CRN) and Food Supplements Foundation, Europe, and on the Scientific Council of the International Alliance of Dietary Supplements Associations (IADSA). Y. Yuexin consults to CRN-I. J. C. Griffiths is an employee of CRN-International. J. N. Hathcock serves as a consultant for the Council for Responsible Nutrition and CRN-International. In these roles, he provides risk assessments for nutrients and bioactives, and makes recommendations on the principles and specifics of nutrient reference values. None of the authors declares any conflict of interest in providing their solely scientific opinion for this review.

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- 🖄 Springer

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7 March 2014

Dear Attendee:

CRN-I is delighted to inform you that we have available the journal publication resulting from our scientific symposium, **Bioactives: Qualitative Nutrient Reference Values for Life-stage Groups?** held in Kronberg im Taunus, Germany on 1 November 2013.

Published in the *European Journal of Nutrition*, "Exploring the benefits and challenges of establishing a DRI-like process for bioactives" is an open-access article. Please feel free to share the article with your colleagues and others interested in nutrition, dietary reference intakes, essential and non-essential nutrients, adequate intake and bioactives. CRN-I hopes the symposium and subsequent journal article encourage regulatory agencies and the research communities to examine the science surrounding bioactive compounds more diligently and foster understanding of the potential benefits.

**Exploring the benefits and challenges of establishing a DRI-like process for bioactives** Lupton JR, Atkinson SA, Chang N, et al. Eur J Nutr. 2014 Feb 25. [Epub ahead of print] Available at: http://link.springer.com/article/10.1007/s00394-014-0666-3

We look forward to seeing you again at future CRN-I scientific events. Visit the CRN-I website at <u>www.crn-i.ch</u> for updates or join our e-mailing list by contacting Haiuyen Nguyen at hnguyen@crn-i.ch.

Best regards,

James C Griffiths, PhD Vice President, Scientific & International Affairs Council for Responsible Nutrition-International Tel: +1-202-204-7662 Mobile: +1-301-789-8830 Fax: +1-202-204-7701 E-mail:

From: Sent: To:	Suzanne Harris Friday, February 28, 2014 1:55 Pl s.chang@g	> M griffith.edu.au; Cohen, Sa ; mdoyle@uga.edu; adaı ; Catherine Field	amuel M (scohen@unmc.edu); mdrew@u.washington.edu;
	; j ; Rodrig	; john.c.peters@ucder uez, Felipe {PI}	; Joanne Lupton; iver.edu;
	; Geoff	Sn	nith, Lewis L. (Prof.)
	m; ; Flavi	kwallace@d.umn.edu; we o Zambrone	eavercm@purdue.edu;
Cc:	Debbie Wells		Fleming, Melinda S
		; Usui-Etsuko(?? ??)	;
	Chelsea L. Bishop; c	; tim.	goss@ucdenver.edu; ; Burnand,Valerie,VEVEY,CT-
	RSA	); haan@purdue.edu; C	Christine Lagerquist
Subject: Attachments:	One ILSI Advisory Groups and Bo Tab 03-f Implementation Plan.p	oard committees optx	

TO: ILSI Board of Trustees

FROM: Suzie Harris

During the January 2014 meeting of the ILSI Board of Trustees, the attached implementation plan for the One ILSI strategy was approved. I am writing to invite you to join one of the two advisory groups – the Science Advisory Group led by Alan Boobis and Peter van Bladeren or the Value/Stakeholder Advisory Group led by Todd Abraham, Sam Cohen and Geoff Smith. These two groups will oversee the work being done in the four thematic areas from the standpoint of the One ILSI strategic priorities for the purpose of offering ideas for strengthening the activities being undertaken. The advisory groups will meet quarterly to review progress for the strategic priorities and to suggest next steps.

If you are interested in actively participating in one of these group, please let me know.

Jerry Hjelle is also looking for champions for the four thematic areas. These individuals will serve as resources for the thematic area teams led by the branch professional staff. The champions will work to help the thematic area leaders develop strategies and identify funding opportunities. This role is a more active one that being part of an advisory group. If you are interested, please let me or Jerry know.

The third opportunity for involvement in ILSI Board activities is to join one of the two standing committees that are currently operating -- Financial Oversight Committee or the Publications Committee. Both groups would welcome new members. If you are interested in joining either of these two committees, please let me know.

Thank you for considering these requests.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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<sup>T</sup>Initial team leaders with input from all ILSI entities

Best practices and shared learnings shape program development and implementation

From: Sent: To:		Suzanne Harris Monday, February 10, 2014 1:10 s.chang@griffith.edu.au; (	PM ; Smith, Lewis L	; Joanne Lupton; Rodriguez, . (Prof.)	Felipe {PI} ;
Cc:		; Chelsea L	Bishop; Christi · Beth-Ellen	ne Lagerquist Berny: Shawn Sullivan: Beth	
Subject:		Brueggemeyer ILSI Financial Oversight conferer	nce calls for 201	4	
TO:	ILSI Board of Tru	stees Financial Oversight Commi	ttee		
FROM:	Suzie Harris				
Thank you to the calls. Based on y	ose who responde your responses, th	ed to my poll for dates for the ILS ne best days for these quarterly c	I Financial Over alls are:	sight Committee conference	
Tuesday, April 2	9				
Monday, July 28					

Monday, October 27

Please mark these dates in your calendars. The calls will begin at 9:00 a.m. Eastern Daylight Time and should not run longer than one hour.

I will send an agenda with financial statements to you with the dial-in instructions about one week before each call. Please let me know if you have any questions.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From:Suzanne HarrisSent:Friday, February 07, 2014 9:58 AMTo:Joanne LuptonSubject:Your reimbursement request

Good morning, Joanne. I hope you are doing well.

I approved your request for expense reimbursement from the ILSI Annual Meeting in Bermuda with the exception of the seat change fee. I think it was \$176.

We do not normally reimburse such charges unless there is a medical reason. Please let me know if that was the case. If so, please also send me a doctor's note or some other justification for the expense – sorry, this is an audit requirement.

I am more than happy to work with you to resolve this issue. Please let me know if you have any questions.

Best regards,

Suzie

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From:	Suzanne Harris		
Sent:	Friday, February 07, 2014 9:43 AM		
То:	s.chang@griffith.edu.au;	; Joanne Lupton; Rodriguez, Felipe {P	·I}
	); Sn	mith, Lewis L. (Prof.)	
Cc:	; Chelsea L. Bis	shop; I ; Christine	
	Lagerquist (	)	
Subject:	Polling to set the ILSI Financial Over	rsight Committee conference calls for 2014	
-	-		
TO:	ILSI Board of Trustees Financial Oversight Committee	e	
	Cursis Usersia		
FROIVI:	Suzie Harris		

Please indicate on which days listed below you expect to be available for a one-hour conference call beginning at 9:00 a.m. Eastern Daylight Time to review the quarterly ILSI financial statements. Then return the information to me.

Tuesday, April 22 Wednesday April 23	
Monday, April 28 Tuesday, April 29 Wednesday, April 30	
Tuesday, July 22 Wednesday, July 23	
Monday, July 28 Tuesday, July 29 Thursday, July 31	
Wednesday, October 22 Thursday, October 23 Friday, October 24	
Monday, October 27 Tuesday, October 28 Wednesday, October 29 Thursday, October 30 Friday, October 31	  

Please let me know if you have any questions.

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From: Sent: To: Subject:

Joanne Lupton Monday, February 03, 2014 10:24 PM Courtney Gaine; Erdman, John W RE: China recommended intakes for bioactives

Courtney, I am very familiar with this. I gave the keynote lecture for the CRN-I symposium on bioactives in Germany, and I just finished the paper resulting from that the Monday we were in Bermuda! As soon as the paper has been accepted I will send you a copy. Dr. Yang is looking for people to review (and clean up the English for their most recent version of DRIs which they hope to get out later this year. I can explain if you want, J

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Courtney Gaine [mailto
Sent: Monday, February 03, 2014 4:21 PM
To: Joanne Lupton; Erdman, John W
Subject: FW: China recommended intakes for bioactives

Hi Joanne and John,

Good seeing both in Bermuda. Joanne, I never said thank you AND apologized for putting you on the spot. You're input to the bioactives social really made it special, and we all really appreciate it.

I just received the below email with attachment from Andrew. He said it was alright if I shared it. I wanted to know if you had heard the latest – Joanne, this sounds similar to what you had heard last year in China. Let me know your thoughts if you have any.

Thanks and talk with you all soon,

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121 From: Andrew Shao [mailto ]
Sent: Monday, February 03, 2014 5:05 PM
To: Courtney Gaine
Subject: FW: China recommended intakes for bioactives

### Courtney,

Attached and below is some relevant information on China's efforts to establish recommended intakes for bioactives. This whole thing has been a mystery to me, so after returning from the ILSI annual meeting I asked some members of my team who are China and APAC-focused to look into it further. Here are some responses:

"I reached out my old colleagues on this and was told that the committee is holding the information closely and they could not get the draft document. However, the new DRI is going to be published around May this year. Some bioactives being considered include lutein, CQ10, omega-3s, soy isoflavone, lycopene, phytosterols, fructooligosaccharides, glucosamine, proanthocyanidins, anthocyanins, quercetin,  $\alpha$ -lipoic acid, and L-carnitine. For lutein, the suggested provisional level is 6 mg/day with UL of 40 mg/day. However, I do not have the levels for other bioactives at this time.

My understanding is that the provisional levels set for bioactives are based on the endpoints related to their health benefits and reduction of the risk for chronic diseases, which differs from traditional DRI principle used by IOM.

It is worth noting that this is being done jointly by the nutritionists from both China and Korea so the DRI setting for bioactives is also on-going for Korea. There will be another joint meeting discussing the function and DRI for plant-based bioactives in May in Korea, which may be of interest to us."

"we understand that the new version of China DRI/RNI has not been published yet. It should be probably out in April. According to what I found so far, in addition to the revised EAR, RDA, AI and UL, 3 other categories including Proposed Intake in preventing non-communicable diseases (PI-NCD), Acceptable Macronutrient distribution range (AMDR) and specific proposed level (SPL) for phytochemicals will be added.

Attached please find the presentation that I have just found explaining the proposed SPL for phytochemicals/ bioactives, the proposed list includes 18 bioactives:

FOS Anthocyanin, Resveratrol, Catechol. Quercetin, Curcumin, Chlorogenic acid, Lutein, Zeaxanthin, Lycopene, Proanthocyanidins, Isoflavones, Phytoesterol, Isothiocyanates, Allicin, Gallic, Glucosamine, GABA, Alpha-lipoic acid L-carnitine"

My message to the various APAC branches and China branch, was that these efforts should be harmonized and be well coordinated worldwide, if at all possible. Also, although I have not seen the details, I'm a bit concerned about the scientific framework (or lack thereof) applied by China to come up with these recommendations. Andrew

From: Sent: To: Subject: Attachments: Courtney Gaine Monday, February 03, 2014 4:21 PM Joanne Lupton; Erdman, John W FW: China recommended intakes for bioactives Yang-CRN-I-2013 (new DRI).pdf

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Recent experiences in China for bioactive compounds: **Specific Proposed Levels** Setting

Prof. Yang Yuexin

Chinese Nutrition society



vxvang@cnsoc.org

# Key information

# Developing SPL for phytochemicals Defining the process of SPI

### Limitations & Challenges Key elements & results





- Goals of the DRI Expert Committee
- 1) Revised and Setting Recommended Intake Values RNI and Al
- -Both RNI and AI are intended to be used as goals in planning nutritious diets
- 2) Facilitating Nutrition Research and Policy EAR
- -EAR values for the scientific basis upon which the RNI values are set
- Establishing Safety Guidelines UL
- -Indispensable to consumers who take supplements or -Identify potentially hazardous levels of nutrient intake consume foods or beverages to which vitamins or minerals have been added

<ul> <li>4) Preventing Chronic Diseases</li> <li>The DRI committee takes into account chronic disease prevention, wherever appropriate prevention, wherever appropriate</li> <li>PI ( preventing intake -NCD)</li> <li>the committee set lifelong intake goals for Na , K , WtC at levels believed in the later years</li> <li>AMDR for FAT , CHO and Protein</li> <li>Specific Proposed Level (SPL), a diet that provides adequate Non - Nutrients Substance while reducing the risk of chronic diseases</li> <li>The DRI committee has made separate recommendations for specific sets of people (specific ade ranges).</li> </ul>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

lels: 87 experts in 7 groups	Definition , methods, formula, application	• E, CHO , Fat, and fat acids: DHA , EPA , n-3 • Protein	• Vit A , Vit E • Vit D , Vit K	<ul> <li>VitB1, B2, B6, B12, Folic acid,</li> <li>Vit C, Niacin, Choline, Biotin, Pantothenic acid</li> </ul>	<ul> <li>Zinc , Iron , I , se, cobalt</li> <li>Cu, Mn, Mo, Cr , F</li> </ul>	• Ca , P, Mg , K , Na, • chloride	<ul> <li>Water, Fiber</li> <li>18 Phytochemicals</li> </ul>
Expert Review Par	Introduction	Macronutrient	fat-soluble vitamins 4	water -soluble vitamins 10	Trace Elements 10	Macro-elements 6	

Components o	of the Dietary Reference Intakes
DRI component	Description
Estimated Average Requirement (EAR)	Reflects the estimated median requirement and is particularly appropriate for applications related to planning and assessing intakes for groups of people.
Recommended Nutrient Intake (RNI)	Derived from the EAR and intended to cover the requirements for 97–98 percent of the population.
Adequate Intake (AI)	Used when an EAR/RNI cannot be developed; average intake level based on observed or experimental intakes.
Tolerable Upper Intake Level (UL)	Tolerable Upper Intake Level (UL) Highest average intake that is likely to pose no risk.
Estimated Energy Requirement (EER)	Average dietary energy intake predicted to maintain energy balance in a healthy adult of defined a gender, weight, height and level of physical advection that is consistent with good health.

New Concepts	Developed
Component	Description
Acceptable Macronutrient Distribution Range (AMDR)	An intake range for an energy source associated with reduced risk of chronic disease. Fat , fat acid , CHO, Ca,
Proposed intake (PI)	Dietary Goal for Preventing Non-communicable Chronic Disease Na, K,     ,
Specific proposed level (SPL)	Dietary level for Preventing Specific chronic Disease
non nutrients components (phytochemicals) Tolerable Upper Intake Level (UL)	SPL predicted to maintain health in a healthy adult. Tolerable Upper Intake Level (UL) ,Highest verage intake that is likely to pose no risk.
	most from NOAEL or LOAEL, or ADI

# What is SPLs ?

- SPLs : Specific Proposed Level (abbreviations SPLs).
- SPL and UL are a comprehensive set of phytochemical values for healthy populations that can be used for a guide for the diet.

Principles : The SPLs reflect the current state of scientific knowledge with respect to nonnutrient guide and are published as a series of reports by the CNS

WHY Setting SPL and UL for Non –nutrients components? 

Foods consist of thousands of different chemicals each has the potential of being beneficial, neutral, or harmful to the body -some may be beneficial in some ways and harmful in other people or when taken at differing doses or at different -some chemical may exert different effects on different

When considering concentrated supplements of phytochemicals life stages

-Though most naturally occurring substances are safe for -Be aware that any normally beneficial substance, even water, can be toxic when taken in too high a dose

--adequate and safe dosages been established by most healthy people when consumed in foods

research evidence

# Why use novel concept SPL ?

Difference with nutrient and non nutrient Definition

- And non-nutrient are not, maybe just Essential nutrient for body with the lack ifespan essential of symptoms .
- science required for DRI value Substantial scientific database
- digestion , absorption , metabolism , interaction.
  - Established process
- EAR ----X---- RNI OF RDA
- Intake ----X---- AI , lack FC database
- Age group ---X, limitation for infants \children \\woman。。



### from literature

# Non-nutrient substances

- Non-nutrient bioactive substances 非营养素生物活性物质
- bioactive substances 生物活性物质
  - Dietary ingredient 膳食成分
- Photochemical 植物化合物
- Botanical 植物药, deriving from plants
- Botanical ingredient 植物有效成分
- Extract 提取物



	ene	thocyanidins	Ones	sterol	)cvanates	, Gallic,	samine		Lipoic Acid (LA)		
ss list	茆红素 Lycop	花青素 Proant	豆异黄酮 Isoflav	物固醇 Phytos	流氰酸盐 Isothic	恭素 Allicin	坒葡萄糖 Gluco	氨基丁酸 GABA	流辛酸 alpha-	<b>刺碱</b>	
nutrients substance	water 番	Dietary fiber	FOS Sotthhousein	anumoyanın 植	Resveratrol 异 <sub>4</sub>	Catechol	<b>Q</b> uercetin	Curcumin	Chlorogenic acid a∄	Lutin Zeaxanthin	
1-uou	水 職令凭強	<b>府 艮                                   </b>	低聚果糖	花色甙	白藜芦醇	儿茶酚(儿茶素	榭皮素 (角黄素)	姜黄素	绿原酸	<b>叶黄素</b>	

Types of study used as a basis for Specific Proposed Level generate knowledge eve s where studies n vitro and ani nal hey are also used acui medienèms studies on marily to denve upper tolerable intale ar dver dosages. an humans are insufficient - Depletion/repletion of vitamins and minerals Rančomised, controlled studies Organ studies Other types of in vitro stud es Ospending on the model best Mice, rets, guinea pigs etc., Classical rutation studies suited for the purpose Crees sectional studies Bicavailati ity studies Case-control studies - Tssuesaturation Prospective studies. Bacteria studies - Ea ance studies Intervention studies Cell sturies <u>j</u>pidemiclog cal lavto studies Experimental studies dservation studies, **Tuma**75 Ånimel and as a starting point for ocservational soudres are cetennice requirements c'etary reference values used as a basis both to Eqerimental and











# UL approaches

- NOEL (no observed effect level)
- LOEL (lowest observed effect level)
- OSL (the observed safe level)
- HOI (the highest observed intake)


trier trier sial e es fc	ed by ou t dietary ffect in t r healthy	ion/Effect servation ingredi he prev y adults	on or experi ents that he ention of ch	Potentia ment, ave ronic	l classificatio ביוויביופי בייני]
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ana ana ana 1979.	影	meostatic		i la	d supplement
	を 構築 構築 「」 「」	detected		Food	5



# Example summary on Curcumin RCT -meta analysis

Author and year	Countr Subjects	N (T/C)	durati on	Dose & methods	Biomarker /Results
Pungcharoenkul 2009	<b>长泰国</b> healthy adults 24	T1: 8 T2:8 C: 8	7d T1: T2 C: C:	姜黄素500mg/d 姜黄素1g/d 维生素E200IU/d	血清氧自由基清除 能力1、血清总胆 固醇1、甘油三酯1
<u>Khajehdehi P</u> 2011	糖尿病病 伊朗 人	T: 20 C: 20	ت با م	姜黄素500mg/d Dmg/d	与对照组相比,血 清TGF-81、IL-81、 尿蛋白排出」
Usharani P 2008	糖尿病病 印度 人	T: 36 C: 36	Ü H S	姜黄素300mg/d 0mg/d 11	与对照组相比,血 清IL-6、TNF-a等 炎症因子」
Sahebkar A 2013	不同人群 Meta分 析	T: 133 C: 90	岸 じ 単 景	姜黄素45mg-6g/d 阿托伐他汀、维 素E或安慰剂	血清总胆固醇、 ELDL-C、甘油三酯 和HDL-C水平改变 无统计学意义
Hamai H 2006	日本 静止期肠炎病人	T: 45	Ü ₩ ₩	姜黄素2g/d 0mg/d	肠炎活动指数、内 镜检查指数改善

	relative risk (RR;95%CI)	0.95 (0.78-1.16)	0.93 (0.80-1.07)	0.96 (0.75-1.22)	1.17 (0.90-1.53)	1.2 (0.90-1.60)	0.79 (0.63-0.99) 0.95 (0.82-1.10.)	
cancer	End point	活检确诊	临床确诊	临床确诊	备 所 通 後	临床确诊	临床确诊	hort
of breast	up/lower intake (µg/d)	≥3160 vs <1422	22281 vs <1000	5939 vs 1006	6838 vs1219	21782 vs <576	<b>绝经前:8796</b> vs1376;绝经后: 8796vs 1376	ective co
e risk	duratio n (y)	4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	7.6	0.8	9 9	S S	<b>14.0</b>	brosp
educe	2	1008	2879	44	1452病例 /5239对照			e or
ds and n	Subjects	Postmenopau sal women	绝经后妇女	绝经前妇女	绝经前妇女	绝经前和 绝经后妇女	绝经前和 绝经后妇女	ospectiv
arotenoi	Long term study	Sweden / prospective	UK/prospective	美国/前瞻性	加拿大前瞻性	美国/前瞻性	<b>美国/</b> 前端	Gt
O	Author	Larsson 2010	Cul,2008	Cho,2003	Terry,2002	Horn- Ross2002	Zhang 1999	

表3 叶黄素与乳腺癌发生风险研究



	Group C: 5 资料限制, Information insufficient	Allicin	Glucosamine	DF	Isothiocyanates	Quercetin	Lipoic acid	Chlorogenic acid			
ended for adults (draft )	Group B: UL 值的建议	Lutein 60 mg/d	Lycopene 50mg/d	curcumin 180 mg/d	Resveratrol 2.5g/d	Proanthocyanin 800mg	phytosterol 12.4g-3.9g	Fruit -oligosaccharide 15/d	Soy Isoflavone 80mg	L-carnitine 2000mg/d	
UL: recomm	Group A: Not necessary.	Water	Catchiness	<b>r-GABA</b>	Anthocyanin						

T



# The importance of SPLs and UL of Phytochemicals

- 2)Further understanding of the absorption,d metabolism, 3)Establish the procedure method, puts forward the 1)First time to evaluate data of phytochemicals Scientific significance function
  - guiding value; first suggested a new concepts Temporary Guidence Levels
- Social & practical significance 1)To avoid overeating
- 3)To increase the natural life-span of healthy humans. 2) To prevent lifestyle-related diseases
- Evidence based PL

## Limitations and Challenges

- 1. Limited human data regarding Phyto-chmicals in global
- Limited data concerning genetic variations to affect Phytonutrients requirements or .... such as Soy Isoflavone
- marginal (sub clinical) " deficiency" as well as progression of chronic diseases. And in specific vulnerable population 3. Limited data on the surrogate biomarker to reflect status of groups.

food composition are not sufficiently available for assessment of some phyto-nutrients intake. 4. Limited data on food composition database

### to quantify a healthy diet should be not only including essential nutrients but also others For lifespan

## Lifespan essential concept

polyphenol plant sources, there is clinical and epidemiological for reaching the full (genetically-determined) lifespan; we Unlike vitamics, polyphenols are not required for growth and development and for maintaining vital body functions throughout life. Nevertheless, for selected polyphenols and This means that they are, like some other nutrients, essential evidence showing reduction in the risk of chronic diseases. have termed this 'lifespan essential'(1).

Weiters Americal of Nutritions (2008), 99, Suppl. 3, 855-858 © The Authors 2003

Dietary reference intake (DRI) value for dietary polyphenols: are we heading in the right direction?

### Acknowledgements



# Prof.Chenyx, prof. Zhaify, prof.Yangxg

### 16 experts SPL expert penal

### 15 experts Scientific Committee:

### 80 more All experts in working panel



### 2010-2013



## Primary Uses of DRIs

- The four primary uses of the DRIs are: To assess the intakes of individuals
- To assess the intakes of population groups
- To plan diets for individuals
- To plan diets for groups

relevant to DRI use include dietary guidance, institutional planning for food-assistance programs, food labeling, Some of the dietary planning activities that are most food planning, military food and nutrition planning, food fortification, developing new or modified food products, and food-safety assurance.



## Primary Uses of SPL and UL

played by ..., that could contribute to the prevention of the SPLs put on evaluating scientific evidence for the role Oo perspective has been accounted for in setting the major diet-related chronic diseases. recommendation

# The primary uses of the SPLs and UL are:

- In the prevention of major diet-related chronic diseases
- To assess the intakes of individuals
- For food-safety assurance, during new or functional food product development



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From:	John Faulkner
Sent:	Wednesday, January 15, 2014 9:04 AM
Subject:	ILSI North America December Food Safety and Nutrition Science Briefs (attached)
Attachments:	Food Safety Briefs December 2013.pdf; Nutrition Briefs December 2013.pdf

Hello and Happy New Year,

The attached Food Safety and Nutrition Science Briefs are compiled each month after a review of articles published in the most recent issues of the major journals of nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion are those we believe address areas of greatest interest to ILSI North America's technical and project committees.

Our **December** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: <a href="http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx">http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</a>

If there is someone you know in your organization who should be receiving these briefs, please pass their contact information along and I will add them to our distribution list.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



### **Nutrition Briefs**

### December 2013

### Type 2 Diabetes

Beverage-Consumption Patterns and Associations with Metabolic Risk Factors among Low-Income Latinos with Uncontrolled Type 2 Diabetes

M.L. Wang, S.C. Lemon, B. Olendzki, M.C. Rosal

Journal of the Academy of Nutrition and Dietetics, Vol. 113, No. 12; pp. 1695-1703, 2013

Link to full text: Click here

**Significance**:Interventions directed at diabetes risk factors among low-income Latinos with diabetes can benefit from consideration of beverage-consumption behaviors as an important strategy to reduce caloric and sugar intake.

In the United States, Latinos experience disproportionately higher rates of type 2 diabetes (T2DM) and diabetes-related complications than non-Latino whites. Sugar-sweetened beverage (SSB) consumption is strongly associated with increased risk of developing T2DM. Reducing caloric intake, particularly from energy-dense, low-nutrient foods or beverages, can be an effective and key strategy for metabolic and weight control. Low-income Latinos (87.7% Puerto Rican) participating in a diabetes self-management intervention trial (n=238) provided cross-sectional, descriptive data on beverage-consumption patterns, anthropometric outcomes, and metabolic characteristics. Beverages accounted for 1/5<sup>th</sup> of the total daily caloric intake. SSBs and milk beverages, respectively, contributed 9.6% of calories to overall daily caloric intake.

### Metabolic Syndrome

Fast Food Consumption and the Risk of Metabolic Syndrome After 3-Years of Follow-Up: Tehran Lipid and Glucose Study

Z. Bahadoran, P. Mirmiran, F. Hosseini-Esfahani, F. Azizi

*European Journal of Clinical Nutrition*, Vol. 67, No. 12; pp. 1303–1309, 2013 Link to full text: Click here

**Significance:** Higher consumption of fast foods had undesirable effects on metabolic syndrome after 3-years of follow-up in Iranian adults.

This longitudinal study investigated whether fast food consumption could affect the occurrence of metabolic syndrome (MetS) after 3-years of follow-up in 1476 adults aged 19–70 y. The mean age of participants was  $37.8\pm12.3$  y, and mean BMI was  $26.0\pm4.5$  kg/m<sup>2</sup> at baseline. Participants in the highest quartile of fast food consumption were younger (33.7 vs. 43.4 years, P<0.01). Higher consumption of fast food was accompanied with more increase in serum triglyceride levels and triglyceride to HDL-C ratio after the 3-year follow-up. After adjustment for all potential confounding variables, the risk of

### **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx MetS, in the highest quartile of fast foods compared with the lowest, was 1.85 (95% CI=1.17–2.95). The effects of fast food consumption on the occurrence of MetS were more pronounced in adults <30 years, and participants who had greater waist-to-hip ratio, consumed less phytochemical-rich foods or had low-fiber diet (P<0.05).

### Lipids

### Comparison of Effects of Long-Term Low-Fat vs. High-Fat Diets on Blood Lipid Levels in Overweight or Obese Patients: A Systematic Review and Meta-Analysis

L. Schwingshackl, G. Hoffmann

Journal of the Academy of Nutrition and Dietetics, Vol. 113, No. 12; pp. 1640-1661, 2013

Link to full text: Click here

**Significance:** The results of our meta-analysis do not allow for an unequivocal recommendation of either low-fat or high-fat diets in the primary prevention of cardiovascular disease.

This systematic review and meta-analysis focused on randomized controlled trials (n=32) assessing the long-term effects of low-fat diets compared with diets with high amounts of fat on blood lipid levels. Decreases in total cholesterol (weighted mean difference [WMD] -4.55 mg/dL [-0.12 mmol/L], 95% CI -8.03 to -1.07; P=0.01) and LDL-cholesterol (WMD -3.11 mg/dL [-0.08 mmol/L], 95% CI -4.51 to -1.71; P<0.0001) were significantly more pronounced following low-fat diets, whereas rise in HDL-cholesterol (WMD 2.35 mg/dL [0.06 mmol/L], 95% CI 1.29 to 3.42; P<0.0001) and reduction in triglycerides (WMD -8.38 mg/dL [-0.095 mmol/L], 95% CI -13.50 to -3.25; P=0.001) were more distinct in the high-fat diet groups. Including only hypocaloric diets, the effects of low-fat vs. high-fat diets on total cholesterol and LDL-cholesterol were abolished. Meta-regression revealed that lower total cholesterol was associated with lower intakes of saturated fat and higher intakes of polyunsaturated fat, and increases in HDL-cholesterol were related to higher amounts of total fat largely derived from monounsaturated fat in high-fat diets, whereas increases in triglycerides were associated with higher intakes of carbohydrates.

### **Cardiovascular Disease**

### Quantity and Variety in Fruit and Vegetable Intake and Risk of Coronary Heart Disease

S.N. Bhupathiraju, N.M. Wedick, A. Pan, J.E. Manson, K.M. Rexrode, W.C. Willett, et al.

American Journal of Clinical Nutrition, Vol. 98, No. 6; pp. 1514-1523, 2103 Link to full text: Click here

**Significance:** Absolute quantity, rather than variety, in fruit and vegetable intake is associated with a significantly lower risk of CHD.

The independent roles of quantity and variety in fruit and vegetable intake in relation to incident coronary heart disease (CHD) was examined prospectively in 71,141 women from the Nurses' Health Study (1984–2008) and 42,135



men from the Health Professionals Follow-Up Study (1986–2008) who were free of diabetes, cardiovascular diseases, and cancer at baseline. Variety was defined as the number of unique fruit and vegetables consumed at least once/ week. Potatoes, legumes, and fruit juices were not included in our definition of fruit and vegetables. During follow-up, 2582 CHD cases were documented in women and 3607 cases in men. In multivariable analyses, after adjustment for dietary and nondietary covariates, those in the highest quintile of fruit and vegetable intake had a 17% lower risk (95% CI=9%, 24%) of CHD. A higher consumption of citrus fruit, green leafy vegetables, and  $\beta$ -carotene– and vitamin C–rich fruit and vegetables was associated with a lower CHD risk. Conversely, quantity-adjusted variety was not associated with CHD.

### **Food Allergy**

### A Pilot Study of Omalizumab to Facilitate Rapid Oral Desensitization in High-Risk Peanut-Allergic Patients

L.C. Schneider, R. Rachid, J. LeBovidge, E. Blood, M. Mittal, D.T. Umetsu Journal of Allergy and Clinical Immunology, Vol. 132, No. 6; pp. 1368-1374, 2013 Link to full text: Click here

**Significance:** Among children with high-risk peanut allergy, treatment with omalizumab may facilitate rapid oral desensitization and qualitatively improve the desensitization process.

This study examined the safety and efficacy of oral desensitization in peanut-allergic children in combination with a brief course of anti-IgE mAb (omalizumab [Xolair]). Oral peanut desensitization was performed in peanut-allergic children at high risk for developing significant peanut-induced allergic reactions. Omalizumab was administered before and during oral peanut desensitization. Subjects (n=13) with a median peanut-specific IgE level of 229 kUA/L and a median total serum IgE level of 621 kU/L, who failed an initial double-blind placebo-controlled food challenge at peanut flour doses of ≤100 mg were enrolled. After pretreatment with omalizumab, all 13 subjects tolerated the initial 11 desensitization doses given on the first day, including the maximum dose of 500 mg peanut flour, requiring minimal or no rescue therapy. Twelve subjects then reached the maximum maintenance dose of 4000 mg peanut flour/day in a median time of 8 weeks, at which point omalizumab was discontinued. All 12 subjects continued on 4000 mg peanut flour/day and subsequently tolerated a challenge with 8000 mg peanut flour (equivalent to about 20 peanuts), or 160 to 400 times the dose tolerated before desensitization.

### Sleep

### Short Sleep Duration is Associated With a Lower Mean Satiety Quotient in Overweight and Obese Men

J. McNeil, V. Drapeau, A.R. Gallant, A. Tremblay, É. Doucet, J-P. Chaput European Journal of Clinical Nutrition, Vol. 67, No. 12; pp. 1328–1330, 2013 Link to full text: Click here

**Significance:** Short-duration sleepers had a lower mean satiety quotient compared with recommended sleep duration sleepers; however, this did not coincide with increased energy intake.



Satiety quotient (SQ) and energy intake (EI) according to sleep duration, quality and timing were examined in 75 overweight/obese men (age: 41.1±5.8 years; BMI 33.6±2.9 kg/m<sup>2</sup>) who completed visual analogue scales for appetite sensations before, immediately after and every 10 minutes for 1 hour following a standardized breakfast. Mean SQ was calculated from four appetite sensations. The Pittsburgh Sleep Quality Index identified short-duration (<7 h/ night) and 'recommended sleep duration' ( $\geq$ 7 h/night) sleepers, poor (score  $\geq$ 5)- and good (score <5)-quality sleepers and late (midpoint of sleep >0230 hours) and early (midpoint of sleep  $\leq$ 0230 hours) sleepers. Short-duration sleepers had a lower mean SQ compared with recommended sleep duration sleepers (6.5±4.9 vs. 8.8±4.3 mm/100 kcal; P=0.04). The mean SQ between poor and good (6.9±4.6 vs. 8.7±4.6 mm/100 kcal; P=0.78) sleepers were not significantly different. EI did not differ between the sleep groups.

### Experimental Sleep Curtailment Causes Wake-Dependent Increases in 24-H Energy Expenditure as Measured by Whole-Room Indirect Calorimetry

A. Shechter, R. Rising, J.B. Albu, M-P. St-Onge American Journal of Clinical Nutrition, Vol. 98, No. 6; pp. 1433-1439, 2013 Link to full text: Click here

Significance: Short- compared with habitual-sleep is associated with an increased 24-h EE of ~92 kcal (~5%)—lower than the increased energy intake observed in prior sleep-curtailment studies.

This randomized, crossover study examined the effects of sleep curtailment on 24-h energy expenditure (EE) and respiratory quotient (RQ) in 10 females (aged 22–43 y; BMI 23.4–27.5 kg/m<sup>2</sup>) using whole-room indirect calorimetry under fixed-meal conditions. Participants were studied under short- (4 h/ night) and habitual- (8 h/night) sleep conditions for 3 d, with a 4-wk washout period between visits. Standardized weight-maintenance meals were served at 0800, 1200, and 1900 with a snack at 1600. Measures included EE and RQ during the sleep episode on day 2 and continuously over 23 h on day 3. Shortcompared with habitual-sleep resulted in significantly higher (±SEM) 24-h EE (1914.0 ± 62.4 compared with 1822.1 ± 43.8 kcal; P = 0.012). EE during the scheduled sleep episode (0100–0500 and 2300–0700 in short- and habitual-sleep conditions, respectively) and across the waking episode (0800–2300) were unaffected by sleep restriction. RQ was unaffected by sleep restriction.

### **Special Report**

### Revising the Daily Values May Affect Food Fortification and in Turn Nutrient Intake Adequacy

M.M. Murphy, J.H. Spungen, L.M. Barraj, R.L. Bailey, J.T. Dwyer Journal of Nutrition, Vol. 143, No. 12; pp. 1999-2006, 2013 Link to full text: Click here

**Significance:** This modeling exercise will help to inform decisions in revising the daily values from the newer Dietary Reference Intakes.



The Nutrition Facts panel on food labels in the U.S. currently displays Daily Values (DVs) that are based on outdated RDAs. The FDA plans to update the DVs based on the newer Dietary Reference Intakes (DRIs), but there is controversy regarding the best method for calculating new DVs from the DRIs. To better understand the implications of DV revisions, intake of 8 micronutrients were modeled using NHANES 2007-2008 data and 2 potential methods for calculating DVs: the population-weighted Estimated Average Requirement (EAR) and the population-coverage RDA. In each scenario, levels of fortified nutrients were adjusted to maintain the current %DV. Usual nutrient intakes and percentages with usual intakes less than the EAR were estimated for the U.S. population and subpopulations aged  $\geq 4$  y (n=7976). For most nutrients, estimates of the percentage of the U.S. population with intakes below the EAR were similar regardless of whether the DV corresponded to the population-weighted EAR or the population-coverage RDA. Potential decreases were observed in adequacy of nutrients of concern for women of childbearing age, namely iron and folate (up to 9% and 3%, respectively), adequacy of calcium among children (up to 6%), and adequacy of vitamin A intakes in the total population (5%) assuming use of the population-weighted EAR compared with the population-coverage RDA for setting the DV.

### About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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### **Food Safety Briefs**

### December 2013

### E. Coli

### Internalization of Escherichia coli O157:H7 following Spraying of Cut Shoots When Leafy Greens Are Regrown for a Second Crop

M.C. Erickson, C.C. Webb, J.C. Díaz-Pérez, L.E. Davey, A.S. Payton, I.D. Flitcroft, et al.

Journal of Food Protection, Vol. 76, No. 12; pp. 2052-2056, 2013

Link to full text: Click here

**Significance:** Cut plants of spinach or lettuce sprayed with irrigation water at a lower contamination level did not detect internalized E. coli O157:H7 2 days later and therefore would not likely be of concern when the crop was harvested.

Both spinach and lettuce were grown to harvest, cut, and then regrown after spraying the cut shoots with irrigation water contaminated with Escherichia coli O157:H7. Plant tissue was collected on the day of spraying and again 2 and 14 days later for analysis of total and internalized E. coli O157:H7 populations. Internalization of E. coli O157:H7 occurred on the day of spraying, and larger populations were internalized as the level in the spray increased. Internalized E. coli O157:H7 in shoots cut 5 days prior to exposure to E. coli O157:H7–contaminated water were not significantly different from levels in shoots cut on the same day of spraying with contaminated water. Two days after spraying plants with a high level of E. coli O157:H7 (7.3 log CFU/ml), levels of internalized E. coli O157:H7 decreased by ca. 2.6 and 1.3 log CFU/g in Tyee and Bordeaux spinach, respectively, whereas populations of internalized E. coli O157:H7 decreased very little (ca. 0.4 log CFU/g) in lettuce plants that had been sprayed either on the same day as cutting or 1 day after cutting.

### Salmonella

Effects of Water, Sodium Hypochlorite, Peroxyacetic Acid, and Acidified Sodium Chlorite on In-Shell Hazelnuts Inoculated with Salmonella Enterica Serovar Panama

L.D. Weller, M.A. Daeschel, C.A. Durham, M.T. Morrissey

Journal of Food Science, Vol. 78, No. 12; pp. M1885–M1891, 2013

Link to full text: Click here

**Significance:** Acidified sodium chlorite showed the greatest potential for use as a postharvest sanitation treatment.

This study analyzed the effectiveness of 3 chemical sanitizers for reducing Salmonella on in-shell hazelnuts. Treatments of water, sodium hypochlorite (NaOCl; 25 and 50 ppm), peroxyacetic acid (PAA; 80 and 120 ppm),

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ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx and acidified sodium chlorite (ASC; 450, 830, and 1013 ppm) were sprayed onto hazelnut samples inoculated with Salmonella enterica serovar Panama. Inoculation achieved S. Panama populations of approximately 8.04 log CFU/ hazelnut. Surviving S. panama populations were evaluated using tryptic soy agar, incubated 3 h, and then overlaid with xylose lysine deoxycholate agar. All of the chemical treatments significantly reduced S. Panama populations (P≤0.0001). The most effective concentrations of ASC, PAA, and NaOCl treatments reduced populations by 2.65, 1.46, and 0.66 log units, respectively.

### Preadaptation to Cold Stress in Salmonella enterica Serovar Typhimurium Increases Survival during Subsequent Acid Stress Exposure

J. Shah, P.T. Desai, D Chen, J.R. Stevens, B.C. Weimer Applied and Environmental Microbiology, Vol. 79, No. 23; pp. 7281-7289, 2013

Link to full text: Click here

**Significance:** Preadaptation to cold stress rescues Salmonella from the deleterious effect of subsequent acid stress exposure by induction of genes involved in stress response and repair pathways, by modification of aerobic respiration and redox modulation.

This study tested the hypothesis that abiotic stresses encountered during food processing alter the metabolic mechanisms in Salmonella that enable survival and persistence during subsequent exposure to the host gastrointestinal acidic environment. Out of the four different abiotic stresses tested, (cold, peroxide, osmotic, and acid), preadaptation of the log-phase culture to cold stress (5°C for 5 h) significantly enhanced survival during subsequent acid stress (pH 4.0 for 90 min). The gene expression profile of Salmonella preadapted to cold stress revealed induction of multiple genes associated with amino acid metabolism, oxidative stress, and DNA repair, while only a few of the genes in the above-mentioned stress response and repair pathways were induced upon exposure to acid stress alone. Preadaptation to cold stress decreased the NAD+/NADH ratio and hydroxyl (OH·) radical formation compared with those achieved with the exposure to acid stress alone, indicating alteration of aerobic respiration and the oxidative state of the bacteria.

### Listeria

### Efficacy of Antimicrobials Extracted from Organic Pecan Shell for Inhibiting the Growth of Listeria spp.

D. Babu, P.G. Crandall, C.L. Johnson, C.A. O'Bryan, S.C. Ricke Journal of Food Science, Vol. 78, No. 12; pp. M1899–M1903, 2013 Link to full text: Click here

**Significance:** Pecan shell extracts may prove to be very effective alternative antimicrobials against food pathogens and supplement the demand for effective natural antimicrobials for use in organic meat processing.

This study developed and tested natural antimicrobials derived from organic pecan shells. Unroasted and roasted organic pecan shells were subjected to solvent free extraction to produce antimicrobials that were tested against



### Food Safety Briefs

Listeria spp. and L. monocytogenes serotypes to determine the minimum inhibitory concentrations (MIC) of antimicrobials. The effectiveness of pecan shell extracts was further tested using a poultry skin model system and the growth inhibition of the Listeria cells adhered onto the skin model were quantified. The solvent free extracts of pecan shells inhibited Listeria strains at MICs as low as 0.38%. The antimicrobial effectiveness tests on a poultry skin model exhibited nearly a 2 log reduction of the inoculated cocktail mix of Listeria strains when extracts of pecan shell powder were used. The extracts also produced greater than a 4 log reduction of the indigenous spoilage bacteria on the chicken skin.

### Inhibition of Listeria monocytogenes by Propionic Acid–Based Ingredients in Cured Deli-Style Turkey

K.A. Glass, L.M. McDonnell, R. Von Tayson, B. Wanless, M. Badvela Journal of Food Protection, Vol. 76, No. 12; pp. 2074-2078, 2013 Link to full text: Click here

**Significance:** Propionate-based ingredients inhibit growth of Listeria monocytogenes on sliced, high-moisture, cured turkey and can be considered as an alternative to reduce sodium-based salts while maintaining food safety.

This study determined the inhibition of Listeria monocytogenes by propionic acid–based ingredients in high-moisture, cured turkey stored at 4 or 7°C. Six formulations of sliced, cured (120 ppm of NaNO2 ), deli-style turkey were tested, including control without antimicrobials, 3.2% lactate-diacetate blend (LD), 0.4% of a liquid propionate-benzoate–containing ingredient, or 0.3, 0.4, and 0.5% of a liquid propionate–containing ingredient. The control without antimicrobials supported rapid growth, with >2 log average/mL rinsate increase within 4 weeks of storage at 4°C, whereas growth was observed at 6 weeks for the LD treatment. For both replicate trials, all treatments that contained liquid propionate or propionate-benzoate limited L. monocytogenes growth to an increase of <1 log through 9 weeks storage at 4°C. Sporadic growth (>1-log increase) was observed in individual samples for all propionate-containing treatments at weeks 10, 11, and 12. As expected, L. monocytogenes grew more rapidly when products were stored at 7°C, but trends in relative inhibition were similar to those observed at 4°C.

### **Foodborne Pathogens**

Effect of Electropermeabilization by Ohmic Heating for Inactivation of Escherichia coli O157:H7, Salmonella enterica Serovar Typhimurium, and Listeria monocytogenes in Buffered Peptone Water and Apple Juice

### I-K. Park, D-H. Kang

Applied and Environmental Microbiology, Vol. 79, No. 23; pp. 7122-7129, 2013 Link to full text: Click here

Significance: Ohmic heating can more effectively reduce bacterial populations at reduced temperatures and shorter time intervals, especially in acidic fruit juices such as apple juice.



The effect of electric field-induced ohmic heating for inactivation of Escherichia coli O157:H7, Salmonella enterica serovar Typhimurium, and Listeria monocytogenes in buffered peptone water (BPW) (pH 7.2) and apple juice (pH 3.5; 11.8 °Brix) was investigated. Bacterial reduction resulting from ohmic heating was significantly different from that resulting from conventional heating at 58°C and 60°C in BPW and at 55°C, 58°C, and 60°C in apple juice for intervals of 0, 10, 20, 25, and 30 s. These results show that ohmic heating led to additional bacterial inactivation at sublethal temperatures. Transmission electron microscopy (TEM) observations and the propidium iodide (PI) uptake test were conducted after treatment at 60°C for 0, 10, 20, 25 and 30 s in BPW to observe the effects on cell permeability due to electroporation-caused cell damage. PI values when ohmic and conventional heating were compared were significantly different, and these differences increased with increasing levels of inactivation of three food-borne pathogens.

### Risk Factors Associated with Salmonella and Listeria monocytogenes Contamination of Produce Fields

L.K. Strawn, Y.T. Gröhn, S. Warchocki, R.W. Worobo, E.A. Bihn, M. Wiedmann Applied and Environmental Microbiology, Vol. 79, No. 24; pp. 7618-7627, 2013

Link to full text: Click here

**Significance:** This study provides new data that will assist growers with science-based evaluation of their current Good Agricultural Practices and implementation of preventive controls that reduce the risk of preharvest contamination.

A cross-sectional study was conducted to determine management practices associated with a Salmonella- or Listeria monocytogenes-positive field and to quantify the frequency of these pathogens in irrigation and nonirrigation water sources. Over 5 weeks, 21 produce farms in New York State were visited. Field-level management practices were recorded for 263 fields, and 600 environmental samples (soil, drag swab, and water) were collected and analyzed for Salmonella and L. monocytogenes. Salmonella and L. monocytogenes were detected in 6.1% and 17.5% of fields (n=263) and 11% and 30% of water samples (n=74), respectively. The majority of pathogen-positive water samples were from nonirrigation surface water sources. Multivariate analysis showed that manure application within a year increased the odds of a Salmonellapositive field (odds ratio [OR]=16.7), while the presence of a buffer zone had a protective effect (OR=0.1). Irrigation (within 3 days of sample collection) (OR=6.0), reported wildlife observation (within 3 days of sample collection) (OR=6.1), and soil cultivation (within 7 days of sample collection) (OR=2.9) all increased the likelihood of an L. monocytogenes-positive field.

### Food Allergy

### Soy in Wheat – Contamination Levels and Food Allergy Risk Assessment

B.C. Remington, S.L. Taylor, D.B. Marx, B.J. Petersen, J.L. Baumert Food and Chemical Toxicology, Vol. 62; pp. 485–491, 2013

Link to full text: Click here

**Significance:** The avoidance of wheat-based products by soy-allergic consumers does not appear to be necessary.



### Food Safety Briefs

In the U.S., packaged food ingredients derived from allergenic sources must be clearly labeled. However, no requirement exists to declare the presence of residues of raw agricultural commodities due to agricultural commodity comingling. Clinical reports of allergic reactions to undeclared soy in wheat-based products do not exist suggesting that a low degree of risk is posed by wheatbased products that are comingled with soy. Detectable soybean residues (>2.5 ppm soy flour) were found in 62.8% of commercially available wheat flours at concentrations of 3–443 ppm soy flour (1.6–236 ppm soy protein). Conservative probabilistic risk assessments predict a risk of allergic reaction among the most sensitive soy-allergic individuals of  $2.8\pm 2.0/1000$  soy-allergic user eating occasions of foods containing wheat flour. However, the predicted reactions occur at exposure levels below the lowest eliciting dose observed to provoke objective reactions in clinical oral soy challenges.

### A Pilot Study of Omalizumab to Facilitate Rapid Oral Desensitization in High-Risk Peanut-Allergic Patients

L.C. Schneider, R. Rachid, J. LeBovidge, E. Blood, M. Mittal, D.T. Umetsu Journal of Allergy and Clinical Immunology, Vol. 132, No. 6; pp. 1368-1374, 2013

Link to full text: Click here

Significance: Among children with high-risk peanut allergy, treatment with omalizumab may facilitate rapid oral desensitization and qualitatively improve the desensitization process.

This study examined the safety and efficacy of oral desensitization in peanut-allergic children in combination with a brief course of anti-IgE mAb (omalizumab [Xolair]). Oral peanut desensitization was performed in peanut-allergic children at high risk for developing significant peanut-induced allergic reactions. Omalizumab was administered before and during oral peanut desensitization. Subjects (n=13) with a median peanut-specific IgE level of 229 kUA/L and a median total serum IgE level of 621 kU/L, who failed an initial double-blind placebo-controlled food challenge at peanut flour doses of ≤100 mg were enrolled. After pretreatment with omalizumab, all 13 subjects tolerated the initial 11 desensitization doses given on the first day, including the maximum dose of 500 mg peanut flour, requiring minimal or no rescue therapy. Twelve subjects then reached the maximum maintenance dose of 4000 mg peanut flour/day in a median time of 8 weeks, at which point omalizumab was discontinued. All 12 subjects continued on 4000 mg peanut flour/day and subsequently tolerated a challenge with 8000 mg peanut flour (equivalent to about 20 peanuts), or 160 to 400 times the dose tolerated before desensitization.

### **Mycotoxins**

### Matrix Binding of Ochratoxin A during Roasting

A. Bittner, B. Cramer, H-U. Humpf Journal of Agricultural and Food Chemistry, Vol. 61, No. 51; pp. 12737–12743, 2013

Link to full text: Click here

**Significance:** The formation of ochratoxin A esters is a further explanation for the loss of ochratoxin A during coffee roasting.



This study describes the binding of ochratoxin A to coffee polysaccharides via esterification as a further thermal reaction. This ester formation was studied by heating ochratoxin A with methyl  $\alpha$ -d-glucopyranoside, a model compound to mimic polysaccharides. From this experiment,  $(22 \rightarrow 6')$  ochratoxin A-methyl- $\alpha$ -d-glucopyranoside ester was isolated and characterized as a reaction product, showing the general ability of ochratoxin A for esterification with carbohydrates at roasting temperatures. Subsequently, a sample preparation protocol for the detection of ochratoxin A saccharide esters based on an enzymatic cleavage and purification using immunoaffinity chromatography was developed and applied. The detection was carried out by high-performance liquid chromatography-tandem mass spectrometry (HPLC–MS/MS), which detected ochratoxin A polysaccharide esters formed during roasting of artificially contaminated coffee, confirming the results of the previous model experiments.

### **Heavy Metals**

Daily Bioaccessible Levels of Selected Essential but Toxic Heavy Metals from the Consumption of Non-Dietary Food Sources

T. Tongesayi, P. Fedick, L. Lechner, C. Brock, A. Le Beau, C. Bray Food and Chemical Toxicology, Vol. 62; pp. 142–147, 2013 Link to full text: Click here

**Significance:** Exposure from various sources of toxic elements is additive, therefore, lower levels than recommended limits in one source may not guarantee safety from a particular chemical toxicant.

Researchers and regulatory bodies tend to focus on non-essential toxic elements when testing for inorganic chemical pollutants in food. Both toxic and essential elements are increasingly getting into the food chain from the extensive use of agrochemicals and the use of contaminated water, raw sewage and untreated industrial effluent to irrigate crops. A holistic testing protocol for chemical contaminants in food should be the norm in order to protect human health, especially considering that the essential elements are poisonous above certain thresholds. Eating contaminated foods that are not considered to be dietary sources of the essential poisons may result in an inadvertent overdose, especially considering that consumers may be taking food supplements that are recommended as sources of the essential elements. This study measured the levels of manganese and zinc in rice and calculated the daily bioaccessible levels of the two elements. The daily bioaccessible levels were significantly higher than the recommended daily intakes in most of the samples.

### Determination of Essential Elements (Copper, Manganese, Selenium And Zinc) in Fish and Shellfish Samples. Risk and Nutritional Assessment and Mercury–Selenium Balance

P. Olmedo, A.F. Hernández, A. Pla, P. Femia, A. Navas-Acien, F. Gil Food and Chemical Toxicology, Vol. 62; pp. 299-307, 2013 Link to full text: Click here

**Significance:** Significance: The estimated daily intakes of the elements studied represented very low percentages of their reference values for person weighing 60 kg, so the intake of these elements through fish and shellfish would not pose any risk for the average consumer.



Fish and shellfish are important sources of toxic heavy metals and essential elements in the diet. In this study, levels of Cu, Mn, Se and Zn were determined in 43 of the most frequently consumed fresh, canned and frozen fish and shellfish products. The potential human health risks for the consumers and the nutritional value of the products analyzed were assessed. The mercury-selenium ratios and the selenium health benefit value (Se-HBVs) were calculated. The highest concentrations of Cu were found in shrimp and prawn as they have hemocyanin (a copper-containing protein) that functions as an oxygen–transport molecule. Mn levels were higher in canned bivalve molluscs, such as cockle and clam, and in fresh common sole. Tuna and swordfish presented the most remarkable concentrations of selenium. The highest concentration of the essential metals analysed was found for Zn, especially in fresh and canned mussels. All the species analyzed showed beneficial Hg:Se ratios and Se-HBVs, except for blue shark and cat shark and gilt-head bream because of their high Hg levels and low Se content, respectively.

### **Risk Assessment**

### Quantitative Risk Assessment of Foods Containing Peanut Advisory Labeling

B.C. Remington, J.L. Baumert, D.B. Marx, S.L. Taylor Food and Chemical Toxicology, Vol. 62; pp. 179–187, 2013

Link to full text: Click here

**Significance:** The probabilistic approach could provide the food industry with a quantitative method to assist with determining when advisory labeling is most appropriate.

This study determined the residual levels of peanut in various packaged foods bearing advisory labeling, compared similar data from 2005 and 2009, and determined any potential risk for peanut-allergic consumers. Of food products bearing advisory statements regarding peanut or products that had peanut listed as a minor ingredient, 8.6% and 37.5% contained detectable levels of peanut (>2.5 ppm whole peanut), respectively. Peanut-allergic individuals should be advised to avoid such products regardless of the wording of the advisory statement. Peanut was detected at similar rates and levels in products tested in both 2005 and 2009. Advisory-labeled nutrition bars contained the highest levels of peanut and an additional market survey of 399 products was conducted. Probabilistic risk assessment showed the risk of a reaction to peanut-allergic consumers from advisory-labeled nutrition bars was significant but brand-dependent. Peanut advisory labeling may be overused on some nutrition bars but prudently used on others.

### About Us

The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx

From:	Courtney McComber
Sent:	Friday, January 10, 2014 8:28 AM
То:	Courtney McComber
Cc:	Courtney Gaine; Ashley Jarvis
Subject:	INVITATION - ILSI North America Bioactives Reception - January 19
Attachments:	Bioactives Invitation - 19 Jan 2014.jpg

### Sent on behalf of Courtney Gaine

Dear ILSI/ILSI North America Annual Meeting Guest,

Please see the attached invitation to a reception sponsored by the ILSI North America Bioactives Committee on Sunday, 19 January at the Fairmont Southampton. The Committee welcomes you to some snacks and refreshments to hear about some of their work and socialize. We hope you can make it. Please RSVP to me ) by next Wednesday, 15 January, if you plan to attend.

Thank you,

Courtney Kelly McComber ILSI North America Program and Conference Manager 1156 Fifteenth Street NW Suite 200 Washington, DC 20005 202-659-0074 ext. 143 202-659-3859 (fax)



### You're Invited ....

ILSI North America Bioactives Social in Bermuda



Come hear about the committee's recent projects and socialize over some of our favorite bioactive food and drink ingredients (*including wine*).



Date: Sunday, 19 January 2014 Time: 5:00pm – 6:30pm Room: Poinciana II

### RSVP by Wednesday, 15 January to: Courtney McComber

202-659-0074 ext. 143



From: Sent: To: Cc: Subject: Joanne Lupton Thursday, January 09, 2014 1:08 PM Amanda Haight Chelsea L. Bishop RE: Invitation to ILSI North America Board Dinner at Annual Meeting

Thanks for inviting me, Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Amanda Haight [mailto: ]
Sent: Thursday, January 09, 2014 12:28 PM
To: Joanne Lupton
Cc: Chelsea L. Bishop
Subject: Invitation to ILSI North America Board Dinner at Annual Meeting

Dear Dr. Lupton,

On Saturday evening, 18 January 2014, ILSI North America will hold its annual Board Dinner. You are cordially invited to attend. This year, we will be going to an on-site restaurant and we ask that attendees gather at the hotel's front entrance at 6:15pm.

To assist with our planning, please confirm your plans to attend and send your response back by return email.

Name: \_\_\_\_Joanne Lupton\_\_\_\_\_

Yes, I will attend. \_x\_\_\_\_ No, I cannot attend.\_\_\_\_

If you have a guest accompanying you to the Annual Meeting, that person is included in the Board dinner. Please provide your guest's name in the space below:

\_\_\_\_\_no guest\_\_\_\_\_

Please let me know if you have any questions. I look forward to seeing you at Annual Meeting!

Thank you,

Amanda

Amanda Haight Executive Assistant ILSI North America 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005 202-659-0074 Ext. 128

From:	Courtney Gaine
Sent:	Thursday, January 09, 2014 12:52 PM
То:	Courtney Gaine
Cc:	Sharon Weiss; Courtney McComber; Heather Steele
Subject:	AGENDA: ILSI/ILSI NA Annual Meeting Carbohydrates Forum
Attachments:	Agenda Carbs Forum-20 Jan 2014.pdf

Dear 2014 ILSI/ILSI North America Annual Meeting Carbohydrates Forum Registrants,

You are receiving this email because you noted during registration that you planned to attend this year's Carbohydrates Forum. The event will take place on **Monday, 20 January from 5:30 – 7:30 p.m. EST in the 'Gardenia II' room** on the Lobby Level of the Fairmont Southampton Hotel. \*\**Refreshments will be served.* 

Our featured speakers this year will be Dr. John Sievenpiper of St. Michael's Hospital, University of Toronto, and Dr. Mei Chung of Tufts University. Both speakers will focus on their current research projects regarding sugars and health. In addition to these talks, we anticipate a lively discussion to ensue from these and other short presentations and updates. Please see the attached agenda for more information.

We look forward to seeing you all in Bermuda soon.

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121


1156 Fifteenth Street, NW Suite 200 Washington, DC 20005

#### Agenda: International Life Sciences Institute 2014 Annual Meeting Carbohydrates Forum

#### Monday, 20 January 2014 5:30p.m. – 7:30p.m. Eastern Time The Fairmont Southampton, Bermuda, Room: TBD

**Objective:** To hear and discuss findings of new research related to sugars and health outcomes; discuss global issues related to sugars; and address any additional international issues related to carbohydrate science

Chairs: Susan Roberts, *The Coca-Cola Company* and Julie Jones, *St. Catherine University*Organizer: Courtney Gaine, *ILSI North America*Sponsor: ILSI North America Technical Committee on Carbohydrates

I. Welcome and Introduction (C. Gaine)

#### II. Global Updates related to Carbohydrates (S. Roberts, J. Jones)

- a. WHO Nutrition Guidance Expert Advisory Group (NUGAG) Report
- b. The Scientific Advisory Committee on Nutrition (SACN) Dietary Carbohydrates and Health report
- c. New books on Carbohydrates
- d. Glycemic Index Updates
  - i. Oldways Italian GI Summit
  - ii. International Carbohydrate Quality Consortium
  - iii. Canadian Nutrition Society Meeting
- e. Fiber Updates

#### III. Featured presentations

*Fructose-containing sugars and health: A story lost in translation?* John Sievenpiper

Applications of Sugars-and-Health Evidence Map – from topic generation, evidence synthesis, to future research needs. Mei Chung

Panel Q&A

IV.	Overview of new Canadian Trial (C. Kendall, J. Sievenpiper)	6:45 p.m.
V.	Branch Updates Regarding Sugars and other Carbohydrates	7:00 p.m.
VI.	General Discussion and Other Updates	7:20 p.m.
VII.	Adjourn	7:30 p.m.

#### 6:00 p.m.

5:30 p.m.

5:35 p.m.



#### **Anticipated Participants**

Nelson Almeida Miguel Alonso-Alonso Sofia Amarra Harvey Anderson Joan Apgar Viviana Aranda Aldo Baccarin **Charles Baker** Roger Bektash Elizabeth Bell MarielaBerezovsky **Richard Black** Anita Boddie Ary Bucione Lionel Buratti Jessica Campbell PaulineChan **Jenny Chang** Nordine Cheikh YiFang Chu Mei Chung Stuart Craig Susan Crockett Kerr Dow **Ray DeVirgiliis** Adam Drewnowski Johanna Dwyer Gerhard Eisenbrand Mark Empie **John Fletcher Brent Flickinger Courtney Gaine Jennifer Garrett** Marcella Garsetti Danielle Greenberg Lizette Guizar Miriam Gutierrez Philip Guzelian Peggy Guzzie-Peck Hiroaki Hamano **Rob Hamer** Laura Harkness Suzie Harris **Eric Hentges** Jim Hill

Kellogg Company Harvard Medical School **ILSI Southeast Asia Region** University of Toronto The Hershey Company **ILSI South Andean ILSI Brasil** The Sugar Association Mars Asia Pacific General Mills Inc. ILSI Brasil PepsiCo McDonald's Corporation **DuPont Brazil** Nestle General Mills **ILSI Southeast Asia Region ILSI-Taiwan Pro Tem Committee** Monsanto PepsiCo **Tufts University DuPont Nutrition & Health General Mills** Cargill **ILSI North America** University of Washington Tufts University Medical School University of Kaiserslautern Empecor PepsiCo Archer Daniels Midland Company **ILSI North America** McCain Foods Unilever PepsiCo Omnilife Mondelez International **Clinical Toxicology** Janssen R&D ILSI Japan Unilever R&D Vlaardingen PepsiCo ILSI Global and ILSI Research Foundation **ILSI North America** University of Colorado



Lucy Hwang National Taiwan University Jong Kuen Jang DAESANG Corp. Ashley Jarvis **ILSI North America Julie** Jones St. Catherine University Michael Kelley Wm Wrigley Jr. Co. Cyril Kendall University of Toronto Chor San Khoo **ILSI North America** Ioohee Kim Ewha Woman's University Shuichi Kimura **ILSI** Japan **ILSI MesoAmerica Gisela Kopper** Anne Kurilich **McCain Foods** Tamotsu Kuwata University of Human Arts and Sciences Catherine Kwik-Uribe Mars, Incorporated Ewha Woman's University Oran Kwon Dot Lagg Mars, Incorporated Laurent Le Bellego **Danone Research** Clare Leonard Mondelez International GmbH DeAnn Liska **Biofortis Research** Beate Lloyd The Coca-Cola Company Joanne Lupton Texas A&M University Antonio Mantoan Mead Johnson Nutrition Courtney McComber ILSI North America Helene McNulty University of Ulster Indra Mehotra Cargill, Incoporated Debra Miller The Hershey Company General Mills Sarah Moberg Libby Muldoon Center for Environmental Risk Assessment Elsa Murano Agricul **Juan Navia** McNeil Nutritionals, LLC Maria Fernanda Nunez University of Toronto/ILSI North America Nestec Ltd. Nestle Research Center John O'Brien Laura Judith Otálora Cortés Mead Johnson Nutrition Pai Panandiker ILSI-India **Ki-Hwan Park Chung-Ang University Christine** Pelkman **Ingredion Incorporated** Sue Potter Tate & Lyle PepsiCo Maike Rahn Kristi Reimers **ConAgra Foods** Claudia Riedt Dr. Pepper Snapple Group The Coca-Cola Company Susan Roberts Sylvia Rowe SR Strategy Institute for Food Technologists John Ruff Dave Schmidt International Food Information Council Seth Prahlad **Biotech Park Lucknow** Una Shih **ILSI** Taiwan Fred Shinnick Senomyx, Inc. John Sievenpiper St. Michael's Hospital



Rekha Sinha Marianne Smith Edge Eric Stice Shawn Sullivan Maha Tahiri Keng Ngee Teoh Katherine L. Tucker Peter van Bladeren Stella Volpe Chin-Kun Wang Kathy Wiemer Josephine Wills Felicia Wu Myeong-Ae Yu Paul Zanno Paula Ziegler

ILSI-India International Food Information Council **Oregon Research Institute** ILSI General Mills ILSI Southeast Asia Region Northeastern University Nestle Drexel University Chung Shan Medical University General Mills European Food Information Council Michigan State University ILSI Korea Dr Pepper Snapple Group Inc Academy of Nutrition and Dietetics



#### **Featured Speakers' Biographies**

#### John Sievenpiper, MD, PhD, St. Michael's Hospital, University of Toronto

Dr. Sievenpiper completed his MSc and PhD training under Prof Vladimir Vuksan and Postdoctoral Fellowship training under Prof. David Jenkins in the Department of Nutritional Sciences, Faculty of Medicine, University of Toronto. He completed his MD at St. Matthew's University, School of Medicine with clinical training across England and Scotland. He is currently the Knowledge Synthesis Lead of the Toronto 3D Knowledge Synthesis and Clinical Trials unit at St. Michael's Hospital, University of Toronto and a Resident Physician in the department of Pathology and Molecular Medicine at McMaster University. His research interests are focused on using meta-analytical techniques and randomized trials to investigate the effect of diet on cardiometabolic risk. He is an investigator on several large grants including 4 Canadian Institutes of Health Research (CIHR) grants. Dr. Sievenpiper has been appointed to the Clinical Practice Guidelines Expert Committee for Nutrition Therapy of both the Canadian Diabetes Association (CDA) and European Association for the study of Diabetes (EASD), as well as the American Society for Nutrition (ASN) writing panel for a scientific statement on the metabolic and nutritional effects of fructose, sucrose and high fructose corn syrup. Dr. Sievenpiper has authored 89 scientific papers and 12 book chapters.

#### Mei Chung, PhD, MPH, Tufts University

Dr. Mei Chung is a research assistant professor at the Nutrition/Infection Unit, Department of Public Health and Community Medicine, School of Medicine, Tufts University. Before transitioned to Tufts University, she was an assistant director of the Agency for Healthcare Research and Quality's (AHRQ) designated Tufts Evidence-based Practice Center (EPC) at Tufts Medical Center. Her primary research interest is to conduct methodological research in applying and improving evidence-based methods specifically for the field of nutrition and public health. She is the lead author and a co-author in a series of research aiming to advance the role of systematic reviews in nutrition research and applications. She also led the evidence report, *Vitamin D and Calcium: A Systematic Review of Health Outcomes*, which was used by the Institute of Medicine's Committee to review Dietary Reference Intakes for Vitamin D and Calcium.

From:	Suzanne Harris >
Sent:	Wednesday, January 08, 2014 1:33 PM
То:	Joanne Lupton
Cc:	Chelsea L. Bishop
Subject:	Agenda and briefing documents for the ILSI Board of Trustees meeting Saturday, January 18
Attachments:	Tab 01-a Agenda v2.doc; Lupton - 2014 Schedule - 01.02.2014.doc

Dear Joanne,

The ILSI Board of Trustees will meet on **Saturday, January 18, beginning at 8:00 am in Poinciana 1 at the Fairmont Southampton Hotel in Bermuda.** A light breakfast will be available at 7:30 am and lunch will be served in Windows at noon.

The agenda for the Board meeting is attached along with your personalized schedule for ILSI and ILSI Research Foundation activities during the annual meeting.

The briefing documents for the Board meeting are available for you to download from the ILSI Board portal – <a href="https://www.ilsiextra.org/ilsi/bot/meetings/SitePages/Home.aspx">https://www.ilsiextra.org/ilsi/bot/meetings/SitePages/Home.aspx</a>

A Board notebook with most of these documents will also be given to you at the ILSI Registration desk. Please take time to read these documents before the Board meeting.

The "Branch Resource" documents listed at the end on the portal will not be in your Board book – we are saving trees. I hope you will review these documents as they provide a picture of what the branches are doing.

Please let me know if you have any questions or need additional information. I am looking forward to seeing you in Bermuda.

Best regards,

Suzie

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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## 2014 ILSI Annual Meeting Southampton, Bermuda

### **ILSI Board of Trustee Schedule**

### Dr. Joanne Lupton

Date and Time		Meeting	Location		
		Fri Jan 17			
Fri Jan 17 Fri Jan 17	8:00 am – 4:45 pm 12:00 pm – 1:30 pm	ILSI Branches Meeting ILSI Branches Lunch	Poinciana I Poinciana Foyer		
		Sat Jan 18			
Sat Jan 18 Sat Jan 18 Sat Jan 18	8:00 am – 12:00 pm 12:00 pm – 1:00 pm 2:30 pm – 5:30 pm	ILSI Board of Trustees Meeting Board of Trustees Lunch ILSI Asian Branches Meeting	Gardenia II Windows Gardenia I		
	Sun Jan 19				
Sun Jan 19 Sun Jan 19 Sun Jan 19 Sun Jan 19 Sun Jan 19	11:45 am – 2:00 pm 2:00 pm – 5:00 pm 5:00 pm – 6:00 pm 6:00 pm –7:00 pm 7:00 pm – 9:00 pm	ILSI SEAR Meeting ILSI Assembly of Members ILSI Research Foundation CIMSANS Poster Reception Opening Reception	Gardenia I Poinciana III Gardenia III Poinciana Foyer Pool Deck (Back-up Windows)		
	Mon Jan 20				
Mon Jan 20 Mon Jan 20	7:00 am – 8:30 am 8:30 am – 12:00 pm	ILSI-India Breakfast Meeting ILSI RF Scientific Session: <i>Data Transparency</i>	Gardenia I Poinciana I		
Tue Jan 21					
Tue Jan 21 Tue Jan 21 Tue Jan 21 Tue Jan 21	7:00 am – 8:30 am 12:00 pm – 2:00 pm 2:00 pm – 5:30 pm 7:00 pm – 10:00 pm	ILSI Japan Breakfast ILSI Latin America Branches Meeting ILSI Discussion Forum: <i>One ILSI</i> Closing Reception	Gardenia I Gardenia I Poinciana III Beach (Back-Up Ocean Club)		

If there are any other meetings you would like to attend that are listed in the schedule as "Committee Members and invited guests," please see Suzie Harris.

#### ILSI Board of Trustees Meeting

Saturday, 18 January 2014 8:00 am –Noon Southampton, Bermuda

#### AGENDA

I.	Call to Order	Dr. Sam Cohen
II.	Approval of Minutes from the 20 November ILSI Board of Trustees Conference Call (Tab 2)	Dr. Sam Cohen
III.	President's Report	Dr. Jerry Hjelle
IV.	<ul> <li>Presentation of the One ILSI Strategy and the Implementation Process (Tab 3)</li> <li>a. Transition Team recommendations</li> <li>b. Thematic areas as implementation tool</li> <li>c. Process for studying the Governance recommendations</li> <li>d. Approval of the One ILSI Strategy</li> </ul>	
V.	Impact of Communications (Tab 4)	Mr. Michael Shirreffs
VI.	Report from the Publications Committee (Tab 5)	Dr. Suzie Harris
VII.	Report of the Financial Oversight Committee (Tab 6)	Dr. Liz Westring
	a. 2013 Year-end Projections and 2014 Budget	
VIII.	Adoption of the ILSI Budget for 2013	Dr. Sam Cohen
	BREAK – PHOTO (30 minutes)	
IX.	Report from the ILSI Research Foundation (Tab 7)	Dr. Dennis Bier
X.	Report from the ILSI Platform for International Partnerships (Tab 8)	Dr. Suzie Harris
XI.	<ul><li>Report of the Nomination Review Committee (Tab 9)</li><li>a. Introduction of Nominees to the ILSI Board of Trustees</li><li>b. Election of Officers and Executive Committee Members</li><li>c. Election of Trustees to the ILSI Research Foundation Board</li></ul>	Dr. Flávio Zambrone
XII.	Comments from the ILSI Board Chair	Dr. Sam Cohen

XIII. Other Business (Tab 10) a. New Branch Proposals

- b. Plans for 2015 and 2016 Annual Meetings

Dr. Sam Cohen Dr. Michael Knowles Dr. Suzie Harris

XIV. Adjournment

From:	Suzanne Harris
Sent:	Wednesday, December 18, 2013 7:35 AM
То:	Joanne Lupton
Subject:	RE: Update on the ILSI Nomination Review Commitee business decision needed

I understand that long emails are challenging, Joanne. Thanks for your "all yes" vote.

Suzie

From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Tuesday, December 17, 2013 6:12 PM
To: Suzanne Harris
Subject: RE: Update on the ILSI Nomination Review Commitee business -- decision needed

Sorry Suzie, I must not have read through the entire email. I vote "yes" on all of the proposals, Joanne Lupton

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Suzanne Harris [mailto ]
Sent: Tuesday, December 17, 2013 3:45 PM
To: Joanne Lupton
Subject: RE: Update on the ILSI Nomination Review Committee business -- decision needed

There are more than two, Joanne. Two for the ILSI Board. One for the ILSI Executive Committee and three for the RF Board.

Could you re-phrase your reply?

Suzie

 From: Joanne Lupton [mailto:jlupton@tamu.edu]

 Sent: Tuesday, December 17, 2013 4:39 PM

 To: Van Bladeren,Peter,VEVEY,CT-RSA; Suzanne Harris

 Cc:
 ; Geoff

 ; Geoff
 ; Flavio Zambrone; Eaton Kunz,Modelmi,VEVEY,CT-RSA;

 Burnand,Valerie,VEVEY,CT-RSA; Chelsea L. Bishop; Shawn Sullivan

 Subject: RE: Update on the ILSI Nomination Review Commitee business -- decision needed

Suzie: I support both of these candidates. Joanne From: Van Bladeren,Peter,VEVEY,CT-RSA Sent: Tuesday, December 17, 2013 3:08 PM To: Suzanne Harris Cc: Joanne Lupton; Geoff ( ); Flavio Zambrone; Eaton Kunz,Modelmi,VEVEY,CT-RSA; Burnand,Valerie,VEVEY,CT-RSA; Chelsea L. Bishop; Shawn Sullivan Subject: Re: Update on the ILSI Nomination Review Commitee business -- decision needed

Dear Suzie I vote yes on all of the proposals Best regards Peter

On 17 déc. 2013, at 21:32, "Suzanne Harris" wrote:

TO: ILSI Board of Trustees Nomination Review Committee

FROM: Suzie Harris

I apologize for my silence. I have been waiting for all the pieces to fall in place. This has now happened.

Before going into the new names, here are the draft minutes from the November 4 conference call, so you can refresh your memory.

As these minutes state, we were waiting on ILSI HESI to nominate a public trustee for the seat now held by Dr. Jay Goodman. HESI has agreed to nominate Dr. Ken Wallace, who is the current Chair of the HESI Board. His bio is attached here.

Another vacancy arose on the ILSI Board since your last call. Dr. Gert Meijer resigned his seat on the ILSI Board. This resignation also removed him from the ILSI Executive Committee.

ILSI Europe submitted Dr. John O'Brien, current Chair of the ILSI Europe Board of Directors, to fill both positions. His bio is attached here.

So I need your input –

**Action:** I support the nominations of Dr. Ken Wallace and Dr. John O'Brien seats on the ILSI Board of Trustees. Dr. Wallace will be nominated for a full three-year term. Dr. O'Brien will be nominated to complete a term which ends in January 2015.

Agreed:\_\_\_\_\_

Action: I support the nomination of Dr. John O'Brien to an at-large seat on the ILSI Board of Trustees Executive Committee.

Agreed:\_\_\_\_\_

The other business that was outstanding at the end of the November 4 conference call was the approval of the nominees for the ILSI Research Foundation Board of Trustees. The foundation's Nominating Committee submited the following three individuals for three-year terms on the ILSI Research Foundation Board of Trustees:

- Dr. Takeshi Kimura, Ajinomoto Company (I) a re-nomination
- Dr. Michael Knowles, The Coca-Cola Company retired (I) a re-nomination
- Dr. Josette Lewis, University of California, Davis (P) new nominee

Dr. Lewis' bio is attached here:

Action: I support the nominations of Drs. Kimura, Knowles and Lewis to the ILSI Research Foundation Board of Trustees.

Agreed:\_\_\_\_\_

### Please indicate your support/or not for each of these decisions. Under the laws of the District of Columbia I must hear back from each of you for this electronic vote to be valid.

With these actions, the committee's work is complete. I have taken the liberty of developing the Nomination Review Committee's report to the ILSI Board of Trustees, which shows all the nominees in one document – attached here:

Please let me know if you have any questions. It would be very helpful to receive your "votes" right away, but certainly by Friday, January 3.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: <u>s</u> www.ilsi.org

Follow ILSI on: <<u>Picture (Device Independent Bitmap)</u> 1.jpg> <<u>Picture (Device Independent Bitmap)</u> 2.jpg>

<NRC 2013-11-04 minutes.docx>

<Wallace Bio.docx>

<John O Brien BIO.doc>

<Lewis Bio.doc>

<Tab 09-a Nomination Review Com 2014 Report.doc>

From: Sent: To:	Suzanne Harris < Thursday, November 07, 2013 10:48 AM			
	(scohen@unmc.edu); Drewnowski, Adam goodman3@msu.edu;	; s.chang@griffith.e	edu.au; Cohen, Samuel M adamdrew@u.washington.edu; marion@vt.edu;	
	Joanne Lupton; Gert Me john.c.peters@ucdenve	eijer r.edu;	); john.milner@ars.usda.gov; ; Rodriguez, Felipe {PI} Geoff	
	Smith, Lewis L. (Prof.)		(Prof.)	
Cc:	weavercm@purdue.edu Fleming, Melinda S	;	Flavio Zambrone Bradford, Jeanne (jbradford@unmc.edu);	
	Usui-Etsuko(?? ??)			
	Christine Lagerquist ( Brueggemever: Michael	; Shirreffs	; haan@purdue.edu; ; Shawn Sullivan; Beth	
Subject:	Agenda, briefing docun ILSI Board of Trustees -	genda, briefing documents and dial-in instructions a special conference call for the SI Board of Trustees Wednesday, November 20 at 9:00 a.m. Eastern Standard Time		
Attachments:	013 Dial-in Information.doc; ILSI BOT 2013-11-20 cc agenda.doc; ILSI BOT 2013-08-05 ninutes.docx; Science_vformat-ed.doc; Value_vformat.docx; .takeholders_vformat.docx; Governance_vformat.docx; hematic_areas_and_strategic_plan_v6.docx			

TO: ILSI Board of Trustees

FROM: Suzie Harris

A special conference call for the ILSI Board of Trustees is scheduled for **Wednesday**, **November 20**, **2013**, **beginning at 9:00 a.m. Eastern Standard Time.** The call will not last longer than one hour.

The dial-in instructions are attached here.

The proposed agenda for the conference call is attached here.

Agenda Item II. Draft minutes from August 5, 2013 conference call

Agenda Item IV. Recommendations for Implementing the ONE ILSI Strategy; management diagram

Please let me know if you have any questions.

An agenda with briefing materials and dial-in instructions will be sent to you about one week before the call. The topic for this call is the Strategic Long Range Plan and I think the call will not run longer than one hour. If you will not be able

to participate, I encourage you to read the material sent in advance of the call and send your comments to full board or to me for distribution to the board.

Please let me know if you have questions or need additional information.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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### **ONE ILSI: Global Partnerships for a Healthier World**



\*Public/private sector Trustees <sup>†</sup>Initial team leaders

Best practices and shared learnings shape program development and implementation

# ILSI Strategic Plan Transition Team Governance

#### Statement of Problem

The strategic review had identified key issues associated with organizational structure of ILSI in so far as each Entity often operates in isolation, creating the situation where the culture within ILSI does not consistently promote co-operative working and sharing of intellectual and technical capital between the Entities. The objective of the Governance Transition Team (GTT) is to help create a "ONE ILSI" strategy, which will enhance the ILSI brand (external positioning) reflecting the collective strength of the organization, which is greater than the sum of its parts.

The GTT identified as its key priorities

- To develop and implement organizational principles and standards to increase the alignment of ILSI Entities
- II) To restructure the ILSI governance to strengthen resource alignment

#### **Strategies**

- I) To develop and implement organizational principles and standards.
  - 1. There will be a global "ONE ILSI" strategy, set globally and executed regionally/locally.
  - 2. Organisational principles and standards needed to promote the "ONE ILSI" strategy will be established through a consultative process that will seek input from all ILSI Entities.
  - 3. The global ILSI BoT (Board of Trustees) shall actively monitor progress on implementation of all parts of the "ONE ILSI" strategy.
  - 4. The global ILSI BoT shall promote effective communication and alignment between all global and regional/local Entities.
  - 5. The ILSI BoT will ensure the development of new operational models designed to specifically promote inter-branch co-operation in identifying and implementing new initiatives.
  - 6. Within the global strategy the regional/local BoT provide feedback of their needs in order to meet their priorities.

#### II) To restructure ILSI governance.

- 1. Negotiate a reduction in Board member numbers and simultaneously provide an agreed structure for the increased involvement of Stakeholders and Board Members at the Annual Meeting.
- 2. Increase the involvement of Executive members of individual Boards of ILSI branches in the ILSI Global Board.
- 3. Further develop the regionalization of individual Entities. Each Region will have appropriate representation on the ILSI Global Board.
- 4. Having reduced the size of the ILSI Global Board, carefully select and invite senior members of public institutions, academics and industrialists to join the Board to provide greater external and contextual advice on ILSI's strategy and development. Maintain a clear majority of public/academic members on the Board.
- 5. Consistent with the tripartite strategy of ILSI, ensure that where it is possible, all Boards, Board Subcommittees, Committees, Task Forces within all Entities have balanced tripartite representation.

- 6. There is considerable variation in the numbers of members of Boards of individual Entities. Boards with large numbers are encouraged to consider adopting similar strategies to that of the ILSI Global Board in order to reduce their size, improve effectiveness and provide strategic leadership.
- 7. Because of the critical role of EDs (Executive Directors) in the organization to the development and success of the "ONE ILSI" strategy, we recommended that there is a greater centralization and co-ordination of the ED's work programs. Several models have been discussed to achieve this and it is clear this subject needs wide and careful consideration before action can be taken. Nevertheless the pivotal role of EDs means that, for the implementation of principles and standards as well as improving resource alignment a more effective co-ordination of their activities is required.

#### **Goals and Timeline**

The GTT is suggesting the following timeline:

To develop and implement the strategy under (I), the GTT believes that all seven of the strategies can be developed by working with the relevant Boards and EDs of Entities to agree the detail on each of these points by the end of 2014, provided the principles outlined under (I) can be agreed by this time. It would be hoped that in January 2015 implementation could be agreed and initiated. Further work is required on the detail of adapted roles and responsibilities, including the RACI principles of Trustees, of Trustees, Executive Committee Members, Global Partnership Team Leaders and Executive Directors. There are already existing bylaws which cover the roles and responsibilities of most of those individuals and it will be necessary to review these to ensure that they fully reflect the operational requirements of a "ONE ILSI' strategy.

For the restructuring of ILSI governance (II) all the items listed (1 to 7) require wider discussion with the ILSI stakeholders. It is hoped that these discussions will be completed by the end of 2014. However it is clear that even if agreement could be reached on all of these points there would be a transition period of 2 to 3 years before all the recommendations could be implemented. It would therefore be prudent to assume that for some of the more contentious issues the end of 2014 may not be achievable and a full understanding of realistic timelines will not be possible until stakeholder engagement is well under way.

#### Budget

The discussions and negotiations associated with the recommendations from the GTT will require time at the next Annual Meeting and we believe this would be best achieved by allowing for an additional day to convene appropriate workgroups to develop a consensus for altered working practices and changes to the bylaws where necessary. We would suppose that additional subteams may also need time at the Annual Meeting and we would hope that through careful co-ordination of our work effort between July 25<sup>th</sup> and January 2014, the minimum amount of extra time at the Annual Meeting can be allocated.

## ILSI Strategic Plan Transition Team Stakeholders

#### Statement of Problem

ILSI seeks to strengthen its base of stakeholder engagement to:

- Broaden the diversity of input and expertise contributing to its scientific programs,
- Enhance, diversify and leverage potential resources (both financial and in-kind) to progress science and improved public health; and
- Support increased uptake and impact of ILSI's scientific outputs.

#### **Strategies**

A. Survey potential new partners to identify areas of interest and scientific priority – ensuring that outreach for ideas extend to a diversity of different stakeholder types.

#### Why? This strategy seeks to build interest and relevancy with new audiences.

- This effort could involve leveraging of existing topic solicitation activities already underway in many of the major branches with a particular emphasis on identification of topics that will help attract and interest new, value-added stakeholder groups. To ensure efficiency and avoid perceived 'competition' it would be optimal to vest one or more senior advisors (at the ILSI Executive Director, ILSI Board etc level) to help prioritize potential areas of cross-branch value.
- Outreach to solicit input on issue areas or challenges must be accompanied by a clear message around what ILSI is prepared to do/offer in follow-up to the input received.

### B. Consider opportunities to leverage existing and create new partnerships through ILSI's broad branch structure and global network.

Why? This strategy seeks to define and demonstrate how/when ILSI branch partnership adds collective value with particular emphasis on creation of new alliances that extend beyond staff connectivity alone.

- Many valuable examples already exist where ILSI branches, both large and small, have partnered effectively to conduct workshops, share expertise, and/or pool resources. Most of these partnerships have existed around a defined event rather than an on-going activity and have focused on the branch staff to branch staff partnership. Opportunity exists to leverage more enduring collaboration, where practical, that also allows different non-ILSI staff entities to be key collaborators in the partnership. For example, ILSI Argentina, ILSI Japan, an academic research institute, and a global health entity.
- Under the direction of the ILSI Global Executive Director, the major scientific global issues for ILSI may serve as coordinating points for collaborative efforts across branches and opportunities to pursue non-traditional funding mechanisms for 'non-traditional' approaches should be considered. For example, perhaps the PIP or other ILSI funding base could offer a 'matching grant' program that matches funds from new stakeholder organizations as an incentive for bringing in new resources.

#### C. Develop guidance/resources to support enhanced multi-sector engagement in ILSI programs

### Why? This strategy will aid in practical implementation of the organization's spoken commitment to diverse stakeholder involvement.

- Two possible approaches may be viable here:
  - Through the implementation of new formal policies/bylaws/best practices adopted at the ILSI Global level (and enforced by the ILSI Board) it may be possible to 'require' branches to commit to a minimum level of multi-sector involvement;
  - By sharing best practices at a staff to staff (or board to board level) across the organization it may be possible to enhance multi-sector and multi-stakeholder involvement in ILSI activities. The branch staff meeting of the ILSI Annual Meeting is one forum where such discussions may be viable.
  - A new branch statistic as to 'how many new public sector stakeholders were added to your activities' in the prior year could be requested and recorded.

### D. Create materials/resources that demonstrate value and relevance to different types of potential stakeholders

### Why? This strategy will allow staff, members, partners to concretely respond to questions of value and impact.

- Consider opportunities to better communicate and advertise existing cross-branch branch strengths as a way to convey the value to both existing and potential future stakeholders.
- Define the 'impact' or successes of ILSI's programs particularly those that build on cross branch or international implementation reach

### E. Review possible organizational structure to facilitate 3rd party donations and financing, such as an ILSI Foundation organization for Asia, Latin America, Africa and other regions as needed.

### Why? To facilitate local and international donations and financing for scientific programs and development work.

- The UN agencies such as WHO and FAO are increasingly decentralized, and are undertaking activities in nutrition and food safety where ILSI can play an important role.
- A regional foundation organization could facilitate 3rd party contributions to partnerships efforts.
- European, Japanese and North American governmental organizations, as well as independent foundations are also looking for partnerships that may be facilitated by such an entity.

#### **Indicators of Achievement**

- Participation from new organizations in ILSI (e.g., groups not previously associated with ILSI);
- New types of resource-support for ILSI (e.g., new partnerships that draw on in-kind of \$\$ resources from partners);
- Availability of written materials that speak to specific audiences.

#### Requirements

The review effort is expected to require 0.5 FTE of GC staff time for 6-12 months, to assist in outreach, coordination and review – on a global basis with all branches.

**One Year Goal** To be discussed.

Five Year Goal

To be discussed.

## ILSI Strategic Plan Transition Team Value

#### Statement of Problem

The challenge is to proactively define what ILSI is versus reactively (and defensively) saying what it is not.

#### Vision

ILSI is recognized within the international scientific community for its contribution to science that can be replicated, adapted, and adopted to improve human health and safety and safeguard the environment.

#### Year 1 Goal (end of 2014)

There will be universal understanding among ILSI professionals of the tools, resources, and cooperative strategies used to communicate ILSI's value to diverse audiences.

#### **Tools and Strategies**

- Develop messages describing ILSI's work and its impact <u>Accountability</u>: drafts by Michael Shirreffs with review and approval by Board of Trustees Executive Committee (BOT Exec Com)
- Determine how to leverage existing and new tools for proactively disseminating the messages <u>Accountability:</u> Steven Parker, tech lead, and Michael Shirreffs and Steven Parker for strategy and implementation
- Create value propositions for each stakeholder group (industry; academia; government; other scientific organizations such as NGOs<sup>1</sup>)
   Accountability due for her Michael Shieneffe with available and accounted by BOT Error Count
  - Accountability: drafts by Michael Shirreffs with review and approval by BOT Exec Com
- Implement system for ongoing, timely reporting of accomplishments and impact <u>Accountability:</u> ILSI branch executive directors and branch board chairs/presidents
- Develop materials that illustrate ILSI's contributions to the public good <u>Accountability</u>: ILSI branch executive directors and branch board chairs/presidents for input and Michael Shirreffs for material development
- Write and implement a comprehensive communications plan that prioritizes audiences; outlines specific steps for using traditional communications tools and social media; and provides guidance on issues management (crisis management)

Accountability: drafts by Michael Shirreffs with review and approval by BOT Exec Com

#### **Indicators of Achievement**

Quantitative indicators of achievement:

- Improved website traffic (number of unique visits, number of pages visited, and length of stay)
- Increased newsletter readership

<sup>&</sup>lt;sup>1</sup> The Stakeholders sub-team may identify additional stakeholder categories

#### Indicators of Achievement (continued)

- Increased social media activity (measured by number of followers, likes, YouTube views, etc.)
- Number of citations of ILSI peer-reviewed publications<sup>2</sup>
- Increased annual meeting attendance<sup>3</sup>
- Increased revenue<sup>4</sup>

Qualitative indicators of achievement:

- Volunteer and staff leadership ability to articulate (quickly concisely) ILSI's purpose and values
- Improvement in awareness and perception of ILSI among all stakeholders (using existing survey results to establish a baseline)
- Accurate characterization of ILSI by the media and other third parties

#### Budget

The current staffing level of 1.4 FTE is adequate to implement the recommendations listed under Tools and Strategies and to track and report on indicators of achievement.

The full communications plan (last bullet under Tools and Strategies) will outline what can be done with existing human resources and tech infrastructure. Budget estimates will be given for alternative strategies and/or for enhancing subcomponents of the plan for leadership to consider.

<sup>&</sup>lt;sup>2</sup> Better communication of scientific outputs would be only one of many factors contributing to increased citation

<sup>&</sup>lt;sup>3</sup> Better communication of meeting value would be only one of many factors contributing to improved meeting attendance

<sup>&</sup>lt;sup>4</sup> Better communication of program, project, or membership value would be only one of many factors contributing to increased revenue

## ILSI Strategic Plan Transition Team Science

#### Statement of Problem

The challenge is to strengthen scientific content among the federation of ILSI branches by enhancing the involvement and input of appropriate parties and to increase the ability to anticipate and prioritize issues, while facilitating the management of these platforms across the ILSI entities.

Much of the activity to achieve the challenge has to be by the branches, and therefore their cooperation is essential to progress this activity. The main role of ILSI GC will be to provide guidance and disseminate best practice, whilst making available some funding to catalyze implementation where necessary.

#### **Strategies**

- Engage external organizations/stakeholders in emerging issue generation
- Identify and ensure that emerging issues are suitably prioritized and the critical issues result in an activity
- Shape ILSI's scientific work into programs to improve the impact
- Assure that all ILSI entities have the ability to know each other's major areas of scientific activity and appropriate mechanisms exist for collaborations and exchange

#### Year 1 (mid-end of 2014) goal

All entities should develop processes for the following:

- 1. Scientific mapping
  - a. Consolidate under the 4 key themes as appropriate
  - b. Identify areas of overlap with other branches
- 2. Emerging issues
  - a. Process to involve range of stakeholders: industry, academic, government, NGOs
  - b. Highlight four key themes and scientific map when soliciting suggestions
    - i. Emphasize that suggestions are not constrained to the key themes and that innovative thinking is welcome
  - c. Establish process for identification and prioritization of proposals
  - d. Consider the following aspects:
    - i. Global relevance
    - ii. Public health impact
    - iii. Potential for expanding sources of support
    - iv. Scope for multi-sector participation and relevance
  - e. Identify topics with potential multi-entity participation and inform ILSI GC
- 3. Internal and external collaboration
  - a. Branches should identify areas of common interest in activities of other branches
    - i. Contribution of expertise
    - ii. Capacity building
  - b. SWOT analysis of other organizations engaged in similar work
    - i. Opportunities for synergy
      - 1. Research collaboration
      - 2. Funding opportunities

- 3. Dissemination of output
- ii. Where to cede the field to others
- 4. Program stewardship
  - a. Policy on access to published output and the underlying data
  - b. Mechanism for review of scientific programs
    - i. Progress
    - ii. Impact: scientific, public health, policy, business practice
    - iii. Identify and develop suitable metrics to enable such evaluation
    - iv. Scientific and economic viability
    - v. Strategic fit to portfolio
  - c. Program oversight by ILSI GC
- 5. Capacity building
  - a. Two-way exchange of expertise and ideas
    - i. Internships from amongst staff
    - ii. Other scientists
    - iii. Involvement of young scientists in scientific activities and committees of ILSI branches
    - iv. Assistance for scientists from ILSI branches to attend appropriate conferences, where this would otherwise not be possible

#### Year 2 (2015)

Implementation and application of processes developed above, if this has not already started.

#### Accountability

Chief executive officers and leadership (chairs and president) of the branches ILSI Executive

#### **Indicators of Achievement**

- All program and project design will involve at least dipartite and where possible tripartite or broader expert participation. Furthermore, the topics addressed should be recognized as needed by at least 3 stakeholder groups (e.g., government, academia, industry, civil society).
  - One year goal No less than 20% of events held by the branch have at least dipartite or broader expert participation and no events are unilateral.
  - Five year goal 100% of events held by the branch have at least dipartite or greater expert participation in their oversight committees or implementation. An aspirational goal is that all topics undertaken by all branches are recognized by at least 3 stakeholder groups to address important public health issues.
  - An increase in external collaboration for identifying and addressing emerging issues
    - One year goal All branches establish a process for identifying emerging issues that that address needs recognized by at least 3 stakeholder groups (e.g., government, academia, industry, civil society).
    - o Establish a process to identify seed money to fund those projects/issues
    - Five year goal Emerging issues process includes at least dipartite and where possible tripartite expert participation and at least one of the emerging issues identified is practically fundable and could result in outside funding.
    - A number of those issues should result in multi-branch issues.

- Branch coordination and collaboration are enhanced and efficient
  - One month goal Restructure ILSI AM Friday meeting to staff to staff technical program coordination
  - One year goal Establish a centrally (ILSI GC) funded webinar or other mechanism for quarterly program manager to program manager coordination using four themes, one theme per quarter, with briefing of issues and current progress, and then open discussion on the issues.
  - Five year goal For every branch there will be at least one event per year that includes expert or financial contribution from another branch.
- Capacity building
  - o Expand the travel grant program
  - o Identify a process for recruiting and training early career experts
  - o Integrate the junior recruiting process and travel grant process?

#### Budget

Some funding will be required for coordination (0.5 - 1 FTE?), teleconferences and/or face-to-face meetings in the first year to help branches in developing suitable processes. Staff visits, particularly to some of the smaller branches may be necessary during this period. Continuing support for coordination will be necessary.

#### ILSI Board of Trustees Mid-year Conference Call

#### Monday, August 5, 2013

#### **DRAFT MINUTES**

#### I. Call to Order

Dr. Sam Cohen, Chair, ILSI Board of Trustees, began the conference call at 9:04 a.m. Eastern Daylight Time. He welcomed the participants and observers (list attached).

He also reviewed the proposed agenda and no changes were requested. The agenda is attached.

#### II. Approval of Minutes from the January 19, 2013 ILSI Board of Trustees Meeting

The minutes were approved as distributed.

#### III. President's Report

Dr. Jerry Hjelle, ILSI President, described the organization as one with about 80 full-time staff worldwide and a \$20 million annual budget. With these resources, ILSI puts on more than 200 scientific meetings per year using an explicit tripartite approach that is highly inclusive. A new branch has been successfully launched in Taiwan with the scope and scale (24 member companies, the majority of which are local) that re-enforces the strength of the ILSI model.

Since the annual meeting in January, Dr. Hjelle has visited ILSI Brasil, ILSI Focal Point in China for their 20<sup>th</sup> anniversary, and ILSI Japan. The scope of these three branches alone is very impressive – stretching from research to capacity-building. He singled out the public health programs in China that deliver micronutrient-fortified complementary food to a million Chinese toddlers and the clean drinking water program in Vietnam being led by ILSI Japan for special attention. Dr. Hjelle encouraged the trustees to visit the ILSI website on a regular basis to keep up with the amazing array of activities.

ILSI's global network is unique and supported by very strong staff in the branches and Research Foundation. The branches have also built strong local relationships. One of the components of the new strategic plan is to focus attention on standardizing the quality of scientific work across all the entities.

#### IV. Report of the Financial Oversight Committee

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, reviewed the financial report through June 30, 2013. ILSI's Financial Oversight Committee met by conference call on July 24 to review the 2012 auditor reports, year-to-date investment performance, and the year-to-date financial statements.

The engagement and audit manager from Johnson Lambert joined the call to present the 2012 audited statements and the required board communication letters. The auditors began their report by informing the committee that there were changes in auditing standards that now require ILSI's stand-alone audited financial statement to be consolidated with ILSI Research Foundation to receive a "clean

opinion". ILSI's stand-alone statement mentions this in the audit report and indicates there is a "qualified opinion" unless both organizations are presented together in a single financial statement. An ILSI stand-alone statement and a statement with ILSI and ILSI RF consolidated have always been issued. However, this is the first year that ILSI's stand-alone statement was issued with a "qualified opinion". Generally accepted accounting principles require consolidation of organizations if there is direct or indirect control. ILSI exercises this control by electing the ILSI RF Board of Trustees.

The committee will be discussing if this auditing standard change brings any changes to their oversight responsibilities, and potential future changes to the statements. For example, one statement may be issued with supplemental information showing a full set of financial statements for both organizations. Other than this change to the auditor's opinion page, the auditors reported that all aspects of the audit were clean, and they did not identify any internal control deficiencies, or propose any audit adjustments.

Also joining the call were the investment advisors from Raffa Wealth Management to review the yearto-date performance of ILSI's investments. ILSI's investment portfolio includes two funds: an operating fund for cash not currently needed for operations and the newly formed board-designated reserve fund. Both funds are conservatively invested in bond and money market funds and were designed to have minimal fluctuations from market volatility.

Due to a sharp rise in interest rates, the bond funds experienced about a 1% decline in value year-todate through June 30th. The market has since settled and the portfolios are currently showing small year-to-date earnings.

The year-to-date internal financial statements were distributed to the trustees in advance of this call. These statements include the June 30 balance sheet with prior year-end comparisons and a year-to-date activity statement through June 30. The ILSI Financial Oversight Committee reviewed these statements. The June 30 balance sheet shows that ILSI is liquid with over \$1.6 million in current assets. All liabilities are in line with expectations.

The year-to-date activity statement shows ILSI's revenues and expenses from January 1 to June 30 compared to the full-year's budget. The first page of the activity statement shows ILSI's unrestricted activities that are funded with branch assessments and press revenue. Through June 30, the revenue and expenses from the unrestricted activities are on track with the budget. Contributions were received to help cover the costs of ILSI's current strategic planning process.

The second page of the activity statement shows the revenues and expenses from restricted or donor funded activities. These activities are also in line with the budget through June 30.

### V. Recommendations from the ILSI Strategic Long-Range Plan Transition Team/ILSI Executive Committee and Implementation

Dr. Hjelle reviewed the process for developing the recommendations, beginning with the Strategic Plan workshop held in January 2013, with 32 trustees and staff. Mr. Tim Fallon facilitated the January workshop, leading the group through a discussion of ILSI's strengths and weaknesses. The tripartite approach was identified as the top strength. Challenges included current anti-science environment, limited resources, limited communications expertise, and the need to be a high performing global

organization. The group developed a strategic map that included four tracks of work – science (foresight and maximum impact), value, stakeholders, and governance.

Dr. Hjelle appointed a transition team to develop implementation steps for 2014. Through monthly conference calls and a face-to-face meeting, the Transition Team developed a series of recommendations that form the "One ILSI" strategy that focuses on enhancing science, increasing value understanding, and identifying new stakeholders. Activities such as the branch staff meeting during the annual meeting can be used to share best practices and thereby build regional strength. One ILSI will require extra effort on the part of branch staff to gain more from the global network, but the federation status will remain in place. The ILSI professional staff will take a greater role in the One ILSI strategy, as they are the people who think about ILSI every day. This role will also be linked to professional development for the staff around the world. In Dr. Hjelle's opinion, all of the proposed recommendations are doable and address the four tracks of the strategic map.

The recommendations for each of the four tracks were distributed to the trustees prior to the conference call. The science track includes enhancing the emerging issues identification process and bringing it to a global level, building inter-branch coordination and program stewardship. Four thematic areas have been identified as tools for communicating ILSI's scientific activities. These are: food and water safety; toxicology and risk science; nutrition, health and well-being; and sustainable agriculture/nutrition security. Most of the work carried out by ILSI entities fits within one of these areas.

The value track recommendations address the need to continue to improve ILSI's ability to communicate to external and internal audience. These tools include the website as well as social media vehicles. The stakeholder recommendations are inter-related with emerging issues and communications. Building new partnerships to leverage ILSI's resources is the desired outcome.

The governance recommendations speak to the need to take a fresh look at the effectiveness of the ILSI Board of Trustees. As it currently operates, the Board meetings are largely informational. The role of the ILSI Executive Committee will also be reviewed.

In terms of next steps, Dr. Hjelle said that key professional staff would be leading work on the four thematic areas, mapping the activities that are ongoing and developing ideas for collaborative activities in each area. The Transition Team will continue to refine their recommendations through monthly conference calls. A second ILSI Board of Trustees conference call will be held in November to receive the final recommendations from the Transition Team. These recommendations will then be debated at the January 2014 ILSI Board of Trustees meeting.

A number of comments were offered by trustees. Dr. Dennis Devlin said that the Transition Team came up with an excellent document. In his view the one voice culture is essential. He raised concern about the second goal as this appears to overlap with the role of the individual branch boards to set their own work plans. It will be important to clearly delineate who decides how the branch resources will be used. Dr. Hjelle said that One ILSI is not a top down approach. Dr. Michael Knowles suggested that the objective is to generate a coordination mindset, with the larger branches helping the smaller branches. Dr. Hjelle pointed out that there numerous examples of regional activities being undertaken by the branches now. Dr. Cohen agreed, noting that further transformation would not happen overnight. The One ILSI strategy sets the general tone for the future. **Action:** Dr. van Bladeren moved that the proposed implementation plan be generally accepted, along with the next steps outlined by Dr. Hjelle. The motion passed with no opposition or abstentions.

#### VI. Publications Committee

Dr. John Milner, Chair of the ILSI Board of Trustees Publications Committee, reported that *Nutrition Reviews* received its third consecutive increase in impact factor this year. He attributed the success to the editors and Ms. Allison Worden, Publications Manager. The committee agreed in the spring that it was not time for the journal to go to an online only format. Many of its readers still use the print version. Dr. Milner also noted that the journal continues to make a profit for ILSI. Finally, he reported that the committee continues to work on a new book – Present Knowledge in Food Safety.

#### VII. Report from the ILSI Research Foundation

A written progress report describing the activities of the three centers of excellence within the ILSI Research Foundation, as well as the nutrition and health promotion activities, was distributed to the trustees prior to the conference call. Dr. Suzie Harris briefly reviewed the report.

The ILSI Research Foundation will have an outreach meeting in Washington, DC on Wednesday, October 9. Representatives from current and potential partner organizations will be invited to a discussion of open data, which will be held at the ILSI Research Foundation office.

#### VIII. Report for the ILSI PIP

A written progress report describing the ILSI Platform for International Partnerships (PIP) activities for the first half of 2013, was distributed to the trustees prior to the conference call. Dr. Harris briefly reviewed the report which included ILSI Health and Environmental Sciences Institute's (HESI) support for the chemical risk assessment network initiated by the World Health Organization (WHO). ILSI PIP is engaged with the Food and Agriculture Organization of the United Nations (FAO) in planning for the 2014 Second International Conference on Nutrition (ICN 2, formerly call ICN +21). ILSI PIP is monitoring WHO's activities relative to developing a new process for dealing with "non-State actor," meaning all organizations that are not national governments.

All branches are welcome to participate in PIP and there is an eight-member public-private advisory group that helps with decision-making. Funding for PIP activities comes from branches, i.e. HESI, and member companies. Dr. Cohen and Dr. Hjelle urged the PIP to do more to communicate the value of its work to the broader ILSI family.

#### IX. Report from the ILSI International Food Biotechnology Committee

A written report describing the ILSI International Food Biotechnology Committee's (IFBiC) activities since January was distributed to the trustees in advance of the conference call. Dr. Harris also reported that IFBiC and the ILSI Research Foundation have been discussing a possible transfer of IFBiC capacity-building activities in food and feed safety to the ILSI Research Foundation. The crop composition database would also be transferred under the proposal. A new center of excellence would be established within the Research Foundation to manage the food and feed safety activities going forward. While a final decision has not been made, should the transfer take place, there will be a financial impact on ILSI. IFBiC's relatively large financial position helps ILSI with cash flow. If these funds

are transferred to the Research Foundation, then the size of ILSI's reserve fund may be impacted. The second impact is that IFBiC was covering a portion of the costs associated with the ILSI Board of Trustees and the ILSI Executive Director. Should the transfer occur, the 2014 ILSI unrestricted budget would need to be adjusted to absorb these expenses.

#### X. Other Business

- a. Branch Staff Travel Grants Dr. Sushila Chang reviewed the travel grant program, including the list of grantees, which was distributed to the trustees in advance of the conference call. She congratulated the branches for actively utilizing this program and thanked the members of the selection committee Dr. Diána Bánáti, Ms. Cecilia Garcia, Dr. P.K. Seth and Dr. Myeong-Ae Yu. The average grant is \$2500. Dr. Seth asked to see the reports from each of the grantees.
- b. Plans for 2014 Annual Meeting Dr. Harris encouraged the trustees to mark the dates for the 2014 ILSI Annual Meeting in Bermuda on their calendars. Electronic invitations will be sent out in early September. The ILSI Board of Trustees meeting will be on Saturday morning, January 18. This is a change from the past where the ILSI Board meeting has been on Saturday afternoon.

#### XI. Adjournment

As there was no further business, Dr. Cohen ended the conference call at 10:35 a.m. Eastern Daylight Time.

Signed: Date:		
Nghện. Date.	Clause al.	Deter
	Nonen	Date.
Dute.	Jighteur	Dutc.

#### ILSI Board of Trustees ILSI Board of Trustees Mid-Year Conference Call

Monday, August 5, 2013 9:00 – 11:00 a.m. Eastern Daylight Time

#### AGENDA

I.	Call to Order	Dr. Sam Cohen
II.	Approval of Minutes from the January 19, 2013 ILSI Board of Trustees Meeting	Dr. Sam Cohen
III.	President's Report	Dr. Jerry Hjelle
IV.	Report of the Financial Oversight Committee	Dr. Liz Westring
V.	Recommendations from the ILSI Strategic Long-range Plan Transition Team/ILSI Executive Committee and Implementation	Dr. Jerry Hjelle
VI.	Publications Committee	Dr. John Milner
VII.	Report from the ILSI Research Foundation	Dr. Suzie Harris
VIII.	Report from the ILSI PIP	Dr. Suzie Harris
IX. X.	Report from the ILSI International Food Biotechnology Committee Other Business	Dr. Suzie Harris
	<ul><li>a. Branch Staff Travel Grants</li><li>b. Plans for 2014 Annual Meeting</li></ul>	Dr. Sushila Chang Dr. Suzie Harris

XI. Adjournment

#### ILSI Board of Trustees Mid-Year Conference Call

Monday, August 5, 2013

#### PARTICIPANTS

Dr. Todd Abraham Dr. Scott Belanger Dr. Alan Boobis Dr. Sushila Chang Dr. Samuel Cohen Dr. Dennis Devlin Dr. Marion Ehrich Dr. Jay Goodman Dr. Suzie Harris Dr. Jerry Hjelle Dr. Takeshi Kimura Dr. Michael E. Knowles Dr. Joanne Lupton Prof. Gert Meijer Dr. John Milner **Dr. John Peters** Prof. Gerhard Rechkemmer Dr. Prahlad K. Seth Mr. Michael Shirreffs Mr. Geoff Smith Dr. Lewis Smith Mr. Shawn Sullivan Dr. Geoff Thompson Dr. Peter van Bladeren Dr. Connie Weaver Dr. Elizabeth Westring Dr. Flávio Zambrone

Observers Dr. Lucia Anelich Ms. Cristina Cisternas Dr. Morven McLean Ms. Syril Pettit Mrs. Sharon Weiss Dr. Ryuji Yamaguchi Mrs. Boon Yee Yeong Dr. Myeong-Ae Yu Mondelēz International The Procter & Gamble Company Imperial College London Griffith University University of Nebraska Medical Center Exxon Mobil Corporation Virginia-Maryland Regional College of Veterinary Medicine Michigan State University ILSI Monsanto Company Ajinomoto Company, Inc. The Coca-Cola Company, retired Texas A&M University

University of Colorado Max Rubner-Institut, Federal Research Institute Lucknow Biotechnology Park ILSI Nutrition Strategies International LLC University of Leicester ILSI Danone Nestec S.A. Purdue University General Mills Planitox

ILSI South Africa ILSI South Andean ILSI Research Foundation ILSI Health and Environmental Sciences Institute ILSI North America ILSI Japan ILSI Southeast Asia Region ILSI Korea

#### ILSI Board of Trustees Conference Call

Wednesday, November 20, 2013 9:00 – 10:00 a.m. Eastern Standard Time

#### PROPOSED AGENDA

I.	Call to Order	Dr. Sam Cohen
II.	Approval of Minutes from the August 5, 2013 ILSI Board of Trustees Conference Call	Dr. Sam Cohen
III.	President's Report	Dr. Jerry Hjelle
IV.	Recommendations from the ILSI Strategic Long-range Plan Transition Team/ILSI Executive Committee and Implementation	Dr. Suzie Harris
V.	Plans for 2014 Annual Meeting	Dr. Suzie Harris
V/I	A diaumment	

VI. Adjournment

#### ILSI Board of Trustees 2013 Conference Call Information 9:00 am – 10:00 am US Eastern Standard Time

Wednesday, November 20, 2013

#### AT&T Direct Toll Free Dial-In Country Number Number Note Australia 1-800-21-2361 FROM BRAZIL (The audio conference requires two-stage dialing. First, dial the AT&T Direct Number. Brazil 0-800-890-0288 888-706-6468 Second, dial the Toll-Free Dial-In Number.) **BRAZIL OTHER** (The audio conference requires two-stage dialing. First, dial the AT&T Direct Number. Brazil 0-800-888-8288 888-706-6468 Second, dial the Toll-Free Dial-In Number.) China 10-800-711-0988 CHINA NETCOM GROUP USERS China 10-800-110-0916 CHINA TELECOM SOUTH USERS Germany 0800-182-9571 Greece 00-800-11-005-8221 000-117 888-706-6468 India Two-stage dialing process required. Japan 00531-11-0061 JAPAN KDD USERS Japan 0066-33-830259 **JAPAN C&W USERS** 0034-800-900351 JAPAN NTT USERS Japan Korea (south) 00798-1-1-005-8221 Mexico 001-888-706-6468 Netherlands 0800-022-7141 Singapore 800-110-1778 Switzerland 0-43-5579014 Caller paid United Kingdom 0808-234-3676 **United States** 888-706-6468

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#### Access code for all calls is 4498699#

From: Sent: To: Cc: Subject: Joanne Lupton Tuesday, November 05, 2013 8:04 PM

Suzanne Harris RE: ILSI Financial Oversight Committee

Beth-Ellen:

Thank you for all that you do for ILSI. I am far from being an expert in nonprofit financial spreadsheets but I actually understand the issues the way you present them. Liz, I imagine (because I'm on the ILSI nominating committee) that Suzie wanted the extra minutes after our call this morning to attempt to convince you to stay as Treasurer of ILSI. I'd like to add my two cents to this also. You have been an exemplary Treasurer and you have worked out a system with Beth-Ellen that seems to work for the two of you. If in any way possible it would be great if you could stand for nomination to stay as treasurer. Your re-nomination is shared by all members of the ILSI nominating committee. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

 From: Beth-Ellen Berry [mailto:bberry@ilsi.org]

 Sent: Tuesday, November 05, 2013 2:54 PM

 To:
 s.chang@griffith.edu.au; goodman3@msu.edu; Joanne Lupton; Rodriguez, Felipe {PI}

 (
 ); Smith, Lewis L. (Prof.)

 Cc: Suzanne Harris

 Subject: ILSI Financial Oversight Committee

To ILSI FOC members,

As requested on today's call, attached is the branch assessment schedule updated through today. Please let me know if you have any questions.

Thank you, Beth-Ellen

Beth-Ellen Berry, CPA Chief Financial Officer International Life Sciences Institute 1156 15th Street, NW, 2nd Floor Washington, DC 20005 Phone: 202-659-0074 Fax: 202-659-3617 www.ilsi.org
From: Suzanne Harris								
Sent: Wednesday, October	30, 2013 4:36 PM							
То:	; s.chang@griffith.edu.au; goodman3@msu.edu; Joanne Lupton (jlupton@tamu.edu);							
Rodriguez, Felipe {PI} Smith, Lewis L. (Prof.)								
Cc: Christine Lagerquist	; carmel.james@griffith.edu.au; clbishop@tamu.edu;							
h ; Beth	Ellen Berry; Shawn Sullivan; Beth Brueggemeyer							
Subject: Agenda, briefing of - Tuesday, November 5, 9:0	locuments and dial-in instructions for the ILSI Financial Oversight Committee conference call 0 a.m. EST							

TO: ILSI Board of Trustees Financial Oversight Committee

FROM: Suzie Harris

The next regular quarterly conference call for the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Tuesday, November 5, beginning at 9:00 a.m. Eastern Standard Time.** Please note that the United States will return to standard time on Sunday, November 3 (falling back one hour). The conference call may run as long as 90 minutes. The dial-in instructions are at the end of this message.

The proposed agenda is attached here:

<< File: FOC 2013-11-05 agd.doc >>

Agenda Item II. Draft minutes from the July 24 conference call

<< File: FOC 2013-07-24 minutes BEB.docx >>

Agenda Item III. 2013 Year-to-date financial report

<< File: ILSI Financial Statements 09302013.pdf >> Agenda Item IV. Report on investment portfolio

<< File: ILSI Performance.pdf >> Agenda Item V. 2013 Year-end projections and proposed 2014 budget

<< File: ILSI 2013 Proj\_2014 Draft Budget.pdf >>

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Please let me know if you have any questions or need additional information.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on: << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >>

From:	Suzanne Harris
Sent:	Thursday, October 31, 2013 1:11 PM
То:	; ; Joanne Lupton; Geoff
	( ); Flavio Zambrone
Cc:	; Chelsea L. Bishop; Shawn Sullivan; Beth
	Brueggemeyer
Subject:	Revised list of nominees for the ILSI Board of Trustees
Attachments:	2014 Nominees for the ILSI Board of Trustees.doc
TO:	ILSI Board of Trustees Nomination Review Committee

FROM: Suzie Harris

I received a re-nomination for the ILSI Board of Trustees from the Asia-Pacific North grouping of branches. Please discard the list of nominees sent with the earlier email and replace it with this list.

Let me know if you have any questions.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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### 2014 Nominees for the ILSI Board of Trustees To Be Elected by the ILSI Assembly of Members

### **Nominees for Re-Election**

Asia-Pacific North	Dr. lk Boo Kwon (l)
Asia-Pacific South	Dr. Sushila Chang (P)
Europe/Africa	Dr. Gerhard Eisenbrand (P)
Latin America	Dra. Sara Valdés (P)

#### **New Nominees**

HESI	(P)
North America	Dr. Michael Doyle (P)*
32 <sup>nd</sup> seat nominee**	Dr. Rhona Applebaum

\*To filled the unexpired term held by Dr. Janet King – term ends in 2015. \*\* See Article IV, Section 1 of the ILSI bylaws.

The following trustees' terms will expire and they will not be re-nominated:

• Dr. Jay Goodman

From: Sent: To:	Suzanne Harris Wednesday, October 30, 2013 3:36 PM s.chang@griffith.edu.au; goodm	nan3@msu.edu; Joanne							
	Lupton; Rodriguez, Felipe {PI}	); Smith, Lewis L. (Prof.)							
Cc:	Christine Lagerquist ( carmel.james@griffith.edu.au; Chelsea L. Bishop; h	; Beth-Ellen							
	Berry; Shawn Sullivan; Beth Brueggemeyer								
Subject:	Agenda, briefing documents and dial-in instructions for the	ILSI Financial Oversight							
	Committee conference call Tuesday, November 5, 9:00 a.m. EST								
Attachments:	ttachments:FOC 2013-11-05 agd.doc; FOC 2013-07-24 minutes BEB.docx; ILSI 2013 Pro Budget.pdf; ILSI Financial Statements 09302013.pdf; ILSI Performance.pdf								

TO: ILSI Board of Trustees Financial Oversight Committee

#### FROM: Suzie Harris

The next regular quarterly conference call for the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Tuesday, November 5, beginning at 9:00 a.m. Eastern Standard Time.** Please note that the United States will return to standard time on Sunday, November 3 (falling back one hour). The conference call may run as long as 90 minutes. The dial-in instructions are at the end of this message.

The proposed agenda is attached here:

Agenda Item II. Draft minutes from the July 24 conference call

Agenda Item III. 2013 Year-to-date financial report

Agenda Item IV. Report on investment portfolio

Agenda Item V. 2013 Year-end projections and proposed 2014 budget

### **Dial-in Instructions**

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Please let me know if you have any questions or need additional information.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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### September 2013 Portfolio Performance & Activity

ILSI - Board Designated Reserve 1156 15th Street, NW Washington, DC 20005

Description	September	YTD
Beginning Value	564,055.44	269,607.51
Net Contributions	0.00	300,140.66
Capital Appreciation	2,280.75	-5,983.87
Income	491.23	3,584.29
Management Fees	0.00	-521.17
Other Expenses	0.00	0.00
Ending Value	566,827.42	566,827.42
Total Investment Gain/Loss	2,771.98	-2,920.75
Time Weighted (gross)	0.49	-0.51
Time Weighted (net)	0.49	-0.62



### September 2013 Portfolio Performance & Activity

ILSI - Operating Reserve 1156 15th Street, NW Washingon, DC 20005

Description	September	YTD
Beginning Value	606,790.57	914,297.62
Net Contributions	0.00	-300,140.66
Capital Appreciation	2,443.89	-7,958.12
Income	526.07	4,353.02
Management Fees	0.00	-791.33
Other Expenses	0.00	0.00
Ending Value	609,760.53	609,760.53
Total Investment Gain/Loss	2,969.96	-4,396.43
Time Weighted (gross)	0.49	-0.50
Time Weighted (net)	0.49	-0.61

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS		9/30/2013 <sup>(1)</sup>		12/31/2012		12/31/2011		12/31/2010	12/31/2009		
Current Assets											
Cash	\$	714 232	\$	509 443	\$	773 370	\$	883 041	\$	817 803	
Short-Term Investments	Ŷ	609.761	Ψ	914.298	Ψ	911.040	Ψ	401.663	Ψ	199.533	
Accounts Receivable		14,426		169,244		119,954		257,151		88,442	
Due From ILSI Entities for Shared Services		104,871		171,782		109,126		156,341		220,499	
Prepaid Expenses and Other Current Assets		35,933		16,979		24,342		31,626		41,058	
Total Current Assets		1,479,223		1,781,746		1,937,832		1,729,822		1,367,335	
Other Assets											
Inventory Net		-		-		-		-		30 364	
Rent Receivable under Shared Space Agreement		359,551		364,147		356,748		334,566		299.076	
Board-Designated Reserve		566,827		269,608		268,446		264,897		256,466	
Total Other Assets		926,379		633,755		625,194		599,463		585,906	
Fixed Assots											
Computer Software and Equipment		363 213		504 523		510 315		282 834		263 103	
Office Eurniture		114 075		114 075		114 075		116 075		116 075	
Leasehold Improvements		723 761		723 761		703 909		703 909		703 909	
Accumulated Depreciation		(630,856)		(672 454)		(508 231)		(376 494)		(344 971)	
Total Net Fixed Assets		570.193		759.904		820.069		726.324		738.116	
		,		,		,		- , -		, -	
Total Assets	\$	2,975,794	\$	3,175,406	\$	3,383,095	\$	3,055,609	\$	2,691,357	
LIABILITES AND NET ASSETS											
Current Liabilities											
Accounts Payable	\$	-	\$	82,373	\$	140,847	\$	88,347	\$	121,559	
Accrued Liabilities		107,565		103,744		80,695		79,435		86,618	
Due to RF and HESI for IFBiC Dissolution		293,699		-		-		-		-	
Deferred Revenue		11,315		102,343		86,498		94,645		116,134	
Total Current Liabilities		412,579		288,460		308,040		262,427		324,311	
Long-Term Liabilities											
Deposits - ILSI Entities		246,000		246,000		246,000		246,000		246,000	
Deferred Rent		827,961		833,414		891,432		932,650		959,595	
Total Long-Term Liabilities		1,073,961		1,079,414		1,137,432		1,178,650		1,205,595	
Total Liabilities		1,486,540		1,367,873		1,445,472		1,441,077		1,529,905	
Net Assets											
Beginning Balance		1,807,533		1,937,623		1,614,532		1,161,451		1,127,072	
Current Year Change		(318,279)		(130,090)		323,092		453,081		34,379	
Total Net Assets		1,489,254		1,807,533		1,937,623		1,614,532		1,161,451	
Total Liabilities and Net Assets	\$	2,975,794	\$	3,175,406	\$	3,383,095	\$	3,055,609	\$	2,691,357	
NET ASSETS - DETAIL											
Unrestricted Operations	\$	580 856	\$	681 148	\$	559 848	\$	418 355	\$	249 469	
Board-Designated Reserve	Ŧ	566.827	Ŷ	269.608	¥	268,446	Ŷ	264.897	Ŧ	256.466	
Strategic Planning		24,241						-			
Restricted Programs (PIP, GTF, Africa, Other)		108,585		107,907		151,425		38,850		-	
International Committees (Pre 09/2013)/Branches		208,746		748,871		957,905		892,430		655,516	
Total Net Assets	\$	1,489,254	\$	1,807,533	\$	1,937,623	\$	1,614,532	\$	1,161,451	
Current Assets Minus Current Liabilities (Liquidity) (2)	¢	1 066 644	¢	1 /02 297	¢	1 620 702	¢	1 /67 206	¢	1 0/2 02/	
Current Ratio <sup>(2)</sup>	Ψ	3.59	Ψ	6.18	φ	6.29	Ψ	6.59	Ψ	4.22	

<sup>(1)</sup> The 2013 balances are interim and have not been fully adjusted for all accrued revenues and expenses. All balances will be fully adjusted and reported on the 2013 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratios vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

#### Internal Financial Statement

INTERNATIONAL LIFE SCIENCES INSTITUTE		ILSI GC		COM	MUNICATION	S	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>			
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	
For the Nine Months Ended Sep 30, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	
	687 554	700 000	0.8%			NI/A			NI/A	687 554	700 000	0.8%	
COMMITTEE ASSESSMENTS	067,554	700,000	90% N/Δ	-	-	N/A N/Δ	-	-	IN/A N/Δ	067,554	700,000	90% N/A	
CONFERENCE/ REGISTRATION FEES	42 046	35,000	120%	_	_	N/A	_	_	N/A	42 046	35,000	120%	
CONTRIBUTIONS	65 000		N/A	-	-	N/A	-	-	N/A	65 000	-	N/A	
FEE FOR SERVICES	65,335	89.000	73%	-	-	N/A	-	-	N/A	65,335	89.000	73%	
SHARED SERVICES REIMBURSEMENT	-		N/A	-	-	N/A	-	-	N/A	-		N/A	
INVESTMENT AND OTHER INCOME	(6,005)	10,000	-60%	-	-	N/A	-	-	N/A	(6,005)	10,000	-60%	
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	253,823	306,300	83%	253,823	306,300	83%	
TOTAL REVENUE	853,930	834,000	102%			 N/A	253,823	306,300	83%	1,107,753	1,140,300	97%	
EXPENSES													
COMMUNICATIONS	6,451	9,360	69%	11,079	17,650	63%	709	1,365	52%	18,240	28,375	64%	
EINANCIAI /DDOEESSIONAL EEES	25 342	20 753	85%			N/A			N/A	25 342	20 753	85%	
TINANCIAL/FROMESSIONAL FEES	23,342	29,755	0570	-	-	19/7	-	-	11/21	23,342	29,733	0070	
GENERAL & ADMINISTRATIVE													
Shared Services Overhead	161,888	227,800	71%	-	-	N/A	-	-	N/A	161,888	227,800	71%	
Rent	67,858	87,467	78%	-	-	N/A	-	-	N/A	67,858	87,467	78%	
Depreciation	-	75,000	0%	-	-	N/A	-	-	N/A	-	75,000	0%	
Other Indirect Deimburgement	8,574	(542,456)	70%	4,073	10,500	45%	2,918	3,590	81%	10,105	25,390	64%	
indirect Reimbursement	(387,578)	(543,456)	71%	131,817	180,212	73%	78,393	106,224	74%	(177,368)	(257,019)	69%	
STAFFING													
Salaries	178,022	250,250	71%	120,052	161,480	74%	71,396	95,183	75%	369,470	506,914	73%	
Benefits	36,720	60,060	61%	26,411	38,755	68%	15,707	22,844	69%	78,839	121,659	65%	
Outside Services	1,436	400	359%	-	-	N/A	-	-	N/A	1,436	400	359%	
CONSULTANTS	20,843	14,100	148%	13,618	26,500	51%	-	-	N/A	34,460	40,600	85%	
IT SUPPORT SERVICES	-	-	N/A	20,000	50,000	40%	-	-	N/A	20,000	50,000	40%	
PUBLICATIONS	4,747	5,625	84%	8,245	15,000	55%	40,061	62,100	65%	53,053	82,725	64%	
MEETINGS													
Travel - Board	45 502	44 000	103%	_		N/A	_	_	NI/A	45 502	44 000	103%	
Travel - Staff	2 281	5 035	45%	6 826	7 500	91%	5 4 1 9	9 300	58%	14 527	21 835	67%	
Travel - Advisors/Speakers/Invitees	16 151	17 830	91%			N/A	2 013	2 800	72%	18 164	20,630	88%	
Group Functions/Business Meals	92.197	68.530	135%	391	1,500	26%	95	1.650	6%	92.683	71.680	129%	
Other Expenses (Audiovisual/Mgmt Fee)	46,332	39,510	117%	-	1,500	0%	-	-	N/A	46,332	41,010	113%	
SUBTOTAL MEETINGS	202,463	174,905	116%	7,218	10,500	69%	7,528	13,750	55%	217,208	199,155	109%	
OTHER PROGRAM EXPENSES	3,872	-	N/A	-	-	N/A	-	3,500	0%	- 3,872	- 3,500	111%	
		402 564			E10 E09			200 557			1 001 710		
TOTAL EXPENSES		402,564	02%		510,596	07%	210,712		70%			13%	
CHANGE IN NET ASSETS	523,291	431,436		(343,112)	(510,598)		37,110	(2,257)		217,289	(81,419)		
NET ASSETS, BEGINNING OF PERIOD	1,282,016	1,282,016		(1,344,339)	(1,344,339)		1,016,957	1,016,957		954,633	954,633		
NET ASSETS, END OF PERIOD	1,805,307	1,713,452		(1,687,451)	(1,854,937)		1,054,067	1,014,700		1,171,923	873,215		
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<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the overall financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTRICTED PROGRAMS			INT'L BRANCH ACTIVITY			IFBI	C COMMITTEE	SHAR	ED SERVICE	S				
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/
For the Nine Months Ended Sep 30, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENUE															
BRANCH/INSTITUTE ASSESSMENT	-	-	N/A	-	-	N/A	-		N/A	-	-	N/A	687,554	700,000	98%
COMMITTEE ASSESSMENTS	-	-	N/A	-	-	N/A	704,000	626,000	112%	-	-	N/A	704,000	626,000	112%
CONFERENCE/ REGISTRATION FEES			N/A	-	-	N/A	-	-	N/A	-	-	N/A	42,046	35,000	120%
CONTRIBUTIONS	94,000	96,000	98%	12,600	-	N/A	-	-	N/A	-	-	N/A	171,600	96,000	179%
FEE FOR SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	65,335	89,000	73%
SHARED SERVICES REIMBURSEMENT	-	-	N/A	-	-	N/A	-	-	N/A	1,033,341	1,455,035	71%	1,033,341	1,455,035	71%
INVESTMENT AND OTHER INCOME	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	(6,005)	10,000	-60%
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	253,823	306,300	83%
TOTAL REVENUE	94,000	96,000	98%	12,600	-	N/A	704,000	626,000	112%	1,033,341	1,455,035	71%	2,951,696	3,317,335	89%
EXPENSES															
COMMUNICATIONS	1 144	1 265	90%	137	215	64%	10 740	12 974	83%	36 713	42 100	87%	66 972	84 929	79%
	1,111	1,200	0070	107	210	0470	10,140	12,014	0070	00,710	42,100	0170	00,072	04,020	1070
FINANCIAL/PROFESSIONAL FEES	-	-	N/A	-	-	N/A	70	-	N/A	32,643	50,640	64%	58,055	80,393	72%
GENERAL & ADMINISTRATIVE															
Shared Services Overhead	_	-	N/A	-	-	N/A	-	-	N/A	-		N/A	161 888	227 800	71%
Rent	_	-	N/A	-	-	N/A	-	-	N/A	97 949	139 565	70%	165,807	227,032	73%
Depreciation			N/A			N/A	8 320	69 640	12%	57,545	17 830	0%	8 320	162 470	5%
Other	_	_	N/A	_	_	N/A	2 667	500	533%	125 325	176 500	71%	144 157	202,390	71%
Indirect Reimbursement	26,236	32,799	80%	4,231	10,121	42%	146,900	214,099	69%	-	-	N/A	-	- 202,000	N/A
STAFFING															
Salaries	23,895	31,119	77%	3,854	9,069	42%	133,789	191,845	70%	597,440	800,000	75%	1,128,447	1,538,947	73%
Benefits	5,257	7,469	70%	848	2,176	39%	29,434	46,043	64%	129,910	192,000	68%	244,288	369,347	66%
Outside Services	350	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	1,786	400	446%
	0.007						05.040		400/	10				o 4 <b>777</b>	000/
CONSULTANTS	3,997	-	N/A	-	-	N/A	25,913	54,177	48%	18	-	N/A	64,388	94,777	68%
IT SUPPORT SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	1,914	8,000	24%	21,914	58,000	38%
	2,400		N1/A			N1/A	40 722	42.024	1100/			NI/A	105 196	106 640	0.00/
PUBLICATIONS	2,400	-	N/A	-	-	N/A	49,733	43,924	113%	-	-	N/A	105,186	126,649	83%
MEETINGS															
Travel - Board	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	45 502	44 000	103%
Travel - Staff	3 382	5 000	68%	7 672	12 860	60%	9 361	1 700	551%	7 412	8 400	88%	42 353	49 795	85%
Travel - Advisors/Speakers/Invitees	990	2 370	42%	25.010	8 000	313%	131 668	153 426	86%	7,412	0,100	N/Δ	175 832	184 426	95%
Group Eurotions/Business Meals	1 324	2,570	265%	0.024	6,510	130%	27 605	6 500	126%	1 010	20.000	20%	134 746	105,420	128%
Other Exponence (Audiovisual/Mamt Eco)	1,524	1 265	205%	3,024	1 270	2020/	27,095	0,500	42070 NI/A	4,013	20,000	2070 NI/A	52 974	42 745	120 /0
Other Expenses (Audiovisual/Night Fee)				2,704		203%		-	IN/A	-		IN/A		43,745	12170
SUBTOTAL MEETINGS	5,696	9,235	62%	44,490	28,740	155%	172,482	161,626	107%	11,431	28,400	40%	451,307	427,156	106%
OTHER PROGRAM EXPENSES	20,476	27,500	74%	-	13,500	0%	623,111	7,517	8289%	-	-	N/A	647,459	52,017	1245%
TOTAL EXPENSES	89 451	109.387		53 560	63 821		1 203 158	802 345	150%	1 033 341	1 455 035	71%	3 269 973	3 652 307	
			3270			0170						. 170			2370
CHANGE IN NET ASSETS	4,549	(13,387)		(40,960)	(63,821)		(499,158)	(176,345)		-	-		(318,279)	(334,972)	
NET ASSETS, BEGINNING OF PERIOD	104,036	104,036		249,706	249,706		499,158	499,158		-	-		1,807,533	1,807,533	
NET ASSETS, END OF PERIOD	108,585	90,649		208,746	185,885			322,813					1,489,254	1,472,561	
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INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			CO	MMUNICATIO	NS	I	LSI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>			
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	2014	2013	2013	2014	2013	2013	2014	2013	2013	2014	
2013 Projection / 2014 Budget	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	
REVENUE													
BBANCH/INSTITUTE ASSESSMENT	740 000	700 000	740 000	-	-	-	-	-		740 000	700 000	740 000	
COMMITTEE ASSESSMENTS	-	-	-	-	-	-	-	-	-	-		-	
CONFERENCE/ REGISTRATION FEES	42,046	35,000	35,000	-	-	-	-	-	-	42,046	35,000	35,000	
CONTRIBUTIONS	95,000	-	-	-	-	-	-	-	-	95,000	-	-	
FEE FOR SERVICES	87,068	89,000	87,068	-	-	-	-	-	-	87,068	89,000	87,068	
SHARED SERVICES REIMBURSEMENT	-	-	-	-	-	-	-	-	-	-	-	-	
	-	10,000	-	-	-	-	-	-	-	-	10,000	-	
PUBLICATIONS - NUTRITION REVIEWS	-	-	-	-	-	-	307,852	306,300	307,852	307,852	306,300	307,852	
TOTAL REVENUE	964,114	834,000	862,068		-	-	307,852	306,300	307,852	1,271,966	1,140,300	1,169,920	
EXPENSES													
COMMUNICATIONS	7,862	9,360	6,640	14,300	17,650	14,300	2,350	1,365	2,350	24,512	28,375	23,290	
FINANCIAL/PROFESSIONAL FEES	30.873	29.753	31.900	-	-	-	-	-	-	30.873	29.753	31.900	
		,	,							,		,	
GENERAL & ADMINISTRATIVE													
Shared Services Overhead	197,400	227,800	127,000	-	-	-	-	-	-	197,400	227,800	127,000	
Rent	77,790	87,467	47,146	-	-	-	-	-	-	77,790	87,467	47,146	
Depreciation	37,547	75,000	24,621	-	-	-	-	-	-	37,547	75,000	24,621	
Other	9,515	11,300	9,520	10,500	10,500	6,000	4,068	3,590	4,580	24,083	25,390	20,100	
Indirect Reimbursement	(465,231)	(543,455)	(290,908)	174,170	180,212	145,905	105,485	106,224	109,142	(185,576)	(257,019)	(35,861)	
STAFFING													
Salaries	239,387	250,250	249,744	156,066	161,480	130,739	94,521	95,183	97,797	489,974	506,913	478,280	
Benefits	57,453	60,060	59,938	37,456	38,755	31,377	22,685	22,844	23,471	117,594	121,659	114,787	
Outside Services	1,436	400	1,400	-	-	-	-	-	-	1,436	400	1,400	
					~~ ~~					10 100			
CONSULTANTS	22,100	14,100	10,550	26,000	26,500	36,500	-	-	-	48,100	40,600	47,050	
IT SUPPORT SERVICES	-	-	-	30,000	50,000	50,000	-	-	-	30,000	50,000	50,000	
				,						,			
PUBLICATIONS	4,750	5,625	4,750	10,000	15,000	15,000	62,100	62,100	67,100	76,850	82,725	86,850	
MEETINGS	50.005	44.000	40.000							50.005		40.000	
Travel - Board	50,205	44,000	46,000	- 7 000	7 500	-	- 0.010		-	50,205	44,000	46,000	
Travel - Stall	1,020	5,035	1,122	7,000	7,500	4,000	0,212	9,300	9,005	17,032	21,035	14,727	
Group Eulerions/Business Meals	17,740	68 530	14,404	500	1 500	1 000	2,013	2,800	2,500	19,701	20,630	84 075	
Other Expenses (Audiovisual/Mamt Fee)	32,232 46 706	39,510	47 650	500	1,500	1,000	230	1,000	750	32,302 46 706	11,000	47 650	
										40,790			
SUBTOTAL MEETINGS	208,802	174,905	191,581	7,500	10,500	5,000	10,475	13,750	12,923	226,777	199,155	209,504	
	2.070							2 500		0.070	0.500	-	
OTHER PROGRAM EXPENSES	3,872	-	-	-	-	-	-	3,500	-	3,872	3,500	-	
TOTAL EXPENSES	433,555	402,565	473,882	465,992	510,597	434,821	301,684	308,556	317,364	1,201,231	1,221,718	1,226,067	
CHANGE IN NET ASSETS	530,559	431,435	388,187	(465,992)	(510,597)	(434,821)	6,168	(2,256)	(9,512)	70,736	(81,418)	(56,146)	
	1 282 016	1 282 016	1 812 575	(1 344 320)	(1 344 320)	(1 810 321)	1 016 057	1 016 057	1 023 125	054 622	054 622	-	
NET AGE IS, BEGINNING OF FERIOD	1,202,010		1,012,075	(1,344,339)	(1,344,339)						904,033		
NET ASSETS, END OF PERIOD	1,812,575	1,713,451	2,200,762	(1,810,331)	(1,854,936)	(2,245,152)	1,023,125	1,014,701	1,013,614	1,025,369	873,215	969,222	

INTERNATIONAL LIFE SCIENCES INSTITUTE	RESTRIC	TED (PIP, GTF	, Africa)	INT'L BR	ANCH ACT	IVITY	IFBI	C COMMITTE	E	SHA	RED SERVIC	ES		TOTAL	
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	2014	2013	2013	2014	2013	2013	2014	2013	2013	2014	2013	2013	2014
2013 Projection / 2014 Budget	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET	PROJECTION	BUDGET	BUDGET
REVENUE															
BRANCH/INSTITUTE ASSESSMENT	-	-	-	-	-	-	-	-	-	-	-	-	740,000	700,000	740,000
COMMITTEE ASSESSMENTS	-	-	-	-	-	-	704,000	626,000	-	-	-	-	704,000	626,000	-
CONFERENCE/ REGISTRATION FEES	-	-	-	-	-	-	-	-	-	-	-	-	42,046	35,000	35,000
CONTRIBUTIONS	106,000	96,000	168,000	12,600	-	12,600	-	-	-	-	-	-	213,600	96,000	180,600
	-	-	-	-	-	-	-	-	-	-	-	-	87,068	89,000	87,068
	-	-	-	-	-	-	-	-	-	1,436,624	1,455,035	1,494,100	1,436,624	1,455,035	1,494,100
	-	-	-	-	-	-	-	-	-	-	-	-	207.952	10,000	207.952
PUBLICATIONS - NOTRITION REVIEWS	-	-	-	-	-	-	-	-	-	-	-	-	307,052	300,300	307,052
TOTAL REVENUE	106.000	96.000	168.000	12.600	-	12.600	704.000	626.000	-	1.436.624	1.455.035	1.494.100	3.531.190	3.317.335	2.844.620
	,		,	,		,	. ,	,		,,-	,,	, - ,	-,,	-,,-	,- ,
EXPENSES															
COMMUNICATIONS	1,555	1,265	1,555	160	215	160	10,740	12,974	-	51,850	42,100	42,000	88,817	84,929	67,005
FINANCIAL/PROFESSIONAL FEES	-	-	-	-	-	-	70	-	-	56,040	50,640	56,700	86,983	80,393	88,600
GENERAL & ADMINISTRATIVE															
Shared Services Overhead	-	-	-	-	-	-	-	-	-	-	-	-	197,400	227,800	127,000
Rent	-	-	-	-	-	-	-	-	-	132,200	139,565	143,700	209,990	227,032	190,846
Depreciation	-	-	-	-	-	-	8,320	69,640	-	23,300	17,830	18,000	69,166	162,470	42,621
Other	-	-	-	-	-	-	2,667	500	-	187,334	176,500	165,000	214,084	202,390	185,100
Indirect Reimbursement	33,315	32,799	30,539	5,361	10,121	5,323	146,900	214,099	-	-	-	-	-	-	-
STAFFING															
Salaries	29,852	31,119	27,364	4,804	9,069	4,770	133,789	191,845	-	784,000	800,000	840,000	1,442,418	1,538,946	1,350,414
Benefits	7,164	7,469	6,567	1,153	2,177	1,145	29,434	46,043	-	185,000	192,000	202,000	340,345	369,347	324,499
Outside Services	350	-	-	-	-	-	-	-	-	-	-	-	1,786	400	1,400
	00.000						05.040	- 4					04.040	o 4 777	17.050
CONSULTANTS	20,000	-	-	-	-	-	25,913	54,177	-	-	-	-	94,013	94,777	47,050
										2 000	8 000	0.000	22.000	59 000	50.000
II SUFFORT SERVICES	-	-	-	-	-	-	-	-	-	2,000	8,000	9,000	32,000	56,000	59,000
	2 400	_	_	_	_	-	40 733	43 924		_	_	_	128 083	126 649	86 850
I OBLICATIONS	2,400	-	-	-	-	-	45,755	40,924	-	-	-	-	120,905	120,045	00,000
MEETINGS															
Travel - Board	_	_	-	_		_	_	_	-	_	-	_	50 205	44 000	46 000
Travel - Staff	8 374	5 000	5 000	7 672	12 860	7 800	9 361	1 700		7 400	8 400	10 000	49,839	49 795	37 527
Travel Advisors/Speakers/Invitees	0,074	2 370	2 200	25.010	8 000	25,000	131 668	153 426	_	7,400	0,400	10,000	177 / 20	184 426	44 252
Group Eurotions/Business Meals	1 324	2,570	2,200	20,010	6,000	23,000	27 605	6 500	-	7 500	20,000	7 700	138 527	104,420	101 075
Other Expenses (Audiovisual/Mart Eco)	1,524	1 265	1,000	3,020	1 270	0,900	27,033	0,500	-	7,500	20,000	7,700	52 229	42 745	51 710
Other Expenses (Audiovisual/Might Fee)	-	1,305	1,200	2,704	1,370	2,000	3,750	-	-	-	-	-	53,336	43,745	51,710
SUBTOTAL MEETINGS	10 688	9 235	9 700	44 492	28 740	44 560	172 482	161 626	-	14 900	28 400	17 700	469.338	427 156	281 464
	10,000	0,200	0,100	,	20,110	,000		.01,020		11,000	20,100	,	100,000	,	201,101
OTHER PROGRAM EXPENSES	75,091	27,500	5,000	13,500	13,500	13,500	623,111	7,517	-	-	-	-	715,574	52,017	18,500
TOTAL EXPENSES	180,415	109,387	80,725	69,470	63,822	69,457	1,203,158	802,344	-	1,436,624	1,455,035	1,494,100	4,090,898	3,652,306	2,870,349
CHANGE IN NET ASSETS	(74,415)	(13,387)	87,275	(56,870)	(63,822)	(56,857)	(499,158)	(176,344)	-	-	-	-	(559,707)	(334,971)	(25,729)
NET ASSETS, BEGINNING OF PERIOD	104,036	104,036	29,621	249,706	249,706	192,836	499,158	499,158	-	-	-	-	1,807,533	1,807,533	1,247,826
		00.040	440.005	400.000	405.004	405.070							4 0 4 7 0 0 0	4 470 500	4 000 007
INET ASSETS, END OF PERIOD	29,621	90,649	116,895	192,836	185,884	135,979		322,813	-		-	-	1,247,826	1,472,562	1,222,097
	<b>-</b>														

#### ILSI Board of Trustees Financial Oversight Committee

### Conference Call Wednesday, July 25, 2013

#### **DRAFT MINUTES**

#### I. Welcome and Review of Agenda

Dr. Liz Westring, ILSI Treasurer and Chair of the ILSI Board of Trustees Financial Oversight Committee, began the conference call at approximately 9:00 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated: Dr. Sushila Chang, Dr. Jay Goodman, Dr. Gerhard Eisenbrand, Dr. Joanne Lupton, Ms. Beth-Ellen Berry, and Dr. Suzie Harris. The following guests participated for portions of the conference call: Ms. Audrey Newton and Mr. Paul Preziotti , with Johnson Lambert, and Mr. Mark Murphy and Mr. Dennis Gogarty, with Raffa Wealth Management.

Dr. Westring review the agenda (attached). No changes were offered.

### II. Approval of Minutes from the April 25, 2013 Conference Call

The minutes were approved as distributed.

### III. 2012 Audit Report – Johnson Lambert

Ms. Newton called attention to the two audit reports and two letters that were circulated to the committee prior to the conference call. The 2012 audit was conducted in two phases, with the first being the planning phase. Ms. Newton said that no changes were made to the plan developed in the earlier phase and that the final report represents where the audit ended up. The ILSI report looks somewhat different because of a sweeping update of auditing standards that was recently completed. Many of the audit report headers have changed as a result of the updates. She also stated that her team used judgment in the audit process, but the procedures are based on risk assessment. Ms. Newton specifically called attention to the last paragraph on page 2, in which ILSI is given a "qualified opinion." She emphasized that nothing is wrong in the report. Because ILSI is related to the ILSI Research Foundation (ILSI elects the ILSI Research Foundation Board of Trustees), the newly revised audit standards require that the financial situation for both organizations be presented in a combined report, which was done. According to the new auditing standards, it is no longer appropriate to present the ILSI audit as a stand-alone report. Ms. Berry noted that for future reports she will find others ways to present the data, e.g., one consolidated report with supplemental statements for each entity.

Dr. Westring asked if the ILSI Financial Oversight Committee should do more to review the financial reports for the ILSI Research Foundation. Ms. Berry indicated that while she did not think so, she would work with Mr. Shawn Sullivan, ILSI General Counsel, to address this question. It will depend on the specific charter for the ILSI Board of Trustees Financial Oversight Committee.

Next Ms. Newton reviewed the Statements of Financial Position, beginning with the cash and cash equivalents which were confirmed by reconciling the ILSI records with those of the outside custodians of the funds. The same process was used to reconcile the value of the investments held by external

vendors. These were assigned a fair market value. Next the auditors check the contributions receivable balance and the payments received. For liabilities, the audit team reviewed these and tested the accuracy of some of the liabilities. They also tested the assignment of liabilities to 2012 and 2013 to ensure these assignments were accurate. In terms of net assets, those listed as unrestricted were tested to determine if they were in fact unrestricted. The same was done for net assets that were listed as temporarily restricted.

The Statements of Activities are on pages 4 and 5 of the 2012 audit report and provide the same information as in the 2011 report, but in different formats. Ms. Berry requested the change in format to show the temporarily restricted net assets in a separate column. In the 2011 report, a single column format was used for both unrestricted and temporarily restricted which she felt wasn't as clear. ILSI's revenue and expenses were tested to ensure that the appropriate approval process was followed and that the individual entries were correctly classified. The auditor conducted an analytical analysis for trends and reviewed the minutes of the ILSI Board of Trustees and Financial Oversight Committee. The auditors also reviewed contracts for executives, when they existed.

Page 6 of the audit provides more detail on expenses using the natural accounts, but the totals tie back to the Statements of Activities. On page 7 is the Statements of Cash Flows which gives details of the changes in the operating cash balance. Ms. Newton pointed out that the increased activity in the 2012 cash flows from investing activities was due to the change in investment custodians in 2012.

Mr. Preziotti reviewed the notes to the financial statement. Note A covers the accounting policies and there were no changes from the prior year. Note B covers investments and how they are categorized in terms of priority for determining fair market value. In 2011, all of the ILSI investments were in Certificates of Deposit. In 2012, these had been diversified. The classification by level does not say anything about the quality or risk of the investment.

Note C lists property and equipment. Note D lists the related party transactions among the ILSI entities co-located together in the Washington office (pp 13-15). Note E lists temporarily restricted net assets, which are donor restricted and specifically calls attention to the move from the ILSI International Organizations Committee (IOC) to the ILSI Platform for International Partnerships (PIP). Note F describes the foundation's pension plan. Note G states ILSI's existing commitments, e.g., office lease and annual meeting hotel contracts. These notes are all similar in format to the 2011 audit report.

Ms. Newton reviewed the consolidated audit for ILSI and affiliates, meaning the ILSI Research Foundation calling attention to differences compared to the ILSI stand-alone audit. The opinion on the "Report of Independent Auditor" page is unqualified. The assets shown on page 2 in the consolidated statements of financial position are greatly increased because of the Research Foundation investments.

Note B on page 12 shows the composition of ILSI's and the Research Foundation's investments. Note E, on page 15, shows much more restricted funds, most of which belong to the Research Foundation. Two new notes appear on page 17, both relating to the Research Foundation. Note H lists contributions receivable related to the Research Foundation's multi-year agreement with CLI (CropLife International). Note I describes an in-kind contribution that was made to the Center for Integrated Modeling of Sustainable Agriculture and Nutrition Security (CIMSANS), part of the Research Foundation.

Ms. Newton reviewed the Board Communication Letter which states that ILSI is using appropriate accounting practices and no changes are needed. No new policies are required either. The letter calls

attention to several notes (B, D, & E) in the audit report that involve management judgment. A new paragraph is included on related party transactions. This is an area of increased focus for auditors under the revised auditing standards.

Regarding the paragraphs dealing with significant difficulties in performing the audit and disagreements with management, Ms. Newton stated that should this have happened, the committee would have been notified immediately. No audit adjustments were identified. The ILSI control structure is very sound and the management very cooperative.

Johnson and Lambert does ask to be notified if ILSI submits the audit report to a third party. The letter ends with the auditors stating that they are independent.

The internal control letter is also known as the "no material weakness" letter. It states that the ILSI has a very solid internal control environment and these controls are operating as designed. Ms. Newton said that Ms. Berry does a great job throughout the year keeping the auditors informed about changes and new plans that impact accounting.

Dr. Westring thanked the auditors for the reports and congratulated Ms. Berry and her staff for their excellent work.

### IV. ILSI Reserve Fund Performance Report -- Raffa Wealth Management

Mr. Murphy and Mr. Gogarty presented the portfolio review for the Board Designated Reserve. This report and one for the Operating Reserve were distributed to the committee prior to the conference call. As the two funds are invested in the same financial products, only one of the two reports was actually described. \$300,000 from what had been called the ILSI Press Fund is now part of the Board Designated Reserve, bringing the value at the end of June to \$564,907.

Mr. Murphy reminded the committee that Raffa has not led the committee through a formal risk tolerance assessment process. He also said the Federal Reserve had been the major driver of the financial market during the second quarter. As a result of Federal Reserve Chairman's statements about the likely winding down of buying of bonds, there was high volatility in US and international stock markets and interest rates spiked. The actual versus targeted allocations are presented on page 3. The actual allocation is in line with the targeted allocation. Page 4 gives the performance summary and shows a decline of about \$5600 over the second quarter as a result of rising interest rates. In July, the bond market settled down and the portfolio has seen an increase of \$1100 form income and capital appreciation. Using the asset class performance to benchmark comparison, short term bonds are doing slightly better than the benchmark.

Dr. Westring thanked the Raffa representatives for their report.

### V. Review of 2013 Year-to-date Financial Report

Dr. Harris reminded the committee that the ILSI International Food Biotechnology Committee (IFBiC) is discussing moving the majority of its programs and funding to the ILSI Research Foundation. If this move goes through, the ILSI budget will be impacted in two ways. First, IFBiC pays a portion of the expenses associated with the ILSI Board of Trustees and the ILSI Executive Director. This portion for 2013 is approximately \$80,000. So ILSI will need to find ways to offset the loss of this income to ILSI

Governance and Coordination (GC). The second impact will be on cash flow within ILSI. IFBiC maintained a fairly large cash balance, allowing ILSI additional flexibility. Without these funds, Ms. Berry will need to closely monitor ILSI's cash needs. This may mean that ILSI may not be able to maintain reserves at the amount targeted in the new reserve policy.

Ms. Berry began with the balance sheet, noting that ILSI remains very liquid. Liabilities are in line with expectations.

In terms of the Functional Activity Statement for ILSI GC, Ms. Berry noted that branch assessments for 2013 are being invoiced. To date there are no surprises in the amounts being invoiced. She called attention to the \$35,000 in contributions that were donated for the ILSI strategic planning process. Some of these funds will be used to off-set the cost of the face-to-face strategic planning meeting on July 24-25. The ILSI GC expenses are in line with the 2013 budget, with the exception of higher than budgeted expenses for the 2013 ILSI Annual Meeting. In terms of other unrestricted functions, the communications expense is at 47 percent of budget and the ILSI Press expenses are at 45 percent of budget. Ms. Berry said that it will be the end of 2013 before ILSI will be notified if Wiley will pay extra royalties.

Ms. Berry also reviewed the restricted functions. The ILSI Platform for International Partnerships is still collecting contributions for 2013. The ILSI Focal Point in China's revenue and expenses are as expected. Part of the IFBiC resources is un-depreciated fixed assets (Crop Composition Database) of approximately \$300,000. These assets will be transferred to the ILSI Research Foundation, if IFBiC agrees to move. The Shared Services Group expenses are at 46 percent of budget.

Dr. Goodman noted that while the current financial situation was okay, ILSI will need to increase unrestricted revenue in the future to support the strategic planning responsibilities.

### VI. New Business

None was offered.

### VII. Next Steps

- A third conference call will need to be scheduled in October or November to review the third quarter financial data and the proposed 2014 budget.
- Ms. Berry will check with Mr. Sullivan regarding the committee's responsibility, if any to review the ILSI Research Foundation's financial statements.
- Ms. Berry will work with the auditors to identify the most appropriate way to present the ILSI audit.

#### VIII. Adjournment

As there was no further business, Dr. Westring ended the conference call at approximately 10:30 a.m. Eastern Daylight Time.

Signed:	Date:

### ILSI Board of Trustees Financial Oversight Committee

### **Conference Call**

Wednesday, July 24, 2013 9:00 – 10:30 am Eastern Daylight Time

### AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the April 25, 2013 Conference Call
- III. 2012 Audit Report Johnson Lambert
- IV. ILSI Reserve Fund Performance Report Raffa Wealth Management
- V. Review of 2013 Year-to-date Financial Report
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

### Tuesday, November 5, 2013 9:00 – 10:30 am Eastern Standard Time

### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the July 24, 2013 Conference Call
- III. Review of 2013 Year-to-date Financial Report
- IV. ILSI Reserve Fund Performance Report Raffa Wealth Management
- V. Review of 2013 Year-end Projection and Proposed 2014 Budget
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

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From:	Suzanne Harris	>	
Sent:	Tuesday, October 29, 2	013 3:12 PM	
То:		;	; Joanne Lupton; Geoff
		); Flavio Zambro	one
Cc:		Chelsea	L. Bishop; Shawn Sullivan; Beth
	Brueggemeyer		
Subject:	Agenda, briefing mater	rials and dial-in inst	ructions for the ILSI Nomination Review
	Committee conference	call on Monday, N	ovember 4, 2013, 9:00 a.m. EST
Attachments:	NRC 2013-11-04 Agend	da.doc; 2014 Nomi	nees for the ILSI Board of Trustees.doc; 2013
	ILSI Board Member Ter	ms.doc; NRC 2013-	-09-30 minutes.docx; 2014 ILSI Executive
	Committee.doc; ILSI NA	A Nomination to ILS	SI Board

#### Re-sending with bio for Dr. Doyle

TO: ILSI Board of Trustees Nomination Review Committee

FROM: Suzie Harris

The second conference call for the ILSI Nomination Review Committee is scheduled for **Monday, November 4, 2013, beginning at 9:00 a.m. Eastern Standard Time.** Please note that the United States returns from daylight savings time to standard time on Sunday, November 3 (fall back one hour). The conference call will not last longer than one hour.

The proposed agenda for the conference call is attached here:

Agenda Item II. Draft minutes from the September 30, 2013 conference call

Agenda Item III. List of candidates submitted by the branches – Plus bio for Dr. Doyle

Agenda Item V. 2014 ILSI Executive Committee

Agenda Item VI. 2014 Nominees for the ILSI Research Foundation Board of Trustees

Two have been agreed to: Dr. Takeshi Kimura and Dr. Michael Knowles; one more is in the works.

Dr. Phil Guzelian will not be re-nominated.

#### **Dial-In Instructions**

If you are calling from:	Please dial:
Brazil	0-800-890-0288, then dial 888-706-6468; <b>or</b> 0-800-888-8288, then dial 888-706-6468
Singapore	800-110-1778

Switzerland0-43-5579014 - caller paidUnited Kingdom0808-234-3676United States of<br/>America1-888-706-6468

The access code for everyone is 4498699 #.

Let me know if you will be in another country, so that I can send you the toll free number for that country.

Please let me know if you have any questions.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on: \_

From: Sent: To: Cc: Subject: Sharon Weiss Tuesday, September 17, 2013 1:23 PM Suzanne Harris Beth Brueggemeyer ILSI NA Nomination to ILSI Board

Suzie:

The ILSI NA Nominating Committee held its first meeting earlier today and agreed to nominate Dr. Michael Doyle as the person suggested to fill the vacancy on the ILSI Board created by the resignation of Dr. Janet King earlier this year. We understand, that the term would expire in January 2015. Below is the most recent biosketch we have for Mike.

Sharon

**Dr. Michael P. Doyle** is regent's professor and director, Center for Food Safety, University of Georgia. A native of Madison, Wisconsin, he received his B.S., M.S., and Ph.D. degrees from the University of Wisconsin in bacteriology/food microbiology. From 1977 to 1980 he was senior project leader of corporate microbiology at Ralston Purina Company, and from 1980 to 1991 he advanced from assistant professor to Wisconsin Distinguished Professor of Food Microbiology, Food Research Institute,

University of Wisconsin--Madison. He has published more than 500 scientific papers on food microbiology and food safety topics and has received several awards for his research accomplishments, including the Nicholas Appert Award of the Institute of Food Technologists. He is a fellow of the American Academy of Microbiology, the American Association for the Advancement of Science, the Institute of Food Technologists and the International Association for Food Protection, and is a member the Institute of Medicine of the National Academies.

Sharon Weiss, MS, CAE Deputy Executive Director ILSI North America 1156 Fifteenth Street, NW, Suite 200 Washington, DC 20005 202-659-0074, ext 119

### ILSI Board of Trustees Nomination Review Committee

### **Conference Call**

## November 4, 2013 9:00 – 10:00 Eastern Standard Time

### Agenda

- I. Welcome and Opening Remarks
- II. Review of Minutes from the September 30, 2013 Conference Call
- III Review of Nominations for the ILSI Board of Trustees
- IV. Discussion of Nominees for ILSI Vice Chair and Treasurer
- V. Discussion of Nominees for the At-Large Seats on the ILSI Executive Committee
- VI. Review of Nominees for the Research Foundation Board of Trustees
- VII. Next Steps
- VI. Adjournment

From: Sent: To: Cc: Subject: Sharon Weiss Tuesday, September 17, 2013 1:23 PM Suzanne Harris Beth Brueggemeyer ILSI NA Nomination to ILSI Board

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Sharon

**Dr. Michael P. Doyle** is regent's professor and director, Center for Food Safety, University of Georgia. A native of Madison, Wisconsin, he received his B.S., M.S., and Ph.D. degrees from the University of Wisconsin in bacteriology/food microbiology. From 1977 to 1980 he was senior project leader of corporate microbiology at Ralston Purina Company, and from 1980 to 1991 he advanced from assistant professor to Wisconsin Distinguished Professor of Food Microbiology, Food Research Institute,

University of Wisconsin--Madison. He has published more than 500 scientific papers on food microbiology and food safety topics and has received several awards for his research accomplishments, including the Nicholas Appert Award of the Institute of Food Technologists. He is a fellow of the American Academy of Microbiology, the American Association for the Advancement of Science, the Institute of Food Technologists and the International Association for Food Protection, and is a member the Institute of Medicine of the National Academies.

Sharon Weiss, MS, CAE Deputy Executive Director ILSI North America 1156 Fifteenth Street, NW, Suite 200 Washington, DC 20005 202-659-0074, ext 119

#### **ILSI Board of Trustees Nomination Review Committee**

#### Conference Call Monday, September 30, 2013

#### **DRAFT MINUTES**

#### I. Welcome and Opening Remarks

Dr. Peter van Bladeren, Chair, ILSI Board of Trustees Nomination Review Committee, began the conference call at approximately 9:00 a.m. Eastern Daylight Time. In addition to Dr. van Bladeren, the following trustees and staff participated in the conference call: Dr. Alan Boobis, Dr. Joanne Lupton, Mr. Geoff Smith, Dr. Flávio Zambrone, Dr. Suzie Harris and Mr. Shawn Sullivan.

Dr. van Bladeren welcomed the members of the committee and thanked them for agreeing to serve in this important activity.

The agenda for the conference call is attached.

#### II. Review of Committee Responsibilities

At Dr. van Bladeren's request, Dr. Harris reviewed the charge to the committee which includes:

- Reviewing and approving nominees for the ILSI Board of Trustees
- Reviewing and approving nominees for the ILSI Research Foundation Board of Trustees
- Nominating candidates for Chair, Vice Chair, and Treasurer of the ILSI Board of Trustees, as well as nominating candidates for the at-large seats on the ILSI Executive Committee.

#### III. Process for Nominating ILSI Trustees and ILSI Research Foundation Trustees

a. Review of board seat allocation evaluation – Dr. Harris reviewed the make-up of the 31-member ILSI Board of Trustees, which is described in detail in Article IV, section 3(b) of the ILSI bylaws. The calculation of the 16 proportionally allocated seats was distributed to the committee prior to the call. Dr. Harris reviewed the steps in the calculation and noted that the results for 2014 indicate that no change in the allocation of these seats is necessary.

Action: The members of the Nomination Review Committee agreed with the proportional allocation results.

b. Review of expired terms on the ILSI Board of Trustees – A list of the current members of the ILSI Board of Trustees with the names of the trustees whose three-year terms will expire in January 2014 highlighted was circulated to the committee prior to the conference call. They are: Dr. Sushila Chang, Prof. Gerhard Eisenbrand, Dr. Jay Goodman, Dr. Ik Boo Kwon, and Dra. Sara Valdés. Dr. Janet King resigned from the Board in mid-2013, so her seat also needs to be filled.

The branches to which each of these seats is allocated have been notified that the individual's term is up or that the trustee resigned. The branch(es) may re-nominate the individual or select someone else who qualifies for the seat, meaning that they are either qualified for a public or private sector seat. Dr. Harris asked that the branch nominations be submitted by October 15, 2013. If a new person (one not currently serving on the ILSI Board of Trustees is nominated, the branch(es) will be asked to provide a bio for the individual so that the ILSI Nomination Review Committee may use it to determine the suitability of the nominee for the seat.

In January 2013, the ILSI Assembly of Members elected Dr. Rhona Applebaum as the 32<sup>nd</sup> member of the ILSI Board of Trustees, which is allowed under the bylaws (Article IV, section 1) on an annual basis. So if she is to remain a member of the Board, she will need to be re-nominated because none of the private sector seats assigned to ILSI North America is open.

Nominations may also be made by any member of the ILSI Board of Trustees. The committee will review all nominations, using the criteria for public trustees as a guide for those being considered as public trustees. The committee will then submit the names of the approved candidates to the ILSI Assembly of Members for election.

c. Review of expired terms on the ILSI Research Foundation Board of Trustees – A list of the current members of the ILSI Research Foundation Board of Trustees with the names of the trustees whose three-year terms will expire in January 2014 highlighted was circulated to the committee prior to the conference call. These individuals are: Dr. Phil Guzelian, Dr. Takeshi Kimura, and Dr. Michael Knowles. The ILSI Research Foundation Board of Trustees Nominating Committee will select candidates for these three seats either by re-nominating existing trustees or selecting new candidates. These names will be submitted to the ILSI Board of Trustees Nomination Review Committee.

The ILSI Board of Trustees Nomination Review Committee will review the submission and decide on a slate of candidates to present to the ILSI Board of Trustees. The ILSI Board elects the ILSI Research Foundation trustees.

### IV. Discussion of Process for Selecting Nominees for ILSI Chair, Vice Chair, Treasurer, and Atlarge Members of the ILSI Executive Committee

A list of the current membership of the ILSI Executive Committee (officers and at-large members) was circulated to the committee prior to the call. The officers of the Board serve two-year terms. In January 2014, the term of the current Chair, Dr. Sam Cohen; current Vice Chair, Dr. John Milner; and current Treasurer, Dr. Liz Westring, will expire.

The ILSI Board of Trustees adopted a succession plan for the ILSI President and Chair which calls for the Nomination Review Committee to decide if the Vice President and Vice Chair are qualified to move into the President and Chair positions, respectively, when each of these office terms expire.

Action: The committee members unanimously agreed that Dr. Milner should be nominated for the office of Chair of the ILSI Board of Trustees.

For the position of Vice Chair the committee reviewed the list of possible candidates, public trustees. It was suggested that the current executive committee had a number of North American trustees and that selecting a Vice Chair from another region should be considered. Dr. Boobis agreed to ask Dr. Lewis Smith if he would be interested in serving. Dr. Boobis was also suggested as a possible Vice Chair as was Dr. Zambrone. Dr. Connie Weaver was suggested as well, though she is a North American trustee. The committee agreed to discuss nominees for this office further during the next committee conference call.

Action: The committee members unanimously agreed to re-nominate Dr. Westring for the position of Treasurer.

The at-large seats on the executive committee are elected annually. Dr. Harris described the understanding reached in 2004 that the following branches will have representation on the ILSI Board of Trustees Executive Committee – ILSI Europe (currently represented by Dr. Gert Meijer in an at-large seat), ILSI HESI (currently represented by Dr. Sam Cohen whose term as Chair expires), ILSI Japan (currently represented by Dr. Kuwata in an at-large seat), and ILSI North America (currently represented by the ILSI President (Dr. Jerry Hjelle), Vice Chair (Dr. Milner) and Treasurer (Dr. Westring).

The number of public trustees on the executive committee must be equal to or greater than the number of industry trustees. For this reason of public-private trustees balance, Dr. Marion Ehrich, an ILSI Research Foundation representative to the ILSI Board of Trustees is currently an at-large member. In 2011, the ILSI Nomination Review Committee agreed that the ILSI Research Foundation should always be represented on the ILSI Executive Committee and by a public trustee. The other two branch regions are also currently represented on the executive committee – Dra. Sara Valdés as the secretary, from the Latin American region, and Mr. Geoff Smith, an at-large member from the Asia-Pacific South region.

Dr. van Bladeren noted that under the new One ILSI strategy the ILSI Executive Committee will be given more responsibility and there is interest in having the major branch leaders serve on the committee.

The committee agreed to wait until more is known about who will be nominated to the ILSI Board of Trustees before trying to sort through the at-large seats on the executive committee.

### V. Next Steps

- Dr. Harris will confirm with Dr. Milner and Dr. Westring that they are willing to be nominated for the offices of Chair and Treasurer, respectively.
- Dr. Harris will collect nominees for the ILSI Board of Trustees and the ILSI Research Foundation Board of Trustees and circulate these to the committee prior to the next committee conference call.
- Committee members will consider who should be nominated as the Vice Chair
- The next committee conference call will be schedule for after October 15, which is the deadline for nominations for the ILSI Board of Trustees.

#### VI. Adjournment

As there was no further business, Dr. van Bladeren ended the conference call at 9:40 a.m. Eastern Daylight Time.

Cianadi	Data
Signed:	Date:

### ILSI Board of Trustees Nomination Review Committee

### **Conference Call**

### September 30, 2013 9:00 – 10:00 Eastern Daylight Time

### Agenda

- I. Welcome and Opening Remarks
- II. Review of Committee Responsibilities
- III Process for Nominating ILSI Trustees and ILSI RF Trustees
  - a. Review of board seat allocation evaluation
  - b. Review of expired terms on the ILSI Board of Trustees
  - c. Review of expired terms on the ILSI Research Foundation Board of Trustees
- IV. Discussion of Process for Selecting Nominee for ILSI Chair, Vice Chair, Treasurer, and At-large Members of the ILSI Executive Committee

### V. Next Steps

- a. Date for next conference call
- VI. Adjournment

				TERM
TRUSTEE	AFFILIATION	INSTITUTE	ELECTED	EXPIRES
Dr. Todd Abraham	Kraft Foods, USA	North America (I)	2012	2015
Dr. Rhona Applebaum*	Coca-Cola Company	**	2013	2014*
Dr. Scott Belanger		HESI (I)	2013	2016
Dr. Alan Boobis	Imperial College London, UK	HESI (P)	2012	2015
Dr. Sushila Chang	Singapore University of Technology and Design	Asia/Pacific-So. (P)	2011	2014
Dr. Samuel Cohen*	University of Nebraska Medical Center, USA	HESI (P)	2013	2016
Dr. Dennis Devlin	Exxon-Mobil	HESI (I)	2013	2016
Dr. Adam Drewnowski	University of Washington, USA	RF (P)	2012	2015
Dr. Marion Ehrich*	VA-MD Regional College of Veterinary Medicine, USA	RF (P)	2013	2016
Prof Gerhard Eisenbrand	University of Kaiserslautern, Germany	Europe (P)	2011	2014
Dr. Jay I. Goodman	Michigan State University, USA	HESI (P)	2011	2014
Dr. Jerry Hjelle*	Monsanto Company, USA	North America (I)	2013	2016
Dr. Takeshi Kimura	Ajinomoto Company, Japan	Asia/Pacific-No. (I)	2012	2015
Dr. Janet King	Children's Hospital Oakland Research Institute, USA - <b>Resigned</b>	North America (P)	2012	2015
Dr. Michael E. Knowles	The Coca-Cola Company, Belgium	Europe (I)	2013	2016
Dr. Tamotsu Kuwata*	University of Japan	Asia/Pacific-No. (P)	2013	2016
Dr. Ik Boo Kwon	Lotte Company, Korea	Asia/Pacific-No. (I)	2011	2014
Dr. Joanne Lupton	Texas A&M University, USA	North America (P)	2012	2015
Dr. Gert Meijer*	Unilever (formerly)	Europe (I)	2013	2015
Dr. John Milner*	USA	North America (P)	2012	2015
Dr. John Peters	University of Colorado	RF (P)	2013	2016
Prof. Gerhard Rechkemmer	Federal Research Institute of Nutrition and Food, Germany	Europe (P)	2013	2016
Mr. Felipe Rodríguez	PepsiCo, Mexico	Latin America (I)	2012	2015
Dr. Prahlad.K. Seth	Biotechnology Park, India	Asia Pacific – So. (P)	2012	2015
Mr. Geoff Smith*	Nutrition Strategies International, Singapore	Asia Pacific – So. (I)	2013	2016
Dr. Lewis Smith	MRC, UK	HESI (P))	2012	2015
Dr. Geoff Thompson	Groupe Danone, Belgium	Europe (I)	2012	2015
Dr. Sara Valdés *	University of Mexico, Mexico	Latin America (P) Mexico	2011	2014
Dr. Peter Van Bladeren	Nestlé Research Centre, Switzerland	Europe (I)	2012	2015
Dr. Connie Weaver	Purdue University, USA	North America (P)	2013	2016
Dr. Elizabeth Westring*	General Mills, USA	North America (I)	2013	2016
Dr. Flávio A.D. Zambrone	Planitox, Brazil	Latin America (P) (Brazil)	2012	2015

\*Member, Executive Committee. Officers last elected 2013 for staggered terms/Members At-large elected annually. TOTAL TRUSTEES: 32 - 16 Public Members/16 Industry Members.

\*\* Dr. Applebaum was elected to the 32<sup>nd</sup> seat for a year as well as to the office of Vice-President.

From:	Suzanne Harris					
Sent:	Tuesday, October 29, 2013 3:05 PM					
То:	k; Joanne Lupton; Geoff					
	( ; Flavio Zambrone					
Cc:	; Chelsea L. Bishop; Shawn Sullivan; Beth					
Subject:	Brueggemeyer Agenda, briefing materials and dial-in instructions for the ILSI Nomination Review					
Attachments:	NRC 2013-11-04 Agenda.doc; 2014 Nominees for the ILSI Board of Trustees.doc; 2013 ILSI Board Member Terms.doc; NRC 2013-09-30 minutes.docx; 2014 ILSI Executive Committee.doc					
TO: ILSI Board of Trus	tees Nomination Review Committee					
FROM: Suzie Harris						
The second conference call for the beginning at 9:00 a.m. Eastern S standard time on Sunday, Noven	ne ILSI Nomination Review Committee is scheduled for <b>Monday, November 4, 2013,</b> tandard Time. Please note that the United States returns from daylight savings time to hber 3 (fall back one hour). The conference call will not last longer than one hour.					
The proposed agenda for the cor	nference call is attached here:					
Agenda Item II. Draft minutes fro	om the September 30, 2013 conference call					
Agenda Item III. List of candidates submitted by the branches						
Agenda Item V. 2014 ILSI Execut	ive Committee					
Agenda Item VI. 2014 Nominees	for the ILSI Research Foundation Board of Trustees					
Two have been agreed to: Dr. Takeshi Kimura and Dr. Michael Knowles; one more is in the works.						
Dr. Phil Guzelian will not be re-no	ominated.					
Dial-In Instructions						
If you are calling from: Please	dial:					

Brazil	0-800-890-0288, then dial 888-706-6468; <b>or</b> 0-800-888-8288, then dial 888-706-6468
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United Kingdom	0808-234-3676

United States of America 1-888-706-6468

The access code for everyone is **4498699** #.

Let me know if you will be in another country, so that I can send you the toll free number for that country.

Please let me know if you have any questions.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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Position	Name	Entity	<b>Term Expires</b>	
			E.C./B of T	
<mark>Chair</mark>	Dr. John Milner (P)	North America	2016/2015	
Vice Chair	(P)		2016/	
President	Dr. Jerry Hjelle (I)	North America	2015/2016	
Vice President	Dr. Rhona Applebaum (I)	North America	2015/2014	
<b>Treasurer</b>	Dr. Liz Westring(I)	North America	2014/2016	
Secretary	Dr. Sara Valdeś (P)	Latin America (Mex.)	2015/2014	
At-Large	Dr. Marion Ehrich (P)	<b>Research Foundation</b>	2014/2016	
At-Large	Dr. Gert Meijer (I)	Europe/Africa	2014/2015	
At-large	Dr. Tamotsu Kuwata (P)	Asia/Pacific North	2014/2016	
At-large	Mr. Geoff Smith (I)	Asia/Pacific South	2014/2013	

2013 ILSI Executive Committee

#### **ILSI Board of Trustees Nomination Review Committee**

#### Conference Call Monday, September 30, 2013

#### **DRAFT MINUTES**

#### I. Welcome and Opening Remarks

Dr. Peter van Bladeren, Chair, ILSI Board of Trustees Nomination Review Committee, began the conference call at approximately 9:00 a.m. Eastern Daylight Time. In addition to Dr. van Bladeren, the following trustees and staff participated in the conference call: Dr. Alan Boobis, Dr. Joanne Lupton, Mr. Geoff Smith, Dr. Flávio Zambrone, Dr. Suzie Harris and Mr. Shawn Sullivan.

Dr. van Bladeren welcomed the members of the committee and thanked them for agreeing to serve in this important activity.

The agenda for the conference call is attached.

#### II. Review of Committee Responsibilities

At Dr. van Bladeren's request, Dr. Harris reviewed the charge to the committee which includes:

- Reviewing and approving nominees for the ILSI Board of Trustees
- Reviewing and approving nominees for the ILSI Research Foundation Board of Trustees
- Nominating candidates for Chair, Vice Chair, and Treasurer of the ILSI Board of Trustees, as well as nominating candidates for the at-large seats on the ILSI Executive Committee.

#### III. Process for Nominating ILSI Trustees and ILSI Research Foundation Trustees

a. Review of board seat allocation evaluation – Dr. Harris reviewed the make-up of the 31-member ILSI Board of Trustees, which is described in detail in Article IV, section 3(b) of the ILSI bylaws. The calculation of the 16 proportionally allocated seats was distributed to the committee prior to the call. Dr. Harris reviewed the steps in the calculation and noted that the results for 2014 indicate that no change in the allocation of these seats is necessary.

Action: The members of the Nomination Review Committee agreed with the proportional allocation results.

b. Review of expired terms on the ILSI Board of Trustees – A list of the current members of the ILSI Board of Trustees with the names of the trustees whose three-year terms will expire in January 2014 highlighted was circulated to the committee prior to the conference call. They are: Dr. Sushila Chang, Prof. Gerhard Eisenbrand, Dr. Jay Goodman, Dr. Ik Boo Kwon, and Dra. Sara Valdés. Dr. Janet King resigned from the Board in mid-2013, so her seat also needs to be filled.

The branches to which each of these seats is allocated have been notified that the individual's term is up or that the trustee resigned. The branch(es) may re-nominate the individual or select someone else who qualifies for the seat, meaning that they are either qualified for a public or private sector seat. Dr. Harris asked that the branch nominations be submitted by October 15, 2013. If a new person (one not currently serving on the ILSI Board of Trustees is nominated, the branch(es) will be asked to provide a bio for the individual so that the ILSI Nomination Review Committee may use it to determine the suitability of the nominee for the seat.

In January 2013, the ILSI Assembly of Members elected Dr. Rhona Applebaum as the 32<sup>nd</sup> member of the ILSI Board of Trustees, which is allowed under the bylaws (Article IV, section 1) on an annual basis. So if she is to remain a member of the Board, she will need to be re-nominated because none of the private sector seats assigned to ILSI North America is open.

Nominations may also be made by any member of the ILSI Board of Trustees. The committee will review all nominations, using the criteria for public trustees as a guide for those being considered as public trustees. The committee will then submit the names of the approved candidates to the ILSI Assembly of Members for election.

c. Review of expired terms on the ILSI Research Foundation Board of Trustees – A list of the current members of the ILSI Research Foundation Board of Trustees with the names of the trustees whose three-year terms will expire in January 2014 highlighted was circulated to the committee prior to the conference call. These individuals are: Dr. Phil Guzelian, Dr. Takeshi Kimura, and Dr. Michael Knowles. The ILSI Research Foundation Board of Trustees Nominating Committee will select candidates for these three seats either by re-nominating existing trustees or selecting new candidates. These names will be submitted to the ILSI Board of Trustees Nomination Review Committee.

The ILSI Board of Trustees Nomination Review Committee will review the submission and decide on a slate of candidates to present to the ILSI Board of Trustees. The ILSI Board elects the ILSI Research Foundation trustees.

### IV. Discussion of Process for Selecting Nominees for ILSI Chair, Vice Chair, Treasurer, and Atlarge Members of the ILSI Executive Committee

A list of the current membership of the ILSI Executive Committee (officers and at-large members) was circulated to the committee prior to the call. The officers of the Board serve two-year terms. In January 2014, the term of the current Chair, Dr. Sam Cohen; current Vice Chair, Dr. John Milner; and current Treasurer, Dr. Liz Westring, will expire.

The ILSI Board of Trustees adopted a succession plan for the ILSI President and Chair which calls for the Nomination Review Committee to decide if the Vice President and Vice Chair are qualified to move into the President and Chair positions, respectively, when each of these office terms expire.

Action: The committee members unanimously agreed that Dr. Milner should be nominated for the office of Chair of the ILSI Board of Trustees.

For the position of Vice Chair the committee reviewed the list of possible candidates, public trustees. It was suggested that the current executive committee had a number of North American trustees and that selecting a Vice Chair from another region should be considered. Dr. Boobis agreed to ask Dr. Lewis Smith if he would be interested in serving. Dr. Boobis was also suggested as a possible Vice Chair as was Dr. Zambrone. Dr. Connie Weaver was suggested as well, though she is a North American trustee. The committee agreed to discuss nominees for this office further during the next committee conference call.

Action: The committee members unanimously agreed to re-nominate Dr. Westring for the position of Treasurer.

The at-large seats on the executive committee are elected annually. Dr. Harris described the understanding reached in 2004 that the following branches will have representation on the ILSI Board of Trustees Executive Committee – ILSI Europe (currently represented by Dr. Gert Meijer in an at-large seat), ILSI HESI (currently represented by Dr. Sam Cohen whose term as Chair expires), ILSI Japan (currently represented by Dr. Kuwata in an at-large seat), and ILSI North America (currently represented by the ILSI President (Dr. Jerry Hjelle), Vice Chair (Dr. Milner) and Treasurer (Dr. Westring).

The number of public trustees on the executive committee must be equal to or greater than the number of industry trustees. For this reason of public-private trustees balance, Dr. Marion Ehrich, an ILSI Research Foundation representative to the ILSI Board of Trustees is currently an at-large member. In 2011, the ILSI Nomination Review Committee agreed that the ILSI Research Foundation should always be represented on the ILSI Executive Committee and by a public trustee. The other two branch regions are also currently represented on the executive committee – Dra. Sara Valdés as the secretary, from the Latin American region, and Mr. Geoff Smith, an at-large member from the Asia-Pacific South region.

Dr. van Bladeren noted that under the new One ILSI strategy the ILSI Executive Committee will be given more responsibility and there is interest in having the major branch leaders serve on the committee.

The committee agreed to wait until more is known about who will be nominated to the ILSI Board of Trustees before trying to sort through the at-large seats on the executive committee.

### V. Next Steps

- Dr. Harris will confirm with Dr. Milner and Dr. Westring that they are willing to be nominated for the offices of Chair and Treasurer, respectively.
- Dr. Harris will collect nominees for the ILSI Board of Trustees and the ILSI Research Foundation Board of Trustees and circulate these to the committee prior to the next committee conference call.
- Committee members will consider who should be nominated as the Vice Chair
- The next committee conference call will be schedule for after October 15, which is the deadline for nominations for the ILSI Board of Trustees.

#### VI. Adjournment
As there was no further business, Dr. van Bladeren ended the conference call at 9:40 a.m. Eastern Daylight Time.

Cianadi	Data
Signed:	Date:

## ILSI Board of Trustees Nomination Review Committee

## **Conference Call**

## September 30, 2013 9:00 – 10:00 Eastern Daylight Time

## Agenda

- I. Welcome and Opening Remarks
- II. Review of Committee Responsibilities
- III Process for Nominating ILSI Trustees and ILSI RF Trustees
  - a. Review of board seat allocation evaluation
  - b. Review of expired terms on the ILSI Board of Trustees
  - c. Review of expired terms on the ILSI Research Foundation Board of Trustees
- IV. Discussion of Process for Selecting Nominee for ILSI Chair, Vice Chair, Treasurer, and At-large Members of the ILSI Executive Committee

## V. Next Steps

- a. Date for next conference call
- VI. Adjournment

		REGION/		TERM
TRUSTEE	AFFILIATION	INSTITUTE	ELECTED	EXPIRES
Dr. Todd Abraham	Kraft Foods, USA	North America (I)	2012	2015
Dr. Rhona Applebaum*	Coca-Cola Company	**	2013	2014*
Dr. Scott Belanger		HESI (I)	2013	2016
Dr. Alan Boobis	Imperial College London, UK	HESI (P)	2012	2015
Dr. Sushila Chang	Singapore University of Technology and Design	Asia/Pacific-So. (P)	2011	2014
Dr. Samuel Cohen*	University of Nebraska Medical Center, USA	HESI (P)	2013	2016
Dr. Dennis Devlin	Exxon-Mobil	HESI (I)	2013	2016
Dr. Adam Drewnowski	University of Washington, USA	RF (P)	2012	2015
Dr. Marion Ehrich*	VA-MD Regional College of Veterinary Medicine, USA	RF (P)	2013	2016
Prof Gerhard Eisenbrand	University of Kaiserslautern, Germany	Europe (P)	2011	2014
Dr. Jay I. Goodman	Michigan State University, USA	HESI (P)	2011	2014
Dr. Jerry Hjelle*	Monsanto Company, USA	North America (I)	2013	2016
Dr. Takeshi Kimura	Ajinomoto Company, Japan	Asia/Pacific-No. (I)	2012	2015
Dr. Janet King	Children's Hospital Oakland Research Institute, USA - <b>Resigned</b>	North America (P)	2012	2015
Dr. Michael E. Knowles	The Coca-Cola Company, Belgium	Europe (I)	2013	2016
Dr. Tamotsu Kuwata*	University of Japan	Asia/Pacific-No. (P)	2013	2016
Dr. Ik Boo Kwon	Lotte Company, Korea	Asia/Pacific-No. (I)	2011	2014
Dr. Joanne Lupton	Texas A&M University, USA	North America (P)	2012	2015
Dr. Gert Meijer*	Unilever (formerly)	Europe (I)	2013	2015
Dr. John Milner*	USA	North America (P)	2012	2015
Dr. John Peters	University of Colorado	RF (P)	2013	2016
Prof. Gerhard Rechkemmer	Federal Research Institute of Nutrition and Food, Germany	Europe (P)	2013	2016
Mr. Felipe Rodríguez	PepsiCo, Mexico	Latin America (I)	2012	2015
Dr. Prahlad.K. Seth	Biotechnology Park, India	Asia Pacific – So. (P)	2012	2015
Mr. Geoff Smith*	Nutrition Strategies International, Singapore	Asia Pacific – So. (I)	2013	2016
Dr. Lewis Smith	MRC, UK	HESI (P))	2012	2015
Dr. Geoff Thompson	Groupe Danone, Belgium	Europe (I)	2012	2015
Dr. Sara Valdés *	University of Mexico, Mexico	Latin America (P) Mexico	2011	2014
Dr. Peter Van Bladeren	Nestlé Research Centre, Switzerland	Europe (I)	2012	2015
Dr. Connie Weaver	Purdue University, USA	North America (P)	2013	2016
Dr. Elizabeth Westring*	General Mills, USA	North America (I)	2013	2016
Dr. Flávio A.D. Zambrone	Planitox, Brazil	Latin America (P) (Brazil)	2012	2015

\*Member, Executive Committee. Officers last elected 2013 for staggered terms/Members At-large elected annually. TOTAL TRUSTEES: 32 - 16 Public Members/16 Industry Members.

\*\* Dr. Applebaum was elected to the 32<sup>nd</sup> seat for a year as well as to the office of Vice-President.

## 2014 Nominees for the ILSI Board of Trustees To Be Elected by the ILSI Assembly of Members

## **Nominees for Re-Election**

Asia-Pacific South	Dr. Sushila Chang (P)
Europe/Africa	Dr. Gerhard Eisenbrand (P)
Latin America	Dra. Sara Valdés (P)

## **New Nominees**

Asia-Pacific North	(1)
HESI	(P)
North America	Dr. Michael Doyle (P)*
32 <sup>nd</sup> seat nominee**	Dr. Rhona Applebaum

\*To filled the unexpired term held by Dr. Janet King – term ends in 2015. \*\* See Article IV, Section 1 of the ILSI bylaws.

The following trustees' terms will expire and they will not be re-nominated:

- Dr. Jay Goodman
- Dr. Ik Boo Kwon

## ILSI Board of Trustees Nomination Review Committee

## **Conference Call**

## November 4, 2013 9:00 – 10:00 Eastern Standard Time

## Agenda

- I. Welcome and Opening Remarks
- II. Review of Minutes from the September 30, 2013 Conference Call
- III Review of Nominations for the ILSI Board of Trustees
- IV. Discussion of Nominees for ILSI Vice Chair and Treasurer
- V. Discussion of Nominees for the At-Large Seats on the ILSI Executive Committee
- VI. Review of Nominees for the Research Foundation Board of Trustees
- VII. Next Steps
- VI. Adjournment

From:John FaulknerSent:Wednesday, October 23, 2013 8:28 AMSubject:Your ILSI North America Scientific Briefs -- Are Attached!Attachments:ILSI North America Food Safety Brief Sept 2013.pdf; ILSI North America Nutrition Brief<br/>Sept 2013.pdf

Hello,

The Food Safety and Nutrition science briefs we highlight each month are compiled after a review of the articles published in the most recent issues of the major journals in nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion typically report on topics of current interest to ILSI North America's technical and project committees.

Our "new look" **September** briefs are attached in pdf form to this e-mail. These, along with prior science briefs always remain accessible electronically via the ILSI North America website: <a href="http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx">http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</a>

Please let me know if there is someone in your company who should be receiving the briefs and I'll add them to our distribution list. I look forward with sharing a new set of briefs with you next month.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126



# **Nutrition Briefs**

## September 2013

## **Cardiovascular Disease**

## Olive Oil has a Beneficial Effect on Impaired Glucose Regulation and other Cardiometabolic Risk Factors. Di@bet.es Study

F. Soriguer, G. Rojo-Martínez, A. Goday, A. Bosch-Comas, E. Bordiú, F. Caballero-Díaz, et al.

*European Journal of Clinical Nutrition*, Vol. 67, No. 9; pp. 911–916, 2013 Link to full text: http://www.nature.com/ejcn/journal/v67/n9/full/ejcn2013130a.html

**Significance:** Consumption of olive oil has a beneficial effect on different cardiovascular risk factors, particularly in the presence of obesity, impaired glucose tolerance or a sedentary lifestyle.

This population-based, cross-sectional, cluster sampling study examined the association between consumption of olive oil and the presence of cardiometabolic risk factors in the context of a large study representative of the Spanish population. 4572 individuals aged  $\geq 18$  years in 100 clusters (health centers) were randomly selected with a probability proportional to population size. Around 90% of the Spanish population use olive oil, at least for dressing, and slightly fewer for cooking or frying. The preference for olive oil is related to age, educational level, alcohol intake, BMI and serum glucose, insulin and lipids. People who consume olive oil (vs sunflower oil) had a lower risk of obesity (OR=0.62 (95% CI)=0.41–0.93, P=0.02)), impaired glucose regulation (OR=0.49 (95% CI=0.28–0.86, P=0.04)), hypertriglyceridemia (OR=0.53 (95% CI=0.33–0.84, P=0.03)) and low HDL-cholesterol levels (OR=0.40 (95% CI=0.26–0.59, P=0.0001)).

## Common Genetic Loci Influencing Plasma Homocysteine Concentrations and their Effect on Risk of Coronary Artery Disease

J.B.J. van Meurs, G. Pare, S.M. Schwartz, A. Hazra, T. Tanaka, S.H. Vermeulen, et al.

American Journal of Clinical Nutrition, Vol. 98, No. 3; pp. 668-676, 2013 Link to full text: http://ajcn.nutrition.org/content/98/3/668.full

**Significance:** Common genetic variants that influence plasma tHcy concentrations are not associated with risk of coronary artery disease in white populations.

This study tested whether common genetic polymorphisms associated with variation in total homocysteine (tHcy) are also associated with coronary artery disease (CAD). A meta-analysis of genome-wide association studies (GWAS) on tHcy concentrations in 44,147 individuals of European descent

## **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx was conducted. Polymorphisms associated with tHcy (P<10<sup>-8</sup>) were tested for association with CAD in 31,400 cases and 92,927 controls. Common variants at 13 loci, explaining 5.9% of the variation in tHcy, were associated with tHcy concentrations, including 6 novel loci in or near MMACHC ( $2.1 \times 10^{-9}$ ), SLC17A3 ( $1.0 \times 10^{-8}$ ), GTPB10 ( $1.7 \times 10^{-8}$ ), CUBN ( $7.5 \times 10^{-10}$ ), HNF1A ( $1.2 \times 10^{-12}$ ), and FUT2 ( $6.6 \times 10^{-9}$ ), and variants previously reported at or near the MTHFR, MTR, CPS1, MUT, NOX4, DPEP1, and CBS genes. Individuals within the highest 10% of the genotype risk score (GRS) had 3-µmol/L higher mean tHcy concentrations than did those within the lowest 10% of the GRS (P =  $1 \times 10^{-36}$ ). The GRS was not associated with risk of CAD (OR: 1.01; 95% CI: 0.98, 1.04).

## SFAs do not Impair Endothelial Function and Arterial Stiffness

T.A.B. Sanders, Fiona J Lewis, Louise M Goff, and Philip J Chowienczyk on behalf of the RISCK Study Group

American Journal of Clinical Nutrition, Vol. 98, No. 3; pp. 677-683, 2013 Link to full text: http://ajcn.nutrition.org/content/98/3/677.full

**Significance:** The replacement of saturated fatty acids with monounsaturated fatty acids or carbohydrates in healthy subjects does not affect vascular function.

The effects of replacing saturated fatty acids (SFAs) with monounsaturated fatty acids (MUFAs) or carbohydrates on endothelial function and arterial stiffness were tested in a parallel-designed randomized controlled trial in 121 insulin-resistant men and women. Vascular function was measured after 1 mo of consumption of a high-SFA (HS) diet and after 24 wk after random assignment to the HS diet or diets that contained <10% SFAs and were high in either MUFAs or carbohydrates. No significant differences were found for 112 participants. Flow-mediated dilation with the HS diet was 6.7±2.2%, and changes (95% CIs) after 6 mo of intervention were +0.3 (-0.4, 1.1), -0.2 (-0.8, 0.5), and -0.1 (-0.6, 0.7) with HS, high-MUFA (HM), and high-carbohydrate (HC) diets, respectively. After consumption of the HS diet, the geometric mean  $(\pm SD)$  pulse wave velocity was 7.67 $\pm$ 1.62 m/s, and mean percentages of changes (95% CIs) were -1.0 (-6.2, 4.3) with the HS diet, 2.7 (-1.4, 6.9) with the HM diet, and -1.0 (-5.5, 3.4) with the HC diet. With the HS diet, the geometric mean ( $\pm$ SD) plasma 8-isoprostane  $F_{2a}$ -III concentration was 176 $\pm$ 85 pmol/L, and mean percentage of changes (95% CIs) were 1 (-12, 14) with the HS diet, 6(-5, 16) with the HM diet, and 4(-7, 16) with the HC diet.

## Type 2 Diabetes

Chromium Nicotinate Has No Effect on Insulin Sensitivity, Glycemic Control, and Lipid Profile in Subjects with Type 2 Diabetes

M.M. Guimaraes, A.C. Martins Silva Cavalho, M.S. Silva

Journal of the American College of Nutrition, Vol. 32, No. 4; pp. 243-250, 2013 Link to full text: http://www.tandfonline.com/doi/full/10.1080/07315724.2013.81 6598#.UkjKZiigdt8

**Significance:** Supplementation at 50 and 200  $\mu$ g of chromium nicotinate did not promote glycemic control, increase insulin sensitivity, or change the lipid profile of subjects with diabetes.



#### Nutrition Briefs

In a double-blind clinical trial, the effect of chromium nicotinate supplementation on insulin sensitivity, glycemic control, and lipid profile was examined in 56 overweight individuals with type 2 diabetes. Subjects were randomized into 3 groups: placebo (NC<sub>0</sub>), 50  $\mu$ g (NC<sub>50</sub>), and 200  $\mu$ g (NC<sub>200</sub>) of chromium nicotinate. In the beginning, most subjects showed low concentrations of serum chromium (71.88%), regular levels of urinary chromium (80.65%), and insulin resistance (73.80%). The serum chromium concentrations did not differ among the groups over time (p=0.2549). The changes in serum chromium and urine concentrations did not relate to changes in fasting glucose. At 90 days of intervention, there was no significant difference between groups in fasting glucose, glycosylated hemoglobin, homeostasis model assessment insulin resistance (HOMA-IR), total and LDL-cholesterol; there was an increase in homeostasis model assessment  $\beta$ -cell function (HOMA- $\beta$ ; p=0.0349) and HDL-cholesterol; p=0.0425) in the NC<sub>0</sub> group and a reduction of triglycerides in the NC<sub>0</sub> (p=0.0177) and NC<sub>50</sub> (p=0.0336) groups.

## Higher Dietary Flavonol Intake Is Associated with Lower Incidence of Type 2 Diabetes

P.F. Jacques, A. Cassidy, G. Rogers, J.J. Peterson, J.B. Meigs, J.T. Dwyer Journal of Nutrition, Vol. 143, No. 9; pp. 1474-1480, 2013

Link to full text:

**Significance:** This study supports previous experimental evidence of a possible beneficial relationship between increased flavonol intake and risk of type 2 diabetes.

This study determined if habitual intakes of specific flavonoid classes are related to incidence of type 2 diabetes (T2D). 2915 members of the Framingham Offspring cohort who were free of T2D at baseline from 1991 to 2008 were followed. Dietary intakes of 6 flavonoid classes and total flavonoids were assessed using a validated, semiquantitative food frequency questionnaire. 308 incident cases of T2D during a mean follow-up period of 11.9 y (range 2.5–16.8 y) were observed. After multivariable adjusted, time-dependent analyses, which accounted for long-term flavonoid intake during follow-up, each 2.5-fold increase in flavonol intake was associated with a 26% lower incidence of T2D [HR = 0.74 (95% CI: 0.61, 0.90); P-trend = 0.003] and each 2.5-fold increase in flavan-3-ol intake was marginally associated with an 11% lower incidence of T2D [HR = 0.89 (95% CI: 0.80, 1.00); P-trend = 0.06]. No other associations between flavonoid classes and risk of T2D were observed.

## **Food Allergy**

## Peanut Protein in Household Dust is Related to Household Peanut Consumption and is Biologically Active

H.A. Brough, A.F. Santos, K. Makinson, M. Penagos, A.C. Stephens, A. Douiri, et al.

Journal of Allergy and Clinical Immunology, Vol. 132, No. 3; pp. 630-638, 2013

Link to full text:

**Significance:** Peanut protein in dust is biologically active and should be assessed as a route of possible early peanut sensitization in infants.



This study sought to explore the relationship between reported household peanut consumption (HPC) and peanut protein levels in an infant's home environment and to determine the biological activity of environmental peanut. Peanut protein was quantified in wipe and dust samples collected from 45 homes with infants by using a polyclonal peanut ELISA. There was a positive correlation between peanut protein levels in the infant's bed, crib rail, and play area and reported HPC over 1 and 6 months. On multivariate regression analysis, HPC was the most important variable associated with peanut protein levels in the infant's bed sheet and play area. Dust samples containing high peanut protein levels induced dose-dependent activation of basophils in children with peanut allergy.

This study sought to explore the relationship between reported household peanut consumption (HPC) and peanut protein levels in an infant's home environment and to determine the biological activity of environmental peanut. Peanut protein was quantified in wipe and dust samples collected from 45 homes with infants by using a polyclonal peanut ELISA. There was a positive correlation between peanut protein levels in the infant's bed, crib rail, and play area and reported HPC over 1 and 6 months. On multivariate regression analysis, HPC was the most important variable associated with peanut protein levels in the infant's bed sheet and play area. Dust samples containing high peanut protein levels induced dose-dependent activation of basophils in children with peanut allergy.

## Sweeteners

Very High Fructose Intake Increases Serum LDL-Cholesterol and Total Cholesterol: A Meta-Analysis of Controlled Feeding Trials

Y.H. Zhang, T. An, R.C. Zhang, Q. Zhou, Y. Huang, J. Zhang Journal of Nutrition, Vol. 143, No. 9; pp. 1391-1398, 2013 Link to full text: http://jn.nutrition.org/content/143/9/1391.full

**Significance:** Very high fructose intake (>100 g/d) increases serum LDL-cholesterol and total cholesterol concentrations.

A systematic review and meta-analysis of human, controlled, feeding trials involving isocaloric fructose exchange for other carbohydrates was performed to quantify the effects of fructose on serum total cholesterol (TC), LDL-cholesterol, and HDL-cholesterol in adults. Twenty-four trials (with a total of 474 participants) were included in the meta-analysis. In an overall pooled estimate, it was shown that fructose exerted no effect on HDL-cholesterol. Meta-regression analysis indicated that fructose dose was positively correlated with the effect sizes of TC and LDL-cholesterol. Subgroup analyses showed that isocaloric fructose exchange for carbohydrates increased TC by 13.0 mg/dL [(95% CI: 4.7, 21.3)] and LDL-cholesterol by 11.6 mg/dL [(95% CI: 4.4, 18.9)] at >100 g fructose/d. However, no effect was shown on TC or LDL-cholesterol when the fructose intake was  $\leq 100$  g/d.



## **Blood Pressure**

## Acute Ingestion of Beetroot Bread Increases Endothelium-Independent Vasodilation and Lowers Diastolic Blood Pressure in Healthy Men: A Randomized Controlled Trial

D.A. Hobbs, M.G. Goulding, A. Nguyen, T. Malaver, C.F. Walker, T.W. George, et al.

Journal of Nutrition, Vol. 143, No. 9; pp. 1399-1405, 2013 Link to full text: http://jn.nutrition.org/content/143/9/1399.full

**Significance:** Enriching bread with beetroot may be a suitable vehicle to increase intakes of cardioprotective beetroot in the diet and may provide new therapeutic perspectives in the management of hypertension.

The acute effects of beetroot bread (BB) on microvascular vasodilation, arterial stiffness, and blood pressure (BP) were investigated in 23 healthy men. Subjects received 200 g bread containing 100 g beetroot (1.1 mmol nitrate) or 200 g control white bread (CB; 0 g beetroot, 0.01 mmol nitrate) in an acute, randomized, open-label, controlled crossover trial. The incremental area under the curve (0–6 h after ingestion of bread) for endothelium-independent vasodilation was greater (P=0.017) and lower for diastolic BP (DBP; P=0.032) but not systolic (P=0.99) BP after BB compared with CB. These effects occurred in conjunction with increases in plasma and urinary nitrate (P<0.001) and nitrite (P<0.001). BB acutely increased endothelium-independent vasodilation and decreased DBP.

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The North American branch of the International Life Sciences Institute (ILSI North America) is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply.

ILSI North America carries out its mission by sponsoring research programs, professional and educational programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.



1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx



# **Food Safety Briefs**

## September 2013

## E. Coli

Efficacy of Plant-Derived Antimicrobials as Antimicrobial Wash Treatments for Reducing Enterohemorrhagic Escherichia Coli O157:H7 on Apples

S.A. Baskaran, A. Upadhyay, A. Kollanoor-Johny, I. Upadhyaya, S. Mooyottu, M.A.R. Amalaradjou, et al.

Journal of Food Science, Vol. 78, No. 9, pp. M1399-M1404

Link to full text: http://onlinelibrary.wiley.com/doi/10.1111/1750-3841.12174/full

Significance: Carvacrol and  $\beta$ -resorcylic acid could be used as antimicrobial wash solution on apples for reducing E. coli O157:H7.

This study investigated the efficacy of 3 GRAS-status, plant-derived antimicrobials (PDAs), trans-cinnamaldehyde (TC), carvacrol (CR), and  $\beta$ -resorcylic acid (BR) applied as antimicrobial washes for killing Escherichia coli O157:H7 on apples. Apples inoculated with a 5 strain mixture of E. coli O157:H7 were subjected to washing in sterile deionized water containing 0% PDA (control), 0.15% TC, 0.35% TC, 0.15% CR, 0.30% CR, 0.5% BR, or 1% BR for 1, 3, and 5 min at 23 °C in the presence and absence of 1% soil. All PDAs were more effective in reducing E. coli O157:H7 compared to the water wash treatment (P<.05) and reduced the pathogen by 4- to 5-log CFU/apple in 5 min. Chlorine (1%) was the most effective treatment reducing the pathogen on apples to undetectable levels in 1 min (P<0.05). No bacteria were detected in the wash solution containing CR and BR; however, E. coli O157:H7 was recovered in the control wash water and treatment solutions containing TC and chlorine.

## Fate of Shiga Toxin–Producing O157:H7 and Non-O157:H7 Escherichia coli Cells within Refrigerated, Frozen, or Frozen Then Thawed Ground Beef Patties Cooked on a Commercial Open-Flame Gas or a Clamshell Electric Grill

J.B. Luchansky, A.C.S. Porto-Fett, B.A. Shoyer, J. Phillips, V. Chen, D.R. Eblen, et al.

Journal of Food Protection, Vol. 76, No. 9; pp. 1500-1512, 2013

Link to full text: http://www.ingentaconnect.com/content/iafp/ jfp/2013/00000076/0000009/art00002

**Significance:** Cooking ground beef patties that were refrigerated, frozen, or freeze-thawed to internal temperatures of 71.1 and 76.6°C was effective for eliminating ca. 5.1 to 7.0 log CFU of E. coli O157:H7 and STEC per g.

## **Contact Us**

ILSI North America 1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

www.ilsi.org/NorthAmerica/ Pages/HomePage.aspx

Ground beef patties were inoculated with a 6-strain cocktail of non-O157:H7 Shiga toxin-producing Escherichia coli (STEC) or a five-strain cocktail of E. coli O157:H7 (ca. 7.0 log CFU/g). Patties were pressed and then refrigerated or frozen or frozen and then thawed before cooking to internal temperatures of 60-76.6°C. For E. coli O157:H7, cooking refrigerated patties to 71.1 or 76.6°C decreased E. coli O157:H7 numbers from an initial level of ca. 7.0 log CFU/g to a final level of  $\leq 1.0 \log CFU/g$ , whereas decreases to ca. 1.1 to 3.1 log CFU/g were observed when refrigerated patties were cooked to 60.0 or 65.5°C. For patties that were frozen or freeze-thawed and cooked to 71.1 or 76.6°C, E. coli O157:H7 numbers decreased to ca. 1.7 or ≤0.7 log CFU/g. Likewise, pathogen numbers decreased to ca. 0.7 to 3.7 log CFU/g in patties that were frozen or freeze-thawed and cooked to 60.0 or 65.5°C. For STEC, cooking refrigerated patties to 71.1 or 76.6°C decreased pathogen numbers from ca. 7.0 to  $\leq 0.7$ log CFU/g, whereas decreases to ca. 0.7 to 3.6 log CFU/g were observed when refrigerated patties were cooked to 60.0 or 65.5°C. For patties that were frozen or freeze-thawed and cooked to 71.1 or 76.6°C, STEC numbers decreased to a final level of ca. 1.5 to  $\leq$  0.7 log CFU/g. Likewise, pathogen numbers decreased from ca. 7.0 to ca. 0.8 to 4.3 log CFU/g in patties that were frozen or freezethawed and cooked to 60.0 or 65.5°C.

## Salmonella

## Modeling the Influence of Temperature, Water Activity and Water Mobility on the Persistence of Salmonella in Low-Moisture Foods

S.M. Santillana Farakos, J.F. Frank, D.W. Schaffner International Journal of Food Microbiology, Vol. 166, No. 2; pp. 280–293, 2013 Link to full text: http://www.sciencedirect.com/science/article/pii/ S0168160513003425

**Significance:** The Weibull model provided the best description of Salmonella survival kinetics in low water activity foods.

This study determined how the physical state of water in low-moisture foods influences the survival of Salmonella and used this information to develop mathematical models that predict the behavior of Salmonella in these foods. Whey protein powder of differing water mobilities was produced by pH adjustment and heat denaturation, and then equilibrated to water activity  $(a_w)$  levels between 0.19±0.03 and 0.54±0.02. Powders were inoculated with a four-strain cocktail of Salmonella, vacuum-sealed and stored between 21and 80°C. Survival data was fitted to the log-linear, the Geeraerd-tail, the Weibull, the biphasic-linear and the Baranyi models. The Weibull model provided the best description of survival kinetics for Salmonella. Secondary models were developed and then validated in dry non-fat dairy and grain, and low-fat peanut and cocoa products within the range of the modeled data. Water activity significantly influenced the survival of Salmonella at all temperatures, survival increasing with decreasing aw. Secondary models were useful in predicting the survival of Salmonella in various low-moisture foods providing a correlation of R=0.94 and an acceptable prediction performance of 81%.



## Listeria

#### Multistate Outbreak of Listeriosis Associated with Cantaloupe

J.T. McCollum, A.B. Cronquist, B.J. Silk, K.A. Jackson, K.A. O'Connor, S. Cosgrove, et al.

New England Journal of Medicine, Vol. 369, No. 10; pp. 944-953, 2013 Link to full text: http://www.nejm.org/doi/full/10.1056/NEJMoa1215837

**Significance:** Raw produce, including cantaloupe, can serve as a vehicle for listeriosis.

This study investigated a nationwide listeriosis outbreak that occurred in the United States during 2011. An outbreak-related case was defined as a laboratory-confirmed infection with any of five outbreak-related subtypes of Listeria monocytogenes isolated during the period from August 1 through October 31, 2011. 147 outbreak-related cases were identified in 28 states; 86% were  $\geq$ 60 years of age. Of 145 patients for whom information about hospitalization was available, 99% were hospitalized and 22% died. Patients with outbreak-related illness were significantly more likely to have eaten cantaloupe than were patients  $\geq$ 60 years of age with sporadic illness (OR, 8.5; 95% CI, 1.3 to  $\infty$ ). Cantaloupe and environmental samples collected during the investigation yielded isolates matching all five outbreak-related subtypes, confirming that whole cantaloupe produced by a single Colorado farm was the outbreak source. Unsanitary conditions identified in the processing facility operated by the farm probably resulted in contamination of cantaloupes with L. monocytogenes.

## Growth Modeling of Listeria monocytogenes in Pasteurized Liquid Egg

M. Ohkochi, S. Koseki, M. Kunou, K. Sugiura, H. Tsubone Journal of Food Protection, Vol. 76, No. 9; pp. 1549-1556, 2013 Link to full text: http://www.ingentaconnect.com/content/iafp/ jfp/2013/00000076/00000009/art00007

**Significance:** This model can be used to estimate the kinetics and range of Listeria monocytogenes growth in pasteurized liquid egg under refrigerated temperature.

The growth kinetics of Listeria monocytogenes and natural flora in commercially produced pasteurized liquid egg was examined at 4.1 to 19.4°C, and a growth simulation model that can estimate the range of the number of L. monocytogenes bacteria was developed. The experimental kinetic data were fitted to the Baranyi model, and growth parameters, such as maximum specific growth rate ( $\mu_{max}$ ), maximum population density ( $N_{max}$ ), and lag time ( $\lambda$ ), were estimated. As a result of estimating these parameters, we found that L. monocytogenes can grow without spoilage <12.2°C, and we then focused on storage temperatures <12.2°C in developing secondary models. The  $N_{max}$ of L. monocytogenes was modeled as a function of temperature. A tertiary model of L. monocytogenes was developed using the Baranyi model and  $\mu_{max}$ and  $N_{max}$  secondary models. Predictive simulations under both constant and



#### Nutrition Briefs

fluctuating temperature conditions demonstrated a high accuracy, represented by root mean square errors of 0.44 and 0.34, respectively. The predicted ranges also seemed to show a reasonably good estimation, with 55.8 and 51.5% of observed values falling into the prediction range of the 25th to 75th percentile, respectively.

## **Foodborne Pathogens**

## Survival of Foodborne Pathogens on Inshell Walnuts

T. Blessington, C.G. Theofel, E.J. Mitcham, L.J. Harris International Journal of Food Microbiology, 3; pp. 341–348, 2013 Link to full text: http://www.sciencedirect.com/science/article/pii/ \$0168160513003516

**Significance:** Bacterial foodborne pathogens are capable of long-term survival on the surface of inshell walnuts even when initial levels are low.

The survival of Salmonella enterica Enteritidis PT 30 or five-strain cocktails of S. enterica, Escherichia coli O157:H7, and Listeria monocytogenes was evaluated on inshell walnuts during storage. Inshell walnuts were separately inoculated with an aqueous preparation of the pathogens at levels of 10 to 4 log CFU/nut, dried for 24 h, and then stored at either 4°C or ambient conditions for 3 weeks to more than 1 year. During the initial 24-h drying period, bacterial levels declined by 0.7 to 2.4 log CFU/nut. After the inoculum dried, further declines of approximately 0.1 log CFU/nut/month of Salmonella Enteritidis PT 30 levels were observed on inshell walnuts stored at 4 °C; at ambient conditions the rates of decline ranged from 0.55 to 2.5 log CFU/nut/month. Reductions in bacterial levels from the beginning to end of storage were 0.7, 0.2, and 2.3 log CFU/nut for Salmonella, E. coli O157:H7, and L. monocytogenes, respectively.

## Effect of Various Conditions on Inactivation of Escherichia coli O157:H7, Salmonella Typhimurium, and Listeria monocytogenes in Fresh-Cut Lettuce using Ultraviolet Radiation

Y-H. Kim, S-G. Jeong, K-H. Back, K-H. Park, M-S. Chung, D-H. Kang International Journal of Food Microbiology, Vol. 166, No. 3; pp. 349-355, 2013 Link to full text: http://www.sciencedirect.com/science/article/pii/ S016816051300384X

**Significance:** UV radiation under optimized conditions could reduce foodborne pathogens without adversely affecting color quality properties of fresh-cut lettuce.

The effect of various conditions on inactivation of foodborne pathogens and quality of fresh-cut lettuce during ultraviolet (254 nm, UVC) radiation was investigated. Lettuce was inoculated with a cocktail of Escherichia coli O157:H7, Salmonella Typhimurium, and Listeria monocytogenes and treated at different temperatures, distances between sample and lamp, type of exposure, UV intensities, and exposure times, sequentially. UV radiation was most effective when distance from UV lamp to the sample was minimal (10 cm) and radiation area was maximal (two-sided exposure). All UV intensities significantly reduced the three pathogens after 10 min exposure, but the effect of



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treatment was correlated with UV intensity and exposure time. Color values and texture parameters of lettuce subjected to UV treatment under the optimum conditions (25 °C, 10 cm between sample and lamp, two-sided exposure, 6.80 mW/cm<sup>2</sup>) were not significantly different from those of nontreated samples up to 5 min exposure. However, these qualities significantly changed at prolonged treatment time.

## Quantifying Transfer Rates of Salmonella and Escherichia coli O157:H7 between Fresh-Cut Produce and Common Kitchen Surfaces

D.A. Jensen, L.M. Friedrich, L.J. Harris, M.D. Danyluk, D.W. Schaffner Journal of Food Protection, Vol. 76, No. 9; pp. 1530-1538, 2013 Link to full text: http://www.ingentaconnect.com/content/iafp/ jfp/2013/00000076/00000009/art00005

**Significance:** Surface moisture and direction of transfer have the greatest influence on microbial transfer rates.

This study quantified the cross-contamination rates between a variety of freshcut produce and common kitchen surfaces (ceramic, stainless steel, glass, and plastic) using scenarios that differ by cross-contamination direction, surface type, produce type, and drying time/moisture level. A five-strain cocktail of rifampin-resistant Salmonella was used in transfer scenarios involving celery, carrot, and watermelon, and a five-strain cocktail of rifampin-resistant Escherichia coli O157:H7 was used in transfer scenarios involving lettuce. When the food contact surface was freshly inoculated, >90% of the inoculum was almost always transferred to the cut produce item. If the inoculated food contact surfaces were allowed to dry for 1 h, median transfer was generally >90% for carrots and watermelon but ranged from <1 to ~70% for celery and lettuce. Freshly inoculated celery or lettuce transferred more bacteria (<2 to ~25% of the inoculum) compared with freshly inoculated carrots or watermelon (approximately <1 to 8%). After 1 h of drying, the rate of transfer from inoculated celery, carrot, and lettuce was <0.01 to ~5% and <1 to ~5% for watermelon.



## **Food Allergy**

## Peanut Protein in Household Dust is Related to Household Peanut Consumption and is Biologically Active

H.A. Brough, A.F. Santos, K. Makinson, M. Penagos, A.C. Stephens, A. Douiri, et al.

Journal of Allergy and Clinical Immunology, Vol. 132, No. 3; pp. 630-638, 2013

Link to full text: http://www.jacionline.org/article/S0091-6749(13)00365-5/fulltext

**Significance:** Peanut protein in dust is biologically active and should be assessed as a route of possible early peanut sensitization in infants.

This study sought to explore the relationship between reported household peanut consumption (HPC) and peanut protein levels in an infant's home environment and to determine the biological activity of environmental peanut. Peanut protein was quantified in wipe and dust samples collected from 45 homes with infants by using a polyclonal peanut ELISA. There was a positive correlation between peanut protein levels in the infant's bed, crib rail, and play area and reported HPC over 1 and 6 months. On multivariate regression analysis, HPC was the most important variable associated with peanut protein levels in the infant's bed sheet and play area. Dust samples containing high peanut protein levels induced dose-dependent activation of basophils in children with peanut allergy.

## **Food Packaging**

## Improving the Capacity of Polypropylene To Be Used in Antioxidant Active Films: Incorporation of Plasticizer and Natural Antioxidants

M. del Mar Castro López , C. López de Dicastillo , J.M. López Vilariño, M.V. González Rodríguez

Journal of Agricultural and Food Chemistry, Vol. 61, No. 35; pp 8462-8470, 2013

Link to full text: http://pubs.acs.org/doi/full/10.1021/jf402670a

**Significance:** The poly(propylene glycol)-block-poly(ethylene glycol)block-poly(propylene glycol)-modified polypropylene is a potential system to be used in active packaging.

Two types of active antioxidant food packages with improved release properties, based on polypropylene (PP) as one of the most common polymers used in food-packaging applications, were developed. Incorporation of catechin and green tea as antioxidant provided PP with 6 times higher stabilization against thermal oxidation. Release of natural antioxidants (catechins, gallic acid, caffeine, and quercetin) into various food simulants from that nonpolar matrix were improved by blending poly(propylene glycol)-block-poly(ethylene glycol)-block-poly(propylene glycol) (PPG-PEG-PPG) as plasticizer into the polymer formulation. Increasing release levels between 10- and 40-fold into simulant A and between 6 and 20-fold into simulant D1 resulted from the incorporation of catechin and green tea as antioxidants and PPG-PEG-PPG as plasticizer into the film formulation. The efficiency of the antioxidants in the food simulants after the release process was also corroborated through antioxidant activity tests.

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1156 15th Street, NW Suite 200 Washington, DC 20005

Tel: 202.659.0074 Fax: 202.659.3859 ilsina@ilsi.org

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From: Sent: To:	Suzanne Harris <s> Wednesday, October 09, 2013 9:56 AM k; s.chang@griffith.edu.au; Cohen, Samuel M (scohen@unmc.edu); ; adamdrew@u.washington.edu; Drewnowski, Adam ); goodman3@msu.edu;</s>	
	Joanne Lupton; Gert Meijer john.c.peters@ucdenver.edu; ; Smith, Lewis	); john.milner@ars.usda.gov; ; Rodriguez, Felipe {PI} ; Geoff s L. (Prof.)
Cc:	weavercm@purdue.edu; ; Fleming, Melinda S ( Usui-E Chelsea L. Bishop; linda.reynolds@ars.us	; Flavio Zambrone Bradford, Jeanne (jbradford@unmc.edu); ); Etsuko(?? ??) sda.gov; tim.goss@ucdenver.edu;
Subject:	; Christine Lagerquist ( Brueggemeyer Date for a special conference call for the November 20 at 9:00 a.m. Eastern Stand	; haan@purdue.edu; ; Shawn Sullivan; Beth e ILSI Board of Trustees Wednesday, lard Time

FROM: Suzie Harris

Thank you to those of you who responded to the poll for this conference call. Based on the responses I received, the best day for the call is **Wednesday**, **November 20**, **2013**, **beginning at 9:00 a.m. Eastern Standard Time**.

An agenda with briefing materials and dial-in instructions will be sent to you about one week before the call. The topic for this call is the Strategic Long Range Plan and I think the call will not run longer than one hour. If you will not be able to participate, I encourage you to read the material sent in advance of the call and send your comments to full board or to me for distribution to the board.

Please let me know if you have questions or need additional information.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From: Sent: To: Cc: Subject:	Su Wi Za Po	uzanne Harris /ednesday, October 09, 2013 9:40 AM ; Joanne Lupton; Geoff ambrone ; Chelsea olling for date for a second ILSI Nomination Review Committee conferer	); Flavio a L. Bishop nce call
TO:	ILSI Board of Truste	ees Nomination Review Committee	
FROM:	Suzie Harris		
Peter van Bladeren is available for a one-hour conference call beginning at 9:00 a.m. Eastern Time on the days listed below. Please let me know your availability for these days.			
Friday, October 25			
Monday, Novem Tuesday, Novem Thursday, Nover	nber 4 nber 5 nber 7		

Thank you. Let me know if you have any questions.

## Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From: Sent: To: Cc:	Suzanne Harris < Monday, October 07, 2013 1:46 PM a Joanne Lupton; Geoff ); Flavio Zambrone Chochard-Odde,Fabiana,VEVEY,CT-ISP
Subject: Attachments:	Chelsea L. Bishop; Shawn Sullivan Bios for the current ILSI Board of Trustees ILSI BIOS MASTER 2013 without new trustees.docx; ILSI Bios for new trustees 2013.doc
TO:	ILSI Board of Trustees Nomination Review Committee
FROM:	Suzie Harris

Thank you all for participating in the initial Nomination Review Committee conference call last Monday. I will send minutes from that call to you shortly.

As agreed I attached the bios for the current ILSI Board of Trustees to this message. There are two files – the second one is for those nominated this past January.

I will poll for the committee's second call shortly as well.

Please let me know if you have any questions.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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## 2013 Nominees for the ILSI Board of Trustees

#### Applebaum, Rhona S., PhD

*Dr. Rhona S. Applebaum* is the Vice President and Chief Scientific and Regulatory Officer at The Coca-Cola Company where she leads Global Scientific and Regulatory Affairs (SRA), including The Coca-Coca Company's Beverage Institute for Health and Wellness. SRA is responsible for driving evidence-based research and education programs in energy balance, health, physical activity, and food safety; advancing regulatory science strategies; communicating company positions on SRA matters; providing systems guidance on SRA strategic priorities and expanding networks and partnerships with key stakeholder groups to advance dialogue and understanding concerning our products, our ingredients, our policies and programs. Dr. Applebaum joined The Coca-Cola Company in 2004 and was recently elected by The Coca-Cola Company's Board of Directors as a Vice President of the Company.

Dr. Applebaum serves on numerous committees including the Department of State's Advisory Committee on International and Economic Policy, the Center for Disease Control Foundation's Corporate/CDC Roundtable on Global Health Threats, the EPODE International Advisory Committee, and the Harvard Medical School Global Health Advisory Council.

She served on The Center for Strategic and International Studies Commission on Smart Global Health and as a member of the Science Advisory Board of the US Food and Drug Administration (FDA).

Dr. Applebaum received her B.A. from Wilson College in history and biology, her M.S. in nutrition and food science from Drexel University and her Ph.D. in food microbiology and food safety from the University of Wisconsin. She has authored/co-authored numerous scientific publications and has presented at many national and international scientific and regulatory meetings.

#### Belanger, Scott E., PhD

*Scott Belanger* is presently a Research Fellow in Procter & Gamble's corporate safety organization where he has broad leadership responsibilities for environmental toxicology, science, and technology guidance from an environmental perspective. He holds degrees from the University of Wisconsin (B.S.), Bowling Green State University (M.S.) and Virginia Tech (Ph.D. and post-doctoral appointment). Prior to joining P&G in 1989, he was an Assistant Professor in Environmental Toxicology at the University of Louisiana-Lafayette. During his tenure at P&G Scott directed research at P&G's Experimental Stream Facility in southwestern Ohio evaluating the ecological impacts of P&G's highest volume detergent chemicals. L ater he assumed responsibility for P&G's global environmental toxicology function including guidance for upstream technology development on environmental matters. Scott is a recognized authority in the responses of aquatic life to man-made and natural stressors and has authored over 100 published scientific articles, books and book chapters on these topics. He has served on numerous national and international panels providing advice to organizations such as the U.S. Environmental Protection Agency, the OECD (Organization for Economic Cooperation and Development, an international governing body), the European Commission, the Japanese Ministry of Environment, Trade and Industry, and Environment Canada.

Presently in P&G's Corporate Environmental Stewardship Organization he directs research on ecological and toxicological responses of fish, invertebrates and algae to consumer product chemicals and advises P&G broadly on the development of new technologies and issues relating to sustainable development.

#### Devlin, Dennis J., PhD

*Dr. Devlin* received his B.A. in Biology from St. Louis University, M.S. in Environmental Engineering from Washington State University and a Ph.D. in Toxicology from Dartmouth College in 1987. Upon completing his Ph.D., he joined the Special Projects Group at Exxon Biomedical Sciences, Inc. where he worked on site and product risk assessments. In 1988, he was made Group Head of the Performance Products toxicology consulting group. Dr. Devlin transferred to the Brussels headquarters of Exxon Chemical International, Inc. in 1991 where he directed the toxicology program for European Exxon business groups and area offices. During this period he took a lead role representing industry in communications with the European scientific,

business and regulatory communities regarding health and environmental issues and helped coordinate industry research between the US and Europe on key health-based issues. In 1994, Dr. Devlin returned to the U.S. and assumed Section Head responsibilities for the Environmental Sciences Consulting Group, which provided support to Exxon affiliates worldwide. He led a program investigating the health effects of global climate change and was a lead contributor to the European Union's benzene risk assessment on behalf of industry sponsors. Following the merger of Exxon and Mobil, Dr. Devlin was appointed Section Head of Lubes, Fuels and Specialties consulting support. I n 2002 he became Director of Toxicology and Environmental Sciences. In this role, he led ExxonMobil's organization for toxicology and environmental sciences, ensuring that worldwide affiliates and support organizations received effective consulting services, science development, and field support. He also had oversight responsibility for work processes involving hazard and risk assessment, laboratory operations, and animal testing and use. In 2009, Dr. Devlin assumed the role of Environmental Health Advisor for Exxon Mobil Corporation where he provides strategic guidance for environmental health policy and planning. He is also Chairman of the Petroleum Industry HPV Testing Group Oversight Committee and a member of the ILSI HESI Board of Trustees.

## Meijer, Gert W., PhD

*Prof. Gert Meijer* is Vice-President Global Nutrition, and Head of the Unilever Nutrition Network at Unilever R&D, based in Vlaardingen, The Netherlands. He received his B.Sc. and M.Sc., cum laude, in Human Nutrition from the Agricultural University in Wageningen, and his Ph.D., cum laude, in 1991, at the University of Utrecht in The Netherlands.

Prof. Meijer worked at the National Institute of Public Health in The Netherlands, from 1991 to 1994. In 1994 he joined the Unilever Nutrition Centre in Vlaardingen. Before his transfer to the USA in 1999, he coordinated the program of nutrition intervention studies to establish the cholesterol-lowering efficacy of plant sterol esters. Until September 2003, Prof. Meijer was the Director of Nutrition Science for Unilever Bestfoods North America. Before assuming his current role, he was the Director of the Unilever Health Institute. He is also Visiting Professor at the University of Ulster.

#### Peters, John C., PhD

*Dr. John C. Peters* is Associate Professor of Medicine at the University of Colorado, Denver. He is also Chief of Strategy and Innovation at the new Colorado Center for Health and Wellness on the Anschutz Medical Campus of the University of Colorado, in Denver. Prior to joining the faculty at the University of Colorado in September of 2011 he spent 26 years at the Procter & Gamble Company in a variety of Research and Development positions in food and beverage, health care and corporate new business development. He received degrees in Biochemistry from the University of California at Davis and the University of Wisconsin at Madison, respectively. Over the past 30 years, Dr. Peters has conducted and managed research in a variety of areas including obesity, diabetes, lipid absorption and metabolism, and vitamin and mineral bioavailability. He is also involved in several public health initiatives promoting healthy lifestyle behaviors: He is cofounder and CEO of the America on the Move Foundation (www.americaonthemove.org) and past President of the International Life Science Institute Center for Health Promotion. He served on two National Academies of Science, Institute of Medicine Committees on reducing and preventing childhood obesity. He sits on advisory boards of the Arkansas Biosciences Research Institute and the ILSI Research Foundation. Dr. Peters has published over 115 scientific papers and reviews. He co-authored the book "The Step Diet."

#### Gerhard Rechkemmer, Prof. Dr. rer. nat. Dr. rer. nat. habil.

*Gerhard Rechkemmer, Prof. Dr. rer. nat. Dr. rer. nat. habil.*, is President and Professor of the Max Rubner-Institute (Federal Research Institute of Nutrition and Food) in Karlsruhe. He holds a Honorary Professorship at the Karlsruhe Institute of Technology (KIT) and an Associate Professorship for Physiology at the School of Veterinary Medicine in Hannover. He is a member of the board of the German Nutrition Society (DGE) and of the Senate Commission on Food Safety of the German Research Council (DFG). Currently he is a member of the Board of Directors of ILSI Europe. His major research interests are in the area of bioactive food constituents and their physiological and health impact with a focus on gastrointestinal and metabolic functions. He was involved in several European projects in the past years, e.g. PASSCLAIM, BRAFO, EURRECA, EUROFIR.

## Abraham, Todd, PhD

*Dr. Todd Abraham* is Senior Vice President of Global Research, Nutrition and Technology Strategy for Mondelēz International (formally Kraft Foods). He is responsible for long term cross category Research Programs as well as Research support to Business Divisions. He also oversees the Research and Nutrition Groups at the Glenview, East Hanover, Whippany, Munich, Germany, and Reading, UK sites. B efore moving to Kraft / Nabisco as Sr. Vice President, Product Development, Nabisco Foods Company, he held previous leadership positions in Marketing and R&D at Pillsbury and Procter and Gamble with both North American and International experience. Todd completed his Sc.B. in Chemistry at Brown University in Providence, RI. He received his Ph.D. in Chemistry from the University of Pennsylvania in 1981 and his M.B.A. from The Wharton School in May, 1981.

## Boobis, Alan R., Professor, OBE, PhD, CBiol, FSB, FBTS

Prof. Alan Boobis is professor of biochemical pharmacology in the Department of Medicine, Imperial College London and Director of the Health Protection Agency Toxicology Unit. He has been a member of Imperial College London (mainly at the Royal Postgraduate Medical School, which merged with the College in 1997) for over 35 years. His main research interests lie in mechanistic toxicology, drug metabolism, toxicity pathway analysis and increasingly over the last 20 years or so, in the application of knowledge in these areas to risk assessment. He has published over 220 original research papers and until recently was an Editor-in-Chief of Food and Chemical Toxicology. He is a member of a number of national and international advisory committees, including several IPCS working groups, JECFA, JMPR (co-chair) and the UK Committee on Carcinogenicity. He was a member (1993-1999) and deputy chairman of the U.K. Advisory Committee on Pesticides (1999-2002). He was a member (2003-2009) and deputy chair (2009-2012) of the UK Committee on Toxicity, a member of the EFSA Panel on Contaminants in the Food Chain (2009-2012) and a member (2003-2006) and deputy chair (2006-2009) of the EFSA Panel on Plant Protection Products. He is past chairman of the Board of Trustees of ILSI HESI, current vice-president of ILSI Europe and is involved in several ILSI/HESI projects. He received an OBE for his work on the risk assessment of pesticides in 2003.

#### Chang, Sushila, PhD

*Dr. Sushila Chang* is presently at the Singapore University of Technology and Design. Dr. Chang was Professor and Director of the Office of Undergraduate Education at The University of Queenslan(UQ), in Brisbane, Australia until fall 2011. S he was formerly Coordinator of the Biotechnology program at UQ and prior to joining UQ she was senior director and director of the School of Life Sciences and C hemical Technology, Ngee Ann Polytechnic, Singapore. Chang received a BSc in biology from the University of London, and MSc and PhD degrees from the University of Paris VII. She also holds a graduate certificate in intellectual property law from the National University of Singapore. Before joining Ngee Ann Polytechnic, Dr. Chang was a biochemist with Eastreco Pte., Ltd. (Nestle's research & development in southeast Asia), where she planned studies for indigenous raw materials and supervised analyses and developed products such as sauces, noodles, and soups. Prior to this, she was a teaching/research fellow at the University of Paris V and at the Laboratory of Cellular Biology and Toxicology, University of Paris VII.

## Cohen, Samuel M., MD, PhD

Dr. Samuel Cohen received his M.D. and Ph.D. degrees from the University of Wisconsin -Madison in 1972. He completed a residency in anatomic and clinical pathology at St. Vincent Hospital, Worcester, Massachusetts, in 1975, and became board certified the following year. He was a visiting professor in the department of Dr. Nobuyuki Ito at Nagoya City University Medical School, Nagoya, Japan, from 1976 to 1977, a staff pathologist at St. Vincent Hospital from 1975 to 1981, and associate professor of pathology at the University of Massachusetts Medical School from 1977 to 1981. In 1981, he became Professor and Vice Chairman of Pathology in the College of Medicine and Professor at the Eppley Institute, University of Nebraska Medical Center. In 1992, he was named Chairman of the Department of Pathology and Microbiology at Nebraska. Dr. Cohen's research has focused on mechanisms of carcinogenesis, with a focus on the role of cell proliferation in the carcinogenic process, primarily utilizing the urinary bladder as a model system. Mos t recently this has involved investigations into the mechanisms of bladder carcinogenesis produced by arsenicals and PPAR agonists. Research with PPAR agonists has recently led to investigations into mechanisms of induction of hemangiosarcomas. In addition, his research has involved clinical investigations of various aspects of urologic pathology as well as extrapolation between animals and humans. He also has been active in mathematical modeling efforts and applications to risk assessment. This research has resulted in more than 300 publications. He has been a member of numerous NIH, EPA, FDA, WHO, IARC and National Academy of Sciences study sections and scientific panels, was a member of the National Toxicology Program's Board of Scientific Counselors, and currently serves on the NIEHS Board of Scientific Counselors. He is on the editorial boards of six scientific journals in the areas of toxicology, pathology, and carcinogenesis, and is a reviewer for several other journals. He was president of the SOT Carcinogenesis Specialty Section and the SOT Central States Chapter of the Society of Toxicology. He was the recipient of the Society's Arnold J. Lehman Award in 2001 and was named Distinguished Scientist in Cancer Research by the Japanese Foundation for Cancer Research in 2004. H e continues to be active in human surgical pathology, subspecializing in urologic pathology, and is listed as one of the "Best Doctors in America." He has been actively involved with ILSI, RSI, and HESI since 1985, serving as a member of the ILSI and HESI Board of Trustees since 2007 and 2001 (respectively) and is currently chairman of the ILSI Board.

## Drewnowski, Adam, PhD

*Dr. Adam Drewnowski* is the director of the Center for Public Health Nutrition and the Center for Obesity Research at the University of Washington, where he is a professor of Epidemiology and adjunct professor of Medicine. Dr. Drewnowski is also a member of the Fred Hutchinson Cancer Research Center in Seattle.

Dr. Drewnowski's work covers nutritional science, sensory science, and the economics of food choice behavior. His earlier work focused on the role of taste in food selection, with emphasis on the sensory response to sugar and fat. His current work deals with the socioeconomic determinants of health and geographic disparities in the rates of obesity and diabetes. Dr. Drewnowski is the author of the Nutrient Rich Foods Score, a method to assess nutrient density of foods based on the nutrient-to-energy ratio. The NRF nutrient profiling model has potential applications in estimating the affordability and sustainability of foods and diets.

In 2005, Dr. Drewnowski received the French Food Spirit Award from the association of French food industries for his studies on diet quality in France. In 2012, Dr. Drewnowski was the recipient of the Prix Benjamin Delessert. He is currently Visiting Professor at the University Pierre et Marie Curie, Paris VI.

Prior to joining the University of Washington, Dr. Drewnowski was Director of the Human Nutrition Program at the University of Michigan School of Public Health and Professor in the Departments

of Environmental and Industrial Health, Psychology, and Psychiatry. Dr. Drewnowski obtained his MA degree in biochemistry from Balliol College, Oxford University; PhD degree in psychology from the Rockefeller University in New York and completed a postdoctoral fellowship in cognitive psychology at the University of Toronto. He began his scientific career as Assistant Professor in the Laboratory of Human Behavior and Metabolism at the Rockefeller University Hospital. Dr. Drewnowski also serves on the Board of Trustees for ILSI and ILSI Research Foundation.

## Ehrich, Marion, PhD

Dr. Marion Ehrich is a professor at Virginia-Maryland Regional College of Veterinary Medicine in Blacksburg, VA, and Virginia Tech Carilion School of Medicine, Roanoke. In addition to the teaching of pharmacology and toxicology to veterinary, medical and graduate students, her professional responsibilities include service in the Veterinary Medical Teaching Hospital Pharmacy and in the Toxicology Diagnostic Laboratory. Dr. Ehrich has a B.S. in pharmacy from South Dakota State University, a M.S. in pharmacology/toxicology from the University of Chicago, and a Ph.D. in pharmacology/toxicology from the University of Connecticut at Storrs. She has been teaching at VMRCVM since 1980, the year in which she became a member of the Society of Toxicology and a Diplomate of the American Board of Toxicology. She was elected a fellow of the Academy of Toxicological Sciences in 1999. Dr. Ehrich's primary research activities are associated with the comparative neurotoxicities of antiesterase pesticides, with both in vivo and in vitromodels used for study. Dr. Ehrich was the 2003-2004 President of the Society of Toxicology. She served as Treasurer for the Board of Directors of the American Board of Toxicology (1985-89) and as Secretary for the Society of Toxicology (1992-94). She has also chaired SOT's Education Committee (1990-92), SOT's Regulatory Affairs and Legislative Action Committee (1997-98), and the Toxicology Education Foundation (2000-2001). In addition, she serves/served on the editorial boards for Fundamental and Applied Toxicology, the American Research, the Journal of Toxicology Journal of Veterinary and Environmental Health, NeuroToxicology and the International Journal of Toxicology. She served on review panels for the National Academy of Sciences that dealt with Gulf War and Health and with Low-Level Effects of Chemical Warfare Agents and on EPA-sponsored review panels that dealt with Common Mechanisms of Toxicity for organophosphorus compounds and c arba-mates when doing risk assessments under conditions of multiple exposures, and on a recent NIEHS review group assessing in vitro replacements for animal testing.

## Eisenbrand, Prof. Gerhard

*Prof. Gerhard Eisenbrand* is Senior Research Professor at the University of Kaiserslautern, Department of Chemistry, Division of Food Chemistry and Toxicology. His research focuses on mechanisms of actions of (geno)toxic agents and their biotransformations within mechanistic toxicology and cancer research. In the context of dose- and structure/activity studies he is interested in interactions of natural and process-related food constituents/ contaminants with biomolecules. Mechanistic studies are complemented by in- vivo and b y human intervention studies, aimed at the development and use of biomarkers concerning food safety issues and food related human health effects. Prof. Eisenbrand is a long standing member of the ILSI Europe Board of Directors.

## Goodman, Jay I., PhD

*Dr. Jay Goodman* is a professor of Pharmacology and Toxicology at Michigan State University, where he has served on the faculty since 1971. A Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences, Dr. Goodman is pursuing research focused on di scerning the role(s) of altered DNA methylation as an epi genetic mechanism underlying the aberrant gene expression involved in carcinogenesis, and testing the hypothesis that susceptibility to carcinogenesis is related inversely to the capacity to maintain

normal methylation patterns. He is a former president of the Society of Toxicology (SOT), and served as a m ember of the SOT's Task Force to Improve the Scientific Basis for Risk Assessment. Dr. Goodman was an Associate Editor of Toxicological Sciences, and he currently serves as an associate editor of Toxicology, and Regulatory Toxicology and Pharmacology. Dr. Goodman was a member of the Advisory Committee to the Director of the Centers for Disease Control and Prevention, the Board of Scientific Counselors of the National Toxicology Program, the Board of Directors of the American Board of Toxicology and the Board of Directors of the Academy of Toxicological Sciences, and was an expert reviewer at the U.S. Environmental Protection Agency's Workshop on Cancer Risk Assessment Guidelines. Dr. Goodman is currently a member of the Board of Scientific Counselors, NIH, National Institute of Environmental Health Sciences. He holds a doctorate in pharmacology from the University of Michigan (1969), and was a postdoctoral fellow in the McArdle Laboratory for Cancer Research, University of Wisconsin

## Hjelle, Jerry J., PhD

*Dr. Jerry* Hjelle is Vice President, Science Policy at the Monsanto Company. He is responsible for the development of Science Policy to improve agricultural technology development worldwide. His primary focus of research has involved toxicology, food safety and risk assessment, and he has led groups involved in the research and development of human and animal drugs, food ingredients, and, most recently, agricultural chemistries and biotechnologies. From 1997-2010, Dr. Hjelle led Monsanto's Regulatory Organization, a gl obal group responsible for conducting health and environmental research and obtaining global regulatory approvals for the company's emergent and existing products. He is Vice President of the International Life Sciences Institute (ILSI), a global scientific organization that advances science by engaging academic, private sector and government scientists in areas including food and nutrition, health and environmental safety and risk assessment. He is also Vice Chairman of the ILSI Research Foundation. Dr. Hjelle received a doctorate from the University of Colorado in 1982, completed a post-doctoral fellowship in Toxicology at the University of Kansas Medical Center and served on the faculty at the School of Veterinary Medicine at the University of Wisconsin-Madison. He is a D iplomat of the American Board of Toxicology and member of the Society of Toxicology.

#### Kimura, Takeshi, PhD

*Dr. Takeshi Kimura* studied Cell and Molecular Biology at University of London, King's College and obtained a PhD in Biochemistry from University of London in 1984.

He was Visiting Fellow and Visiting Associate at the National Institutes of Health in the USA from 1984 to 1989. In 1989 he joined Ajinomoto and worked at the Central Research Laboratories and External Scientific Affairs department at head office. He then served as head of the Washington DC Office from 1992 to 1997. In 1998 he started the Basic Safety Research Group at the Institute of Life Sciences. From 2005 to 2010 he served as General Manager of Quality Assurance and External Scientific Affairs Department. He became Corporate Executive Officer in 2009. C urrently, he is General Manager of R&D Planning Department. He is also a member of the ILSI research Foundation Board of Trustees for International Life Sciences Institute Research Foundation, Chief Executive Officer for the International Glutamate Technical Committee, Board Member for International Council on Amino Acid Science, and Member of APEC Policy Partnership on Food Security.

## Knowles, Michael E., BPharm PhD CChem FRSC, FIFST

*Dr. Michael Knowles* is Vice President Global Scientific and Regulatory Affairs, The Coca-Cola Company.

Michael studied at the University of Nottingham where he was awarded a BPharm (1st Class Hons) in Pharmaceutical Chemistry. He was awarded a PhD for his work in medicinal chemistry, which he extended as a ICI post-doctoral fellow for a further two years.

Michael was employed in the UK Ministry of Agriculture, Fisheries and Food's Food Science Division, initially as a Senior Research Fellow, eventually to become Head of the Food Science Laboratory. In 1985, he became Head of Food Science Division in London and Chief Scientist (Fisheries and Food) and Under-Secretary Food Science Group, on 1 August 1989 until the end of 1991 when he joined Coca-Cola Greater Europe. From 1992 until 1999 he was SRA Director for Greater Europe Group, with additional responsibilities for Middle East Division and Africa Group, then Group SRA Director for Europe, Eurasia and Middle East Group and finally for the European Union Group. He was then appointed Managing Director of the Beverage Institute for Health and Wellness and Chief Scientific Officer for the European Union Group. Now he is VP Global Scientific and Regulatory Affairs, The Coca-Cola Company, based in Brussels. His personal research interests have been in the field of chemical aspects of food safety, publishing numerous papers in peer-reviewed scientific journals.

Dr. Knowles is Past President of ILSI.

## Kuwata, Tamotsu, Ph.D

Dr. Tamotsu Kuwata is Chairman of the Health and Nutrition Department at The University of Human Arts and Sciences. In 2007 Dr. Kuwata was promoted to Professor at the University. From 1968 – 2007 Dr. Kuwata worked for Meiji Dairies Corporation (Japan) where he held a wide range of product development, research, and managing roles. He retired as the Managing Director of their Division of Research and Development in June 2007 and is now Senior Scientific Advisor for all research & development activities. He received his MS in dairy science, specializing in the biochemistry of milk proteins, and his PhD in agriculture, specializing in the functionality of milk whey proteins, from Hokkaido University. Following graduation, he joined Meiji Dairies Corporation, where he managed several research & development sections, including infant, enteral, and sports nutrition, as well as dairy ingredients for the food industry. Dr. Kuwata's specialties are the management of research activities involving special foods and appetite and the effect of eating habits on healthy aging. He served as chairperson of the organizing committees for the 3rd, 4th and 5th International Conferences on Nutrition and Aging held in Tokyo during 1999, 2003 and 2007. He is a trustee and/or councilor for over 10 food nutrition and bioscience academic societies.

#### Kwon, Ik-Boo, PhD

*Dr. lk-Boo Kwon* is Executive Advisor of Lotte Research & Development Center. He obtained his undergraduate degree in food engineering at Yonsei University; and graduate degree in fermentation engineering at Kangweon University. Dr. Kwon has worked for the Lotte Company since 1965. Among Dr. Kwon's many professional affiliations over the years are, president of the Committee of Food Research Institute; civil advisor, presidential Advisory Council for Science and Technology; chief editor, Korean Society of Food Science Technology; and advisor in food additives, Korea Food and Drug Administration. Dr. Kwon is listed in the Marquis Who's Who Series in World, Asia, and Science & Engineers Who Built Korea's Prosperity; and is the recipient of the Korea Civil Merit Medal.

## Lupton, Joanne R., PhD

*Dr. Joanne R. Lupton* is a Distinguished Professor, Regent's Professor and University Faculty Fellow at Texas A&M University and holder of the William W. Allen Endowed Chair in Human Nutrition. She chaired the Macronutrients Panel for the Dietary Reference Intakes, Food and Nutrition Board, National Academy of Sciences, and also chaired the National Academy panel to determine the definition of dietary fiber. She spent one year at the Food and Drug Administration helping to develop levels of scientific evidence required for health claims and served on the 2005 Dietary Guidelines Committee. She is a member of the Institute of Medicine, and is currently on the Food and Nutrition Board. Her research is on the effect of diet on colon physiology and colon cancer with a particular focus on dietary fiber and n-3 fatty acids.

Dr. Lupton is equally committed to teaching and research and has received a number of teaching awards including the national USDA teaching award and the Association of Former Students at Texas A&M Teaching award. She has mentored more than 50 MS and PhD students while at Texas A&M. She received the Dannon mentoring award in 2004.

Dr. Lupton is Past President of the American Society for Nutrition (ASN) and she is currently serving on the Board of Trustees of ILSI North America, and ILSI Global. Her undergraduate degree is from Mt. Holyoke College and her Ph.D. in Nutrition is from the University of California at Davis.

#### Milner, John, PhD

Dr. John Milner is Director, USDA Beltsville Human Nutrition Research Center, From 2001 – 2012 he was Chief of the Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute. From 1989 to 2000, he was Head of and a Professor in the Department of Nutrition at The Pennsylvania State University, where he also served as Director of the Graduate Program in Nutrition. Before joining Penn State, he was a faculty member for 13 years in the Food Science Department and in the Division of Nutritional Sciences at the University of Illinois-Urbana-Champaign. While at the University of Illinois he served as the Director of the Division of Nutritional Sciences and as an Assistant Director of the Agricultural Experiment Station. Dr. Milner earned a Ph.D. from Cornell University in nutrition, with a minor in biochemistry and physiology and a B.S. in Animal Sciences from Oklahoma State University. He is a member of several professional organizations, including the American Society for Nutrition, American Association of Cancer Research, the American Chemical Society's Food and Chemistry Division, and the Institute of Food Technology. He is a fellow in the American Association for the Advancement of Science, Sigma Xi and an Honorary Member of the American Dietetic Association. He has served in an advisory capacity as a member of the U.S. Department of Agriculture's Human Nutrition Board of Scientific Counselors, Joint USDA/HHS Dietary Guidelines Committee, and for the Food, Nutrition and Safety Committee within the International Life Sciences Institute (ILSI). Dr. Milner has served as president of the American Society for Nutrition (formerly the American Institute of Nutrition) and has testified before the Subcommittee on Appropriations in Washington, D.C. and the Presidential Commission on Dietary Supplement Labels in Baltimore, Maryland. He has served as a member of the National Academy of Sciences Committee on Military Nutrition Research, the U.S. Olympic Committee Dietary Guidelines Task Force, the External Advisory Board for the Pennington Biomedical Research Center, as a member and Vice-Chair for the Counsel of Experts of United States Pharmacopeia Committee on Bioavailability and Nutrient Absorption, a member of the External Advisory Board for the European Commission SeaFood Plus initiative and Chair of the Nutritional Science Council for the American Society for Nutrition. He is currently a member of the Global Board of Trustees for ILSI, member

of the Danone Institute's International Functional Foods and Health Claims Knowledge Center Committee, Member of the McCormick Institute Advisory Committee and member of the World Cancer Research Fund/American Institute for Cancer Research Continuous Update Committee and a member of the Mushroom Research Board. In 2008 he received the David A. Kritchevsky Career Achievement Award in Nutrition from the American Society for Nutrition. Dr. Milner has published more than 200 book chapters, monographs and journal articles. He serves on the editorial boards for Food and Nutrition Research, Nutrition and Cancer, Nutrfood, Journal of Nutritional Biochemistry, Journal of Alternative and Complementary Medicine, Journal of Ovarian Research, and The Journal of Medical Foods. He is a S enior Editor for Cancer Prevention Research. In his current position he promotes research that deals with the physiological importance of dietary bioactive compounds as modifiers of cancer risk and tumor behavior.

## Rodríguez Palacios, Felipe de Jesús

*Felipe Rodríquez* is Director of Research and Development Packaging, Promotions and Food Safety for Mexico, Central America and Caribbean at Pepsico. He joined Pepsico in 2000 as the Director of Research and Development Operations.

Mr. Rodríquez has also worked for Kraft Foods de Mexico from 1990 to 2000, where he served as the Corporate Research and D evelopment and Q uality Assurance Manager and then the Corporate Research and Development Manager. Prior to this he worked as the Technical Services Manager, Corporate Food Safety Manager and Q uality Control Manager for General Foods de Mexico in the late 1980s. He began his industry career in 1986 at CPC as a Trainee Engineer and then New Product Engineer in the Research and Development Department. From 1984 to the present, Mr. Rodríquez served as Professor of Food Additive and Product Development for the Chemistry Faculty of the Universidad Nacional Automoma de Mexico. From 1986 to 2000, Mr. Rodríquez was a Professor of Food Additive and Product Development at the Universidad La Salle and Universidad Iberoamericana in Mexico City. During this period of time, he published 10 articles on food additives and food product development in a local food science magazine, Technologia de Alimentos and Industria Alimentaria.

Mr. Rodríquez has represented Pepsico in ILSI Mexico since 2001. He was elected Treasurer of ILSI Mexico and a member of the Board of ILSI Mexico in 2001. In 2008, he was elected Vice President of ILSI Mexico. He has also served as President of the Asociaión De Tecnologos en Alimentos de Mexico (ATAM) IFT Regional Section 26 in 1991, having served as Secretary and Vice President in prior years. In 1993, Mr. Rodríquez was promoted to the ALACTA Congress in Mexico City. Mr. Rodríquez graduated cum laude as a Pharmaceutical Chemist Food Technology from Universidad Nacional Autónoma de Mexico.

## Seth, Prahlad K., PhD

*Dr. Prahlad K. Seth* is the Chief Executive Officer of Biotech Park in Lucknow, India and Honorary Emeritus Professor in the Department of Biochemistry at Lucknow University. He is also an Adjunct Professor in the Department of Toxicology at Jamia Hamdard University, New Delhi and Vice President of National Academy of Sciences, India. Formerly he was Director of Industrial Toxicology Research Center now named as Indian Institute of Toxicology Research, Lucknow. He has made some outstanding contributions to toxicology and its growth in India and chaired the Task Force on Toxicogenomics, first such facility set up by Council of Scientific and Industrial Research (CSIR) in the country. Dr. Seth has close interactions with life sciences industries and has been Visiting Scientist and Visiting Professor to several US universities and institutions. Several national and international awards including P.C. Ray Gold Medal Awarded by Indian Science Congress Association, 2009 and Prof. B.K. Bachhawat Memorial Life Time Achievement Award of Indian Academy of Neurosciences, 2006; Board of Trustees Research Award of Chicago Medical School and Fellowships of National Science academies have been conferred on

him. He earned his doctorate in biochemistry from the University of Lucknow in 1967.

## Smith, Geoffry

*Mr. Geoffry Smith* is the founding director of Nutrition Strategies International LLC which deals with food and nutrition issues in developing countries. In addition, he is the Chairman of the Essential Micronutrients Foundation, a non-profit organization which addresses micronutrient deficiencies globally as a public health issue. Prior to his current positions, Mr. Smith was the Global Director, Health Chelates for Akzo Nobel Functional Chemicals, and directed the global business for these compounds in food and nutrition as well as pharmaceutical applications. He was responsible for the global project within Akzo Nobel addressing iron deficiency anemia. In addition, Mr. Smith directed the Asia Pacific activities for Akzo Nobel's Innovation Unit. He is a thirty year veteran of the chemical industry in Asia Pacific, and has resided in Singapore for more than 18 years. He is a member of the Nutrition Society of the UK, the American Society of Nutrition and the American Chemical Society. Mr. Smith worked with Akzo Nobel in Singapore and The Netherlands, but is originally from San Francisco, California.

## Smith, Lewis L., BSc, PhD, FRCPath

*Dr. Lewis Smith* is the interim director of the Centre for Translational Therapeutics, University of Leicester, UK. Prior to this he served as the Global Head of Regulatory Sciences for Syngenta. From 1971 to 1991, Lewis was responsible for a number of toxicological research projects in ICI and was ultimately Head of the Biochemical Toxicology Department in the Central Toxicology Laboratory (CTL). In 1991, Lewis left ICI to become Professor of Biochemical Toxicology at the University of Leicester and D irector of both the Medical Research Council's Institute for Environment and Health and the MRC Toxicology Unit. Lewis has published approximately 100 articles, papers or book chapters on v arious aspects of the mechanism of toxicity of drugs, pesticides and industrial chemicals. In 1998, he returned as Director of Zeneca's CTL. After Zeneca merged with Astra in 1999, the biotech and agroscience businesses of AstraZeneca and Novartis were hived off and merged to form Syngenta.

#### Thompson, Geoff, PhD

*Dr. Geoff Thompson* is VP European Public Affairs for Danone and is based in Brussels. He earned a B.Sc and Ph.D in chemistry from the University of Leeds in the UK and then worked as a postdoctoral research fellow at the University of Graz in Austria. He published a number of papers in the field of inorganic reaction kinetics before joining Unilever in the UK where he worked in R&D on a range of topics including dehydration/rehydration, food emulsions, UHT processing and novel food preservation technologies. Following Unilever; he joined Nabisco to set up a new R&D facility in the UK and, when shortly afterwards Nabisco in Europe was acquired by Danone, he moved to France as R&D Director of Belin, one of the Danone biscuit division companies. After this, he moved back to the UK to take up the post of Director with the Jacobs Bakery with responsibilities for R&D, Quality, Food Safety and Crisis Management before being appointed worldwide Director for Quality & Food Safety for the biscuit division of Danone based in Paris. Following this, he became director for corporate scientific & regulatory affairs based in Paris before taking on h is current role for Danone in Brussels as VP European Public Affairs.

*Dr. Thompson* is vice-chairman of the ILSI Europe board, chairman of the food & consumer policy committee of the federation of European food & drinks industries (FoodDrinkEurope) vice-chairman of the European food safety authority (EFSA) stake-holders consultative platform and a B oard member of the European Food & Drink Council. He is also a fellow of the Institute of Food Science & Technology (London) and a fellow of the Royal Society for Public Health (London).

## Valdés Martínez, Sara E., PhD

Dr. Sara Valdés Martínez graduated with honors from the Nacional Autonomus University of Mexico (UNAM) with a BSc degree in food science, and obtained her PhD from the University of Strathclyde in Scotland with a scholarship from the Universidad Nacional Autónoma de México. She is a full-time professor with the Facultad de Estudios Superiores Cuautitlán of UNAM, and has worked at the University for 31 years and at FES-Cuautitlán for 29 years. Dr. Valdés has participated as a speaker in multiple national and internacional courses, seminars, and conferences, and has presented the results of her research studies in international and national forums as well. Since 1983, she has been the head of a research group on food safety and quality, in which the main areas of research are food analysis, aflatoxins in foods, determination of the presence of adulterants in foods, extractions, characterization, and determination of the stability and application of natural colorants. She has obtained several grants for her research projects as well as several recognitions from the associations where she has worked. She has published over 35 papers in national and international magazines, and has directed 110 bachelor's theses, 6 master's theses, and one doctoral thesis. Dr. Valdés was chairwoman to ATAM (National Association of Food Technologists) in 1993 (IFT Section 26), chairwoman of ALACCTA (Latinamerican and Caribbean Association of Food Science and Technology) in 1996 and 1997, a member of the Institute of Food Technologists since 1988, and a councilor of the Institute since 1999. She has participated in IFT in the Committee on Sections and Divisions, the Global Interest Committee, and the Committee on Diversity. She served as councilor for ILSI México from 1995 to 1999, and has been academia chairwoman of ILSI México for the period of 1999-2010. She spent a sabbatical in 2001 at Silliker Mexico. She presently acts as an external advisor to the company as well as an instructor. Dr. Valdés also acts as an advisor to industry. She has been a member of the ILSI Board of Trustees as a representative of Latin America and the Executive Committee since 2004 acting as its Secretary since 2007. She has acted also as part of other ILSI Committees, as the Tripartite Committee and Publications Committee.

#### van Bladeren, Peter, PhD

*Dr. Peter van Bladeren*, Global Head of Regulatory and Scientific Affairs for Nestle (2012), studied organic chemistry in Leiden University followed by a PhD in Toxicology. After a postdoc in the US (Bethesda) and an associate professorship in Wageningen University he joined TNO, the Dutch organization for Applied Science, in Zeist, the Netherlands. In 1994 he was appointed director of TNO Nutrition and Food Research. In addition, in 1991 he became (part-time) professor of toxicology at Wageningen University, a position he still holds today. In 2002 he joined Nestlé as director of the Nestlé Research Centre, Lausanne, Switzerland.

#### Weaver, Connie M., PhD

*Connie M. Weaver, Ph.D.,* is Distinguished Professor and Head of the Department of Nutrition Science at Purdue University, West Lafayette, Indiana. In 2012 she was selected as the Herbert Newby McCoy recipient. This award is the most prestigious research honor given by Purdue University. In 2010 she was elected to membership in the Institute of Medicine of The National Academies, of which she is a member of the Food and Nutrition Board. Also, in 2010 the Women's Global Health Institute (WGHI) was formed at Purdue University with the mission of improving the health of women globally through research and training by proactively identifying the causes and prevention of diseases related to women. In 2008, she became Deputy Director of the National Institutes of Health funded Indiana Clinical and Translational Science Institute. From 2000 to 2010, she was Director of the NIH Purdue-UAB Botanical Research Center to study dietary supplements containing polyphenolics for age-related diseases. Her research interests include mineral bioavailability, calcium metabolism, and bone health. Dr. Weaver is past-president of American Society for Nutritional Sciences. She is on the Board of Trustees of the International Life Sciences Institute, National Osteoporosis Foundation and Science Advisory

Board of Pharmavite. F or her contributions in teaching, Dr. Weaver was awarded Purdue University's Outstanding Teaching Award. H er honors include the Purdue University Health Promotion Award for Women (1993), the Institute of Food Technologists Babcock Hart Award (1997), USDA A.O. Atwater Lecture Award (2003), the NAMS/Glaxo Smith Kline Consumer Healthcare Calcium Research Award (2006), the Purdue University Sigma Xi Faculty Research Award (2006), the American Society for Nutrition Robert H Herman Award (2009), the Natural Products Association's Burton Kallman Scientific Award (2010), and the Linus Pauling Research Prize Award (2011). D r. Weaver was appointed to the 2005 Dietary Guidelines Advisory Committee for Americans. She has published over 260 research articles. Dr. Weaver received a Bachelor of Science and Master of Science in food science and human nutrition from Oregon State University. She received a Ph.D. in food science and human nutrition from Florida State University and holds minors in chemistry and plant physiology.

## Westring, M. Elizabeth, PhD

Dr. Elizabeth Westring serves as the Vice President of Quality and Regulatory Operations for General Mills. In this capacity, she acts as the chief company officer for assuring product safety, regulatory compliance, and product quality. The Quality and Regulatory Operations organization has responsibility for product safety, global regulatory affairs, business unit and manufacturing support, packaging and ingredient quality, product specifications, and labeling. In addition, the organization provides significant external support to industry groups and government agencies through expertise in toxicology, microbiology, and risk assessment. Dr. Westring has been with General Mills for 30 years and has held positions in Quality, R&D, and Marketing. She gained experience in R&D, first as a product developer and later as a department head, in Fruit and Grain Snacks, Betty Crocker Baking Products, Yoplait Yogurt, and Main Meals / Side Dishes. As the marketing manager for new products in Yoplait USA, she was awarded the President's Award for Total Quality. Since joining the Quality and Regulatory Operations group, she has held positions of increasing responsibility including Manager, Analytical Services and Medallion Labs, QRO Director, Ingredients, Packaging, and Labeling, and QRO Director, Business Units and Manufacturing. Dr. Westring has been an active participant in General Mills' recruiting programs and has served as a mentor in the company's diversity mentoring program. She chaired the academic advisory council at California Polytechnic University and was a member of the Clemson Advisory Council. As a member of IFT, she chaired the Committee on Higher Education and the Task Force on Mentoring. Dr. Westring received her undergraduate degree in Biology from the State University of New York at Stony Brook, her M.S. in Clinical Nutrition from University of Nebraska-Lincoln, and her Ph.D. in Food Science from Cornell University.

## Zambrone, Flávio AD, MD, PhD

*Dr. Flávio Zambrone* has been a pr ofessor at the State University of Campinas, Brazil, since 1983, and has been the president of Planitox, a toxicology adviser and consultant company, since 1994. For 15 years, he was coordinator of the Campinas Poison Control Centre, UNICAMP. He has served as the coordinator of the Poison Control Programme at the Health Department of São Paulo State. In 1979 and 1982, Dr. Zambrone was the director of Municipal Health Department in the city of São José dos Campos, São Paulo State, Brazil. Dr. Zambrone is a former scientific director for the ILSI Brasil branch. His current fields of interest include toxicology: animal testing, epidemiology, clinical environmental health, and crisis management. He is a member of the Toxicology Brazilian Society, Human Ecology Brazilian Society, and the Clinical Toxicology American Academy. Dr. Zambrone holds degrees in medicine from the University of Taubaté, São Paulo, Brazil; in public health from the University of Campinas, Brazil; and in toxicology and clinical pharmacology from Université of Paris, France.

From: Sent: To:

Subject:

Joanne Lupton Wednesday, October 02, 2013 7:12 PM Sarah Ohlhorst ); Linda Meyers Courtney Gaine people on the govt nutrition committees

Hello:

Do you have the list of people who are on the govt nutrition committee(of which Cathie Woteki is a co-chair) and the three subcommittees? The reason I ask is that I would like to invite them to a special IOM meeting on how to evaluate bioactives. I tried to get on websites but of course they are all down now. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From:	Suzanne Harris <
To:	; k; Joanne Lupton; Geoff
	; Flavio Zambrone
Cc:	Chochard-Odde, Fabiana, VEVEY, CT-ISP
	Chelsea L. Bishop; Shawn Sullivan; Beth Brueggemeyer
Subject:	Agenda, briefing documents and dial-in information for the ILSI Nomination Review
	Committee conference call Monday, September 30, at 9:00 a.m. EDT
Attachments: NRC 2013-09-30 Agenda.doc; ILSI Bylaws 2012 January 21.pdf; 2013	
	Review Committee.doc; 2013 ILSI Board Member Terms.doc; ILSI Research Foundation
	2013 Board of Trustees Terms.doc; 2013 ILSI Executive Committee.doc; 2014 Board
	Seat Allocation - with PIP.XLS

TO: ILSI Board of Trustees Nomination Review Committee

FROM: Suzie Harris

The initial call for the ILSI Board of Trustees Nomination Review Committee is scheduled for **Monday, September 30, 2013, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not run longer than one hour.

The dial-in information is at the end of this message.

The proposed agenda for the call is attached here.

Agenda Item II. List of tasks

Agenda Item III. a. ILSI bylaws – see Article IV, Section 3(b) for the allocation of seats on the ILSI Board of Trustees; data for the 2014 Board

Agenda Item III. b. Current ILSI Board of Trustees with expiring seats highlighted.

Agenda Item III. c. Current ILSI Research Foundation Board of Trustees with expiring seats highlighted

Agenda Item IV. Current ILSI Executive Committee with expiring seats highlighted; also see bylaws – Article IV, Sections 6 and 7; Article V.

Please let me know if you have any questions.

**Dial-in Instructions** 

If you are calling	Planca diale
from:	I lease ulai.
Brazil	0-800-890-0288, then dial 888-706-6468; <b>or</b> 0-800-888-8288, then dial 888-706-6468
-----------------------------	------------------------------------------------------------------------------------------
Singapore	800-110-1778
Switzerland	0-43-5579014 – caller paid
United Kingdom	0808-234-3676
United States of America	1-888-706-6468

The access code for everyone is **4498699 #**.

Let me know if you will be in another country, so that I can send you the toll free number for that country.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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## 2013 ILSI Nomination Review Committee

#### <u>Membership</u>

Dr. Peter van Bladeren, Chair Dr. Alan Boobis Dr. Joanne Lupton Mr. Geoff Smith Dr. Flávio Zambrone

# <u>Tasks</u>

- Nominate candidates for Chair, Vice Chair and Treasurer of the ILSI Board of Trustees
- Nominate candidates for the at-large members of the ILSI Executive Committee
- Review nominees from the branches for the ILSI Board of Trustees
- Review nominees for the ILSI Research Foundation Board of Trustees

Initial conference call scheduled for September 30, 2013.

### INTERNATIONAL LIFE SCIENCES INSTITUTE

#### BYLAWS

#### **ARTICLE I: GENERAL**

SECTION 1. The name of the non-profit organization shall be International Life Sciences Institute (hereinafter "ILSI"). As used herein, the terms "Assembly of Members" and "Board of Trustees" and the references to officers and committees, and members, unless stated otherwise, shall be those terms as defined in these bylaws. Where necessary or appropriate to the meaning, words of any gender shall include all genders.

SECTION 2. The principal office of ILSI shall be in the District of Columbia, or such other place within or without the District of Columbia as the Board of Trustees may from time to time determine or as the business of ILSI may require.

SECTION 3. The purpose for which ILSI is organized is exclusively scientific, charitable, and/or educational within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986.

SECTION 4. ILSI shall establish an antitrust policy in keeping with the antitrust laws of the District of Columbia, as well as with state and federal antitrust laws, and shall distribute a copy of such policy to the members of ILSI (the "Members") at ILSI business meetings and activities. Such policy shall prohibit discussion or dissemination of such matters as, but not limited to, the following: information concerning pricing, credit, and marketing policies, sales territories, and customers.

## **ARTICLE II: MEMBERSHIP**

SECTION 1. The members shall be those firms, corporations, or other entities that (i) are producers of food, beverages, pharmaceuticals, cosmetics, agricultural and other chemicals, personal care and household products, or containers thereof, forestry and paper products, communications products, transportation products, energy products, or producers of ingredients used therein or in connection therewith, or producers of exercise equipment for human health, or providers of scientific and technical services used in the safety testing or production of the foregoing products; and (ii) are members in good standing of any of the Branches of ILSI (as defined in Article VIII, Section 1 of these bylaws); provided, however, that no trade association and no firm whose business consists principally of providing professional consulting service or advice may be a member of ILSI.

SECTION 2. Should an ILSI branch elect to have a category of membership with limited or restricted rights, those companies that are limited or restricted members of such branch shall not be considered full members of ILSI. They shall not be eligible to vote in the ILSI Assembly of Members, serve on the ILSI Board, or participate in ILSI's international committees. References to members in these bylaws shall not be construed to include those companies who have only limited or restricted membership in an ILSI branch.

SECTION 3. Membership in ILSI shall automatically terminate when a member ceases, for any reason, to be a member of any Branch.

SECTION 4. Each member shall have one vote for each Branch eligible to vote at all meetings of the Assembly of Members, receive all general materials that are relevant to members, and have access to

such relevant information as is generally available to members at ILSI's principal office in the District of Columbia.

#### **ARTICLE III: ASSEMBLY OF MEMBERS**

SECTION 1. The Assembly of Members of ILSI shall consist of designated representatives of members. Each Branch shall submit the names of the designated representatives of the members associated with the Branch in writing to ILSI. Each such member representative shall be an officer or executive of the member and shall have full authority to represent the member in all matters coming before the Assembly of Members. Unless specified otherwise in writing by the member, the member's designated representative to a Branch's Assembly of Members shall serve as the member's designated representative to ILSI's Assembly of Members.

SECTION 2. The term of a member's representative shall automatically expire if and when: (i) the representative ceases to be employed by the member; (ii) the representative's connection with the member is otherwise severed; (iii) the member with which the representative is associated ceases to be a member of a Branch; or (iv) the member designates another representative.

SECTION 3. The annual meeting of the Assembly of Members shall be held each year as soon as convenient following the first day in January, at the call of the Board of Trustees, on at least thirty (30) days' written notice. At each annual meeting, the Assembly of Members will elect representatives to the Board of Trustees in accordance with Article IV of these bylaws. The Assembly of Members shall also consider such other matters as are submitted to it by the Board of Trustees for consideration or action at the annual meeting.

SECTION 4. Special meetings of the Assembly of Members, for any purpose or purposes, unless otherwise prescribed by statute or ILSI's Articles of Incorporation, may be called by the President and shall be called by the President or Secretary at the written request of one-tenth of the members. Such request shall state the purpose or purposes of the proposed meeting.

4(a). Written notice of a special meeting stating the place, date, and time of the meeting and the purpose or purposes for which the meeting is called shall be given to each member not less than ten (10) days before the meeting. Business transacted at any special meeting of the Assembly of Members shall be limited to the purposes stated in the notice.

SECTION 5. One-tenth of the members of the Assembly of Members shall constitute a quorum for the transaction of business. The affirmative vote of a majority of the votes entitled to be cast by the members present at a meeting at which a quorum is present, shall be necessary for the adoption of any matter voted upon by the members.

#### **ARTICLE IV: BOARD OF TRUSTEES**

SECTION 1. The managing body of ILSI shall be the Board of Trustees. The number of Trustees of ILSI shall be no less than fifteen and, except in the most unusual circumstances where thirty-two Trustees may be elected for up to one year, no more than thirty-one and may be increased or decreased from time to time by amendment to the bylaws.

SECTION 2. The Board of Trustees shall: (i) supervise, control, and direct the affairs of ILSI; (ii) establish policies and determine any changes in such policies; (iii) actively carry out ILSI's objectives; (iv) supervise the disbursement of funds; and (v) adopt such rules and regulations for the conduct of ILSI's business as shall be advisable. SECTION 3. The Assembly of Members shall elect each year, by a majority vote of the members present at a meeting at which there is a quorum, Trustees to the Board of Trustees according to the composition requirements set forth in Article IV, Section 3(b) of these bylaws. If a vacancy occurs among the Trustees, the Assembly of Members shall elect another Trustee to fill the unexpired term.

3(a). At each annual meeting, the Assembly of Members shall elect Trustees for a term of three (3) years to succeed those whose terms then expire, with the objective that approximately one-third of the Board of Trustees shall be elected each year.

3(b). The thirty-one (31) member ILSI Board of Trustees shall consist of a number of Public Trustees (who are employeed by or are recent retirees from universities, research institutes, foundations, and government or quasi-government bodies), at least equal to the number of Trustees who are representatives of (or recent retirees from) members. Each of the designated ILSI Global Regions and the ILSI Health and Environmental Sciences Institute ("HESI") shall be represented on the Board of Trustees by at least one Public Trustee and one Trustee who is a representative of (or recent retiree from) a member. The Research Foundation (as defined in Article IX, Section 1 of these bylaws) shall be represented by three Public Trustees who shall be nominated by the Research Foundation. The remaining "At-Large" Trustee positions on the Board of Trustees shall be allocated to the Global Regions and HESI by the Nomination Review Committee in proportion to the total amounts of (i) financial assessments paid by the Global Region or HESI to ILSI; (ii) voluntary contributions made to ILSI, the Research Foundation, or a specific Component of the Research Foundation by a Global Region or HESI; and (iii) the total revenue generated by the Global Region or HESI during the previous calendar year. The formula to weigh the above factors shall be as follows: financial assessments shall count for 50%, voluntary contributions shall count for 25%, and total revenue shall count for 25%. The total amount of voluntary contributions must equal at least 50% of the total amount of financial assessments to be included in the formula. If voluntary contributions do not meet this minimum threshold, then financial assessments shall count for two-thirds and total revenue shall count for one-third.

3(c). Any Trustee elected by the Assembly of Members may be removed from office, at any time, by a majority vote of the members present at a meeting at which there is a quorum.

SECTION 4. The Board of Trustees may hold meetings, both regular and special, either within or without the District of Columbia at such time and place as shall from time to time be determined by the board. Special meetings may be called by the President on three (3) days' notice to each Trustee. Special meetings shall be called by the President or Secretary in like manner and on like notice on the written request of two Trustees. A quorum consists of one-third of the Board of Trustees and the one-third must include at least two officers of ILSI. Except as otherwise expressly provided by law or these bylaws, the act of a majority of the Board of Trustees present at any meeting at which there is a quorum shall be the act of the Board of Trustees.

SECTION 5. The Board of Trustees shall meet at least annually, as soon as convenient following the first day in January at the call of the president on at least thirty (30) days' written notice.

SECTION 6. There shall be an Executive Committee of ILSI composed of the officers and up to four (4) members at-large from the Board of Trustees. The Executive Committee shall have all the powers of the Board of Trustees to transact business and routine affairs between meetings, but it may not take extraordinary actions. All transactions of the Executive Committee shall be reported in full at the next, regularly scheduled meeting of the Board of Trustees. The at-large members of the Executive Committee shall be elected by the Board of Trustees at their annual meeting for a term of one (1) year each.

SECTION 7. The Executive Committee shall consist of a number of Public Trustees at least equal to the number of Trustees who are representatives of members.

### **ARTICLE V: OFFICERS**

SECTION 1. The officers of ILSI shall be elected by and from the Board of Trustees and shall include a Chair, a President, a Vice Chair, a Vice President, a Secretary, a Treasurer, and such other officers as may be elected in accordance with the provisions of this Article. In addition, the Executive Director shall be an unelected officer of the organization.

SECTION 2. The Chair shall preside at all meetings of the Board of Trustees and shall have such duties as are assigned by the Board of Trustees.

SECTION 3. The President shall preside at all meetings of the Executive Committee and the Assembly of Members. He shall be the highest elected officer and, as such, shall be responsible for the general and active management of ILSI, and shall see to the carrying out of all orders and resolutions of the Board of Trustees and the Assembly of Members.

SECTION 4. The Vice Chair shall have such duties as are assigned by the Chair or the Board of Trustees, and shall assist the Chair as he may require. The Vice Chair shall perform all duties of the Chair during the latter's absence, disability, refusal to act, or resignation until such time as the Chair resumes the duties of his office or a successor is elected and qualified.

SECTION 5. The Vice President shall have such duties as are assigned by the President and Board of Trustees, and shall assist the President as he may require. The Vice President shall perform all duties of the President in the event of the latter's absence, disability, refusal to act, or resignation until such time as the President resumes the duties of his office or a successor is elected and qualified.

SECTION 6. The Secretary shall: (i) ensure that all official correspondence and all official papers and records of ILSI are kept at ILSI's principal office in the District of Columbia; (ii) ensure that all notices of meetings of the Board of Trustees and Assembly of Members are issued; and (iii) in general, perform all duties incident to the office of Secretary and such other duties as from time to time may be assigned to him by the President or by the Board of Trustees.

SECTION 7. The Treasurer shall: (i) be responsible for the funds of ILSI; (ii) ensure that funds are collected and deposited in such banks or depositories, or invested, as may be approved by the Board of Trustees; and (iii) ensure that disbursements are made as ordered by the Board of Trustees. He shall render to the President and Board of Trustees, at its regular meetings or when the Board of Trustees requires, an account of all ILSI financial transactions, as well as an account of the financial condition of ILSI.

SECTION 8. All elected officers shall be elected by the Board of Trustees, and each shall serve for a term of two (2) years, or until either they are reelected or their successors are elected and qualified. Any vacancy occurring in any elected office of ILSI shall be filled by the Board of Trustees.

SECTION 9. Any officer of ILSI, elected or appointed, may be removed by the Board of Trustees, whenever, in its judgment, the best interests of ILSI will be served by such removal. Removal of an officer will be without prejudice to the contract rights, if any, of the person so removed. Election of an officer does not itself create contract rights.

#### **ARTICLE VI. FINANCIAL OVERSIGHT COMMITTEE**

SECTION 1. The President of ILSI shall appoint a Financial Oversight Committee, consisting of at least three members of the Board of Trustees, one of whom shall be the Treasurer. The Treasurer shall

serve as Chair of the Financial Oversight Committee. Each member of the Financial Oversight Committee shall be free from any relationship that, in the opinion of the Board of Trustees, would interfere with the exercise of his or her independent judgment as a member of the Committee. Among other relevant matters, members of the Financial Oversight Committee should obtain the ability to understand financial statements, to evaluate accounting firm bids to undertake auditing, and to make sound financial decisions on behalf of ILSI.

SECTION 2. The Financial Oversight Committee shall have the following responsibilities: (i) to provide the Board of Trustees with accurate and transparent statements of ILSI's finances in order that the Board of Trustees may have the information needed to make its decisions; (ii) to make recommendations to the Board regarding investment strategy and policies; (iii) to review ILSI's annual financial statements and reports, including the compliance of ILSI's accounting and financial management systems and reports with generally accepted accounting principles for nonprofit organizations; (iv) after consulting with management, to review and recommend to the Board of Trustees the independent auditors to be selected to audit the financial statements; (v) to review and forward to the Board of Trustees communications of the external auditors, with such comments of its own as may be appropriate; and (vi) to periodically review ILSI's system of internal controls, including its risk management systems, and make recommendations to the Board of Trustees for changes it considers desirable.

#### **ARTICLE VII. COMPENSATION COMMITTEE**

SECTION 1. The President of ILSI shall appoint a Compensation Committee consisting of three trustees, none of whom shall have a conflict of interest with respect to the review and determination of the compensation of ILSI employees. The Compensation Committee shall review the compensation of the Executive Director and such other employees of ILSI the Compensation Committee determines appropriate annually, and whenever a modification in compensation is proposed. The review shall include an evaluation of the performance of the employees and an analysis of appropriate comparability data. Based on its review, the Compensation Committee shall recommend just and reasonable compensation amounts for the employees to the Executive Committee. At the request of the ILSI President or the Chair of the Board of Trustees, the Compensation Committee shall review any issue involving staff compensation and benefits.

SECTION 2. The Compensation Committee shall adequately document the basis for its determinations concurrently with making those determinations (within 60 days of the decision or the date of the next meeting of the Board of Trustees, whichever is later). Such documentation shall consist of written or electronic records of the Compensation Committee (such as meeting minutes), which must note a) the terms of the transaction and the date it was approved; b) the members of the Compensation Committee who participated in the transaction that was approved and those who voted on it; c) the comparability data obtained and relied upon and how the data were obtained; and d) any actions taken with respect to consideration of the transaction by anyone who is otherwise a member of the Board of Trustees but who had a conflict of interest with respect to the decision on the compensation

# **ARTICLE VIII: NOMINATION REVIEW COMMITTEE**

SECTION 1. The President of the Board of Trustees shall appoint a Nomination Review Committee, consisting of at least three members of the Board of Trustees, one of whom shall be chairman, to (i) nominate candidates for the officers of ILSI (Chair, President, Vice Chair, Vice President, Secretary, and Treasurer), and the at-large members of the Executive Committee; (ii) develop or review written criteria for the selection of Trustees representing the Branches/Regions, HESI and the Research Foundation; (iii) ensure compliance with these criteria and the composition requirements of Article IV, Section 3 of these bylaws; (iv) review annually the allocation of Trustee positions among the Branches/Regions, HESI, and the Research Foundation; and (v) recommend to the Board of Trustees the total number of Trustee positions to which each Branch/Region, HESI, and the Research Foundation is entitled. The Nomination Review Committee, which shall be appointed at least four weeks prior to the annual meeting, shall present the slate of candidates to serve for their designated position and term and shall report these nominations for Trustees at the annual meeting of the Assembly of Members, and its nominations for officers and the at-large members of the Executive Committee at the annual meeting of the Board of Trustees.

## **ARTICLE IX: EXECUTIVE DIRECTOR**

SECTION 1. The Board of Trustees may employ a salaried staff head who shall have the title of Executive Director and whose terms and conditions of employment shall be specified by the President, in consultation with the Board of Trustees.

SECTION 2. The Executive Director shall manage and direct activities of ILSI, as prescribed by the President, in consultation with the Board of Trustees. He shall report and be responsible to the President. Subject to the approval of the President, he shall employ and may terminate the employment of staff necessary to carry on the work of ILSI and fix their compensation within ILSI's salary administration plan, guidelines, and approved budget. Also, subject to the approval of the President, he shall define the duties of the staff, supervise their performance, establish their titles and delegate those responsibilities of management as shall, in his judgment, be in the best interests of ILSI.

# **ARTICLE X: BRANCHES AND HESI**

SECTION 1. The Board of Trustees may approve the establishment of Branches to carry on activities in a country or a geographical region consistent with the goals and purposes of ILSI. Each Branch shall be incorporated as, or be a division of, a nonprofit entity qualified as such under the laws of its particular country (or one of the countries in the geographic region that the Branch represents). The branch bylaws, policies, and procedures shall be consistent with those of ILSI.

SECTION 2. Each Branch may assess its own membership dues and fees to support activities within its designated geographical area. Each Branch is responsible for its own activities and financial affairs and for obtaining the funds necessary to support its activities.

SECTION 3. The Branch management shall see that all orders and resolutions of the ILSI Assembly of Members and Board of Trustees, pertaining to the Branch are carried into effect; they shall orient all personnel responsible for the operation of the Branch to the goals and objectives of ILSI and its principles of operation; they shall review the financial records and administrative operations of the Branch with the officers of ILSI; they shall coordinate Branch activities with ILSI activities through regular contact with the ILSI President and ILSI's principal office in the District of Columbia; and they shall exercise such control over the dissemination of information, produced by the Branch, as is appropriate and consistent with policies of the ILSI Board of Trustees regarding dissemination of information.

SECTION 4. A Branch must establish an organizational structure that will include an assembly of members and a board of trustees (or their equivalents), and may include committees, subcommittees, task forces or working groups necessary to carry on the activities of the Branch.

SECTION 5. Each Branch shall submit at the annual meetings of the ILSI Assembly of Members and Board of Trustees a report of the activities of the Branch. The Branch shall also submit to the President by May 1st of each year a copy of the Branch annual financial statements for the past year.

SECTION 6. There shall be a Health and Environmental Sciences Institute ("HESI"), which may or may not be a separately incorporated organization, and which shall not necessarily represent a specific country or geographical region, to consider environmental, risk assessment, and other scientific issues of interest to its members. It shall, in all other matters, operate similarly to a Branch.

## **ARTICLE XI: RESEARCH FOUNDATION**

SECTION 1. There shall be a Research Foundation, which may or may not be a separately incorporated organization, to support the scientific research and educational activities of ILSI. In the absence of a Research Foundation Board of Trustees, the functions of that group shall be the responsibility of the ILSI Board of Trustees. The Research Foundation Board of Trustees may recognize or establish Components (e.g., institutes, centers, or other such substructures) under the Research Foundation to investigate matters of public health or safety, sponsor research, and/or assume such other duties as may be assigned by the Board of Trustees. A Component may or may not be a separately incorporated organization.

SECTION 2. The Research Foundation shall have a Council of Scientific Advisors to (i) provide general guidance regarding the Foundation's research agenda and (ii) facilitate communication and cooperation among the Components. The Council of Scientific Advisors shall be appointed by, and be subject to, the Research Foundation Board of Trustees. The members of the Council of Scientific Advisors shall be eminent scientists from universities, government agencies, quasi-government bodies, research institutes, and foundations.

SECTION 4. At the annual meetings of the ILSI Assembly of Members and Board of Trustees, the Research Foundation shall provide a report of its activities and annual budget for informational purposes.

## **ARTICLE XII: COMMITTEES**

SECTION 1. The Board of Trustees may create or establish, from time to time, such committees, subcommittees, task forces, or working groups as it deems necessary or appropriate to carry out the activities of ILSI. Any such committee, subcommittee, task force, or working group shall have the authority or powers delegated to it by the Board of Trustees and shall operate according to the general policies, procedures and guidelines of ILSI.

## ARTICLE XIII: LEGAL COUNSEL

SECTION 1. ILSI shall be represented by qualified legal counsel who shall be retained by the president with the approval of the Board of Trustees. Legal counsel shall render those legal services as are required by a charitable, scientific, and educational foundation organized within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as well as such other legal advice and services as may be requested by the President, Executive Director, and/or the Board of Trustees.

## **ARTICLE XIV: FISCAL YEAR**

SECTION 1. The fiscal year of ILSI shall begin on the first day of January of each year.

### ARTICLE XV: ASSESSMENTS AND FINANCES

SECTION 1. The Board of Trustees shall determine the amounts of the annual assessments for support of ILSI by the Branches, HESI and the Research Foundation, as well as the times and conditions for the payment of such assessments.

SECTION 2. Each year at the annual meeting of the Assembly of Members, the Board of Trustees shall present a budget for ILSI for informational purposes only. The Board of Trustees shall approve and adopt such budget at its annual meeting.

### **ARTICLE XVI: PROCEDURE**

SECTION 1. Procedure shall be governed by such rules as the Board of Trustees may from time to time adopt. In the absence of the Trustees adopting any such rules, the Chair shall rule on matters of procedure.

#### **ARTICLE XVII: AMENDMENTS**

SECTION 1. These bylaws may be altered, amended, or repealed or new bylaws may be adopted at any regular or special meeting of the Board of Trustees upon an affirmative vote of three-fourths of the Trustees present at any meeting of the Board of Trustees at which there is a quorum. If any alteration, amendment, repeal, or addition of new bylaws is to be made at a special meeting of the Board of Trustees, notice of such alteration, amendment, repeal, or addition shall be contained in the notice of such special meeting.

## **ARTICLE XVIII: INDEMNIFICATION**

SECTION 1. ILSI shall indemnify any trustee, officer, employee, agent, or volunteer, or any person who may have served at its request as a trustee, officer, employee, agent, or volunteer of another corporation, whether for profit or not for profit, against expenses actually and necessarily incurred by him in connection with the defense of any actions, suit, or proceeding in which he is made a party by reason of being or having been such trustee, officer, employee, agent, or volunteer, except in relation to matters as to which he shall be adjudged in such action, suit, or proceeding to be liable for negligence or misconduct in the performance of a duty. Such indemnification shall not be deemed exclusive of any other rights to which such trustee, officer, employee, agent, or volunteer may be entitled, under any bylaw, agreement, vote of the Board of Trustees, or otherwise.

SECTION 2. The Board of Trustees may authorize the purchase of insurance on behalf of any trustee, officer, employee, agent, or volunteer against any liability asserted against or incurred by him that arises out of such person's status as a trustee, officer, employee, agent, or volunteer or out of acts taken in such capacity, whether or not ILSI would have the power to indemnify the person against that liability under law.

SECTION 3. If any part of this Article shall be found in any action, suit, or proceeding to be invalid or ineffective, the validity and the effectiveness of the remaining parts shall not be affected.

# **ARTICLE XIX: DISSOLUTION**

SECTION 1. Upon the dissolution of ILSI, the Board of Trustees shall, after paying or making provision for the payment of all the liabilities of ILSI, dispose of all the assets of ILSI exclusively for the purposes of ILSI in such manner, or to such organization(s) organized and operated exclusively for the purposes as shall at the time qualify as an exempt organization(s) under Section 501(c)(3) of the Internal Revenue Code of 1986 or the corresponding provision of any future United States Internal Revenue Law, as the Board of Trustees shall determine. Any such asset not so disposed of shall be disposed of by the appropriate court for the District of Columbia, exclusively for such purposes or to such organization(s), as said court shall determine.

# International Life Sciences Institute 2014 Board of Trustees Seat Allocation

	2012 Total	% of 2012 Total	2012 ILSI	% of 2012 ILSI	2012 Contributions	% of 2012 Contributions	% of Board Seats Based on Weighted Avg	2014 Number of At-Large	2013 Number of At- Large	Recommended
Region	Revenue	Revenue	Assessment	Assessment	to ILSI & RF	to ILSI & RF	Percentages	Seats	Seats	rounding
Asia/Pacific-North	1,772,161.79	11.11%	57,275.55	9.42%	12,000.00	1.39%	7.83%	1.25	1	1
Asia/Pacific-South	1,808,449.38	11.33%	49,488.00	8.14%	-	0.00%	6.90%	1.10	1	1
Europe & Africa	3,944,392.13	24.72%	150,606.00	24.76%	36,000.00	4.16%	19.60%	3.14	4	4
HESI	3,493,775.00	21.90%	150,000.00	24.66%	308,690.95	35.63%	26.71%	4.27	4	4
Latin America	1,181,060.43	7.40%	50,831.00	8.36%	-	0.00%	6.03%	0.96	1	1
North America	3,755,094.00	23.54%	150,000.00	24.66%	509,690.95	58.83%	32.92%	5.27	5	5
Total	15,954,932.73	100.00%	608,200.55	100.00%	866,381.90	100.00%	100.00%	16.000	16	16

# 2012 Branch Total Revenue and Assessment Fee

	Total	ILSI	
	Revenue	Assessment	
ILSI Branch	US\$	US\$	
			-
Asia/Pacific - North			
China Focal Point	327,285	15,888	
Japan	1,266,172	34,853	
Korea	178,705	6,535	-
Total	1,772,162	57,276	
Asia/Pacific - South			
India	396,787	4,060	Α
Southeast Asia	1,411,662	45,428	
Total	1,808,449	49,488	-
Europe & Africa			
Europe	3,930,574	150,000	
North Africa	-	-	
South Africa	13,818	606	_
Total	3,944,392	150,606	
Latin America			
Argentina	100.542	4.716	
Brazil	664.316	28.292	
Mexico	155.084	6.683	
North Andean	179.898	8.234	
South Andean	81.221	2,906	
Total	1,181,060	50,831	-
	8,706,064	308,201	

A: 2012 Projection which we used for AOM

Entity	Account	Subaccount	Entr	Inv#	Date C	ompany	Amount	Region	Comment
ILSI	40320	01-890000-70-8900-70	009326	IN18974730	3/31/2012 AJINOMOTO CO		12,000.00	Asia/Pacific-North	PIP
							12,000.00		
ILSI	40320	01-890000-70-8900-70	009326	IN18974760	3/31/2012 NESTEC		12,000.00	Europe & Africa	PIP
ILSI	40320	01-890000-70-8900-70	009433	IN18974750	8/31/2012 UNILEVER RESEA	RCH NUTR CENTR	12,000.00	Europe & Africa	PIP
ILSI	40320	01-890000-70-8900-70	009456	IN18974720	8/31/2012 DSM NUTRITIONA	L PRODUCTS	12,000.00	Europe & Africa	PIP
							36,000.00		
ILSI	40320	03-707000-01-0001-10	009534	IN18980540	1/28/2013 COCA-COLA COM	PANY	49,500.00	HESI/NA	
ILSI	40320	03-707000-01-0001-10	009544	IN18980890	12/31/2013 COCA-COLA COM	PANY	32,000.00	HESI/NA	
ILSI	40320	03-929000-29-9290-70	019665		8/31/2012 Coca fund for a me	eting	3,881.90	HESI/NA	
ILSI	40320	03-929090-29-9290-70	009483	IN18979090	10/31/2012 COCA-COLA COM	PANY	20,000.00	HESI/NA	
ILSI	40320	03-929400-29-9290-70	009441	18976930	8/31/2012 Monsanto Compan	у	500,000.00	HESI/NA	
ILSI	40320	01-890000-70-8900-70	009324	IN18974700	3/31/2012 COCA-COLA COM	PANY	12,000.00	HESI/NA	PIP
							617,381.90		
ILSI	40320	03-592213-30-7922-50	009391	IN18976750	6/22/2012 General Mills		10,000.00	NA	
ILSI	40320	03-700000-01-0001-10	009391	IN18977490	6/22/2012 General Mills		20,000.00	NA	
ILSI	40320	03-772090-26-7720-70	009370	IN18975440	5/29/2012 CONAGRA FOODS	6	50,000.00	NA	
ILSI	40320	03-929050-29-9290-70	009496	IN18979190	11/30/2012 Mars, Incorporated		40,000.00	NA	
ILSI	40320	03-929050-29-9290-70	009570	18980130	12/31/2012 CONAGRA FOOD	3	20.000.00	NA	
ILSI	40320	03-929090-29-9290-70	009302	IN18975100	3/22/2012 ILSI NORTH AMER	RICA	25,000,00	NA	
ILSI	40320	01-890000-70-8900-70	009324	IN18974770	3/31/2012 Senomyx. Inc.		12.000.00	NA	PIP
ILSI	40320	01-890000-70-8900-70	009337	IN18974710	4/27/2012 KRAFT FOODS		12,000.00	NA	PIP
ILSI	40320	01_890000_70_8900_70	009421	IN18974690	7/31/2012 MARS INC		12,000.00	NA	PIP
ILO1	40020	01 000000 10 0000 10	000421	11110074000			201 000 00		
II SI	40320	01-895112-70-8950-40	019734		9/30/2012 HESI Contrubtion to	n IFBiC	5 000 00	Outside Individual	HESI nav for IEBiC committee
ILSI	40320	01_890000_70_8900_70	009511	IN18979530	12/26/2012 COCA-COLA COM	PANY	50,000,00	Outside Individual	Special fund for fellowshin
	40320	03-707000-01-0001-10	010665	11110373550	8/31/2012 II SI China travel ex	(n reim	3 000 00	Outside Individual	Pick travel reimb
	40320	03-700000-01-0001-10	010000	18075360	2/29/2012 BLOOMBERG L P	(p.ieim	25,000.00	Outside Individual	Nex liaver relinb.
	40320	03 700000 01 0001 10	000200	CK1450			1 500 00	Outside Individual	
11.01	40320	03-700000-01-0001-10	009309	IN119072900	1/31/2012 COOD LEE INTED		150 000 00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009200	IN 10972090			150,000.00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009403	IN 10977210			EE 119 00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009411	IN 16977240	7/24/2012 FIGNEER RI-BREL 7/21/2012 ELITI DAGENE PR		55,116.00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009420	IN 10977230	10/21/2012 FOTORAGENE BR		21 000 00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009403	IN 16979000	1/21/2012 CROPLIFE INTER		21,000.00	Outside Individual	
11.01	40320	03-929013-29-9290-70	009000	11110900290	1/31/2013 CROPLIFE INTERI 12/21/2013 Ded AD for CLL Cou		150,000.00	Outside Individual	
ILOI	40320	03-929013-29-9290-70	020073	10140070400	12/31/2012 RCd AR IOI CEI COI		550,000.00		
ILSI	40320	03-929050-29-9290-70	009503	IN 18979490	11/30/2012 CROPLIFE INTERI		40,000.00	Outside Individual	
ILSI	40320	03-929060-29-9290-70	009519	IN 18979680	12/28/2012 AMERICAN CHEM		50,000.00		
ILSI	40320	03-929062-29-9290-70	020305	1140070470	5/29/2012 R/C Environment o		47,275.00		
ILSI	40320	03-929070-29-9290-70	009481	IN18978170	10/31/2012 AMERICAN CHEM		15,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009302	IN 18973890	3/22/2012 ATLANTIUM TECH	INOLOGIES, LTD	10,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009391	IN18973990	6/22/2012 DIVERSEY, INC.		15,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009411	IN18976760	7/24/2012 ECULAB, INC.		20,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009441	IN18976770	8/31/2012 AQUAFINE CORPO	JRATION	5,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009441	IN18977530	8/31/2012 AQUAFINE CORPO	JRATION	5,000.00	Outside Individual	
ILSI	40320	03-929080-29-9290-70	009441	IN18977540	8/31/2012 AQUAFINE CORPO	DRATION	5,000.00	Outside Individual	
ILSI	40320	03-929090-29-9290-70	009259	IN18973930	1/31/2012 THE PEW CHARIT	ABLE TRUSTS	25,000.00	Outside Individual	
ILSI	40320	03-929090-29-9290-70	009473	IN18978510	9/30/2012 ILLINOIS INSTITU	TE OF TECHNOLO	17,500.00	Outside Individual	
ILSI	40320	03-929092-29-9290-70	009499	IN18979200	11/30/2012 THE PEW CHARIT	ABLE TRUSTS	25,000.00	Outside Individual	
ILSI	40320	01-841500-72-8410-30	009433	IN18975520	8/31/2012 KELLOGG COMPA	ANY .	10,000.00	Outside Individual	
ILSI	40320	01-841500-72-8410-30	009450	ACH08/16	8/16/2012 MARS, INC		7,667.00	Outside Individual	
ILSI	40320	01-841500-72-8410-30	009527	IN18978470	12/31/2012 AJINOMOTO CO		10,000.00	Outside Individual	
ILSI	40320	01-895112-70-8950-40	009543	IN18981210	12/31/2012 CROPLIFE INTERI	NATIONAL AISBL	17,500.00	Outside Individual	
						1,	,545,560.00		

	Asia/Pacific-North	12,000.00
	Europe & Africa	36,000.00
	HESI/NA	617,381.90
	NA	201,000.00
	Outside Individual	1,545,560.00
	Grand Total	2,411,941.90
Count Doesn't Count - Outside Total		866,381.90 1,545,560.00 2,411,941.90

TB:

ILSI 196,167.00 RF 2,215,774.90 Total 2,411,941.90

# ILSI Board of Trustees Nomination Review Committee

# **Conference Call**

# September 30, 2013 9:00 – 10:00 Eastern Daylight Time

# Agenda

- I. Welcome and Opening Remarks
- II. Review of Committee Responsibilities
- III Process for Nominating ILSI Trustees and ILSI RF Trustees
  - a. Review of board seat allocation evaluation
  - b. Review of expired terms on the ILSI Board of Trustees
  - c. Review of expired terms on the ILSI Research Foundation Board of Trustees
- IV. Discussion of Process for Selecting Nominee for ILSI Chair, Vice Chair, Treasurer, and At-large Members of the ILSI Executive Committee

# V. Next Steps

- a. Date for next conference call
- VI. Adjournment

Position	Name	Entity	<b>Term Expires</b>
			E.C./B of T
<mark>Chair</mark>	Dr. Sam Cohen (P)	HESI	2014/2013
Vice Chair	Dr. John Milner (P)	North America	2014/2015
President	Dr. Jerry Hjelle (I)	North America	2013/2015
Vice President Dr. Rhona Applebaum (I)		North America	2015/2014
Treasurer Dr. Liz Westring(I)		North America	2014/2013
Secretary	Dr. Sara Valdeś (P)	Latin America (Mex.)	2015/2014
At-Large	Dr. Marion Ehrich (P)	<b>Research Foundation</b>	2014/2016
At-Large Dr. Gert Meijer (I)		Europe/Africa	2014/2015
At-large Dr. Tamotsu Kuwata (P)		Asia/Pacific North	2014/2016
At-large	Mr. Geoff Smith (I)	Asia/Pacific South	2014/2013

2013 ILSI Executive Committee

TRUSTEE	AFFILIATION	REPRESENTATION	ELECTED	TERM EXPIRES
			(January)	(January)
Dr. Dennis M. Bier *	Baylor College of Medicine	At-large (P)	2012	2015
Dr. Jim Bus	Dow Chemical	At-large (I)	2012	2015
Dr. Adam Drewnowski	University of Washington	ILSI Board (P)	2013	2016
Dr. Lynn Frewer	Newcastle University	At-large (P)	2013	2016
Dr. Philip Guzelian	U. of Colorado Health Sciences Center	At-large (P)	<mark>2011</mark>	<u>2014</u>
Dr. Jerry Hjelle *	Monsanto Company	ILSI President (I)	2013	2015
Dr. James W. Jones	University of Florida	At-large (P)	2013	2016
Dr. Takeshi Kimura*	Ajinomoto Co., Inc.	ILSI Board (I)	<mark>2011</mark>	2014
Dr. Michael Knowles	The Coca-Cola Company	ILSI Board (I)	<mark>2011</mark>	2014
Dr. John Peters *	University of Colorado, Denver	At Large (P)	2012	2015
Dr. Peter van Bladeren	Nestlé Research Centre	ILSI Board (I)	2013	2016

# \* Officers

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Dr. Marion Ehrich will serve as an ex officio member of the ILSI Research Foundation Board of Trustees for 2013-16, while she completes a new term on the ILSI Board of Trustees.

From: Sent: To:	Suzann Wednes	e Harris sday, September 18, 2013 4:09 PM s.chang@griffith.edu	.au; goodman3@msu.edu; Joanne
	Lupton;	Rodriguez, Felipe {PI}	; Smith, Lewis L. (Prof.)
Cc:	Christin	e Lagerquist iamas@ariffith.edu.au: Cholsoa L. Bishon:	· Poth Ellon
	Berry; S	hawn Sullivan; Beth Brueggemeyer	, Detti-Elleri
Subject:	Third qu Novem	Jarter conference call for the ILSI Financia ber 5, 2013 at 9:00 a.m. Eastern Standard	al Oversight Committee Tuesday, Time
TO:	ILSI Board of Trustees Fir	nancial Oversight Committee	
FROM:	Suzie Harris		

Thank you to those of you who responded to the poll for a date for the third quarter conference call for the ILSI Financial Oversight Committee. Based on your responses, the best day is **Tuesday, November 5, 2013, beginning at 9:00 a.m. Eastern Standard Time.** The call may run as long as 90 minutes as you will be reviewing the 2014 proposed ILSI budget.

Please mark this date and time on your calendars. I will send an agenda, briefing documents and dial-in instructions about one week prior to the conference call.

Please let me know if you have any questions.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From: Sent: Subject: John Faulkner > Thursday, September 12, 2013 2:10 PM Your Link to ILSI North America's Science Briefs

Hello,

The science briefs we highlight are compiled after a review of the articles published in the most recent issues of the major journals in nutrition and those from the fields of chemical and microbiology food safety. The articles selected for inclusion typically report on topics of current interest to ILSI North America's technical and project committees.

The **July and August** science briefs as well as prior science briefs are now accessible electronically via the ILSI North America website: <u>http://www.ilsi.org/NorthAmerica/Pages/ScienceBriefs.aspx</u>

Please let me know if there is someone in your company who should be receiving the briefs and I'll add them to our distribution list. I look forward with sharing a new set of briefs with you next month.

Best regards,

John

John Faulkner Director of Membership and Communications ILSI North America 1156 15th Street, NW, #200 Washington, DC 20005 202-659-0074 ext. 126

From:	Suzanne Harris
Sent:	Friday, September 06, 2013 9:58 AM
То:	; ; Joanne Lupton; Geoff
	); Flavio Zambrone
Cc:	Chelsea L. Bishop; Beth Brueggemeyer; Shawn
	Sullivan
Subject:	Date for the initial ILSI Nomination Review Committee conference call Monday, September 30, 2013
TO:	ILSI Board of Trustees Nomination Review Committee
FROM:	Suzie Harris

Thank you all for responding so quickly to my poll for a date for the committee's initial conference call. While no one day works for everyone, the best day is **Monday, September 30, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not run longer than one hour. Please mark this day and time on your calendars.

I will send you an agenda with briefing documents about one week prior to the conference call. Please let me know if you have any questions.

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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Thank you for agreeing to serve on this important committee. I will do my best to make the process as efficient as possible.

Please indicate on the September calendar below which days you are available for a one hour conference call beginning at 9:00 a.m. Eastern Daylight Time and return the information to me. I will confirm the day that works best for the whole committee.

Let me know if you have any questions.

# Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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SEPTEMBER 2013							
Monday	Tuesday Wednesday Thursday Friday						

9	10	11	12	13
16	17	18	19	20
23	24	25	26	27
30				

From: Sent: To: Subject: Suzanne Harris Tuesday, September 03, 2013 1:43 PM Joanne Lupton RE: An invitation

Thank you. Will send out a poll for date for the first conference call as soon as I hear back from the others who were invited.

Best regards,

Suzie

From: Joanne Lupton [mailto:jlupton@tamu.edu] Sent: Tuesday, September 03, 2013 2:42 PM To: Suzanne Harris Subject: RE: An invitation

That's fine Suzie, Thanks, J

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Suzanne Harris [
Sent: Tuesday, September 03, 2013 1:41 PM
To: Joanne Lupton
Cc: Chelsea L. Bishop
Subject: An invitation

Dear Joanne,

Peter van Bladeren has accepted Jerry Hjelle's invitation to serve as the chair of the ILSI Board of Trustees Nomination Review Committee this year. Peter and Jerry asked me to invite you to serve as a member of the committee.

The tasks for the ILSI Nomination Review Committee this year will be:

- 1. Review nominations from branches for seats on the ILSI Board of Trustees 6 seats are up for re-election, plus Rhona Applebaum's seat (she is in a one year special seat).
- 2. Nominate a candidate for ILSI Vice Chair (John Milner will move up to Chair in January assuming the committee nominates him)
- 3. Review nominations for the ILSI Research Foundation Board of Trustees (three seats Guzelian, Kimura, and Knowles).

Are you willing to serve? There will be at least two and perhaps three conference calls of the committee this fall. The first will be in September. Hope to hear back from you soon.

Best regards,

Suzie

Suzanne S. Harris, Ph.D. Executive Director

International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on: 🖪 토

From: Sent: To: Cc: Subject: Suzanne Harris > Tuesday, September 03, 2013 1:41 PM Joanne Lupton Chelsea L. Bishop An invitation

Dear Joanne,

Peter van Bladeren has accepted Jerry Hjelle's invitation to serve as the chair of the ILSI Board of Trustees Nomination Review Committee this year. Peter and Jerry asked me to invite you to serve as a member of the committee.

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Best regards,

Suzie

Suzanne S. Harris, Ph.D. Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on: 🖪 토

From: Sent: To:	Suzanne Harris Thursday, August 01, 20	> )13 1:42 PM		
		; s.chang@griffith.edu.au;	Cohen, Samuel M	
	(scohen@unmc.edu);		; adamdrew@u.washingto	on.edu;
	marion@vt.edu;	e; goodma	n3@msu.edu;	
	); jo	hn.milner@ars.usda.gov; jc ; Rodriguez, Felipe {PI}	Joanne Lupton; Gert N hn.c.peters@ucdenver.edu;	∕leijer
		Geoff	); Smith, Lewis L. (Prof	.)
	;	weavercm@purdu	ie.edu;	;
Cc:		Bradf	ord, Jeanne (jbradford@unmo	c.edu);
	Fleming, Melinda S (		;	
		(	; Chelsea L. Bishop;	
	linda.reynolds@ars.usda	a.gov; tim.goss@ucdenver.@	edu;	
haan@purdue.edu; Chris		du; Christine Lagerquist		
		; Beth-Ellen Be	erry; Michael Shirreffs; Shawn	Sullivan
Subject:	Reminder and additiona	al material for the ILSI Boar	d of Trustees mid-year confer	ence
	call Monday, August	5, 2013 at 9:00 a.m. EDT		
Attachments:	2013 Dial-in Informatio recommendations_ms_e	n.doc; ILSI BOT 2013-08-05 edit.docx	, cc agenda.doc; SP ONE ILSI S	Strategy

TO: ILSI Board of Trustees

FROM: Suzie Harris

The mid-year conference call for the ILSI Board of Trustees is scheduled for **Monday**, **August 5**, **2013**, **beginning at 9:00 a.m. Eastern Daylight Time.** The call will not run longer than two hours. I hope you will make every effort to participate

The dial-in instructions are attached along with the proposed agenda. I posted the briefing materials on the ILSI Board of Trustees ILSI EXTRA page.

To access the Board page, go to <u>https://www.ilsiextra.org/ilsi/bot/meetings/SitePages/Home.aspx</u>. Enter the following information:

Username: ILSI-Board Password: 1978Bot1156

In addition to these documents, I have attached a short description of the ILSI Strategic Plan Transition Team recommendations and next steps. I encourage you to review prior to the conference call.

Please let me know if you have any questions or need additional information.

# Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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### **ONE ILSI Strategy**

In January 2013, the ILSI Board of Trustees accepted the strategic map developed through an inclusive process and directed that a transition team be appointed to develop an implementation plan for the map. It is clear from these discussions that ILSI has many strengths – global networks, tripartite approach, and strong scientific expertise. Thus, ILSI has the opportunity to build on its strengths to achieve broader effectiveness. The transition team met monthly since the annual meeting and developed a set of recommendations which have been reviewed and approved by the ILSI Executive Committee. The recommendations all point to the importance of implementing a One ILSI Strategy.

### **Goals of the One ILSI Strategy**

- All ILSI entities work together to achieve shared goals to improve human and environmental health and safety
- All ILSI entities coordinate and cooperate on individual activities to maximize the use of human and financial resources.
- A "One Voice" culture whereby all ILSI entities communicated value and impact in a consistent manner

### Specific Recommendations in Four Prior Areas – Science, Value, Stakeholders and Governance

<u>Science</u> – To the extent possible, consolidate ILSI entity work into four themes (food and water safety; toxicology and risk science; nutrition health and well-being; and agriculture sustainability/nutrition security.

Develop an emerging issues process at the global level

Increase inter-branch cooperation for scientific activities, including capacity building

Develop a program stewardship program to set publications standards and foster high level scientific contributions

Support professional development of ILSI entity staff and young scientists

Value - Proactively define ILSI for internal and external audiences

Provide messages describing ILSI's work – past and present

Leverage existing and new tools for proactively disseminating these messages

Create value propositions for all stakeholder groups (industry, academia, government and other scientific organizations)

Develop materials that illustrate ILSI's contributions to the public good

Stakeholders - Identify potential new partners and determine their areas of interest

Leverage new partnerships across the whole of ILSI

Examine opportunities to facilitate third party donations and financing

Governance – Enhance effectiveness of ILSI governance

Develop and implement organizational principles and standards

Engage branch executive directors to implement the One ILSI strategy

This work will be initiated at once with help from the branch led themes. New, coordinated activities will be developed in each of the four themes to demonstrate the value of leveraging expertise and resources. The outcome of these efforts will be presented to the Board in January 2014, with specific next steps recommendations.

The Governance Sub-team also recommended reviewing options for changing the make-up of the ILSI Board of Trustees. This work will be given to a small group that is geographically representative of the organization and includes branch leaders as well as ILSI trustees. The group will be asked to report back to the ILSI Board of Trustees in January 2015 the options they see as viable.

# **Next Steps**

Having had an opportunity to hear the transition team recommendations, the ILSI Board of Trustees is asked to endorse the ongoing efforts to bring more clarity and specificity to the team recommendations for each of the four strategic platforms – science, value, stakeholders and governance. The thematic areas will be developed further as well by the ILSI entities.

The ILSI Board of Trustees will have a second conference call in November to receive more detail plans on how these recommendations will be implemented and the financial resources needed to do so. The Board will then consider ratifying the more detailed plan at the January 2014 Board meeting.

# ILSI Board of Trustees Mid-Year Conference Call

Monday, August 5, 2013 9:00 – 11:00 a.m. Eastern Daylight Time

# PROPOSED AGENDA

I.	Call to Order	Dr. Sam Cohen	
II.	Approval of Minutes from the January 19, 2013 ILSI Board of Trustees Meeting	Dr. Sam Cohen	
III.	President's Report	Dr. Jerry Hjelle	
IV.	Report of the Financial Oversight Committee	Dr. Liz Westring	
V.	Recommendations from the ILSI Strategic Long-range Plan Transition Team/ILSI Executive Committee and Implementation	Dr. Jerry Hjelle	
VI.	Publications Committee	Dr. John Milner	
VII.	Report from the ILSI Research Foundation	Dr. Suzie Harris	
VIII.	Report from the ILSI PIP Dr. Suzie Harri		
IX.	Report from the ILSI International Food Biotechnology Committee	Dr. Suzie Harris	
X.	Other Business		
	<ul><li>a. Branch Staff Travel Grants</li><li>b. Plans for 2014 Annual Meeting</li></ul>	Dr. Sushila Chang Dr. Suzie Harris	
XI.	Adjournment		

# ILSI Board of Trustees 2013 Conference Call Information 9:00 am – 11:00 am US Eastern Daylight Time

# Monday, August 5, 2013

Country	AT&T Direct	Toll Free Dial-In Number	Note
Australia		1-800-21-2361	
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			(The audio conference requires two-stage
			dialing. First, dial the AT&T Direct Number.
Brazil	0-800-890-0288	888-706-6468	Second, dial the Toll-Free Dial-In Number.)
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			dialing First dial the AT&T Direct Number
Brazil	0-800-888-8288	888-706-6468	Second, dial the Toll-Free Dial-In Number.)
China		10-800-711-0988	CHINA NETCOM GROUP USERS
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Germany		0800-182-9571	
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If you are calling from a country not listed, please contact Beth Brueggemeyer

# Access code for all calls is 4498699#

From:	Suzanne Harris
Sent:	Wednesday, July 31, 2013 12:21 PM
То:	Joanne Lupton
Cc:	'Connie Weaver' (weavercm@purdue.edu)
Subject:	RE: long overdue synopsis of ILSI biomarkers symposium

I expect to hear back from the editorial team of *Nutrition Reviews* next week.

Suzie

From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Friday, July 26, 2013 10:35 AM
To: Suzanne Harris
Cc: 'Connie Weaver' (weavercm@purdue.edu)
Subject: RE: long overdue synopsis of ILSI biomarkers symposium

Thanks Suzie, J

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Suzanne Harris [
Sent: Friday, July 26, 2013 9:28 AM
To: Joanne Lupton
Cc: 'Connie Weaver' (weavercm@purdue.edu)
Subject: RE: long overdue synopsis of ILSI biomarkers symposium

Will do and will let you know, Joanne.

Suzie

From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Friday, July 26, 2013 10:26 AM
To: Suzanne Harris
Cc: 'Connie Weaver' (weavercm@purdue.edu)
Subject: RE: long overdue synopsis of ILSI biomarkers symposium

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review going back to when the IOM reports on biomarkers came out since I'm very familiar with the initial report and the follow up workshop. Joanne

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To: Weaver, Connie M; Joanne Lupton
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Suzie

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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From: Weaver, Connie M [mailto:weavercm@purdue.edu]
Sent: Friday, July 26, 2013 9:05 AM
To: Joanne Lupton; Suzanne Harris
Subject: RE: long overdue synopsis of ILSI biomarkers symposium

Fine with me. Connie

Sent from my Verizon Wireless Droid

-----Original message----- **From:** Joanne Lupton <<u>ilupton@tamu.edu</u>> **To:** "Weaver, Connie M" <<u>weavercm@purdue.edu</u>>, "Suzanne Harris **Sent:** Fri, Jul 26, 2013 10:34:23 GMT+00:00 **Subject:** RE: long overdue synopsis of ILSI biomarkers symposium I've looked at the instructions to authors for Nutrition Reviews and also for Advances in Nutrition, and I think the latter may be the best since they prefer the current direction the subject is going in and also shorter papers. If the two of you agree I'll send a letter out to the authors (the presenters at the ILSI meeting). Joanne

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From: Weaver, Connie M [mailto:weavercm@purdue.edu]
Sent: Thursday, July 25, 2013 8:16 PM
To: Joanne Lupton; Suzanne Harris
Subject: RE: long overdue synopsis of ILSI biomarkers symposium

Joanne, This is excellent. The one thing that I would suggest is to clarify that it is biomarker for health outcomes in the title as there are also biomarkers for intake/exposure and other things. This would make a good paper. Are you up for the task? Connie

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Sent: Thursday, July 25, 2013 1:43 PM
To: Weaver, Connie M; Suzanne Harris
Subject: long overdue synopsis of ILSI biomarkers symposium

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From: Sent: To: Subject: Joanne Lupton Sunday, July 28, 2013 4:51 PM Suzanne Harris Info on IFBIC

Hi Suzie:

Could you explain to me what IFBIC does. After the important information you provided on our finance committee call I tried to get online and figure out what IFBIC does but I couldn't find the information. Thanks, J

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862 From: Sent: To: Cc: Subject: Joanne Lupton Friday, July 26, 2013 9:26 AM Suzanne Harris 'Connie Weaver' (weavercm@purdue.edu) RE: long overdue synopsis of ILSI biomarkers symposium

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Suzie

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long overdue synopsis of ILSI biomarkers symposium
Synopsis of the Workshop.docx

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# Synopsis of the Workshop "Biomarkers – Are We Making Progress? Organized by International Life Sciences Institute

Prepared by Joanne Lupton, Chair of the Workshop

The theme of the Workshop was to suggest a process for evaluating biomarkers so that they would be "accredited" as being scientifically valid and would be accepted by regulatory agencies and scientists alike. The goal of establishing such an accreditation process would be to raise the level of science on relating food substance/nutrients to decreased risk of disease or a health related condition. If "validated" biomarkers were available and used in epidemiological and clinical trials it would be easier to compare studies across laboratories which would further advance the science.

The Program began with *Dr. Paula R. Trumbo, Acting Director of Nutrition Programs at the US Food and Drug Administration, providing the US Perspective on the challenge of validating biomarkers for use in food-related health claims.* She discussed the importance of surrogate endpoints for the scientific review of health claims, and stated that there is continued interest on the part of FDA in the state of the scientific evidence for the qualification of potential surrogate endpoints . She discussed the FDA-funded Institute of Medicine study on evaluating biomarkers of chronic disease risk, and noted both the recommendation from the report as well as challenges in identifying surrogate endpoints. Importantly, she described the biomarker qualification program at FDA's Center for Drug Evaluation and Research (CDER), and used it as a potential process for validating biomarkers for food rather than drugs.

Next, Dr. Albert Flynn, Professor in Nutrition at University College of Cork, Ireland, provided the *European Perspective on the Challenge of validating biomarkers for use in food-related health claims*. He discussed how the European Food Safety Authority (EFSA) considers the use of biomarkers as outcomes for human studies for substantiation of specific types of health claims on foods. Health claims on disease risk reduction are based on reduction of a known risk factor for development of a disease. Biomarkers are risk factors for the disease. Similar to FDA, EFSA does not have many of these risk factors (biomarkers).

Dr. Jan Willem van der Laan, a Senior assessor in Pharmacology and Toxicology for the Medicines Evaluation Board in Utrecht, the Netherlands, discussed *approaches used for validating biomarkers for use in drug discovery/claims* and how those claims compared to food claims. He made the point that biomarkers for drug studies focus on important diseases, not on health. For example, LDLcholesterol levels are considered a biomarker of the relative risk for coronary heart disease. The most important parameters to be measured are disease symptoms/morbidity; survival/premature mortality; and clinical condition (quality of life). He went through the process that the Medicines Evaluation Board uses to validate a biomarker, and showed that since the introduction of this process 12 "advices" on biomarkers have been completed and 5 are ongoing. H led us through the qualification of biomarkers of nephrotoxicity and how they can serve as models for qualification of other biomarkers.

Dr. Ben van Ommen, Principal Scientist at TNO (the Dutch organization for applied scientific research) took a different approach. Rather than evaluating biomarkers of disease he asked the question: *"Can we design biomarkers of <u>health</u> that are applicable in nutrition research?"* In this provocative talk, Dr. van Ommen argued that health is not merely the absence of disease but rather it is characterized by the "ability to adapt". He termed this adaptive capacity "phenotypic flexibility," and provided examples such as glucose regulation, optimal inflammatory stress responses, and oxidative stress regulation. Too much or too little of certain food components can negatively impact this flexibility, whereas for most nutrients (taken in appropriate amounts) help to maintain this flexibility.

Dr. Loek Pijls, currently at the Nestle Research Center in Switzerland and formerly the Senior Scientist at the ILSI European Branch in Brussels, provided the latest information from the *ILSI Europe Marker Initiative: What makes a marker a marker?* Dr. Pijls concentrated on the question of how to decide whether or not something measurable actually 'marks' or reflects current or future health or functioning? Interestingly, he stated that responsiveness to dietary intervention is not a criterion for a marker's validity. Rather, something is a valid marker of health if it marks an aspect of health. Once that is established then one can study whether or not diet impacts that health aspect. ILSI Europe has taken on the area of immunity and developed a system for grading and weighing criteria for validity or markers. They are now in the process of defining how this system can be adapted for other health benefit areas.

Dr. Joanne R. Lupton, Distinguished Professor of Nutrition at Texas A&M, and Chair of this workshop, led the panel discussion at the end of the session with all speakers (above) participating. The major conclusions from this workshop were: (1) There is a need to have a validation process for biomarkers. (2) We can learn a lot from pharma as to how this validation process might work. (3) Adapting a "health claim" evaluation process for biomarkers provides important information as to how a pharma process could be adapted for foods. (4) The current EFSA process for health claims which focusses on biomarkers that are validated risk factors for the disease is an important concept because it defines the process and also removes some of the uncertainty in having to prove that foods/nutrients have an effect on those biomarkers. 5) It is now time to start thinking about biomarkers for *health* rather than decreased risk of disease and this is an important concept.

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Thursday, July 25, 2013 12:44 PM
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long overdue synopsis of ILSI biomarkers symposium
Synopsis of the Workshop.docx

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So sorry this is so late. I'm a bit discouraged by the lack of resources to support programs for ILSI (particularly after yesterday's financial phone call) but I understand. Take a look at the summary statement for the synopsis. I think this could make a good paper if done right. Any ideas? Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Sent: To:	Suzanne Harris Monday, July 22, 2013 2:41 PM								
	(scohen@unmc.edu); marion@vt.edu;	; s.chang@griffith.edu.au; Co e; goodman3	ohen, Samuel M adamdrew@u.washington.ed 3@msu.edu;	lu;					
	j	ohn.milner@ars.usda.gov; joh Rodriguez, Felipe {PI} Geoff	Joanne Lupton; Gert Meije n.c.peters@ucdenver.edu; ; Smith, Lewis L. (Prof.)	r					
		; weavercm@purdue.	edu; ;						
Cc:	Fleming, Melinda S	m; Bradfor	rd, Jeanne (jbradford@unmc.edu	);					
	linda.reynolds@ars.us	da.gov; tim.goss@ucdenver.ed ; haan@purdue.edu Beth-Ellen Beri	; Chelsea L. Bishop; lu; i; Christine Lagerquist rv: Michael Shirreffs: Shawn Sulliv	/an					
Subject:	, Agenda and Dial-in in: Monday, August 5, 1	structions for the ILSI Board of 2013 at 9:00 a.m. EDT	Trustees mid-year conference c	all					
Attachments:	2013 Dial-in Information	on.doc; ILSI BOT 2013-08-05 c	c agenda.doc						

TO: ILSI Board of Trustees

FROM: Suzie Harris

The mid-year conference call for the ILSI Board of Trustees is scheduled for **Monday, August 5, 2013, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not run longer than two hours. I hope you will make every effort to participate

The dial-in instructions are attached along with the proposed agenda. I will post the briefing materials on the ILSI Board of Trustees ILSI EXTRA page as the day for the meeting draws closer and will let you know when they are posted.

To access the Board page, go to <u>https://www.ilsiextra.org/ilsi/bot/meetings/SitePages/Home.aspx</u>. Enter the following information:

Username: ILSI-Board Password: 1978Bot1156

Please let me know if you have any questions or need additional information.

**Suzanne S. Harris, Ph.D.** Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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## ILSI Board of Trustees Mid-Year Conference Call

Monday, August 5, 2013 9:00 – 11:00 a.m. Eastern Daylight Time

## PROPOSED AGENDA

I.	Call to Order	Dr. Sam Cohen
II.	Approval of Minutes from the January 19, 2013 ILSI Board of Trustees Meeting	Dr. Sam Cohen
III.	President's Report	Dr. Jerry Hjelle
IV.	Report of the Financial Oversight Committee	Dr. Liz Westring
V.	Recommendations from the ILSI Strategic Long-range Plan Transition Team/ILSI Executive Committee and Implementation	Dr. Jerry Hjelle
VI.	Publications Committee	Dr. John Milner
VII.	Report from the ILSI Research Foundation	Dr. Suzie Harris
VIII.	Report from the ILSI PIP	Dr. Suzie Harris
IX.	Report from the ILSI International Food Biotechnology Committee	Dr. Suzie Harris
X.	Other Business	
	<ul><li>a. Branch Staff Travel Grants</li><li>b. Plans for 2014 Annual Meeting</li></ul>	Dr. Sushila Chang Dr. Suzie Harris
XI.	Adjournment	

## ILSI Board of Trustees 2013 Conference Call Information 9:00 am – 11:00 am US Eastern Daylight Time

### Monday, August 5, 2013

Country	AT&T Direct	Toll Free Dial-In Number	Note
Australia		1-800-21-2361	
			FROM BRAZIL
			(The audio conference requires two-stage
			dialing. First, dial the AT&T Direct Number.
Brazil	0-800-890-0288	888-706-6468	Second, dial the Toll-Free Dial-In Number.)
			BRAZIL OTHER
			dialing First dial the AT&T Direct Number
Brazil	0-800-888-8288	888-706-6468	Second, dial the Toll-Free Dial-In Number.)
China		10-800-711-0988	CHINA NETCOM GROUP USERS
China		10-800-110-0916	CHINA TELECOM SOUTH USERS
Germany		0800-182-9571	
Greece		00-800-11-005-8221	
India	000-117	888-706-6468	Two-stage dialing process required.
Japan		00531-11-0061	JAPAN KDD USERS
Japan		0066-33-830259	JAPAN C&W USERS
Japan		0034-800-900351	JAPAN NTT USERS
Korea (south)		00798-1-1-005-8221	
Mexico		001-888-706-6468	
Netherlands		0800-022-7141	
Singapore		800-110-1778	
Switzerland		0-43-5579014	Caller paid
United			
Kingdom		0808-234-3676	
United States		888-706-6468	

## The access code for all calls is 4498699#

If you are calling from a country not listed, please contact Beth Brueggemeyer

## Access code for all calls is 4498699#

From: Sent: To:	Suzanne Harris < > Wednesday, July 17, 2013 3:49 PM ; s.chang@griffith.edu.au; g e ; Joanne Lupton; Rodriguez, F ( ; Smith, Lewis L. (Prot	Joodman3@msu.edu; elipe {PI} f.)
Subject:	Chelsea L. Bishop; Beth-Ellen Berry; Shawn Sullivan; Be Agenda, biefing documents and dial-in instructions for Committee conference call Wednesday, July 24, 20	, eth Brueggemeyer or the ILSI Financial Oversight 13 at 9:00 a.m. EDT
Attachments:	FOC 2013-07-24 agd BEB.doc; FOC 2013-04-25 minut 2012 ILSI Internal Control Ltr.pdf; 2012 ILSI Board Ltr.p AFS.PDF; ILSI BDR 062013.pdf; ILSI Ops 062013.pdf; IL 06302013.pdf	esBEB.docx; 2012 ILSI AFS.PDF; odf; 2012 ILSI Consolidated .SI Financial Statements

TO: ILSI Board of Trustees Financial Oversight Committee

#### FROM: Suzie Harris

A conference call for the ILSI Board of Trustees Financial Oversight Committee is scheduled for **Wednesday**, July 24, 2013, beginning at 9:00 a.m. Eastern Daylight Time. The call may run as long as 90 minutes. The dial-in instructions are at the end of this message.

The proposed agenda is attached here.

Agenda Item II. Draft minutes from April 25, 2013 ILSI Financial Oversight Committee conference call

Agenda Item III. 2012 ILSI audit report, Internal control letter, Board communication letter, and consolidated ILSI and RF audit report

Agenda Item IV. Portfolio reports from Raffa Wealth Management – Board designated reserve and Operating reserve

Agenda Item V. 2013 Year-to-date financial report

Please let me know if you have any questions or need additional information.

#### **Dial-in Instructions**

If you are calling from:	Please dial this toll-free number
Australia	1-800-21-2361
Germany	0800-182-9571
Mexico	001-888-706-6468
United Kingdom	0808-234-3676
USA	1-888-706-6468

The access code for everyone is **4498699 #**. If you are going to be in another country, please let me know so that I can send you the toll free number from that country.

#### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

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#### **ILSI Financial Oversight Committee**

#### Conference Call Thursday, April 25, 2013

#### **DRAFT MINUTES**

#### I. Welcome and Review of the Agenda

Dr. Liz Westring, ILSI Treasurer and Chair, ILSI Financial Oversight Committee, began the conference call at 9:03 a.m. Eastern Daylight Time. In addition to Dr. Westring, the following trustees and staff participated in the conference call: Dr. Gerhard Eisenbrand, Dr. Jay Goodman, Dr. Lewis Smith, Ms. Beth-Ellen Barry, Dr. Suzie Harris and Mr. Shawn Sullivan.

Dr. Westring reviewed the agenda (attached). No topics were offered for discussion under new business.

#### II. Approval of Minutes from the December 14, 2012 Conference Call

The minutes were approved as distributed.

#### III. Review of 2013 Year-to-date Financial Report

The balance sheet and functional activity statement were distributed to the committee prior to the conference call. In reviewing the balance sheet, Ms Berry reminded the committee members that a balance sheet captures assets, liabilities, and net assets on a particular day. The data provided for March 31, 2013 are interim balances, meaning that they are not fully accrued and cannot be compared to the year-end balances. The 2012 data have not been audited yet, but the other year-end balances are audited.

In terms of current assets, ILSI is very liquid with over \$1.5 million including cash of \$549 thousand and short term investments of \$613 thousand. The "Due from ILSI Entities" is high at the end of March because it includes the amounts owed to ILSI from ILSI NA, HESI, and RF for the 2013 annual meeting expenses which have now been reconciled and are included in the March activity statements. Under "Other Assets", Ms. Berry called attention to the line called "Board-designated Reserve." This line is now a combination of the ILSI Press Investment Fund and \$300,000 taken from the short term investment line under "Current Assets" to form the new Board-designated Reserve as approved during the 2013 ILSI Annual Meeting. The reserve fund is to be valued at approximately 50 percent of the annual unrestricted ILSI budget. Under Liabilities, Ms. Berry said there was nothing unusual or unexpected.

Next, she reviewed the income statement which shows activity over a period of time – January 1 through March 31, 2013 – and compares the activity to the annual budget. She began her review with the unrestricted operations, which include ILSI Governance and Coordination (GC), ILSI Communications and ILSI Press. For ILSI GC, Ms. Berry pointed out that the process of invoicing branches and the Research Foundation for the 2013 ILSI assessment has not yet begun. To date there is no indication that the revenue from the assessment will be less than the 2013 budget. Revenue is also listed from the 2013 ILSI Annual Meeting registration fees. The restricted contributions were received from the ILSI

member companies who are supporting the ILSI Strategic Plan Transition Team activities. The income in the fee for service line represents reimbursement from the ILSI Research Foundation for Dr. Harris' time. Total income is 10 percent of budget which is not unexpected for this point in the year.

In terms of ILSI GC expenses, most of the travel expenses for the 2013 ILSI Annual Meeting are included. The food and audio-visual expenses were about \$15,000 higher than budgeted.

The ILSI Communications expenses are as expected. The ILSI Press revenue comes from the guaranteed royalty payment from ILSI's publishing partner, Wiley-Blackwell, and the editorial stipend they provide. Both of these revenue streams are on track and the expenses are as expected.

Ms. Berry also quickly reviewed the restricted activities, including the ILSI Platform for International Partnerships (PIP)/Global Travel Fund. No new funding is currently being sought for the Global Travel Fund, but contributions are being solicited for ILSI PIP. The International Branch Activity covers ILSI Focal Point in China expenses transacted in the DC office including the fellowship programs and some of their annual meeting expenses. The International Food Biotechnology Committee (IFBiC) is actively collecting assessments for 2013 and has spent 21 percent of budgeted expenses. The last activity is the Shared Services Group, which is the overhead pool shared by the four Washington-based corporations on a full-time equivalence basis. The total expenses for 2013 is on track with the budget.

#### IV. Audit Plans

Ms. Berry reported that the auditors spoke with Dr. Westring in December 2012 to present the audit plan and to ask her to identify any areas of concern that she had. Dr. Westring said she had a great discussion with them. The auditors then conducted some preliminary testing in January 2013, and will be on site for two weeks beginning May 6 to complete the audit field work. The report is expected to be available in July.

#### V. Investment Policy for Expanded Reserve Fund

The newly approved reserve fund policy was distributed to the committee prior to the conference call. Ms. Berry called attention to point 5 which states how the reserve funds will be invested. At present the funds are in very low-risk fixed income securities and are not earning anything. This is the way the ILSI Press Fund had been invested.

A summary of how the other Washington-based ILSI entity investment portfolios were allocated was also distributed to the committee prior to the call. Ms. Berry made clear that she was not recommending specific changes, but encourage the committee to begin thinking about their investment policy. The ILSI Research Foundation also has a very conservative policy and is earning 2.84 percent.

Ms. Berry reminded the committee that there are two kinds of risk -1) equity losses and 2) inflation that can also reduce the value of a portfolio. Raffa Wealth Management will be happy to provide the committee with investment advice, but prefer to base this advice on an understanding of how much risk the committee is willing to accept and their investment time horizon. This information would be collected through an electronic survey of the committee members, for which Raffa would charge a fee.

After some discussion of the investment philosophies of various trustees, the committee agreed that a representative from Raffa should be invited to the next committee conference call, which is scheduled for July 24. Ms. Berry agreed to ask Raffa what the risk survey would cost.

#### VI. New Business

None was offered.

#### VII. Next Steps

- Ms. Berry will contact Raffa Wealth Management to invite them to make a presentation during the next committee call on July 24, and will ask them how much they would charge for a risk tolerance survey of the committee.
- Ms. Berry will invite the audit firm to give their report of the 2012 audit during the July 24 call as well.

#### VIII. Adjournment

As there was no further business, Dr. Westring thanked the members for their participation and ended the conference call at approximately 9:35 a.m. Eastern Daylight Time.

Signed: \_\_\_\_\_\_ Date: \_\_\_\_\_\_

### ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

## Thursday, April 25 9:00 – 10:00 am Eastern Daylight Time

## AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the December 14, 2013 Conference Call
- III. Review of 2013 Year-to-date Financial Report
- IV. Audit Plans
- V. Investment Policy for Expanded Reserve Funds
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

## ILSI Board of Trustees Financial Oversight Committee

#### **Conference Call**

## Wednesday, July 24, 2013 9:00 – 10:30 am Eastern Daylight Time

#### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the April 25, 2013 Conference Call
- III. 2012 Audit Report Johnson Lambert
- IV. ILSI Reserve Fund Performance Report Raffa Wealth Management
- V. Review of 2013 Year-to-date Financial Report
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

#### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS	6/	30/2013 <sup>(1)</sup>		12/31/2012		12/31/2011		12/31/2010		12/31/2009	1	2/31/2008
Current Accete												
Cash	\$	854 553	¢	509 443	¢	773 370	¢	883 041	¢	817 803	¢	043 770
Short-Term Investments	Ψ	607 699	Ψ	914 298	Ψ	911 040	Ψ	401 663	Ψ	199 533	Ψ	
Accounts Receivable		21 069		169 244		119 954		257 151		88 442		215 941
Due From II SI Entities		130 459		171 782		109 126		156 341		220 499		183 944
Prepaid Expenses and Other Current Assets		10 379		16 979		24 342		31 626		41 058		85 345
Total Current Assets		1,624,160		1,781,746		1,937,832		1,729,822		1,367,335		1,429,009
Other Assets												
Inventory, Net		-				-		-		30,364		71,933
Rent Receivable under Shared Space Agreement		361,419		364,147		356,748		334,566		299,076		202,732
Board-Designated Reserve		564,907		269,608		268,446		264,897		256,466		234,356
I otal Other Assets		926,326		633,755		625,194		599,463		585,906		509,020
Fixed Assets												
Computer Software and Equipment		676,083		594,523		510,315		282,834		263,103		247,482
Office Furniture		114,075		114,075		114,075		116,075		116,075		118,621
Leasehold Improvements		723,761		723,761		703,909		703,909		703,909		703,909
Accumulated Depreciation		(672,454)		(672,454)		(508,231)		(376,494)		(344,971)		(291,591)
Total Net Fixed Assets		841,465		759,904		820,069		726,324		738,116		778,421
I otal Assets	\$	3,391,951	\$	3,175,406	\$	3,383,095	\$	3,055,609	\$	2,691,357	\$	2,716,450
LIABILITES AND NET ASSETS												
Current Liabilities												
Accounts Pavable	\$	-	\$	82 373	\$	140 847	\$	88 347	\$	121 559	\$	249 241
Accrued Liabilities	÷	105.826	Ŧ	103,744	Ť	80.695	Ť	79,435	Ť	86.618	Ŧ	75.324
Deferred Revenue		11.315		102.343		86.498		94.645		116.134		104.101
Total Current Liabilities		117,141		288,460		308,040		262,427		324,311		428,666
Long Torra Liakilitian												
Long-Term Liabilities		246 000		246 000		240.000		240.000		240.000		240.000
Deposits - ILSI Entities		246,000		240,000		240,000		246,000		246,000		246,000
Total Long Torm Liabilition		1 076 166		1 070 414		1 127 432		932,030		1 205 505		914,712
Total Long-Term Liabilities		1,070,100		1,079,414		1,137,432		1,176,050		1,205,595		1,100,712
Total Liabilities		1,193,307		1,367,873		1,445,472		1,441,077		1,529,905		1,589,378
Net Assets												
Beginning Balance		1,807,533		1,937,623		1,614,532		1,161,451		1,127,072		930,509
Current Year Change		391,111		(130,090)		323,092		453,081		34,379		196,563
Total Net Assets		2,198,644		1,807,533		1,937,623		1,614,532		1,161,451		1,127,072
Total Liabilities and Net Assets	\$	3,391,951	\$	3,175,406	\$	3,383,095	\$	3,055,609	\$	2,691,357	\$	2,716,450
NET ASSETS - DETAIL												
Unrestricted Operations	\$	481,558	\$	681,148	\$	559,848	\$	418,355	\$	249,469	\$	159,903
Board-Designated Reserve		564,907		269,608		268,446		264,897		256,466		234,356
Coca Cola Company Marketing Contribution		3,872		3,872		29,216		38,850		-		-
PIP/GTF Restricted Funds		113,279		104,035		122,208		-		-		-
International Committees/Branches		1,035,028	<u> </u>	748,871	<u> </u>	957,905	~	892,430	-	655,516	*	732,813
l'otal Net Assets	\$	2,198,644	\$	1,807,533	\$	1,937,623	\$	1,614,532	\$	1,161,451	\$	1,127,072
Current Assets Minus Current Liabilities (Liquidity) (2)	¢	1 507 010	¢	1 /02 297	¢	1 620 702	¢	1 /67 206	¢	1 0/2 024	¢	1 000 342
Current Ratio (2)	Ψ	13 97	φ	6 19	φ	6 20	φ	6 50	φ	1,040,024	Ψ	1,000,040
ourrent Natio		13.07		0.10		0.29		0.39		4.22		5.55

<sup>(1)</sup> The 2013 balances are interim and have not been fully adjusted for all accrued revenues and expenses. All balances will be fully adjusted and reported on the 2013 financial statement audit.

(2) ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratios vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current liability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			COM	MUNICATION	II	SI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>			
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/
For the Six Months Ended June 30, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
	440.000	700 000	620/			NI/A			N1/A	440.000	700.000	639/
	440,000	700,000	03%	-	-	N/A	-	-	N/A	440,000	700,000	03% N/A
CONFERENCE/ REGISTRATION FEES	42 046	35.000	120%	-	-	N/A N/Δ	-	-	N/A N/Δ	42 046	- 35.000	120%
CONTRIBUTIONS	45 000		N/A	_	_	N/A	_	_	N/A	45 000		N/A
EFE FOR SERVICES	43 201	89 000	49%	-	-	N/A	-	-	N/A	43 201	89 000	49%
SHARED SERVICES REIMBURSEMENT		-	N/A	-	-	N/A	-	-	N/A		-	N/A
INVESTMENT INCOME	(10,423)	10,000	-104%	-	-	N/A	-	-	N/A	(10,423)	10,000	-104%
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	198,826	306,300	65%	198,826	306,300	65%
TOTAL REVENUE	559,824	834,000	67%		 -	 N/A	198,826	306,300	65%	758,649	1,140,300	67%
EXPENSES												
COMMUNICATIONS	4,909	9,360	52%	7,431	17,650	42%	477	1,365	35%	12,818	28,375	45%
FINANCIAL/PROFESSIONAL FEES	20,142	29,753	68%	-	-	N/A	-	-	N/A	20,142	29,753	68%
GENERAL & ADMINISTRATIVE												
Shared Services Overhead	108 096	227 800	47%	-	_	N/A	-	-	N/A	108 096	227 800	47%
Rent	46,144	87.467	53%	-	-	N/A	-	-	N/A	46,144	87.467	53%
Depreciation		75.000	0%	-	-	N/A	-	-	N/A	-	75.000	0%
Other	8.420	11.300	75%	3.935	10.500	37%	2,141	3,590	60%	14.495	25.390	57%
Indirect Reimbursement	(262,021)	(543,456)	48%	85,047	180,212	47%	48,742	106,224	46%	(128,232)	(257,019)	50%
STAFFING												
Salaries	116,403	250,250	47%	77,457	161,480	48%	44,392	95,183	47%	238,252	506,914	47%
Benefits	29,386	60,060	49%	17,040	38,755	44%	9,766	22,844	43%	56,193	121,659	46%
Outside Services	1,436	400	359%	-	-	N/A	-	-	N/A	1,436	400	359%
CONSULTANTS	14,109	14,100	100%	12,208	26,500	46%	-	-	N/A	26,317	40,600	65%
IT SUPPORT SERVICES	-	-	N/A	20,000	50,000	40%	-	-	N/A	20,000	50,000	40%
PUBLICATIONS	4,747	5,625	84%	8,245	15,000	55%	26,097	62,100	42%	39,088	82,725	47%
MEETINGS			0.50/									0.50/
I ravel - Board	41,968	44,000	95%	-	-	N/A	-	-	N/A	41,968	44,000	95%
Travel - Staff	1,861	5,035	37%	6,826	7,500	91%	3,663	9,300	39%	12,350	21,835	57%
I ravei - Advisors/Speakers/Invitees	13,935	17,830	/8%	-	-	N/A	2,013	2,800	72%	15,949	20,630	//%
Group Functions/Business Means	90,884	68,530	133%	391	1,500	26%	95	1,650	6%	91,370	71,680	127%
Other Expenses (Audiovisual/Might Fee)	46,796	39,510	118%	-	1,500		-	-	N/A	46,796	41,010	114%
SUBTOTAL MEETINGS	195,445	174,905	112%	7,218	10,500	69%	5,771	13,750	42%	208,434	199,155	105%
OTHER PROGRAM EXPENSES	-	-	N/A	-	-	N/A	-	3,500	0%	-	3,500	0%
TOTAL EXPENSES	287,215	402,564	71%	238,580	510,598	47%	137,386	308,557	45%	663,181	1,221,719	54%
CHANGE IN NET ASSETS	272,609	431,436		(238,580)	(510,598)		61,438	(2,257)		95,467	(81,419)	
NET ASSETS, BEGINNING OF PERIOD	1,282,251	1,282,251		(1,344,339)	(1,344,339)		1,016,957	1,016,957		- 954,868	- 954,869	
NET ASSETS, END OF PERIOD	1,554,860	1,713,687		(1,582,919)	(1,854,937)		1,078,395	1,014,700		1,050,336	873,450	
	==========	======						======		========		

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, the Annual Meeting and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the financial activity of ILSI unrestricted operations, a subtotal of these activities is provided.

INTERNATIONAL LIFE SCIENCES INSTITUTE	REST	RICTED: PIP/G	TF	INT'L BR	ANCH ACT	IVITY	IFBIC COMMITTEE		SHAF	ES	TOTAL				
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/
For the Six Months Ended June 30, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
REVENUE															
BRANCH/INSTITUTE ASSESSMENT	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	440,000	700,000	63%
COMMITTEE ASSESSMENTS	-	-	N/A	-	-	N/A	686,000	626,000	110%	-	-	N/A	686,000	626,000	110%
CONFERENCE/ REGISTRATION FEES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	42,046	35,000	120%
CONTRIBUTIONS	72,000	96,000	75%	5,000	-	N/A	-	-	N/A	-	-	N/A	122,000	96,000	127%
FEE FOR SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	43,201	89,000	49%
SHARED SERVICES REIMBURSEMENT	-	-	N/A	-	-	N/A	-	-	N/A	662,911	1,455,035	46%	662,911	1,455,035	46%
INVESTMENT INCOME	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	(10,423)	10,000	-104%
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	198,826	306,300	65%
TOTAL REVENUE	72,000	96,000	75%	5,000	-	N/A	686,000	626,000	110%	662,911	1,455,035	46%	2,184,561	3,317,335	66%
EXPENSES															
COMMUNICATIONS	711	1,265	56%	97	215	45%	7,084	12,974	55%	25,014	42,100	59%	45,723	84,929	54%
												1001			
FINANCIAL/PROFESSIONAL FEES	-	-	N/A	-	-	N/A	-	-	N/A	21,135	50,640	42%	41,276	80,393	51%
GENERAL & ADMINISTRATIVE															
Shared Services Overhead	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	108,096	227,800	47%
Rent	-	-	N/A	-	-	N/A	-	-	N/A	65,205	139,565	47%	111,349	227,032	49%
Depreciation	-	-	N/A	-	-	N/A	-	69,640	0%	-	17,830	0%	-	162,470	0%
Other	-	-	N/A	1,750	-	N/A	1,294	500	259%	73,230	176,500	41%	90,769	202,390	45%
Indirect Reimbursement	21,544	32,799	66%	4,364	10,121	43%	102,324	214,099	48%	-	-	N/A	-	-	N/A
STAFFING															
STAFFING	10 001	24.440	c20/	2.075	0.000	4.40/	02 404	404 045	409/	202.400	000 000	400/	700 447	4 500 047	400/
Salaries	19,621	31,119	63%	3,975	9,069	44%	93,191	191,845	49%	383,408	800,000	48%	738,447	1,538,947	48%
Benefits	4,317	7,469	58%	874	2,176	40%	20,502	46,043	45%	84,350	192,000	44%	166,236	369,347	45%
Outside Services	350	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	1,786	400	446%
CONSULTANTS	-	-	N/A	-	-	N/A	24,425	54,177	45%	18	-	N/A	50,760	94,777	54%
IT SUPPORT SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	1,114	8,000	14%	21,114	58,000	36%
PUBLICATIONS	2 400	_	N/A	-	-	N/A	15 656	43 924	36%	_	-	N/A	57 144	126 649	45%
	2,100		1073			1.071	10,000	10,021	0070			1	01,111	120,010	-1070
MEETINGS															
Travel - Board	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	41,968	44,000	95%
Travel - Staff	3,382	5,000	68%	7,672	12,860	60%	9,361	1,700	551%	7,215	8,400	86%	39,979	49,795	80%
Travel - Advisors/Speakers/Invitees	6,490	2,370	274%	14,113	8,000	176%	57,363	153,426	37%	-	-	N/A	93,915	184,426	51%
Group Functions/Business Meals	1,324	500	265%	9,024	6,510	139%	26,851	6,500	413%	2,221	20,000	11%	130,791	105,190	124%
Other Expenses (Audiovisual/Mgmt Fee)	-	1,365	0%	924	1,370	67%	3,758	-	N/A	-	-	N/A	51,478	43,745	118%
SUBTOTAL MEETINGS	11,196	9,235	121%	31,733	28,740	110%	97,333	161,626	60%	9,436	28,400	33%	358,131	427,156	84%
OTHER PROGRAM EXPENSES	2,619	27,500	10%	-	13,500	0%	-	7,517	0%	-	-	N/A	2,619	52,017	5%
TOTAL EXPENSES	62,757	109,387	57%	42,792	63,821	67%	361,809	802,345	45%	662,911	1,455,035	46%	1,793,450	3,652,307	49%
CHANGE IN NET ASSETS	9,243	(13,387)		(37,792)	(63,821)		324,191	(176,345)					391,111	(334,972)	
NET ASSETS, BEGINNING OF PERIOD	104,036	104,036		249,706	249,706		498,923	498,923		-	-		1,807,533	1,807,533	
NET ASSETS, END OF PERIOD	113,279	90,649		211,914	185,885		823,114	322,578					2,198,644	1,472,561	
	=========			======	=======		=======	========		=========	=======		======	=======	

# **Portfolio Review**

## **ILSI - Operating Reserve**

1156 15th Street, NW Washingon, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2013

Wealth Management, LLC



# **Market Commentary**

**ILSI - Operating Reserve** 

## **Overview**

US stocks had their impressive run snapped by concerns over future Fed moves. The first down month for US stocks since October was driven by comments by Fed chairmen Ben Bernanke that they would likely look to wind down the bond purchase program later this year. The move is earlier than initially anticipated and investors were concerned that rally would not last without Fed support. The statements brought back high volatility to the equity market, which had been absent for much of this year's run. Economic news has been relatively positive overall, supporting the Fed's view of an improving economy. The June employment report showed steady growth, housing continues to improve, retail sales have notched gains, and inflation remains tame. US stocks fell 1.30% in June, but were up 2.69% for the second quarter. Over the year to date US stocks are up 14.06% for the best first half of a year since 1999.

Foreign stocks were the worst performing asset class for the month as worries over China and the Fed's comments sank global markets. There was some positive news in the euro zone with industrial production increasing and the purchasing managers index improving. The bank of Japan elected to make no new moves over the month citing improving economic conditions in the country. However, Chinese manufacturing fell to a nine month low increasing investors' fears of a more substantial slow down. In addition, the country had a growing cash squeeze during June which sent short term interest rates surging above 25% before the central bank intervened. International stocks plunged 4.27% in June and were down 2.79% for the quarter driven primarily by emerging markets. For the year to date foreign stocks are flat, up 0.20%.

As the Fed announced they expect to reduce their bond purchase program later this year if the economy continues to progress, interest rates spiked. The 10 year Treasury yield rose from 2.16% to 2.52% over June and has risen 0.86% since early May. All sectors were down with shorter term bonds significantly outpacing intermediate and long term bonds. In June the broad bond market dropped again falling 1.55% and it sank 2.32% for the quarter. For the year to date the bond market is down 2.44%.

Index Performance	June	YTD	Trl 1 yr.
US Stock (Russell 3000)	-1.30%	14.06%	21.46%
Foreign Stock (FTSE AW ex US)	-4.27%	0.20%	14.43%
Total US Bond Mkt. (BarCap Aggregate)	-1.55%	-2.44%	-0.69%
Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.38%	-0.49%	0.02%
Municipal Bonds (BarCap 1-10yr Muni)	-1.61%	-1.34%	0.34%
Cash (ML 3Month T-Bill)	0.01%	0.04%	0.11%

This data is gathered from what is believed to be reliable sources, but we cannot guarantee its accuracy. Please use your brokerage statements as an accurate reflection of your portfolio.







Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	29.39%	\$178,581.82	30.00%	\$182,309.85	0.61%	\$3,728.03
Short Bond	65.74%	\$399,497.19	65.00%	\$395,004.67	(0.74%)	(\$4,492.52)
Cash	4.87%	\$29,620.48	5.00%	\$30,384.97	0.13%	\$764.49
TOTAL		\$607,699.49		\$607,699.49		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.

Period Ending: 6/30/2013



# **Performance Summary**

**ILSI - Operating Reserve** 

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	613,700.35	914,297.62	914,179.08
Net Contributions	0.00	(300,140.66)	(300,135.84)
Capital Appreciation	(7,314.72)	(8,693.40)	(11,385.16)
Income	1,540.59	2,800.53	5,980.60
Management Fees	(226.73)	(564.60)	(939.19)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	607,699.49	607,699.49	607,699.49
INVESTMENT GAIN	(6,000.86)	(6,457.47)	(6,343.75)

## **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	(1.0%)	(1.0%)	(0.9%)
Portfolio Benchmark	(0.7%)	(0.7%)	(0.6%)

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.


# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2013 Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 



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# **Asset Class Performance Summary**

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	178,582	(2.56%)	(2.64%)	(2.65%)
BarCap US Agg.			(2.33%)	(2.44%)	(2.24%)
Short Bond	9/30/2012	399,497	(0.27%)	(0.13%)	(0.05%)
BarCap 1-5 Yr Gov			(0.65%)	(0.49%)	(0.44%)
Cash	9/30/2012	29,620	0.00%	0.01%	0.01%
ML US Treasury Bill 3 Mon			0.02%	0.04%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	607,699	(0.94%)	(0.88%)	(0.82%)
Total Portfolio (Net of Fees)	9/30/2012	607,699	(0.98%)	(0.95%)	(0.94%)
Portfolio Benchmark			(0.70%)	(0.68%)	(0.57%)

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

**ILSI - Operating Reserve** 

Description	9/30/2012 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2013 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	914,179	(300,136)	(11,385)	5,041	607,699	(0.8%)	NA
Intermediate Bond	274,183	(90,141)	(9,656)	4,196	178,582	(2.4%)	NA
Vanguard Total Bond Market Fund	274,183	(90,141)	(9,656)	4,196	178,582	(2.4%)	NA
Short Bond	594,450	(195,004)	(1,729)	1,781	399,497	0.0%	NA
DFA One Year Fixed	411,450	(135,003)	(148)	1,105	277,404	0.3%	NA
Vanguard Short-Term	183,000	(60,001)	(1,581)	676	122,093	(0.6%)	NA
Cash	45,546	(14,990)	0	(935)	29,620		
Sch Adv Cash Resrv Prem	45,546	(14,990)	0	(935)	29,620		



# Disclaimers

**ILSI - Operating Reserve** 

#### Disclosure

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### **Market Terms**

#### **Accrued Interest**

Interest that has accumulated since the last pay date, but has not yet been paid. Computed using the interest rate of the security.

#### **Beginning/Ending Value**

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#### Expense

Fee charged against a portfolio, reducing portfolio value. Includes Management Fees charged by the advisor.

#### Time Weighted Return (TWR)

Provides a measure of the growth of a portfolio in terms that remove the effect of the timing and size of capital flows.

# **Portfolio Review**

ILSI - Board Designated Reserve 1156 15th Street, NW

Washington, DC 20005

Prepared By: Raffa Wealth Management LLC

June 30, 2013

Wealth Management, LLC



# **Market Commentary**

**ILSI - Board Designated Reserve** 

## **Overview**

US stocks had their impressive run snapped by concerns over future Fed moves. The first down month for US stocks since October was driven by comments by Fed chairmen Ben Bernanke that they would likely look to wind down the bond purchase program later this year. The move is earlier than initially anticipated and investors were concerned that rally would not last without Fed support. The statements brought back high volatility to the equity market, which had been absent for much of this year's run. Economic news has been relatively positive overall, supporting the Fed's view of an improving economy. The June employment report showed steady growth, housing continues to improve, retail sales have notched gains, and inflation remains tame. US stocks fell 1.30% in June, but were up 2.69% for the second quarter. Over the year to date US stocks are up 14.06% for the best first half of a year since 1999.

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Short US Gov. Bonds (BarCap Gov 1-5 Yr)	-0.38%	-0.49%	0.02%
Municipal Bonds (BarCap 1-10yr Muni)	-1.61%	-1.34%	0.34%
Cash (ML 3Month T-Bill)	0.01%	0.04%	0.11%

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# Actual vs. Target Allocation

#### ILSI - Board Designated Reserve

Period Ending: 6/30/2013 Portfolio Inception Date: 9/30/2012

Actual Allocation



Category	Current Percentage	Current Value	Target Percentage	Target Value	Percent Variance	Dollar Variance
Intermediate Bond	29.61%	\$167,260.59	30.00%	\$169,472.15	0.39%	\$2,211.56
Short Bond	65.46%	\$369,813.35	65.00%	\$367,189.65	(0.46%)	(\$2,623.70)
Cash	4.93%	\$27,833.22	5.00%	\$28,245.36	0.07%	\$412.14
TOTAL		\$564,907.16		\$564,907.16		

Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5 or BarCap Govt. 1-3), the Municipal bond index (BarCap 1-10yr Muni Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark corresponds to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark. Indices are not available for direct investment and performance does not reflect expenses of an actual portfolio. Expenses would reduce the annualized return of the portfolio benchmark. Past performance is not a guarantee of future results and any investment can lose value.



# **Performance Summary**

**ILSI - Board Designated Reserve** 

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

# **Portfolio Activity**

	Current Quarter	Year to Date	Since Inception
BEGINNING VALUE	570,516.49	269,607.51	269,574.23
Net Contributions	0.00	300,140.66	300,140.66
Capital Appreciation	(6,836.76)	(6,665.35)	(7,460.80)
Income	1,438.20	2,134.74	3,073.93
Management Fees	(210.77)	(310.40)	(420.86)
Other Expenses	0.00	0.00	0.00
ENDING VALUE	564,907.16	564,907.16	564,907.16
INVESTMENT GAIN	(5,609.33)	(4,841.01)	(4,807.73)

# **Portfolio Returns**

	Current Quarter	Year to Date	Since Inception
Your Portfolio	(1.0%)	(1.0%)	(0.9%)
Portfolio Benchmark	(0.7%)	(0.7%)	(0.6%)

All returns are TWR, net of fees. Returns for greater than 1 year are annualized. Your portfolio benchmark is a custom weighted blend of the US stock index (Russell 3000), the Foreign stock index (FTSE All World Ex. US), the Intermediate bond index (BarCap Aggregate Bond), the Short term bond index (BarCap Govt. 1-5), the Ministrate Borne benchmark (BarCap Muni 1-10yr Bond) and Cash (ML Three Month T-Bill). The weight of each index in your portfolio benchmark correspond to your Target Allocation. Changes to your Target Allocation will be reflected in your portfolio benchmark.



# Portfolio Value Vs Cumulative Net Investment

Period Ending: 6/30/2013 Portfolio Inception Date: 9/30/2012

**ILSI - Board Designated Reserve** 



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# **Asset Class Performance Summary**

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

#### ILSI - Board Designated Reserve

Asset Class Description	Inception Date	Current Value	Current Quarter	Year to Date	Since Inception
Intermediate Bond	9/30/2012	167,261	(2.56%)	(2.64%)	(2.65%)
BarCap US Agg.			(2.33%)	(2.44%)	(2.24%)
Short Bond	9/30/2012	369,813	(0.27%)	(0.14%)	(0.05%)
BarCap 1-5 Yr Gov			(0.65%)	(0.49%)	(0.44%)
Cash	9/30/2012	27,833	0.00%	0.00%	0.01%
ML US Treasury Bill 3 Mon			0.02%	0.04%	0.08%
Total Portfolio (Prior to Fees)	9/30/2012	564,907	(0.95%)	(0.89%)	(0.83%)
Total Portfolio (Net of Fees)	9/30/2012	564,907	(0.98%)	(0.96%)	(0.95%)
Portfolio Benchmark			(0.70%)	(0.68%)	(0.57%)

Your time weighted returns are net of fees unless otherwise stated. Returns for more than a year have been annualized.



# **Position Performance Summary**

#### **ILSI - Board Designated Reserve**

Period Ending: 6/30/2013

Portfolio Inception Date: 9/30/2012

Description	9/30/2012 Value	Net Flows	Capital Appreciation	Income Expenses	6/30/2013 Value	Actual Net (IRR)	Annual Net (IRR)
Portfolio Total	269,574	300,141	(7,461)	2,653	564,907	(1.1%)	NA
Intermediate Bond	81,063	90,141	(6,101)	2,158	167,261	(3.1%)	NA
Vanguard Total Bond Market Fund	81,063	90,141	(6,101)	2,158	167,261	(3.1%)	NA
Short Bond	175,254	195,004	(1,360)	915	369,813	(0.2%)	NA
DFA One Year Fixed	121,200	135,003	(213)	546	256,535	0.2%	NA
Vanguard Short-Term	54,054	60,001	(1,147)	369	113,278	(0.9%)	NA
Cash	13,257	14,995	0	(419)	27,833		
Sch Adv Cash Resrv Prem	13,257	14,995	0	(419)	27,833		



# Disclaimers

**ILSI - Board Designated Reserve** 

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Consolidated Audited Financial Statements

Years ended December 31, 2012 and 2011 with Report of Independent Auditors

# Consolidated Audited Financial Statements

Years ended December 31, 2012 and 2011

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## Report of Independent Auditors

Board of Trustees International Life Sciences Institute and Affiliate Washington, D.C.

We have audited the accompanying consolidated financial statements of International Life Sciences Institute and Affiliate ("the Organization"), which comprise the consolidated statements of financial position as of December 31, 2012 and 2011 and the related consolidated statements of activities and cash flows for the years then ended and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparati on and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, im plementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan a nd perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves perform ing procedures to obtain audit evidence about the am ounts and disclosures in the consolidated financial statem ents. The procedures selected depend on the auditor' s judgment, including the assessment of the risks of m aterial misstatement of the consolidated financial statements, whether due to fraud or error. In m aking those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair present tation of the consolidated financial statements in order to design audit procedures that are appropriate in the circum stances, but not for the purpose of expressing an opinion on the effectiveness of the Organizati on's internal control over financial reporting. Accordingly, we express no such opinion. An aud it also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estim ates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly , in all material respects, the financial position of the Organization as of December 31, 2012 and 2011 and the changes in its net assets and its cash flows for the y ears then ended in accordance with accounting principles generally accepted in the United States of America.

Johnson Jambert LLP

Falls Church, Virginia July 16, 2013

# Consolidated Statements of Financial Position

	December 31,				
		2012		2011	
Assets					
Cash and cash equivalents - Note A	\$	1,330,090	\$	1,069,165	
Investments - Note B		12,899,834		13,284,683	
Accounts receivable		423,805		316,760	
Contributions receivable		801,500		-	
Amounts due from affiliates - Note D		113,619		76,910	
Rent receivable under shared services agreement - Note D		269,073		262,704	
Inventory, net		-		8,564	
Prepaid expenses and other assets		17,233		31,035	
Property and equipment, net - Note C		825,089		853,869	
Total assets	\$	16,680,243	\$	15,903,690	
Liabilities and net assets					
Liabilities:					
Accounts payable	\$	246,097	\$	203,333	
Accrued expenses		181,753		142,529	
Deferred revenue		272,499		162,426	
Deposits payable to affiliates - Note D		206,000		206,000	
Deferred rent		833,414		891,432	
Total liabilities		1,739,763		1,605,720	
Net assets:					
Unrestricted:					
Undesignated		766,071		591,603	
Board-designated		11,856,077		12,166,468	
Total unrestricted net assets		12,622,148		12,758,071	
Temporarily restricted net assets - Note E		2,318,332		1,539,899	
Total net assets		14,940,480		14,297,970	
Total liabilities and net assets	\$	16,680,243	\$	15,903,690	

# Consolidated Statement of Activities

## Year ended December 31, 2012

		Unrestricted		Temporarily Restricted		Total
Revenue:	¢		<i>•</i>		<i><b></b></i>	<b>a</b> 151 a 1 <b>a</b>
Contributions	\$	26,500	\$	2,425,442	\$	2,451,942
Nongovernment grants		899,037		-		899,037
Fees from affiliates - Note D		825,169		-		825,169
Branch assessments		585,179		-		585,179
Committee assessments		550,000		-		550,000
Publications		398,045		-		398,045
Investment income - Note B		377,788		-		377,788
Government grants		302,506		-		302,506
Meeting registration fees		45,397		-		45,397
Professional fees		25,030		-		25,030
		4,034,651		2,425,442		6,460,093
Transfers between funds - Note E		(67,158)		67,158		-
Net assets released from restrictions - Note E		1,714,167		(1,714,167)		
Total revenue		5,681,660		778,433		6,460,093
Expenses:						
Program services:						
Center for Environmental Risk Assessment		1,624,464		-		1,624,464
Center for Risk Science Innovation and Application		646,073		-		646,073
Center for Nutrition and Health Promotion		211,601		-		211,601
Center for Integrated Modeling of Sustainable Agriculture and Nutrition						
Security		65,674		-		65,674
Global coordination		91,721		-		91,721
Communications		429,180		-		429,180
Annual meeting		221,790		-		221,790
Press		285,140		-		285,140
International Food Biotechnology Committee		681,323		-		681,323
Platform for International Partnerships/GTF		164,173		-		164,173
Branch international activity		221,771		-		221,771
Shared services		823,145				823,145
Total program services		5,466,055		-		5,466,055
General and administrative		355,875		-		355,875
Program development		56,171		-		56,171
Total expenses		5,878,101		-		5,878,101
Change in net assets from operations		(196,441)		778,433		581,992
Net change in fair value of investments - Note B		60,518		-		60,518
Change in net assets		(135,923)		778,433		642,510
Net assets, beginning of year		12,758,071		1,539,899		14,297,970
Net assets, end of year	\$	12,622,148	\$	2,318,332	\$	14,940,480

# Consolidated Statement of Activities

## Year ended December 31, 2011

		Unrestricted	,	Femporarily Restricted		Total
Revenue:						
Contributions	\$	1,500	\$	795,774	\$	797,274
Nongovernment grants		672,423		-		672,423
Fees from affiliates - Note D		846,527		-		846,527
Branch assessments		572,580		-		572,580
Committee assessments		826,000		-		826,000
Publications		585,466		-		585,466
Investment income - Note B		383,558		-		383,558
Government grants		141,202		-		141,202
Meeting registration fees		49,263		-		49,263
Professional fees		34,220		-		34,220
		4,112,739		795,774		4,908,513
Net assets released from restrictions - Note E		980,933		(980,933)		-
Total revenue		5,093,672		(185,159)		4,908,513
Expenses:						
Program services:						
Center for Environmental Risk Assessment		1,017,259		-		1,017,259
Center for Risk Science Innovation and Application		451,582		-		451,582
Center for Nutrition and Health Promotion		348,928		-		348,928
Center for Integrated Modeling of Sustainable Agriculture and Nutrition						
Security		7,265		-		7,265
Global coordination		81,391		-		81,391
Communications		347,736		-		347,736
Annual meeting		198,295		-		198,295
Press		280,056		-		280,056
International Food Biotechnology Committee		477,899		-		477,899
International Organizations Committee/GTF		133,391		-		133,391
Branch international activity		182,879		-		182,879
Shared services		842,251	_	-		842,251
Total program services		4,368,932		-		4,368,932
General and administrative		455,652		-		455,652
Program development		204,575		-		204,575
Total expenses		5,029,159		-		5,029,159
Change in net assets from operations		64,513		(185,159)		(120,646)
Net change in fair value of investments - Note B	_	(503,853)	_		_	(503.853)
Change in net assets		(439,340)		(185,159)		(624,499)
Net assets, beginning of year		13,197,411		1,725,058		14,166,387
Net assets, end of year	\$	12,758,071	\$	1,539,899	\$	14,297,970

# Consolidated Statements of Cash Flows

		Years ended 2012	Dece	ember 31, 2011
Cash flows from operating activities				
Change in net assets	\$	642,510	\$	(624,499)
Adjustments to reconcile change in net assets to net cash				
(used in) provided by operating activities:				
Depreciation		177,060		158,936
Net change in fair value of investments		(60,518)		503,853
Allowance for doubtful accounts		(4,000)		-
Changes in operating assets and liabilities:				
Accounts receivable		(103,045)		356,396
Contributions receivable		(801,500)		-
Amounts due from affiliates		(88,229)		35,630
Rent receivable under shared services agreement		(6,369)		(16,361)
Prepaid expenses and other assets		13,802		12,577
Inventory		8,564		84,318
Accounts payable and accrued expenses		81,988		(19,238)
Deferred revenue		110,073		(51,806)
Deferred rent		(58,018)		(41,225)
Due to affiliates		51,519		-
Total adjustments		(678,673)		1,023,080
Net cash (used in) provided by operating activities		(36,163)		398,581
Cash flows from investing activities				
Proceeds from sales or maturities of investments		13,540,936		3,443,186
Purchases and reinvestments of investments		(13,095,556)		(3,969,827)
Purchases of property and equipment		(148,292)		(241,404)
Net cash provided by (used in) investing activities		297,088		(768,045)
Net change in cash and cash equivalents		260,925		(369,464)
Cash and cash equivalents, beginning of year		1,069,165		1,438,629
Cash and cash equivalents, end of year	<u>\$</u>	1,330,090	<u>\$</u>	1,069,165

# Notes to the Consolidated Financial Statements

Years ended December 31, 2012 and 2011

## Note A - Organization and Summary of Significant Accounting Policies

#### Organization

International Life Sciences Institute (ILSI) was incorporated under the laws of the District of Columbia in July 1978 in order to prom ote an understanding and resolution of nutrition, food safety, toxicology, risk assessment, and environmental issues worldwide. Through ILSI, scientific experts from the academic, government, industrial, and public sectors throughout the world collaborate on research and education programs at national and international levels.

ILSI has also established and chartered several branches located throughout the world. ILSI does not maintain a majority voting interest in the governing bodies of these branches; accordingly, these consolidated financial statem ents do not reflect the financial positions, changes in net assets, and cash flows of these branches.

The ILSI Research Foundation (the Foundation), an affiliate of the International Life Sciences Institute (ILSI), was formed in 1984 to create a philanthropic vehicle for ILSI to support original research. Its Board of Trustees, from public and private entities around the world, guide the Foundation in its m ission to deliver ground-breaking science that is useful now and into the future. The Research Foundation's current priority areas of work are currently grouped into four centers of excellence, including The Center for r Environmental Risk Assessment (CERA), The Center for Integrated Modeling of Sustainable e Agriculture & Nutrition Security (CIMSANS), The Center for Nutrition and Health Prometion (CNHP), and The Center for Risk Science Innovation and Application (RSIA).

### Principles of consolidation

The consolidated financial statem ents include the accounts of ILSI and the Foundation (collectively, the Organization). Significant intra-entity accounts and transactions have been eliminated in consolidation.

### Income taxes

Both ILSI and the Foundation are exem pt from the payment of income taxes on their exem pt activities under Section 501(c)(3) of the Internal Revenue Code and are both classified by the Internal Revenue Service (IRS) as other than a private foundation within the meaning of Section 509(a)(1) of the Internal Revenue Code. They also believe that they have appropriate support for any tax positions taken, and as such, do not have any uncertain tax positions that are material to the consolidated financial statements as of December 31, 2012. Income tax returns are generally subject to examination by the IRS for three years after they were filed; there are no examinations being conducted.

# Notes to the Consolidated Financial Statements (Continued)

### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Basis of accounting

The Organization prepares its consolidated financ ial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Accordingly, revenues are recognized when earned and expenses are recognized when the underlying obligations are incurred.

### Use of estimates

The preparation of consolidated financial stat ements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported am ounts and disclosures. Accordingly, actual results could differ from estimates.

#### Cash and cash equivalents

For consolidated financial statem ent purposes, the Organization considers all dem and deposit accounts and highly liquid instruments which are held for current operations to be cash and cash equivalents. All other highly liquid instrum ents, which are included within the Organization' s investment portfolio are set aside for investment purposes.

#### Investments and fair value measurement

Investments in m oney market funds, com mon stock, mutual funds, exchange traded funds, government securities, corporate bonds and notes, unit investm ent trusts, asset backed securities and insurance annuities are carried at fair value in accordance with U.S. GAAP. Interest and dividends are recorded in the consolidated statem ents of activities as investm ent income. Realized gains and losses and unrealized gains and losses are recorded as changes in fair value in the consolidated statem ents of activities. Gains and losses arising f rom the sale, m aturity and other dispositions are accounted for on a specific identification basis calculated as of the trade date.

U.S. GAAP establishes a three-level hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (L evel 1) and the lowest priority to unobservable inputs (Level 3).

Level 1 – Inputs to the valuation m ethodology are quoted prices (unadjusted) for identical assets or liabilities traded in active markets.

Level 2 – Inputs to the valuation m ethodology include quoted prices for sim ilar assets or liabilities in active markets, quoted prices for iden tical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and market-corroborated inputs.

# Notes to the Consolidated Financial Statements (Continued)

### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Investments and fair value management (continued)

Level 3 – Inputs to the valuation m ethodology are unobservable for the asset or liability and are significant to the fair value measurement.

Certificates of deposit held do not m eet the definition of securities under accounting standards and thus are not subject to the fair value disclosure requirements of U.S. GAAP.

### Credit risk

The Organization maintains demand deposits with commercial banks and certificates of deposit and money market funds with financial institutions. At times, certain balances held within these accounts may not be fully guaranteed or insure d by the U.S. federal government. The uninsured portions of cash and m oney market accounts are backed solely by the assets of the underlying institution. As such, the failure of an underlying institution could result in financial loss to the Organization.

#### Market value risk

The Organization also invests some of its funds in professionally managed portfolios containing various types of equity and fixed income securities. Such investments are exposed to market and credit risks. Therefore, the investment balances reported in the accome panying consolidated financial statements may not be reflective of the portfolio's value during subsequent periods.

#### Accounts receivable

Accounts receivable primarily consist of amounts due for publication royalties and sales, federal and non-federal grants, and branch assessments. Accounts receivable are presented net of an allowance for doubtful accounts, if any. The Organization's management periodically reviews the status of all accounts receivable balances for collectibility based on its knowledge of and relationship with the customer and the age of the receivable balance. As a result of these reviews, the Organization had an allowance for doubtful accounts of \$0 and \$4,000 as of December 31, 2012 and 2011, respectively.

### Contributions receivable

Unconditional promises are recorded at their net realizable value. Conditional promises to give are not included as support until such time as the conditions are substantially met.

# Notes to the Consolidated Financial Statements (Continued)

### Note A - Organization and Summary of Significant Accounting Policies (Continued)

### Property and equipment

Acquisitions of property and equipm ent greater than \$5,000 are capitalized at cost and depreciated, using the straight-line m ethod, over the following estimated useful lives: furniture and equipment – four to ten years; com puter software and equipment – three to five years; and leasehold improvements – over the ten-year term of the office lease or remaining portion thereof, unless the asset's useful life is estimated to be shorter.

#### Net assets

For consolidated financial statement purposes, net assets are classified as follows:

<u>Unrestricted</u>: Represents the portion of net assets w hose use is not restricted by donors, even though their use m ay be limited in other respects, such as by board designation. Undesignated net assets represent the funds that are available to support the Organization's general operations. Board-designated net assets represent the funds that the Organization's Board of Trustees has determined should be reserved for long-term investment purposes. The Board has the right to approve expenditures from these reserved funds at any time.

<u>Temporarily restricted</u>: Represents the portion of net assets for which the the Organization has been restricted by donors with specified time or purpose limitations (see Note E).

### *Contributions*

Contributions are recognized as revenue when received or unconditionally prom ised. Contributions are recorded as unrestricted, tem porarily restricted, or perm anently restricted support depending upon the existence and/or natu re of donor restrictions. Support that is restricted by the donor is reported as an increase in tem porarily or perm anently restricted net assets when the contribution is recognized. When a restriction expires (that is, when a stipulated time restriction ends or a purpose restriction is accomplished), the amounts are reclassified to unrestricted net assets and reported in the cons olidated statements of activities as net assets released from restriction. The Organization has not received any support with perm anent donor restrictions.

# Notes to the Consolidated Financial Statements (Continued)

### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Committee and branch assessments

Assessments are charged to com mittee members based on the activity budgeted for the respective committees each year and to the branches based on a percentage of their revenue. Assessments received in advance of the period to which they apply are recorded as deferred revenue until that period occurs.

### Functional allocation of expenses

The costs of providing various program s and other activities have been sum marized on a functional basis in the consolidated statements of activities. Accordingly, indirect expenses have been allocated among the programs and supporting services benefited.

#### Reclassifications

Certain 2011 balances have been reclassified to conform with the current year presentation.

#### Subsequent events

The Organization has perform ed an evaluation of subsequent events through July 16, 2013, which is the date the consolidated f inancial statements were available to be issued and has considered any relevant m atters in preparation of the consolidated financial statem ents and footnotes.

### Note B - Investments and Fair Value Measurements

Investments, recorded at fair value in accordan ce with the U.S. GAAP hierarchy, consist of the following at December 31:

	2012				
	Level 1	Level 2	Level 3	Total	
Fixed income exchange traded funds	\$ 4,764,946	\$ -	\$ -	\$ 4,764,946	
Fixed income mutual funds	3,838,769	-	-	3,838,769	
Equity mutual funds	3,137,368	-	-	3,137,368	
Equity exchange traded funds	952,793	-	-	952,793	
Money market funds	205,958			205,958	
Total investments, at fair value	\$12,899,834	<u>\$</u>	\$	\$12,899,834	

# Notes to the Consolidated Financial Statements (Continued)

### Note B - Investments and Fair Value Measurements (Continued)

Investments, recorded at fair value in accordan ce with the U.S. GAAP hierarchy, consist of the following at December 31:

		20	)]]]	
	Level 1	Level 2	Level 3	Total
Money market funds	\$ 2,185,321	\$ -	\$ -	\$ 2,185,321
Fixed income mutual funds	729,913	-	-	729,913
Equity exchange traded funds	528,294	-	-	528,294
Common stock	483,638	-	-	483,638
Equity mutual funds	457,097	-	-	457,097
Fixed income exchange traded funds	239,556	-	-	239,556
Asset backed securities	-	2,186,507	-	2,186,507
Corporate bonds and notes	-	1,457,287	-	1,457,287
Unit investment trusts	-	365,731	-	365,731
Government securities	-	101,104	-	101,104
Insurance annuities			2,034,381	2,034,381
Total investments, at fair value Certificates of deposit	\$ 4,623,819	\$ 4,110,629	\$ 2,034,381	10,768,829 2,515,854
Total				\$13,284,683

Investments using Level 2 inputs consist of gove rnment securities, corporate bonds and notes, asset backed securities, and unit investm ent trusts. The unit investm ent trusts are priced sim ilar to mutual funds, and the trust com panies provide the values which are updated nightly. The remaining investments are priced using an outside data and pricing company. In determining the fair value of the investm ents, the pricing com pany uses a m arket approach and prices assets using multiple price types of close, bid/ask, high/low, and open pricing. Managem ent believes these estimates to be a reasonable approximation of the fair value of the investments.

In 2011, the Organization's use of Level 3 unobs ervable inputs included two variable annuity contracts (the contracts). The contracts were not readily marketable, and were carried at an estimated fair value as provided by the insurance com pany. The Organization reviewed and evaluated the values provided by the insurance company and agreed with the valuation m ethods and assumptions used in determining the fair value.

# Notes to the Consolidated Financial Statements (Continued)

### Note B - Investments and Fair Value Measurements (Continued)

The contracts contained funds held in a gene ral account, which is an unallocated insurance contract recorded at contract value, a reasona ble estimate of fair value. The general account, whose assets were commingled with other assets of the insurance company, provided a minimum guaranteed interest rate of 2% for the first 10 contract years and 3% thereafter, which was reinvested in the general account. Additional interest enhancements could have been applied to the general fund as a result of increasing treasury rates in comparison to the treasury rate on the date the guarantee period was established. F unds invested in the general account m ay be withdrawn at any tim e, with a withdrawal char ge applied in accordance with the terms of the agreement.

The contract provided a death benefit to the Orga nization in the event of the death of the stated annuitant, a form er board m ember of the Orga nization. The death benefit was equal to the guaranteed minimum death benefit, which was equal to the contract value at December 31, 2011. This investment was not held as of December 31, 2012.

The roll-forward of the Organization's Level 3 fair valued assets, variable annuity contracts, is as follows:

Balance at January 1, 2010	\$	4,648,354
Reinvested interest		140,888
Sales		(2,754,861)
Balance at December 31, 2010		2,034,381
Sales		(2,102,724)
Gain on sales		68,343
Balance at December 31, 2011	<u>\$</u>	

The Organization recognizes transfers between levels of the fair value hierarchy at the end of the period in which circum stances occur causing cha nges in availability of the fair value inputs. There were no transfers between levels during the years ended December 31, 2012 and 2011.

Investment return (loss) consists of the following for the years ended December 31:

		2012		2011
Investment income	\$	377,788	\$	383,558
Net change in fair value of investments		60,518		(503,853)
Total return (loss) on investments	<u>\$</u>	438,306	<u>\$</u>	(120,295)

Investment fees were \$50,507 and \$56,916 for the years ending December 31, 2012 and 2011, respectively.

# Notes to the Consolidated Financial Statements (Continued)

## Note C - Property and Equipment

Property and equipment consists of the following at December 31:

		2012	 2011
Computer software and equipment	\$	717,508	\$ 589,068
Furniture and equipment		125,470	125,470
Leasehold improvements		723,762	 703,909
		1,566,740	1,418,447
Less accumulated depreciation		(741,651)	 (564,578)
-	<u>\$</u>	825,089	\$ 853,869

## **Note D - Related Party Transactions**

The Organization is part of an affiliated group of non-profit organizations, which includes ILSI North America (ILSI N.A.) and ILSI Health and Environmental Sciences Institute (HESI), located in W ashington, DC (the Affiliated Organizations), as well as several international branches. In the ordinary course of doing business, the Organization has a variety of financial transactions with these Affiliated Organizations.

Common expenses (such as accounting, legal, information technology, hum an resources, and business services) that benefit all of the Affiliated Organizations are governed by a shared services agreement, under which ILSI allocates th ese costs to each affiliate based on their total number of full-time equivalents. During the years ended Decem ber 31, 2012 and 2011, ILSI allocated \$434,257 and \$433,613, respectively, of the cost for these shared services to ILSI N.A., and allocated \$388,888 and \$408,644, respectively, of the cost for these shared services to HESI.

The following other transactions occurred between the Organization and a member of the above Affiliated Organizations during the years ended December 31, 2012 and 2011:

<u>Grants and contributions</u>: The Affiliated Organizations periodically award grants am ongst each other for various scientific and research e ndeavors. During the years ended Decem ber 31, 2012 and 2011, the Foundation granted ILSI N.A. \$48,750 and \$15,000, respectively, to conduct grant projects. During the year ended Decem ber 31, 2012, ILSI N.A. Food and Chem ical Safety committee paid the Organization \$25,000 to conduct a Nano Release Food Additives study. No such grant was received in 2011.

# Notes to the Consolidated Financial Statements (Continued)

## **Note D - Related Party Transactions (Continued)**

<u>ILSI branch assessments</u>: As specified in its branch charter agreem ents, all members of an ILSI branch are automatically members of ILSI. Since ILSI does not collect its own dues from these members, ILSI instead charges an annual assessment to the branches in order to provide support for governance and coordination for ILSI's branches. During the years ended December 31, 2012 and 2011, ILSI charged \$150,000 for each of the y ears to ILSI N.A., and charged \$150,000 and \$139,071, respectively, to HESI.

<u>Joint annual meeting</u>: The Organization and its affiliates participate in a joint annual m eeting, and the affiliates hold their own board m eetings and scientific sessions in conjunction with the meeting. ILSI collects each affiliate's share of the annual m eeting income and pays in advance for a portion of the affiliates' share of the joint expenses of the meeting.

ILSI N.A. reim bursed ILSI a net of \$52,525 and \$57,718, respectively, for annual m eeting activity for the years ended Decem ber 31, 2012 and 2011. HESI reim bursed ILSI a net of \$34,835 for annual meeting activity for the year ended December 31, 2012. In 2011, HESI did not participate in ILSI's annual meeting.

<u>Professional service fees</u>: From time to time, the Organization will utilize staff or other resources from another affiliate in carrying out its projects, or conversely, another affiliate will utilize staff or other resources of the Organization. The extent and use of these services is agreed to by the two affiliates in advance, and the af filiate requesting the resources is charged a prof essional fee as compensation. During the years ended Decem ber 31, 2012 and 2011, the Organization charged ILSI N.A. \$12,825 and \$16,575, respectively, for providing these services.

<u>Due from affiliates</u>: At December 31, 2012 and 2011, ILSI N.A. owed the Organization \$56,724 and \$27,494, respectively, for shared services cost allocations, professional service fees, and various other reimbursements of expenses. At December 31, 2012 and 2011, HESI owed the Organization \$56,895 and \$49,416, respectively, for sh ared services cost allocations and professional service fees.

<u>Rent receivable under shared services agreem</u> ent: During 2008, ILSI entered into a lease for office space in W ashington, D.C. (see Note G). Since the above affiliates all share the sam e office space with ILSI, ILSI allocated a portion of its deferred rent liability to each of the affiliates based on the number of full-time equivalents. As such, \$129,977 was allocated to ILSI N.A. and \$139,096 to HESI as of Decem ber 31, 2012. For the year ended Decem ber 31, 2011, ILSI allocated deferred rent of \$125,326 to ILSI N.A. and \$137,378 to HESI.

## Notes to the Consolidated Financial Statements (Continued)

#### Note D - Related Party Transactions (Continued)

<u>Deposits:</u> As part of the shared services agreement, ILSI charged each affiliate a deposit to cover the period of time between when ILSI pays the shared service cost and when the affiliate reimburses ILSI. Deposits held by ILSI on behalf of each affiliate were as follows as of December 31:

	 2012	_	2011
ILSI North America	\$ 116,000	\$	116,000
ILSI Health and Environmental Sciences Institute	 90,000		90,000
	\$ 206,000	\$	206,000

#### **Note E - Temporarily Restricted Net Assets**

Temporarily restricted net assets represent amounts contributed for the following donor-specified purposes:

I I	Balance at December 31, 2011	Contributions	Transfers Between Funds	Releases from Restriction	Balance at December 31, 2012
CIMSANS	\$ 92,734	\$ 540,000	\$ -	\$ (65,673)	\$ 567,061
CERA	144,395	1,136,118	-	(730,513)	550,000
Translational nutrition	, –	50,000	385,472	(140,126)	295,346
ILSI Focal Point in China	327,634	27,667	-	(124,782)	230,519
Global threshold/IAATFS	-	-	175,430	(1,977)	173,453
Branch Activity	48,397	84,500	-	(13,454)	119,443
RSIA Risk perception	99,700	100,000	-	(81,150)	118,550
PAN	110,050	-	-	-	110,050
Platform in International					
Partnerships	-	146,000	67,158	(156,649)	56,509
Staff Global Travel Fund	55,050	-	-	(7,524)	47,526
WIC	50,950	30,000	-	(47,473)	33,477
CARES CLA	10,739	-	-	(377)	10,362
Marketing department	29,216	-	-	(25,344)	3,872
TAKE 10! program support	5,000	-	-	(2,836)	2,164
RSIA Nano	-	15,000	-	(15,000)	-
Meetings	-	3,882	-	(3,882)	-
Priority research campaign	560,902	-	(560,902)	-	-
RSIA Water re-use	-	60,000	-	(60,000)	-
JIFSAN Workshop report	5,132	-	-	(5,132)	-
RSIA Nano Release Food					
Additives	-	112,500	-	(112,500)	-
IFBiC Committees	-	22,500	-	(22,500)	-
RSIA Nano Release		97,275		(97,275)	
Total	<u>\$ 1,539,899</u>	<u>\$ 2,425,442</u>	<u>\$ 67,158</u>	<u>\$ (1,714,167)</u>	<u>\$ 2,318,332</u>

# Notes to the Consolidated Financial Statements (Continued)

## **Note E - Temporarily Restricted Net Assets (Continued)**

	E	Balance at		Releases		Balance at
	De	cember 31,		from	D	ecember 31,
		2010	Contributions	Restriction		2011
Priority research campaign	\$	627,595	\$ -	\$ (66,693)	\$	560,902
CERA		335,825	303,224	(494,654)		144,395
PAN		110,050	-	-		110,050
ILSI Focal Point in China		408,090	30,000	(110,456)		327,634
Branch Activity		89,420	-	(41,023)		48,397
WIC		75,229	20,000	(44,279)		50,950
TAKE 10! program support		1,600	5,000	(1,600)		5,000
CARES CLA		11,350	-	(611)		10,739
Latin American coordination		3,653	-	(3,653)		-
JIFSAN Workshop report		5,132	-	-		5,132
Marketing department		38,850	-	(9,634)		29,216
RSIA Risk perception		18,264	130,000	(48,564)		99,700
CIMSANS		-	100,000	(7,266)		92,734
RSIA Water re-use		-	50,000	(50,000)		-
Staff Global Travel Fund		-	55,050	-		55,050
OECD Workshop		-	2,000	(2,000)		-
RSIA Nano		_	100,500	(100,500)		_
Total	\$	1,725,058	<u>\$ 795,774</u>	<u>\$ (980,933)</u>	\$	1,539,899

### **Note F - Defined Contribution Pension Plan**

The Organization has a Section 403(b) defined cont ribution retirement plan, which covers substantially all of its em ployees. Employer contributions to the plan are calculated at 7% of each participant's salary. Participants may also make voluntary elective deferrals to the plan. For the years ended Decem ber 31, 2012 and 2011, pens ion contribution expenses totaled \$130,751 and \$123,442, respectively.

### Note G - Commitments and Contingencies

### Office Lease

In May 2008, ILSI entered into an operating 1 ease for office space in W ashington, DC, which commenced in September 2008 and expires in January 2019. ILSI received certain concessions from the lease agreement, which have been amortized over the lease term on a straightline basis. The unamortized portion of these incentives is re-ported as deferred rent in the statem ents of financial position.

Rent expense, net of am ortized rent abatements and amounts allocated to affiliates that share space (see Note D), under the office space lease agreem ent totaled \$265,307 and \$294,433 for the years ended December 31, 2012 and 2011, respectively.

# Notes to the Consolidated Financial Statements (Continued)

### Note G - Commitments and Contingencies (Continued)

#### *Office Lease (continued)*

Future annual minimum lease payments, subject to annual operating expense increase, under various leases are as follows:

Year ending December 3	51,	
2013	\$	706,000
2014		740,100
2015		760,100
2016		779,100
2017		798,600
Thereafter		886,906
	\$	4,670,806

### Federal Grants

The Foundation participates in som e federally assisted grant programs which are subject to financial and compliance audits by federal agencies or their representatives. As such, there exists a contingent liability f or potential questioned costs that m ay result f rom such an audit. Management does not anticipate any significant adjustments as a result of such an audit.

### Hotel Commitments

As of Decem ber 31, 2012, the Organization has entered into contracts with several hotels pertaining to future meetings. In the event that the Organization cancels or reduces its contracted provisions, it may be liable for certain penalties or liquidated damages, depending upon the date of cancellation. Minim um future cancellation fees for signed hotel contracts (excluding any applicable sales tax) is approximately \$580,000.

### **Note H - Contributions Receivable**

Total contributions receivable outstanding as of December 31 are as follows:

	2012	
Due within 1 year	\$	251,500
Due between 1 and 5 years		550,000
	\$	801,500

### **Note I - In-Kind Contributions**

The Organization received in-kind program management services of \$40,000 and \$0 in 2012 and 2011, respectively. These am ounts have been in cluded in the statem ents of activities as contribution revenue and Center for Integrat ed Modeling of Sustainable Agriculture and Nutrition Security expense.



#### **Board Communications Letter**

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute Washington, D.C.

We have audited the financial statements of the International Life Sciences Institute (ILSI) for the year ended December 31, 2012, and have issued our report thereon dated July 16, 2013.

The auditor is responsible for form ing and expressing an opinion about whether the financial statements that have been prepared by management with the oversight of those charged with governance are presented fairly, in all material respects, in conformity with accounting principles generally accepted in the United States (U.S. GAAP).

The auditor is also responsible for comm unicating significant matters related to the financial statement audit that are, in the auditor's professional judgment, relevant to the responsibilities of those charged with governance in overseeing the financial reporting process. Generally accepted auditing standards do not require the auditor to design procedures for the purpose of identifying other matters to communicate with those charged with governance.

Consistent with our professional standards, the policy of our firm and our personal commitments to keep the lines of communication open with you, management, and our audit team, we would like to share with you the following.

#### **Significant Accounting Policies and Their Application**

Management is responsible for the selection and use of appropriate accounting policies. As is the case with virtually all organizations, ILSI has available alternative accounting principles from which to choose. The significant accounting policies used by ILSI are described in Note A to the financial statements.

The ILSI parent-only f inancial statements do not include the activity of the IL SI Research Foundation, which is required to be consolidated for financial statements. Presentation of consolidated financial statements is required by accounting principles generally accepted in the United States of America. Accordingly, we have noted such in the auditor's report. We have issued separately consolidated financial statements that include I LSI and ILSI Resear ch Foundation which includes an unmodified auditor's report.

The accounting policies selected and applied by ILSI, except for the matter noted above, are appropriate under the circum stances and are consistent with those used by other not-for-profit organizations. No new significant accounting policies were adopted and the application of existing policies was not changed during 2012. We noted no transactions entered into by ILSI during the year for which there is a lack of authoritative guidance or consensus. We noted no significant transactions that have been recognized in the financial statements in a different period than when the transaction occurred.

#### Management's Judgments and Accounting Estimates

Financial statements require the use of accounting estimates and management judgments. Certain accounting estimates are particularly sensitive b ecause of their significance to th e financial statements and because of the possibility that future events affecting them may differ significantly from those expected. The most sensitive estimates affecting the financial statements were expense classification and the allowance for doubtful account

Certain financial statement disclosures a re particularly sensitive because of m anagement judgments involved and/or their significance to financial statement users. The most sensitive disclosures affecting the financial statements were:

- Note B: Investments and Fair Value Measurements
- Note D: Related Party Transactions
- Note E: Temporarily Restricted Net Assets
- Note G: Commitments and Contingencies

#### **Related Party Relationships and Transactions**

An objective of the audit with respect to related party relationships and transactions is to obtain an understanding of such matters sufficient to be able to recognize fraud risk factors that are relevant to the identification and assessment of the risks of material misstatement due to fraud and conclude whether the financial s tatements, insofar as they are affected by th ose relationships and transactions, achieve fair present tation. An objective of the audit also is to obtain sufficient appropriate audit evidence about whether related party relationships and transactions have been appropriately identified, accounted for and disclose d in the financial statements. Note D of the financial statements includes the disclosure of significant related party transactions.

#### Significant Difficulties in Performing the Audit

We are responsible for discussing with those charged with governance any significant difficulties encountered in dealing with management related to the performance of the audit. No significant difficulties were encountered in performing the audit.

#### **Management Representations and Uncorrected Misstatements**

We have requested certain representations from management that are included in the management representation letter dated July 16, 2013. We have included the management representation letter as an exhibit to this document. We did not identify any significant uncorrected misstatements.

#### Disagreements with Management, Including Matters Discussed and Resolved

We are responsible for discussi ng with those charged with gove rnance any disagreements with management, whether or not satisfactorily resolv ed, about matters that individually or in the aggregate could be significant to IL SI's financial statements or the auditor's report. There were no disagreements with Management.

#### Audit and Management Post-Closing Adjustments

Management recorded three post-closing adjustm ents to contributions, which had no effect on ending net assets. There were no adjustments proposed as a result of our audit.

#### Management's Consultations with Other Accountants

We are not aware of consultations with other accountants regarding audit or accounting issues.

#### Significant Issues Discussed, or Subject to Correspondence with Management

We are responsible for communicating with those charged with governance any significant issues that were discussed or were the subject of correspondence with management. We discussed the basis for our qualified audit opin ion, relating to the om ission of the ILSI Research Foundation activity, with your management team.

#### **Financial Statements Included in Client-Prepared Documents**

We are responsible for reading the information contained in client-prepared documents outside of the financial statements to determine if such information is materially consistent with the audited financial statements. We are not aware of any client-prepared documents that will contain the audited financial statements.

#### Independence

Johnson Lambert LLP is independent with respect to in accordance with the applicable independence rules.

This letter is intended solely for the inform ation and use of you, the Board of Trustees and management and is not intended to be and shouldnot be used by anyone other than these specified parties.

We appreciate the cooperation and courtesies ex tended to us by ILSI's personnel. Should you wish additional clarification of these or any other matters please ask.

Johnson Jambert LLP

Falls Church, Virginia July 16, 2013



International Life Sciences Institute 1156 Fifteenth Street, NW Suite 200 Washington, DC 20005 1.202.659.0074 voice 1.202.659.3859 fax www.ilsi.org

July 16, 2013

Johnson Lambert LLP 3110 Fairview Park Drive, Suite 800 Falls Church, VA 22042

Attn: Paul Preziotti

This representation letter is provided in connection with your audit of the financial statements of International Life Sciences Institute ("ILSI") as of and for the years ended December 31, 2012 and 2011 for the purpose of expressing a qualified opinion as to whether the financial statements present fairly, in all material respects, the financial position, activities, and cash flows of ILSI in accordance with accounting principles generally accepted in the United States (U.S.GAAP) The qualification noted above relates to the omission of the activity of the ILSI Research Foundation from the ILSI (parent-company only) financial statements. Consolidation is required for the preparation of financial statements in accordance with U.S. GAAP.

Certain representations in this letter are described as being limited to matters that are material. Items are considered material, regardless of size, if they involve an omission or misstatement of accounting information that, in the light of surrounding circumstances, makes it probable that the judgment of a reasonable person relying on the information would be changed or influenced by the omission or misstatement.

We confirm that, to the best of our knowledge and belief, as of the date of this letter, having made such inquiries as we considered necessary for the purpose of appropriately informing ourselves:

### Financial Statements

- We have fulfilled our responsibilities, as set out in the terms of the audit engagement dated August 29, 2012 for the preparation and fair presentation of the financial statements in accordance with U.S. GAAP, with the exception of omission of the ILSI Research Foundation activity from the financial statements.
- We acknowledge our responsibility for the design, implementation, and maintenance of internal controls and programs relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error
- We acknowledge our responsibility to ensure that ILSI's operations are conducted in accordance with the provisions of laws and regulations, including compliance with the



provisions of laws and regulations that determine the reported amounts in ILSI's financial statements.

- We acknowledge our responsibility for the design, implementation, and maintenance of internal control to prevent and detect fraud.
- Significant assumptions used by us in making accounting estimates, including those measured at fair value, are reasonable.
- All liabilities resulting from retirement obligations, deferred compensation agreements, and severance packages have been recorded in the financial statements and disclosed in the notes to the financial statements.
- Related party relationships and transactions have been appropriately accounted for and disclosed in accordance with the requirements of U.S. GAAP.
- All events subsequent to the date of the financial statements and for which U.S. GAAP requires adjustment or disclosure have been adjusted or disclosed.
- You did not bring to our attention any uncorrected audit differences during this engagement.
- The effects of all known actual or possible litigation and claims have been accounted for and disclosed in accordance with U.S. GAAP.
- Arrangements with financial institutions involving compensating balances or other arrangements involving restrictions on cash balances, line of credit, or similar arrangements have been properly disclosed.
- ILSI has no plans or intentions that may materially affect the carrying value or classification of assets and liabilities.
- Guarantees, whether written or oral, under which ILSI is contingently liable have been properly reported or disclosed in the financial statements

Material concentrations known to management have been properly disclosed in accordance with U.S. GAAP. Concentrations refer to volumes of business, revenues, available sources of supply, or markets or geographic areas for which events could occur that would significantly disrupt normal finances within the next year.

• The methods and significant assumptions as disclosed in the financial statements were used to determine fair values of financial instruments and result in a measure of fair value appropriate for financial statement measurement and disclosure purposes. The categorization of the ILSI's investments into the hierarchical levels as defined by the


accounting guidance, ASC 820, Fair Value Measurements, is based on the lowest level of significant input to the securities' valuation.

- In regards to the fact that your firm assisted us by drafting the financial statements including appropriate disclosures required by U.S. GAAP, we have:
  - o Made all management decisions and performed all management functions.
  - Designated an individual, Beth-Ellen Berry, who possesses suitable skill, knowledge or experience to oversee the services.
  - Evaluated the adequacy and results of the draft preparation by reviewing and accepting the financial statements as complete and accurate, with the exception of the omission of the activity of the ILSI Research Foundation as noted previously in this letter.
  - Accepted responsibility for the financial statements
- ILSI has satisfactory title to all owned assets, and there are no liens or encumbrances on such assets nor has any asset been pledged as collateral.
- ILSI is an exempt organization under 501(c)(3) of the Internal Revenue Code. Any activities that we are aware that would jeopardize the organization's tax exempt status and all activities subject to tax on unrelated business income or excise tax or other tax have been disclosed to you. All required filings with tax authorities are up to date. We have not been informed of any tax reviews by federal or tax taxing authorities. There is no tax position considered to be uncertain if it was to undergo an inspection by the IRS or state authorities.

## Information Provided

- We have provided you with:
  - Access to all information, of which we are aware that is relevant to the preparation and fair presentation of the financial statements such as records, documentation and other matters;
  - Additional information that you have requested from us for the purpose of the audit; and
  - Unrestricted access to persons within the entity from whom you determined it necessary to obtain audit evidence.
- All transactions have been recorded in the accounting records and are reflected in the financial statements.



- We have disclosed to you the results of our risk assessment as to how and where the financial statements may be materially misstated as a result of fraud.
- We have no knowledge of any fraud or suspected fraud that affects the entity and involves:
  - o Management;
  - o Employees who have significant roles in internal control; or
  - Others when the fraud could have a material effect on the financial statements
- We have no knowledge of any allegations of fraud, or suspected fraud, affecting the entity's financial statements communicated by employees, former employees, analysts, regulators or others.
- We have disclosed to you all known instances of non-compliance or suspected noncompliance with laws and regulations whose effects should be considered when preparing financial statements.
- There have been no communications from regulatory agencies concerning noncompliance with or deficiencies in financial reporting that could have a material effect on the financial statements.
- We are not aware of any pending or threatened litigation and claims whose effects should he considered when preparing the financial statements.
- We have disclosed to you the identity of the entity's related parties and all the related party relationships and transactions of which we are aware.

Beth-Ellen Berry

Chief Financial Officer

Harris

Suzanne Harris Executive Director



#### Internal Control Letter

Financial Oversight Committee of the Board of Trustees International Life Sciences Institute Washington, D.C.

In planning and perform ing our audit of the financ ial statements of International Life Sciences Institute (ILSI) as of and for the year e nded December 31, 2012, in accordance with auditing standards generally accepted in the United States of America, we considered its internal control over financial reporting (internal control) as a basis for designing our auditing procedures for the purpose of expressing our opini on on the financial statem ents, but not for the purpose of expressing our opinion on the effect tiveness of ILSI's internal control. Accordingly, we do not express an opinion on the effectiveness of ILSI's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the norm al course of performing their assigned functions, to prevent, or detect and correct m isstatements on a timely basis. A m aterial weakness is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented, or detected and corrected on a timely basis.

Our consideration of internal control was for the limited purpose described in the first paragraph and was not designed to identify all deficiencies in internal control that m ight be deficiencies, significant deficiencies, or material weaknesses We did not identify any deficiencies in internal control that we consider to be material weaknesses, as defined above.

This communication is intended solely for the information and use of you, the Board of Trustees, management and others within the organization and is not intended to be and should not be used by anyone other than these specified parties.

Schnoon Jambert LLP

Falls Church, Virginia July 16, 2013



Audited Financial Statements

Years ended December 31, 2012 and 2011 with Report of Independent Auditors

# Audited Financial Statements

Years ended December 31, 2012 and 2011

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# Report of Independent Auditors

Board of Trustees International Life Sciences Institute Washington, DC

We have audited the accompanying financial statements of International Life Sciences Institute ("ILSI") (parent-company only), which com prise the statem ents of financial position as of December 31, 2012 and 2011 and the related statem ents of activities, functional expenses and cash flows for the years then ended and the related notes to the financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves perform ing procedures to obtain audit evidence about the am ounts and disclosures in the f inancial statements. The procedures selected depend on the auditor' s judgment, including the assessm ent of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity' s preparation and f air presentation of the f inancial statements in order to design audit procedures that are appropriate in the circum stances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no su ch opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as eval uating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified audit opinion.

#### **Basis for Qualified Opinion**

The ILSI financial statem ents do not include the activity of the ILSI Research Foundation (a related affiliate), which is required to be consolidated f or financial statement purposes in accordance with accounting principles generally accepted in the United States of America. If ILSI had consolidated ILSI Research Foundation, assets, liabilities, net assets and changes in net assets would have increased (decreased) by \$13,504,842, \$371,889, \$13,132,953 and \$772,599 for 2012 and \$12,520,601, \$160,247, \$12,360,354 and (\$947,594) for 2011, respectively. Consolidated financial statements, reflecting the activity of ILSI and ILSI Research Foundation, have been issued with an unmodified opinion dated July 16, 2013.

#### **Qualified** Opinion

In our opinion, except for the om ission of the ILSI Research Foundation activity as described in the Basis for Qualified Opinion paragraph, the financial statements referred to above present fairly, in all material respects, the financial position of International Life Sciences Institute as of December 31, 2012 and 2011 and the changes in its net assets, functional expenses and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Johnson Jambert LLP

Falls Church, Virginia July 16, 2013

# Statements of Financial Position

	December 31,						
		2012		2011			
Assets							
Cash and cash equivalents - Note A	\$	509,439	\$	773,367			
Investments - Note B		1,183,906		1,179,486			
Accounts receivable		169,244		119,959			
Amounts due from affiliates - Note D		171,783		109,127			
Rent receivable under shared services agreement - Note D		364,147		356,748			
Prepaid expenses and other assets		16,977		24,334			
Property and equipment, net - Note C		759,905		820,068			
Total assets	\$	3,175,401	\$	3,383,089			
Liabilities and net assets							
Liabilities:							
Accounts payable	\$	82,372	\$	140,848			
Accrued expenses		103,744		80,694			
Deferred revenue		102,344		86,499			
Deposits payable to affiliates - Note D		246,000		246,000			
Deferred rent		833,414		891,432			
Total liabilities		1,367,874		1,445,473			
Net assets:							
Unrestricted:							
Undesignated		681,148		559,869			
Board-designated		787,953		965,847			
Total unrestricted net assets		1,469,101		1,525,716			
Temporarily restricted - Note E		338,426		411,900			
Total net assets		1,807,527		1,937,616			
Total liabilities and net assets	\$	3,175,401	\$	3,383,089			

# Statement of Activities

# Year ended December 31, 2012

	Temporarily Unrestricted Restricted			Temporarily Restricted	Total
Revenue:					 
Fees from affiliates - Note D	\$	1,208,934	\$	-	\$ 1,208,934
Committee assessments		550,000		-	550,000
Branch assessments		725,179		-	725,179
Publications		370,009		-	370,009
Conference registration fees		35,824		-	35,824
Investment income - Note B		32,640		-	32,640
Grants and contributions				196,167	 196,167
		2,922,586		196,167	3,118,753
Transfers between funds - Note E		(67,158)		67,158	-
Net assets released from restriction - Note E		336,799		(336,799)	 -
Total revenue		3,192,227		(73,474)	3,118,753
Expenses:					
Program services:					
Global coordination		91,721		-	91,721
Communications		429,180		-	429,180
Annual meeting		133,156		-	133,156
Press		285,140		-	285,140
International Food Biotechnology Committee (IFBiC)		681,323		-	681,323
Platform for International Partnerships (PIP)/GTF		164,173		-	164,173
International branches		128,123		-	128,123
Shared services		1,115,458			 1,115,458
Total program services		3,028,274		-	3,028,274
General and administrative		193,322			 193,322
Total expenses		3,221,596			 3,221,596
Change in net assets from operations		(29,369)		(73,474)	(102,843)
Net change in fair value of investments - Note B		(27,246)			 (27,246)
Change in net assets		(56,615)		(73,474)	(130,089)
Net assets, beginning of year		1,525,716		411,900	 1,937,616
Net assets, end of year	\$	1,469,101	\$	338,426	\$ 1,807,527

# Statement of Activities

# Year ended December 31, 2011

	Temporarily			emporarily					
	U	Inrestricted	I	Restricted		Total			
Revenue:									
Fees from affiliates - Note D	\$	1,252,287	\$	-	\$	1,252,287			
Committee assessments		826,000		-		826,000			
Branch assessments		715,985		-		715,985			
Publications		372,138		-		372,138			
Conference registration fees		41,433		-		41,433			
Investment income - Note B		35,610		-		35,610			
Grants and contributions		-		87,050		87,050			
		3,243,453		87,050		3,330,503			
Net assets released from restrictions - Note E		125,743		(125,743)		-			
Total revenue		3,369,196		(38,693)		3,330,503			
Expenses:									
Program services:									
Global coordination		81,391		-		81,391			
Communications		344,956		-		344,956			
Annual meeting		119,675		-		119,675			
Press		280,056		-		280,056			
International Food Biotechnology Committee		477,899		-		477,899			
International Organizations Committee (IOC)/GTF		133,391		-		133,391			
International branches		114,082		-		114,082			
Shared services		1,141,921				1,141,921			
Total program services		2,693,371		-		2,693,371			
General and administrative		291,354				291,354			
Total expenses		2,984,725				2,984,725			
Change in net assets from operations		384,471		(38,693)		345,778			
Net change in fair value of investments - Note B		(22,683)				(22,683)			
Change in net assets		361,788		(38,693)		323,095			
Net assets, beginning of year		1,163,928		450,593		1,614,521			
Net assets, end of year	\$	1,525,716	\$	411,900	<u>\$</u>	1,937,616			

# Statements of Functional Expenses

# Years ended December 31, 2012 and 2011

				Progra	m Services						
	Global Coordination	Commun- ications	Annual Meeting	Press	IFBiC	PIP/GTF	International Branches	Shared Services	Total	General and Administrative	2012 Total
Salaries and benefits	\$ 22,650	\$ 150,929	\$ 11,050	\$ 111,715	\$ 220,633	\$ 35,825	\$ 11,594	\$ 821,893	\$ 1,386,289	\$ 254,388	\$ 1,640,677
Consultants	3,000	107,243	595	-	34,631	900	-	125,989	272,358	10,797	283,155
Travel and meetings	27,888	4,945	95,219	6,903	185,447	8,100	58,698	19,781	406,981	39,484	446,465
Rent	-	-	-	-	-	-	-	93,570	93,570	25,096	118,666
Depreciation	-	-	-	-	16,639	-	-	22,253	38,892	125,318	164,210
Research and program support	16,751	-	-	3,500	-	84,024	46,216	100	150,591	-	150,591
Financial and professional services	-	-	3,019	355	-	-	-	40,532	43,906	25,762	69,668
Equipment and supplies	159	-	-	-	718	-	-	75,105	75,982	1,281	77,263
Communications	886	15,130	3,158	2,817	13,118	1,081	80	47,627	83,897	5,712	89,609
Other	-	10,943	4,575	4,014	1,047	-	1,100	28,946	50,625	4,738	55,363
Publications	-	4,154	5,597	55,294	10,518	2,000	-	-	77,563	-	77,563
Insurance	-	-	-	-	-	-	-	48,366	48,366	-	48,366
Overhead allocation	20,387	135,836	9,943	100,542	198,572	32,243	10,435	(208,704)	299,254	(299,254)	
Total	\$ 91,721	\$ 429,180	\$ 133,156	\$ 285,140	\$ 681,323	\$ 164,173	\$ 128,123	\$ 1,115,458	\$ 3,028,274	\$ 193,322	\$ 3,221,596

								Program	n S	ervices																						
	G	lobal	C	Commun-		Annual		P		IED:C	T			International		Shared			G	eneral and	and 2011											
	Coor	dination		ications	1	Meeting	_	Press		IFBIC	_10	JC/GTF	_	Branches	_	Services		Services		Services		Services		Services		Services		Total	Ad	ministrative		Total
Salaries and benefits	\$	26,945	\$	147,362	\$	5,868	\$	106,031	\$	164,067	\$	24,095	\$	3,471	\$	707,875	\$	1,185,714	\$	264,085	\$	1,449,799										
Consultants		1,790		41,733		157		-		53,215		5,475		-		220,062		322,432		-		322,432										
Travel and meetings		27,920		2,802		92,690		8,416		56,845		7,768		47,823		12,534		256,798		53,368		310,166										
Rent		-		-		-		-		-		-		-		142,453		142,453		24,308		166,761										
Depreciation		-		-		-		-		16,639		-		-		13,064		29,703		116,557		146,260										
Research and program support		-		-		-		1,750		-		73,000		56,400		-		131,150		250		131,400										
Financial and professional services		-		-		3,638		-		-		20		-		58,150		61,808		29,314		91,122										
Equipment and supplies		-		-		-		866		3,246		-		-		76,185		80,297		3,517		83,814										
Communications		1,291		10,304		2,782		8,769		13,863		1,347		369		39,239		77,964		5,375		83,339										
Other		420		2,283		2,456		5,404		15,259		-		2,895		39,678		68,395		8,964		77,359										
Publications		-		7,847		5,578		53,391		7,104		-		-		-		73,920		-		73,920										
Insurance		-		-		-		-		-		-		-		48,353		48,353		-		48,353										
Overhead allocation		23,025		132,625		6,506	_	95,429		147,661		21,686	_	3,124	_	(215,672)		214,384		(214,384)												
Total	\$	81,391	\$	344,956	\$	119,675	\$	280,056	\$	477,899	\$	133,391	\$	114,082	\$	1,141,921	\$	2,693,371	\$	291,354	\$	2,984,725										

# Statements of Cash Flows

		Years ended	1 December 31,			
		2012		2011		
Cash flows from operating activities						
Change in net assets	\$	(130,089)	\$	323,095		
Adjustments to reconcile change in net assets to net cash						
(used in) provided by operating activities:						
Depreciation expense		164,210		146,260		
Net change in fair value of investments		27,246		22,683		
Changes in operating assets and liabilities:						
Accounts receivable		(49,285)		137,192		
Amounts due from affiliates		(62,656)		47,213		
Rent receivable under shared services agreement		(7,399)		(22,182)		
Prepaid expenses and other assets		7,357		7,292		
Accounts payable and accrued expenses		(35,426)		53,760		
Deferred revenue		15,845		(8,146)		
Deferred rent	_	(58,018)		(41,222)		
Total adjustments		1,874		342,850		
Net cash (used in) provided by operating activities		(128,215)		665,945		
Cash flows from investing activities						
Purchases and reinvestments of investments		(1,215,253)		(535,609)		
Sales and maturities of investments		1,183,600		-		
Purchases of property and equipment		(104,060)		(240,004)		
Net cash used in investing activities		(135,713)		(775,613)		
Net change in cash and cash equivalents		(263,928)		(109,668)		
Cash and cash equivalents, beginning of year		773,367		883,035		
Cash and cash equivalents, end of year	\$	509,439	\$	773,367		

# Notes to the Financial Statements

Years ended December 31, 2012 and 2011

## Note A - Organization and Summary of Significant Accounting Policies

#### Organization

International Life Sciences Institute (ILSI) was incorporated under the laws of the District of Columbia in July 1978 in order to prome ote an understanding and resolution of nutrition, food safety, toxicology, risk assessment, and environmental issues worldwide. Through ILSI, scientific experts from the academic, government, industrial, and public sectors throughout the world collaborate on research and education programs at national and international levels.

ILSI has also established and chartered several branches located throughout the world. ILSI does not maintain a majority voting interest in the governing bodies of these branches; accordingly, these financial statements do not reflect the fi nancial positions, changes in net assets, and cash flows of these branches.

These financial statements include only the activities of ILSI and do not include the activities of ILSI Research Foundation (the Foundation), a re lated affiliate. The Foundation is a separate nonprofit organization form ed in 1984 as a philant hropic vehicle for ILSI to support original research addressing critical public health issues. The Foundation is exem pt from the payment of income taxes under Section 501(c)(3) of the Internal Revenue Code.

#### Income taxes

ILSI is exempt from the payment of income taxes on its exempt activities under Section 501(c)(3) of the Internal Revenue Code and is classified by the Internal Revenue Service as other than a private foundation within the meaning of Section 509(a)(1) of the Internal Revenue Code. ILSI believes that it has appropriate support for r any tax positions taken, and as such, does not have any uncertain tax positions that are material to the financial statements as of December 31, 2012. ILSI's income tax returns are generally subject to examination by the IRS for three years after they were filed; there are no examinations being conducted.

## Basis of accounting

ILSI prepares its financial statem ents on the accrual basis of accounting in accordance with accounting principles generally accepted in the united States (U.S. GAAP). Accordingly, revenues are recognized when earned and e obligations are incurred.

## Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires m anagement to make estimates and assumptions that aff ect certain reported am ounts and disclosures. Accordingly, actual results could differ from estimates.

# Notes to the Financial Statements (Continued)

## Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Cash and cash equivalents

For financial statement purposes, ILSI considers all dem and deposit accounts and highly liquid instruments, which are held for current operations to be cash and cash equivalents. All other highly liquid instruments, which are included within ILSI's investment portfolio are set aside for investment purposes.

#### Investments and fair value measurement

Investments in money market funds, mutual funds, corporate bonds and notes are carried at fair value in accordance with U.S. GAAP. Interest a nd dividends are recorded in the statem ent of activities as investment income. Realized gains and losses and unrealized gains and losses are recorded as changes in fair value in the statements of activities. Gains and losses arising from the sale, maturity and other dispositions are accounted for on a specific identification basis calculated as of the trade date.

U.S. GAAP establishes a three-level hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (L evel 1) and the lowest priority to unobservable inputs (Level 3).

Level 1 – Inputs to the valuation m ethodology are quoted prices (unadjusted) for identical assets or liabilities traded in active markets.

Level 2 – Inputs to the valuation m ethodology include quoted prices for sim ilar assets or liabilities in active markets, quoted prices for iden tical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and market-corroborated inputs.

Level 3 – Inputs to the valuation m ethodology are unobservable for the asset or liability and are significant to the fair value measurement.

Certificates of deposit held do not m eet the definition of securities under accounting standards and thus are not subject to the fair value disclosure requirements of U.S. GAAP.

#### Credit risk

ILSI maintains demand deposits with commercial banks and certificates of deposit and money market funds with financial institutions. At times, certain balances held within these accounts may not be fully guaranteed or insured by the U.S. federal government. The uninsured portions of cash and money market accounts are backed solely by the assets of the underlying institution. As such, the failure of an underlying institution could result in financial loss to ILSI.

# Notes to the Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Market value risk

ILSI also invests some of its funds in corpor ate bonds and notes. Such investments are exposed to market and credit risks. Therefore, the i nvestment balances reported in the accom panying financial statements may not be reflective of the portfolio's value during subsequent periods.

#### Accounts receivable

Accounts receivable primarily consist of am ounts due for publication royalties and sales and branch assessments. Accounts receivable are presented net of an allowance for doubtful accounts, if any. ILSI's management periodically reviews the status of all accounts receivable balances for collectibility based on its knowledge of and relationship with the custom er and the age of the receivable balance. As a result of these reviews, ILSI does not believe an allowance for doubtful accounts is necessary as of December 31, 2012 and 2011.

#### Property and equipment

Acquisitions of property and equipm ent greater than \$5,000 are capitalized at cost and depreciated, using the straight-line m ethod, over the following estimated useful lives: furniture and equipment – four to ten years; com puter software and equipment – three to five years; and leasehold improvements – over the ten-year term of the office lease or remaining portion thereof, unless the asset's useful life is estimated to be shorter.

#### Deferred revenue

Deferred revenue prim arily consists of annual m eeting income and branch or com mittee assessments received in advance of the meeting or year to which they apply.

#### Net assets

For financial statement purposes, net assets are classified as follows:

<u>Unrestricted</u>: Represents the portion of net assets w hose use is not restricted by donors, even though their use m ay be limited in other respects, such as by board designation. Undesignated net assets represent the funds that are available to support ILSI's general operations. Board-designated net assets represent the funds that ILSI's Board of Trustees has determined should be reserved for long-term investment purposes. The Board has the right to approve expenditures from these reserved funds at any time.

<u>Temporarily restricted</u>: Represents the portion of net assets for which the use by ILSI has been restricted by donors with specified time or purpose limitations (see Note E).

# Notes to the Financial Statements (Continued)

#### Note A - Organization and Summary of Significant Accounting Policies (Continued)

#### Committee and branch assessments

Assessments are charged to com mittee members based on the activity budgeted for the respective committees each year and to the branches based on a percentage of their revenue. Assessments received in advance of the period to which they apply are recorded as deferred revenue until that period occurs.

#### **Publications**

Publications revenue is recognized on sales and royalties transactions upon transfer of significant risks and rewards of ownership to the buyer. Reve nue is not recognized to the extent there are significant uncertainties regarding recovery of the consideration due, associated costs or the possible return of goods.

#### *Contributions*

Contributions are recognized as revenue when received or unconditionally prom ised. Contributions are recorded as unrestricted, tem porarily restricted, or perm anently restricted support depending upon the existence and/or natu re of donor restrictions. Support that is restricted by the donor is reported as an increase in tem porarily or perm anently restricted net assets when the contribution is recognized. When a restriction expires (that is, when a stipulated time restriction ends or a purpose restriction is accomplished), the amounts are reclassified to unrestricted net assets and reported in the stat ement of activities as net assets released f rom restriction. ILSI has not received any support with permanent donor restrictions.

#### Functional allocation of expenses

The costs of providing various program s and other activities have been sum marized on a functional basis in the statement of activities. Accordingly, indirect expenses have been allocated among the programs and supporting services benefited.

#### **Reclassifications**

Certain 2011 balances have been reclassified to conform with the current year presentation.

#### Subsequent events

ILSI has performed an evaluation of subsequent events through July 16, 2013, which is the date the financial statements were available to be i ssued and has considered any relevant m atters in preparation of the financial statements and footnotes.

# Notes to the Financial Statements (Continued)

#### Note B - Investments and Fair Value Measurements

Investments, recorded at fair value and classi fied in accordance with the U.S. GAAP hierarchy, consist of the following at December 31:

		2012	
	Level 1	Level 2	 Total
Money market funds	\$ 60,814	\$ -	\$ 60,814
Fixed income mutual funds	770,364	-	770,364
Fixed income exchange traded funds	 352,728	 _	352,728
Total investments, at fair value	\$ 1,183,906	\$ 	 1,183,906
		2011	
	Level 1	 Level 2	 Total
Money market funds	\$ 59,123	\$ -	\$ 59,123
Corporate bonds and notes	 _	 52,086	 52,086
Total investments, at fair value	\$ 59,123	\$ 52,086	111,209
Certificates of deposit			 1,068,277
Total			\$ 1,179,486

Investments using Level 2 inputs consist of corporate bonds and notes. The investments reported at fair value are priced using an outside data and pricing company. In determining the fair value of the investments, the pricing company uses a market approach and prices assets using multiple price types of close, bid/ask, high/low, and open pricing. Management believes these estimates to be a reasonable approximation of the fair value of the investments.

ILSI recognizes transfers between levels of the fair value hierarchy at the end of the period in which circumstances occur causing changes in availability of the fair value inputs. There were no transfers between levels during the years ended December 31, 2012 and 2011.

Total investment return consists of the following for the years ended December 31:

		2012	 2011
Interest and dividend income	\$	32,640	\$ 35,610
Change in fair market value of investments		(27,246)	 (22,683)
Total return on investments	<u>\$</u>	5,394	\$ 12,927

Investment fees were \$975 and \$0 for the years ending Decem ber 31, 2012 and 2011, respectively.

# Notes to the Financial Statements (Continued)

#### Note C - Property and Equipment

Property and equipment consists of the following at December 31:

		2012		2011
Computer software and equipment	\$	594,523	\$	510,315
Furniture and equipment		114,075		114,075
Leasehold improvements		723,761		703,909
		1,432,359		1,328,299
Less accumulated depreciation		(672,454)		(508,231)
-	<u>\$</u>	759,905	<u>\$</u>	820,068

#### **Note D - Related Party Transactions**

ILSI has charter agreem ents with an affilia ted group of nonprofit organizations consisting of ILSI Research Foundation (the Foundation), two branches located in W ashington, DC - ILSI North America (ILSI N.A.) and ILSI Health a nd Environmental Sciences Institute (HESI) and several international branches. In the ordinary course of doing business, ILSI has a variety of financial transactions with its Washington, DC based affiliates.

Common expenses (such as for accounting, legal, information technology, human resources, and business services) that benefit the DC-based affiliates are governed by a shared space and services agreement, under which ILSI allocates these costs to each affiliate based on their total number of full-time equivalents. ILSI allocated the total costs of these shared services to each affiliate as follows for the years ended December 31:

	 2012	 2011
ILSI Research Foundation	\$ 292,313	\$ 299,671
ILSI North America	434,257	433,613
ILSI Health and Environmental Sciences Institute	 388,888	 408,644
	\$ 1,115,458	\$ 1,141,928

The following other transactions occurred between ILSI and the members of the above affiliated group during the years ended December 31, 2012 and 2011:

<u>ILSI branch and entity assessm ents</u>: As specified in its branch charter agreem ents, all members of an ILSI branch are automatically members of ILSI. Since ILSI does not collect its own dues from these members, ILSI instead charges an annual assessment to the branches in order to provide support for governance and coordination of ILSI's branches. During the years ended December 31, 2012 and 2011, ILSI charged \$150,000 each year in branch assessments to ILSI N.A. and charged \$150,000 and \$139,071, respectively, in branch assessments to HESI.

# Notes to the Financial Statements (Continued)

#### **Note D - Related Party Transactions (Continued)**

As specified in its entity charter agreem ent, ILSI may set and impose entity assessments on the Foundation. During the years ended Decem ber 31, 2012 and 2011, ILSI charged \$140,000 and \$143,405 in entity assessments to the Foundation, respectively.

<u>Joint annual meeting</u>: Each year, ILSI N.A. and the F oundation participate in a joint annual meeting with ILSI. HESI holds its annual m eeting separately but m ay, from time to tim e, participate in the joint m eeting. Each affiliate holds their own board of trustee and scientific sessions in conjunction with the m eeting. ILSI collects each affiliate's share of the annual meeting income and pays in advance for a portion of each affiliate's share of the joint expenses of the meeting. The following net fees for annual meeting activity were reimbursed to ILSI for the years ended December 31:

	 2012	 2011
ILSI Research Foundation	\$ 41,641	\$ 26,204
ILSI North America	52,525	57,718
ILSI Health and Environmental Sciencess Institute	 34,835	 
	\$ 129.001	\$ 83.922

<u>Professional service fees</u>: From time to time, ILSI will utilize staff or other resources from another affiliate in carrying out its projects, or conversely, another affiliate will utilize staff or other resources of ILSI. The extent and use of these services is agreed to by the two affiliates in advance, and the affiliate requesting the resources is charged a professional fee as compensation. During the years ended December 31, 2012 and 2011, ILSI charged the Foundation \$91,452 and \$106,090, respectively, and charged ILSI N.A. \$2,025 and \$4,110, respectively, for providing these services. During the years ended December 31, 2012 and 2011, ILSI was charged professional fees of \$2,000 and \$20,888, respectively, by the Foundation.

<u>Due from affiliates</u>: ILSI was owed the following am ounts from the above affiliates for shared services cost allocations and various other reim bursements of expenses, which ILSI paid on behalf of the affiliates at December 31:

	 2012	 2011
ILSI Research Foundation	\$ 58,689	\$ 33,117
ILSI North America	56,199	26,594
ILSI Health and Environmental Sciences Institute	 56,895	 49,416
	\$ 171,783	\$ 109,127

# Notes to the Financial Statements (Continued)

#### **Note D - Related Party Transactions (Continued)**

<u>Rent receivable under shared services agreem</u> ent: During 2008, ILSI entered into a lease for office space in W ashington, D.C. (see Note G). Since the above affiliates all share the sam e office space with ILSI, ILSI allocated a portion of its deferred rent liability to each affiliate based on the number of full-time equivalents. As such, ILSI allocated the following deferred rent to each affiliate at December 31:

	 2012	 2011
ILSI Research Foundation	\$ 95,074	\$ 94,044
ILSI North America	129,977	125,326
ILSI Health and Environmental Sciences Institute	 139,096	 137,378
	\$ 364,147	\$ 356,748

<u>Deposits:</u> As part of the shared services agreem ent, ILSI charged each affiliate a deposit to cover the period of time between when ILSI pays the shared service cost and when the affiliate reimburses ILSI. Deposits held by ILSI on behalf of each affiliate were as follows as of December 31:

	 2012	 2011
ILSI Research Foundation	\$ 40,000	\$ 40,000
ILSI North America	116,000	116,000
ILSI Health and Environmental Sciences Institute	90,000	 90,000
	\$ 246,000	\$ 246,000

## **Note E - Temporarily Restricted Net Assets**

Temporarily restricted net assets represent amounts contributed for the following donor-specified purposes:

		Balance at						Releases		Balance at
	December 31,				Transfer from	from		December 31,		
		2011	_(	Contributions	_	IOC to PIP	_	Restriction		2012
ILSI Focal Point in China	\$	327,634	\$	27,667	\$	-	\$	(124,782)	\$	230,519
PIP		-		146,000		67,158		(156,649)		56,509
Staff Global Travel Fund		55,050		-		-		(7,524)		47,526
Marketing department		29,216		-		-		(25,344)		3,872
IFBiC Committees				22,500				(22,500)		-
Total	\$	411,900	\$	196,167	\$	67,158	\$	(336,799)	\$	338,426

# Notes to the Financial Statements (Continued)

	] De	Balance at ecember 31, 2010	Contributions	Releases from Restriction	Balance at December 31, 2011
ILSI Focal Point in China Marketing department Latin American coordination	\$	408,090 38,850 3,653	\$ 30,000	\$ (110,456) (9,634) (3,653)	\$ 327,634 29,216
OECD Workshop Total	\$	450,593	\$ 55,050 2,000 87,050	\$ (2,000) (125,743)	\$ 411,900

## Note E - Temporarily Restricted Net Assets (Continued)

#### **Note F - Defined Contribution Pension Plan**

ILSI has a Section 403(b) defined contribution retir ement plan, which covers substantially all of its employees. Employer contributions to the plan are calculated at 7% of each participant's salary. Participants may also make voluntary elective deferrals to the plan. For the years ended December 31, 2012 and 2011, retirem ent contribution expenses totaled \$77,505 and \$68,731, respectively.

#### Note G - Commitments and Contingencies

#### Office Lease

In May 2008, ILSI entered into an operating lease for office space in W ashington, DC, which commenced in September 2008 and expires in January 2019. ILSI received certain concessions from the lease agreement, which have been amortized over the lease term on a straight-line basis. The unamortized portion of these incentives is reported as deferred rent in accordance with U.S. GAAP in the statem ents of financial position. Rent expense, net of am ortized rent abatements and amounts allocated to affiliates that shar e space (see Note D), under the office space lease agreement totaled \$118,666 and \$166,761 for the years ended Decem ber 31, 2012 and 2011, respectively.

Future annual minimum lease payments, subject to annual operating expense increase, under various leases are as follows:

Year ending December 31,	
2013	\$ 706,000
2014	740,100
2015	760,100
2016	779,100
2017	798,600
Thereafter	 886,906
	\$ 4,670,806

# Notes to the Financial Statements (Continued)

## Note G - Commitments and Contingencies (Continued)

#### Hotel Commitments

As of December 31, 2012, ILSI has entered into contracts with several hotels pertaining to future annual meetings. In the event that ILSI cancels or reduces its contracted provisions, it m ay be liable for certain penalties or liquidated da mages, depending upon the date of cancellation. Minimum future cancellation fees for signed hotel contracts (excluding any applicable sales tax) are approximately \$580,000.

From:	Joanne Lupton
Sent:	Tuesday, July 16, 2013 3:30 PM
То:	Courtney Gaine
Cc:	suzanne@cc.hawaii.edu; Ann Yaktine (AYaktine@nas.edu); Joanne Lupton
Subject:	Proposal for the IOM Bioactives workshop

Dear Courtney:

Ann Yaktine has received approval from IOM to submit our proposal for the Bioactives workshop to potential funders. This would be the full proposal rather than just the concept piece. Should we address the proposal to you or would you prefer that we send it to Dr. Hentges? Once we know to whom to send it Ann will send it out on Monday, July 22.

Sincerely,

Joanne Chair, Program Planning Committee IOM Bioactives Workshop

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862 From: Sent: To: Cc: Subject: Joanne Lupton Thursday, July 04, 2013 11:07 AM Gwen Twillman; 'Yaktine, Ann' 'Courtney Gaine' RE: One pager on December Clinical Conference

Hi Gwen, thanks for sending this. How are we going to work out the issue that December 5 would be free? Don't want the ASN people to think that they are paying for 3 days only to find that day 1 is free to a lot of other people. J

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Gwen Twillman [mailto:
Sent: Wednesday, July 03, 2013 3:32 PM
To: Joanne Lupton; 'Yaktine, Ann'
Cc: 'Courtney Gaine'
Subject: One pager on December Clinical Conference

Hi Ann, Joanne and Courtney,

Thanks so much for your time today. Great call!

Attached is a "one pager" on the December conference. I also attached a PDF of the Save the Date – but I thought the one page Word document would be easier to print out.

I'll touch base with Courtney next week re: funding.

Hope your meeting goes well in CA.

Have a wonderful holiday,

Gwen

#### **Gwen Twillman**

Managing Director, Education & Professional Development American Society for Nutrition 9650 Rockville Pike Bethesda, MD 20814 301-634-7282 direct 301-634-7894 fax

ADVANCES & CONTROVERSIES IN	American Society for Nutrition
CLINICAL NUTRITION	Excellence in Nutrition Research and Practice
December 5-7, 2013 • Washington, DC	www.nutrition.org/meetings/clinical

From:	Joanne Lupton
Sent:	Wednesday, July 03, 2013 10:55 AM
То:	
Cc:	Joanne Lupton; Chelsea L. Bishop; 'Margaret Foster'; Stella S. Taddeo
Subject:	submission of proposal in response to ILSI rfp on fiber database
Attachments:	Foster CV and publications.pdf; Lupton cv and publications.pdf; Development of a
	Comprehensive Fiber Database FINAL.pdf; Phase Two Addendum.pdf

Dear Courtney Gaine and Ashley Jarvis:

Attached please find our proposal submitted in response to your request for proposals on the development of a comprehensive fiber database. The four attachments are: 1) Our five page proposal; 2) An addendum addressing some of the issues which may be considered for a Phase Two proposal; 3) My CV with two papers at the end of the CV and 4) Margaret Foster's CV with two of her publications attached at the end of the CV.

If you have any questions or need additional information please send an email. I will be traveling for most of the next two weeks so if you need to discuss anything please be sure to copy Chelsea Bishop (cc'd above) because she always knows how to contact me.

Sincerely, Joanne Lupton

#### \*\*\*\*\*\*\*

Joanne R. Lupton, Ph.D.

Distinguished Professor Regents Professor and University Faculty Fellow William W. Allen Endowed Chair In Nutrition Staff Assistant: Chelsea Bishop (clbishop@tamu.edu) E-mail: jlupton@tamu.edu Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

#### Margaret Jane Foster Curriculum Vitae

## I. Summary Record of Faculty Appointment

- Office: 4462 TAMU, Medical Sciences Library
- Phone: 979-862-1893
- Email: <u>margaretfoster@tamu.edu</u>
- Rank: Assistant Professor
- Job Title: Systematic Reviews and Research Services Coordinator
- Unit: Medical Sciences Library, Client Services

## **II. Education and Experience**

## A. Education

MPH, University of Texas Health Science Center at Houston, Houston, TX, 8/05-5/09. Major: Behavioral Sciences and Health Promotion

Thesis: A systematic evaluation of the search strategies, methods, and selection of systematic reviews of interventions to prevent obesity

M.S., University of North Texas, Denton, TX, 8/2003. Major: Library and Information Sciences Specialty: Health Informatics

B.S. Texas A&M University, College Station, TX, 12/1998.
 Major: Psychology
 Na degree University of Terror et San Antonia, San Antonia, TX 8/1001

No degree. University of Texas at San Antonio, San Antonio, TX 8/1991- 5/1996.

## **B.** Professional and/or Library Experience

**Systematic Reviews and Research Services Coordinator,** Medical Sciences Library, Texas A&M University, January 2012-

- Guide the establishment of an MSL Center for Systematic Reviews (SR)
- Define, develop, and market CSR services to all MSL constituencies
- Instruct faculty and students on conducting SRs and meta-analyses
- Perform searches according to SR protocol
- Report results in format suitable for publications and grant proposals
- Collaborate with appropriate Evans Library personnel to establish a campus-wide SR service
- Lead campus Refworks support services by maintaining a RefWorks guide, providing training for library staff and faculty, and supporting user needs
- Provide liaison services in support of faculty and student research, promote relevant library services and resources, and communicate information needs of researchers to MSL
- Provide liaison services to the Departments of Kinesiology and Health Education
- Work as part of the Client Services team, delivering clinical and reference services to library clients both onsite and as part of the embedded librarian team

**Joint Assistant Professor,** Department of Health Promotion and Community Health Sciences, School of Rural Public Health, Texas A&M Health Science Center, September 2012-

**Social Sciences and Education Librarian**, Sterling C. Evans Library, Texas A&M University, August 2007 - December 2011

- Provide reference assistance in person, telephone, virtual, and email
- Liaison with the Health and Kinesiology Department (HLKN) and Women's and Gender Studies Department (WGST)
- Provide instructional sessions for the HLKN and WGST departments and assist in other in instructional sessions
- Conduct collection development in subject areas relevant to the HLKN and WGST departments

Adjunct Faculty, School of Library and Information Sciences, University of North Texas May 2005 - May 2008

**Reference Librarian**, School of Public Health Library, University of Texas Health Science Center at Houston, September 2005 - August 2007

- Provide reference assistance in person, phone, and email
- Educate users on library resources through instruction sessions
- Create brochures and other educational materials
- Assess needs of patrons and participate in planning of library activities
- Provide outreach and develop collection for health promotion and behavioral sciences division
- Promote utilization of library resources
- Collaborate faculty to integrate information literacy competencies into the classroom

## **III. Documentation of Publications, Presentations, and Reviewing A. Publications:**

## 1. Refereed Publications

Foster, M. Shurtz, S., and Smith, M. (2013) "Translating Research into Practice: Criteria for Applying Literature Search Results to Your Work". *Health Promotion Practice* accepted May 27, 2013

Foster, M. and Shurtz S. (2013) "Making the CASE for EBM: Critical Appraisal of Summaries of Evidence" *JMLA: Journal of the Medical Library Association* 101(3) 192-198.

**Role**: Developed methods, analyzed results, created graphs and tables, wrote methods and results, edited all sections

Shim, M., Gimeno, D., Pruitt, S.; McLeod, C., Foster, M. J., and Amick III, B (2013). "A systematic review of retirement as a risk factor for mortality". *Applied Demography and Public Health*. Volume 3. Ed. Hoque, N. 3: 277-309. doi 10.1007/978-94-007-6140-7\_17

**Role**: Developed, updated, and managed all search results; screened portion of articles; assisted in writing methods; assisted in editing entire chapter *Note*: *This book is a monograph series of invited, peer reviewed chapters.* 

Stephens, J., Sare, L., Kimball, R., Foster, M., and Kitchens, J. (2011) "The tenure support mechanisms provided by the Faculty Research Committee at Texas A&M University: A Model for Academic Libraries" Library Management 32(8/9), 531-539.

*Role*: Collected portion of data; created all charts and tables after synthesizing data; assisted in editing paper

Shurtz, S. and Foster, M. (2011) "Developing and using a rubric for evaluating evidence-based medicine point-of-care tools" JMLA: Journal of the Medical Library Association, 99(3): 247-54.

**Role:** Created all charts and tables; wrote Methods and Results sections; co-wrote all other sections

*Impact*: selected as 1 of 8 articles selected from JMLA to be part of the Medical Library Association's Independent Reading Program which allows members to receive 1 MLA continuing education contact hour for each article read and analyzed; JMLA impact factor of .988 (median impact factor in the Information and Library Science category is .641); for 2011 this article had 1108 full text views and 439 pdf downloads

vanDuinkerken, W., Coker, C., & Anderson, M. (2010). "PERSPECTIVES ON ...: Looking Like Everyone Else: Academic Portfolios for Librarians" Journal of Academic Librarianship, 36(2), 166-172.

**Role:** Developed guidelines for faculty librarian academic portfolio which was the basis of the article

Yoshii, A., Plaut, D. A., McGraw, K. A., Anderson, M. and Wellik, K. E. (2009) "Analysis of the Reporting of Search Strategies in Cochrane Systematic Reviews" JMLA: Journal of the Medical Library Association 97(1): 21-29.

**Role**: Analyzed data from previous studies and data from study, created all charts and tables; wrote methods and results section; participated in editing all parts of manuscript Impact: Times cited: Scopus- 8; Web of Science-5; Google Scholar-13; JMLA has impact factor of .988 (median impact factor in the Information and Library Science category is .641)

Anderson, M. and Olmstadt W. (2003) "Providing systematic training for patient support groups." Journal of Hospital Librarianship. 3(3): 13-24.

#### **Ongoing research**

Diep, C. S., Foster, M. J., McKyer, ELJ, Goodson, P., Liew, J., and Guidry, J. J. What are Asian-American youth consuming? A systematic literature review. Journal of Immigrant Minority Health. accepted with minor revisions January 18, 2013, resubmitted May 17, 2013

*Role*: Developed search, designed methods, and helped edit all sections.

Foster, M., Shurtz, S., and Pepper, C. Evaluation of best practices in the design of online evidencebased practice instructional modules. Accepted with revisions to *JMLA*, due Jun 27, 2013 *Role: Designed the methods, analyzed results, wrote methods and results, and edited all* parts

Borrego, M., Froyd, J., and Foster, M. Systematic Literature Reviews in Engineering Education and Other Developing Interdisciplinary Fields. Submitted *Journal of Engineering Education* on May 16, 2013

Pepper, C., Carrigan, E., Shurtz, S. and Foster, M. Exploring Librarian Roles in Support of One Health: A Case Study. *Journal of Agricultural & Food Information* submitted April 11, 2013

#### **B.** Presentations

#### 1. Juried Presentations

#### International

Plaut, D., McGraw, K. A., Anderson, M.J., Nguyen, L., Wellik, K. E., and Yoshii, A., "Analysis of the reporting of search strategies in Cochrane Systematic Reviews". Juried poster session with published abstract, North American Conference on Systematic Reviews, Baltimore, MD, 2006

#### National

- Shurtz, S., Foster, M., and Pepper, C. "Evaluation of Best Practices in the Design of Online Evidence-based Practice Instructional Modules" Paper presented at Medical Library Association Conference, Boston, 2013
- Foster, M. "Developing and evaluating a systematic review service" Poster presented at Medical Library Association Conference, Boston, 2013
- Murphy, C. P., Fajt, V. R.. Wickwire, P. Foster, M. J. McEwen, S. A., Morley, P. S. and Scott, H. M. "A scoping review of the peer-reviewed literature for potential interventions to reduce antibiotic resistance in beef cattle: Preliminary results" Paper presented at Antimicrobial Agents in Veterinary Medicine, Rockville, MD October 2012
- Shim, M., Gimeno, D., Pruitt, S.; McLeod, C., Foster, M. J., and Amick III, B. "A systematic review of retirement as a risk factor for mortality". Paper presented at Population Association of America, San Antonio, Texas, 2010
- Cleveland, A. Philbrick, J. L., Pipes, T., and Anderson, M. "Training Future Health Information Professionals to Manage Disaster Situations" Paper presented at Medical Library Association Conference, Honolulu, 2009
- Plaut, D., McGraw, K. A., Anderson, M.J., Nguyen, L., Wellik, K. E., and Yoshii, A., "Analysis of the reporting of search strategies in Cochrane Systematic Reviews". Poster presented at MLA Conference, Philadelphia, 2007
- Olmstadt, William, and Anderson, Margaret J. "Information needs among genetic counselors", Juried poster session with published abstract, 2005 MLA Conference, San Antonio, Texas, 2005

#### **Regional/State**

- Foster, M. and Shurtz, S. "Making the CASE for EBM: The development and evaluation of the Critical Appraisal for Summaries of Evidence (CASE) worksheet" Juried paper session with published abstract, South Central Chapter of the MLA Conference, Baton Rouge, LA, 2011. 1<sup>st</sup> place, Elizabeth K. Eaton Research Award
- Foster, M. and Shurtz, S. "Evidence Based Public Health in Practice: designing an evidence based health intervention" Heart and Stroke Healthy City Liaison Summit, Texas Department of Health, Austin, TX Aug 5, 2011. Duration: 4 hours
- Trumble, J. M., Anderson, M. J., Caldwell, M., Chuang, F., Fulton, S., Howard, A., and Varman, B. "Systematic Evaluation of Evidence Based Medicine Tools for Point of Care", Juried paper session with published abstract 2006, South Central Chapter of the MLA Conference, College Station, Texas, 2006
- Anderson, Margaret J. "Feed the need for Public Health News: RSS Feeds, Blogs, and More", Juried poster session with published abstract, 2006 MLA Conference, College Station, Texas, 2006
- Anderson, Margaret J. "Systematic training for patient support groups", Juried paper session with published abstract, 2002 South Central Chapter of the MLA Conference, San Antonio, Texas, 2002

#### 2. Invited Presentations

Anderson, Margaret J. "Emergency Management 101" presentation, University of North Texas All School Day, Houston, TX, March 2007 Duration: 30 minutes

#### **3.** Other Presentations

**University** (not related to professional assignment)

Anderson, Margaret J. "Virtual Worlds" Instructional Technology Showcase, Oct 31, 2007. Duration: 30 minutes.

Anderson, Margaret J. "A critical evaluation of search filters" TAMU Libraries Research Forum, Nov 2, 2007. Duration: 20 minutes

#### Community

Foster, Margaret J. Interviewed by Matthew Smith "Health Information" Brazos Valley Health, College Station. KEOS. May 26, 2011. Duration: 1 hour

Foster, Margaret J. Interviewed by Matthew Smith "Health Information and Technology Questions" Brazos Valley Health, College Station. KEOS. August 7, 2008. Duration: 1 hour

Foster, Margaret J. Interviewed by Matthew Smith "Fitness Gadgets" Brazos Valley Health, College Station. KEOS. October 2, 2008. Duration: 1 hour

#### C. Reviewing/editing

Peer reviewed article for *Health Promotion Practice*, "Correlates of moderate-to-vigorous physical activity participation in adults with intellectual disabilities"

Invited expert reviewer for review article submitted to Journal of Engineering Education

#### **IV. Documentation of Professional Activities**

#### **A. National Committees**

Medical Library Association, Gottlieb Prize Jury, member, 2013

- Medical Library Association, MLA Research Agenda Systematic Review Project, team leader (1 of 15), 2013
- Medical Library Association, National Program Committee, Invited expert, abstract reviewer, 2013
- Medical Library Association, Veterinary Medical Libraries Section, Editor, Newsletter of the Veterinary Medical Libraries Section of the Medical Library Association, 2001-2004, 2012
- American Library Association, American of College and Research Libraries, Women's Studies Section, Assistant Editor, Women's Studies Section- ALA Newsletter, 2008-2010
- American Library Association, American of College and Research Libraries, Women's Studies Section, member, Electronic Resources and Access Committee, 2008-2010
- American Library Association, American of College and Research Libraries, Women's Studies Section, ex-officio member, WSS Executive Committee 2008-2010

#### **B.** University and System Level Committees

 Appointed, Quality Enhancement Program (QEP) Critically Appraise Relevant Evidence (CARE) committee 2012
 Serve as Lead Technology Coordinator and Content Developer
 Appointed, Massive Open Online Course (MOOC) committee, 2012

#### C. Library Committees

TAMU Libraries, CSI, Tech Trends, 2009 (appointed) TAMU Libraries, CSI, Second Life Group, chair 2009-2010 TAMU Libraries, Academic Portfolio Committee, 2009 (appointed) TAMU Libraries, SFX Menu Redesign Committee, 2009-2010 (appointed) TAMU Libraries, Research Committee, 2009-2011 (elected) TAMU Libraries, SECC Committee, 2010, chair 2011

#### **D.** Teaching and Workshops

#### **1.** Teaching (for credit courses)

- Co-instructor, Evidence Based Medicine and Critical Thinking I (MEID 975), Texas A&M Health Science Center, College of Medicine, Fall 2012, Spring 2013 (1 credit hour)
- Co-instructor, Evidence Based Medicine and Critical Thinking II (MEID 976), Texas A&M Health Science Center, College of Medicine, Fall 2012-Spring 2013 (1 credit hour)
- Co-instructor, Public Health Informatics (SRPH 640), Texas A&M Health Science Center, School of Rural Public Health, Spring 2008-2012 (3 credit hour)
- Co-instructor, Disaster Management for Information Professionals (SLIS 5670), University of North Texas, School of Library and Information Science, Summer 2006-2008 (3 credit hour)
- Co-instructor, Community-Based Health Information (SLIS 5960), University of North Texas, School of Library and Information Science, Summer 2005-2009 (3 credit hour)
- Co-instructor, Evidence Based Public Health (PH 1430), University of Texas School of Public

Health, Spring 2006 (3 credit hour)

- Lead Instructor, Zombies 101: Surviving Freshmen Year (UGST 181-538), Texas A&M University, Fall 2011. Designed to teach incoming freshmen critical thinking skills. (1 credit hour)
- Lead Instructor, Avatars and Second Life (UGST 181-513), Texas A&M University, Fall 2010 (1 credit hour)
- Lead Instructor, Second Life: Flying into Freshmen Year (UPAS 181-511), Texas A&M University, Fall 2009 (1 credit hour)

## 2. Workshops

- Developer and presenter, Systematic Reviews: Role of the Librarian, South Central Chapter of the MLA Conference, Lubbock, TX 6 hours, October 2012
- Developer and presenter, Systematic Reviews: Role of the Librarian, South Central Chapter of the MLA Conference, Baton Rouge, LA, 6 hours, October 2011
  - Impact: This course was evaluated at MLA '11 and scored an overall course grade of 3.81 on a 4.0 scale. (The mean score for all evaluated courses taught at MLA '11 was 3.63 on a 4.0 scale.)
- Co-developer and presenter, Evidence Based Public Health, Medical Sciences Library, presented 4 times: Summer 2010, Summer 2011, Fall 2011, Summer 2012
- Developed and presented, Systematic Review Workshop, Texas A&M University Library, 9 hours over 3 days, offered twice during Fall 2010
- Library facilitator, "Learning to Practice and Teach Evidence-based Health: An intensive workshop", UT MD Anderson Cancer Center, Houston, Texas, 2006-2007

## E. Honors

Academy of Health Information Professionals, accepted as member 2012

- 1<sup>st</sup> place, Elizabeth K. Eaton Research Award, South Central Chapter of MLA, 2011
- Certificate of Appreciation, College of Education & Human Development (TAMU), July 2008

1<sup>st</sup> place, Research Award for Posters, MLA, 2007

1<sup>st</sup> place, Research Award for Contributed Papers, South Central Chapter of MLA, 2006 McLemore Educational Opportunity Scholarship, 2003

2<sup>nd</sup> place, Research Award for Contributed Papers, South Central Chapter of MLA, 2002 Louise David Scholarship, 2001

#### F. Memberships

Academy of Health Information Professionals, 2012 Evidence Based Veterinary Medicine Association, 2012-13 Medical Library Association, 2003-2006, 2010-13 Consumer & Patient Health Information 2011-12 Veterinary Medical Libraries Section 2012-13 Public Health/Health Administration 2011-13 South Central Chapter, Medical Library Association, 2004-5, 2010-13 American Libraries Association 2006, 2008-10 American of College and Research Libraries 2006, 2008-10 Educational & Behavioral Sciences Section, 2008-10 Women's Studies Section, 2008-10 Library Research Round Table 2008-10 Library Instruction Round Table 2006

## G. Advising

Faculty Advisor for Mixed Martial Arts Student Organization, 2008-2013; group provides free self-defense for women on campus once a week in addition to 4 MMA training sessions each week.

#### H. Significant continuing education

Writing Retreat, South Central Chapter, Medical Library Association, 2012, Lubbock, TX, 8 contact hours

Discovery Workshop, National Center for Biotechnology Information (NCBI), 2011, Houston, TX, 2 day course (covered genetics related databases from National Library of Medicine)

ARL Project management institute, Association of College & Research Libraries, Mar 18-19, 2008 Disaster preparedness and planning symposium, Medical Library Association, 2006, 6 contact hours Planning and evaluating health information outreach projects, Medical Library Association, 2006, 6 contact hours

Assessing student learning outcomes, Association of College & Research Libraries, 2005, 3-week online webinar

# Developing and using a rubric for evaluating evidence-based medicine point-of-care tools

#### Suzanne Shurtz, MLIS, AHIP; Margaret J. Foster, MS, MPH

See end of article for authors' affiliations.

DOI: 10.3163/1536-5050.99.3.012

**Objective:** The research sought to establish a rubric for evaluating evidence-based medicine (EBM) point-of-care tools in a health sciences library.

**Methods:** The authors searched the literature for EBM tool evaluations and found that most previous reviews were designed to evaluate the ability of an EBM tool to answer a clinical question. The researchers' goal was to develop and complete rubrics for assessing these tools based on criteria for a general evaluation of tools (reviewing content, search options, quality control, and grading) and criteria for an evaluation of clinical summaries (searching tools for treatments of common diagnoses and evaluating summaries for quality control).

#### INTRODUCTION

Health care providers require quick retrieval of information to efficiently answer questions related to patient care [1]. Evidence-based medicine (EBM) tools, designed for use at the point of care (POC), meet these needs by providing high-quality and synthesized information at the patients' "bedside" [2]. To support clinical information needs, medical and hospital libraries may wish to subscribe to multiple POC tools, owing to the variety in topics covered, the options provided, and the audiences targeted by each tool. To avoid redundancy and to offer the best products for their users, libraries need to periodically reassess available EBM POC resources [2]. What criteria should librarians utilize to evaluate these POC tools? Because these resources are used to make clinical decisions, resources providing the best evidence relevant to patient care would be most desirable. Those who use these tools "need to know how much confidence they can place in the recommendations" [3]. One role of medical librarians is to evaluate the quality of EBM resources so that users can have confidence in the information upon which they base clinical decisions. This is a weighty responsibility, and librarians have an important challenge determining which EBM POC resources to make available to users.

#### BACKGROUND

The Texas A&M University Medical Sciences Library (MSL) is 1 of 5 libraries on the College Station campus of Texas A&M University. MSL houses 120,000 print

This article has been approved for the Medical Library Association's Independent Reading Program <a href="http://www.mlanet.org/education/irp/>">http://www.mlanet</a>

**Results:** Differences between EBM tools' options, content coverage, and usability were minimal. However, the products' methods for locating and grading evidence varied widely in transparency and process.

**Conclusions:** As EBM tools are constantly updating and evolving, evaluation of these tools needs to be conducted frequently. Standards for evaluating EBM tools need to be established, with one method being the use of objective rubrics. In addition, EBM tools need to provide more information about authorship, reviewers, methods for evidence collection, and grading system employed.

#### **Highlights**

- Eleven of the fourteen previous evidence-based medicine (EBM) tool evaluations were based on clinicians evaluating tools based on their perception of the products' ability to answer a clinical question.
- EBM tools' evidence summaries are not updated as often as products claim.
- Although many EBM tools claim to be evidence based, only 74% of the 70 evaluated treatment summaries included graded evidence.

#### Implications

- To offer the best tools for users, medical libraries should evaluate EBM resources regularly, including the quality of the evidence provided.
- Medical librarians have a role to play in evaluating the quality of EBM products and can develop assessment tools to aid in this evaluation.

titles and 1,600 serials, with a collection budget of more than \$1.8 million. One of the library's user groups is the Texas A&M Health Science Center (TAMHSC), which includes the TAMHSC College of Medicine, College of Nursing, School of Graduate Studies, Rangel College of Pharmacy, and School of Rural Public Health. The director of the MSL charged a team of 3 librarians in 2008 to evaluate and determine which EBM POC subscription-based tools the library should keep or purchase, in order to reduce overlap and to ensure that user needs were met. In 2008, MSL subscribed to 5 EBM POC tools: Stat!Ref's ACP PIER, DynaMed, Cochrane Library, Essential Evidence Plus, and MD Consult's First Consult. The librarians were asked to evaluate all subscription EBM POC resources. No directions were given as to how to perform this evaluation. To determine which tools to evaluate and to find best practices for evaluation, the librarians conducted a literature review.

#### LITERATURE REVIEW

The literature review included searching MEDLINE (PubMed), CINAHL (EBSCO), Library Information Science Technology Abstracts (LISTA) (EBSCO), and Google Scholar. Search terms included combinations of "evidence based medicine tools," "point of care tools," "bedside tools," "evaluation," and names of specific tools. The researchers were particularly interested in studies reviewing EBM tools to which the library currently subscribed. UpToDate, Epocrates, and Ovid's Clin-eguide were tools in which users had expressed interest and were also used as search terms. Articles excluded from the search were opinion papers, either letters to editors or journal columns.

Fourteen research-based articles were found evaluating specific features of EBM POC tools for clinical medicine (Table 1). Found studies focused mainly on EBM tools that physicians use. One article was found on tools for clinical laboratory specialists [4]. The current status of each tool mentioned in the articles was verified. Some tools' names had been changed since the article was written, such as InfoPOEMs/ InfoRetriever, which is now Essential Evidence Plus [2, 5–7]. Other products included in studies no longer exist, such as MAXX [8]. Negative reviews of the tools were often later resolved. For instance, a 2003 review of UpToDate found the information for patients weak [9], and UpToDate has since created a version specific for patients [10]. In another example, DynaMed was criticized for not clearly grading its evidence [11], and DynaMed producers responded by creating a description of the levels of evidence used in the product [12].

Retrieved articles varied by who acted as the tool reviewer (the researcher versus the user) and by the platform used during the evaluation (computer versus mobile device). Nearly 80% of the articles included 1 or more clinicians (MDs) as reviewers. Backgrounds of authors varied among medical librarians, practicing physicians, clinical faculty, medical informaticians, graduate students, and research coordinators. The evaluations also took place in a wide range of locations including hospitals, private practice, laboratories, and libraries. Some authors evaluated both free tools, such as Google, and subscription-based tool, such as DynaMed [2, 7, 8, 13–19]. Differences were evident in how EBM tools were defined and compared. One study divided tools into two categories [5]. The first category, "evidencebased resources," included bibliographic databases and summary resources. Resources such as PubMed, Cochrane Database of Systematic Reviews, First Consult, InfoPoems, and DynaMed were referenced in this group. The second group, defined as "review resources," incorporated "evidence-based content"

without an "explicit process to ensure that all relevant literature is selected and appraised" [5]. Examples included AccessMedicine, MD Consult, Stat!Ref, and UpToDate [5]. Other evaluations did not differentiate between bibliographic versus synthesized tools, comparing resources like PubMed, MEDLINE, and Cochrane to UpToDate [5, 7, 15, 17– 19]. Another evaluation defined three EBM tools as "e-textbooks" [20].

Most evaluation metrics in these studies were designed to determine whether answers to clinical questions were retrieved in the tools. Either preselected questions or those formulated at the point of care were used in the evaluations. Methods varied as to how preselected questions were gathered. Some studies additionally factored in the average search time required to locate the answer. One article used a scoring system created by the authors to assess overall content in each tool.

Due to the wide variation in the studies' researchers, methods, and evaluated tools, comparisons between studies and their respective recommendations proved difficult. Overall conclusions varied. Some reviews rated no product higher than another [18, 20], multiple studies rated UpToDate highest [2, 9, 14, 16, 19], and one rated DISEASEDEX highest [6]. UpToDate's easy-to-use interface was cited as a reason for its popularity. Campbell acknowledged that participants in her study had used UpToDate previously and therefore were already familiar with the search interface [2]. Kim explained that "bibliographic databases such as PubMed and Medline [were] difficult to navigate, and current evidencebased synopses or summary sources [had] small databases that cover[ed] a limited content" [5]. Two of the studies that found DynaMed valuable included the product's creator as one of the authors [8, 13].

#### **OBJECTIVES**

While most previous evaluations of EBM tools focused on health professionals' and researchers' perspectives on the ability of a tool to answer a clinical question, the librarians in this study did not feel qualified to determine if a tool sufficiently answered a clinical question. Also, the researchers wanted to ultimately develop a process with which they could regularly evaluate the tools in their collection. Due to these factors, the goal of this study was to assess the attributes, the standards and clarity of evidence grading, and the level of transparency (authorship or review processes) of the tools. The following objectives were identified to achieve these goals:

■ to create a list of subscription-based resources claiming to be EBM POC

• to develop and use an evaluation form to systematically compare the features of these resources

• to methodically evaluate the content and quality control of these resources using commonly searched clinical topics

• to make recommendations about subscriptions to these resources based on these evaluations
<b>Table 1</b> Literature review summary				
Article	Tools evaluated	Reviewer academic qualifications	Evaluation methods	Results
Alper et al., 2001* [8]	Stat!Ref, MD Consult, DynaMed, MAXX <sup>†</sup> , MDChoice com	MDs	20 preselected clinical questions searched	Stat!Ref, DynaMed, MAXX, MD Consult answered 95% of misetions
Alper et al., 2005* [13]	DynaMed	MDs, medical researcher	698 clinical questions at point of care scarched by 52 clinical	DynaMed answered more questions than other sources
Banzi et al., 2010 [18]	5-min Clinical Consult, ACP PIER, BestBETs, CKS, Clinical Evidence, DynaMed, eMedicine, eTG complete, EBM Guidelines, First Consult, GP Notebook, Harrison's Practice, Health Gate, Map of Medicine, Micromedex, Pepid, Harton-a Zuscerdance	Pharmacological researchers	Scoring system used by authors to evaluate overall content	No product rated highest
Campbell and Ash, 2006‡ [2]	OP DODAR, 2011A- WILLENDERING ACP'S PIER, DISEASEDEX, FIRST Consult, InfoRetriever (Essential Evidence Plus), UpToDate	Medical librarian, PhD	Preselected clinical questions searched by 8 clinicians, 3 pharmacists, 5 medical informatics students, 1 MRI technologist, 1 redistrand nurse	UpToDate answered more questions than other sources and preferred for usability
Fenton and Badgett, 2007 [16]	National Guideline Clearinghouse,	MD, PhD	752 preselection and clinical questions	UpToDate answered more questions than National Guideline Clearinghouse
Fox and Moawad, 2003 [9]	UpToDate	MDs	Clinical questions at point of care searched by authors	UpToDate answered most questions quickly
Goodyear-Smith et al., 2008 [20]	DynaMed, MD Consult, UpToDate	PhDs	4 preselected clinical questions searched by 200 clinicians	No product rated highest
Hoogendam et al., 2008§ [19]	UpToDate, PubMed	MDs	2,986 clinical questions at point of care searched by 40 residents. 30 internists	UpToDate answered more questions than PubMed
Jones and Emery, 2004 [6]	DISEASEDEX, DynaMed, UpToDate, InfoRetriever. First Consult. Clin-equide	MDs	Preselected clinical questions searched by authors	DISEASEDEX rated highest
Kim et al., 2008 [5]	DynaMed, InfoPoems, UpToDate, MD Consult, eMedicine, StatlRef	MDs, medical librarian, PhD	Clinical vignettes in pre- and posttests searched in EBM class of 50 residents	Ovid resources** and InfoPoems used most by EBM class; UpToDate, MD Consult used most by control group
Koonce et al., 2004 [17]	UpToDate, Cochrane, HealthGate, Clinical Guidelines	Librarians, MD	40 complex clinical questions (randomly selected); 40 general care clinical questions (selected)	Resource's completely answered 20% of complex questions and 47% of general care
McCord et al., 2007 [14]	UpToDate, Epocrates, MD Consult, DynaMed, eMedicine	MDs, medical students, research coordinator	532 clinical destrons at point of care searched by 25 family medicine residents and 37 clinical faculty	UpToDate rated highest, but Epocrates used most
Schilling et al., 2005 [15]	MEDLINE, UpToDate, MD Consult, Cochrane Library, National Guideline Clastincholuse Micromedex	MDs, MBA	158 clinical questions at point of care searched by 43 internal medicine residents	MEDLINE and UpToDate used most
Schwartz et al., 2003 [7]	TRIP, InfoRetriever	MDs, PhD/MPH	92 clinical questions at point of care searched by 3 clinical faculty	TRIP database used to answer most questions
* Founder of Dynamed. † Tool no longer exists. ‡ Tools evaluated were only those i § Tools evaluated were only those ** Ovid resources included MEDLIN	n which the library was interested. with which the users were familiar. IE, ACP Journal Club, Cochrane, and DARE.			

#### METHODS

#### Tool selection process

Screening criteria. In the spring of 2009, a list of EBM tools was created from those found in the literature review, from tools that patrons had requested, and from tools to which Texas A&M University subscribed. As illustrated in the literature review, definitions for and categories of EBM tools varied. Tools that were subscription based, claimed to be evidence based, claimed to be POC, and focused on clinical content were chosen for the review. Because the original charge from the library director was to compare subscription-based products, free resources were excluded. Evidence of the first three criteria could be found on the product's website or brochures. Emphasis on clinical content was determined by reading product descriptions on the site. A sample of academic medical and hospital libraries' holdings was also reviewed to ensure tools were not missed and to compare the researchers' holdings with that of the sample. The South Central Academic Medical Libraries consortium (SCAMeL), of which MSL is a member, was selected as the sample. Libraries in the consortium vary in size and users or programs supported, providing a spectrum of medical libraries appropriate for the sample that the researchers desired. Each SCAMeL library's website was searched, based on the screening criteria, to find a listing of EBM tools available to their users. No additional tools were found when the SCAMeL holdings were compiled.

The tools found were then were entered into a form made using Zoho Creator, a web-based software product that creates databases with forms and tables [21]. Each tool was screened by at least two reviewers, using an online form created in Zoho Creator [21]. Three screeners discussed discrepancies before coming to a consensus about tools to exclude. This form was completed in 2009 and again in 2010 to show changes in subscriptions.

**Tools selected for evaluation.** Based on the screening criteria, the researchers chose to include the following tools in their evaluation: ACP PIER, BMJ Point of Care, Clin-eguide, DynaMed, Epocrates, Essential Evidence Plus, First Consult, and UpToDate. The authors chose to exclude any tool that was strictly a pharmaceutical resource, as the target for this evaluation was clinical medicine.

#### Evaluation

Each tool was evaluated in two ways: by rating common attributes on a general evaluation form and by determining the tool's ability to provide a treatment summary on commonly diagnosed conditions.

**Part 1: general evaluation.** The general evaluation form, produced in Zoho Creator, was developed to

analyze all parts of the resource and initially included four sections: general characteristics, scope and content, search options, and results presentation. The evaluation form questions were adapted from a presentation by Trumble in 2004 (in which one of the authors participated) [22]. As the evaluation progressed, it became apparent that an important difference between these tools was how the evidence was graded. Evidence that has been compiled and evaluated by authoritative bodies, or in other words, "graded," has the most weight in EBM [2, 23]. Because the reviewers wanted to examine more closely how the evidence was graded, a fifth section was added to the form.

The final evaluation form included the following sections: Section A included measures of general characteristics of the tool, including availability of platform compatibility, simultaneous users, mobile devices accommodated, free version, and available customizations. Section B parameters were the scope and content, including availability of patient handouts, continuing education credits, practice guidelines, and help screens. Section C covered the search options (browsing, guided searches for pharmaceuticals, advanced), navigation, and presentation of the results (readability, adjustments, print options, and other outputs). Section D focused on quality control, including listing of authors or reviewers' names, credentials, and affiliations; the process of becoming an author or reviewer; updating schedule; and any biases (affiliations were considered to constitute a conflict of interest). Section E included the standards used for grading and the clarity of the grading levels.

Part 2: clinical summaries evaluation. During the general evaluation, the researchers also noted that the consistency with which the evidence summaries were graded varied between tools. In summer of 2010, the investigators wanted a snapshot of the extent to which grades were provided for common clinical topics in each tool. A list of common primary diagnoses was located in the Centers for Disease Control and Prevention's "National Ambulatory Medical Care Survey: 2005 Summary" [24]. The investigators selected the top ten diagnoses to search across each EBM tool. For those terms that were very broad (such as malignant neoplasms), librarians selected the most common form of the disease (such as skin cancer). The final list of ten terms searched was: hypertension, upper respiratory infection, arthritis, skin cancer, diabetes, low back pain, ear infection, asthma, high cholesterol, and sinusitis.

A Zoho Creator form was made for each clinical topic addressing the following criteria: Was a section on the topic provided? Was the evidence graded? Was it summarized? Were summary tables provided? For each question, a yes or no option was listed, as well as the number of clicks to find the answer, and a notes field. The number of clicks was counted from the main page to the appropriate section of the results page. Two librarians searched each term in every tool.

Table 2 Summary of general evaluation

Section	Characteristic	Prevalence in evidence-based medicine (EBM) tools (n=8)
Section A: Compatibility and accessibility	Platforms	6 compatible with Windows and Mac; 2 Windows only; 1 also mentioned Unix
	Simultaneous users	7 offered unlimited seats; 1 charged per seat
	Mobile tools	8 mentioned at least 2 mobile platforms
	Offers free version	2 offer a small portion of the site for free
	Customization	2 changed font size; 2 customized patient handouts; 2 created continuing medical education accounts; 1 recorded personal notes; 3 provided no customization
Section B: Content	Patient handouts	5 yes; 1 sometimes; 2 no
	Continuing education (CE)	6 offered some CE credits
	Groups supported by CEs	6 for physicians; 2 also included CEs for nurses and pharmacists
	Practice guidelines	3 always included; 5 sometimes
	Help screens	3 helpful; 4 somewhat helpful; 1 had no help screens
Section C: Search options and results	Browsing	5 offered browsing of some type; 3 did not
	Search for pharmaceutical	7 offered searched
	Advanced	4 provided advanced searching
	Navigation	2 very easy; 3 easy; 3 somewhat
	Readability	7 easy to read; 1 difficult
	Organization	4 very organized; 4 organized
	Ease of printing	2 easy; 6 somewhat easy
	Print outputs	All offered HTML versions only
	Other outputs	All but 1 offered email
Section D: Quality control	Authors listed	5 always, 2 sometimes, and 1 never listed
	Author process	2 described author process
	Credentials	6 listed author credentials
	Affiliations	4 listed author affiliations
	Peer reviewed	7 were peer reviewed
	Editor process	2 listed process for editing or reviewing
	Editors listed	5 listed individual editors
	Editor credentials	5 provided credentials of editors
	Update schedule	6 claimed to update in 6 months or less; 2 claimed within a year
	Biases	No conflicts of interest or biases were noted
Section E: Evidence	Standard of grading	1 used SORT [30]; 2 used GRADE [23]; 2 created own; 3 did not specify
	Clarity of levels	3 clear; 5 somewhat clear

#### RESULTS

#### Part 1: general evaluation

Table 2 summarizes the results of the general evaluation. In terms of platforms available for tools, all but two tools were compatible with PC and Mac computers. Several tools mentioned mobile availability, with DynaMed listing the most mobile platforms. Customizations for all tools were limited to changing the font size and customizing patient handouts. Subscription options were fairly consistent across tools, with only ACP PIER using a charge-per-seat model, while others had switched to unlimited seat access. All evaluated tools included some practice guidelines in their summaries. Six offered some continuing education credits, mostly to physicians. Little variation was seen in search options and presentation of results across tools. However, one obvious difference noted in the search for pharmaceuticals was that some tools offered additional options, such as pill identification, indications, and counter indications.

The quality control of the evidence in the resources was of particular interest to investigators. Most tools listed the authors of individual summaries. DynaMed and UpToDate specified the process to become an author. Most of the tools provided the authors' credentials and affiliations. Two resources, DynaMed and Essential Evidence Plus, explained the process to become an editor, and five of the resources (BMJ Point of Care, DynaMed, Epocrates, First Consult, and UpToDate) listed the editors' names and credentials. Six of the tools claimed to update their summaries in six months or less. The standard of grading was described in five of the tools: One used Strength of Recommendation Taxonomy (SORT) [25]; two used Grading of Recommendations Assessment, Development and Evaluation (GRADE) [23]; and two created their own grading systems. Three of the tools did not specify a grading process or standard.

#### Part 2: clinical summaries evaluation

Table 3 summarizes the results of searching for 10 specific diagnoses treatment summaries in each resource with the exception of BMJ Point of Care, which provides the disease content for Epocrates. Rather than evaluating the same content twice, the investigators chose to search the content solely in Epocrates. A total of 70 treatment summaries were retrieved, 10 for each of the 7 tools. Evidence supporting possible treatments was often summarized in narrative form (average 8.1 times per tool), but not often in table form (average 2.3 times per tool). Transparency in authorship varied, with 5 out of 7 listing individual authors, 4 providing credentials, and 4 providing affiliations. One bias was noted while reviewing the affiliations, with a regional director for Merck listed as an author for ACP PIER. The average number of authors listed in a summary was 1.6 for those 5 tools that listed authors. Fifty-two of the 70 retrieved searches (74%) graded the evidence. DynaMed had the most up-to-date summaries (updated on average within 19 days), while First Consult had

Table 3 Evidence provided in	searches f	or treatme	nt of 10 co	mmon diagr	loses in eacl	h of 7 EBM tools	6		
				Α	uthors			Grading/update	es
	# of summa	aries (n=10)	Individual authors	Mean number of	Authors credentials	Author affiliations	# of summaries with graded	mean # of davs between	Update schedule claimed by
EBM tool	Narrative	Table	listed	authors	listed	listed and bias	evidence (n=10)	updates	product
ACP PIER	9	0	Yes	1.8	Yes	Yes*	10	199	Less than 6 months
Clin-eguide	9	5	No	n/a	n/a	n/a	7	245	Less than 6 months
DynaMed	6	1	No	n/a	n/a	n/a	7	19	6 months to 1 year
Epocrates	7	9	Yes	1.7	Yes	Yes	8	371	Less than 6 months
Essential Evidence Plus	8	1	Yes	1.8	Some	Some	6	278	Less than 6 months
First Consult	9	0	Yes	39	Yes	None	9	449	Less than 6 months

Yes

2.0

1.6

Yes

8 1 \* Regional medical director for Merck listed as an author.

9

the least up to date (updated on average within 449 days). Six tools claimed to update summaries within 6 months or less. For the 10 topics searched, however, only DynaMed met this claim.

0

2.3

#### DISCUSSION

UpToDate

Average

#### **Principal findings**

While some articles in the literature review favored one EBM tool, the major finding of this review was that current EBM POC tools were quite similar relative to their content coverage and search options. Reporting of quality control measures was where researchers noted the greatest difference between tools. Level of transparency of authorship, evidence selection process, and grading standards varied greatly between tools. Transparency in processes is vital to evaluating reliability and completeness to determine possible biases in the evidence. This need for transparency in evidence summaries has been expressed by those developing standards for practice guidelines and systematic reviews [23, 26].

#### **Evaluation of rubrics**

Two rubrics for the review were created: one to evaluate tool characteristics and another to assess the evidence presented in treatment summaries. The Zoho Creator software provided a user friendly and efficient way to develop and complete the rubrics. Overall, the general evaluation rubric was easy to develop due to the resource assessment skill sets common to most librarians. The elements in sections A to C were quickly agreed upon and the information for them found. However, elements in sections D and E were much more difficult to define and locate. The reviewers needed to contact customer service providers in some cases to receive clarification on grading standards. The second rubric, clinical summaries evaluation, was more challenging to create. Determining the clinical topics to search required some research and discussion. Some measures included in the rubric were ultimately omitted from the final assessment. For instance, because the number of clicks

was difficult to standardize between screeners, the number of clicks to find the treatment section and to find the evidence grading were omitted from the findings.

201

251.7

5

7.4

6 months-1 year

#### Strengths and weaknesses

Yes

Limitations of the study lie in what was absent from the review. Understanding the factors affecting SCAMeL institutions' selection of EBM POC tools could have been valuable. Factors such as product cost, budget, and user input might have impacted the selection process more than attributes of the tools themselves. Another omission from this review was free EBM tools. If assessed, these tools might have changed the findings of the study. Lastly, one element that should have been included in the tool evaluation was an analysis of potential bias based on editor affiliations. Only the affiliations of the evidence summary authors were considered.

The span of time, eighteen months, covered by this review was both a strength and a limitation. Researchers had an opportunity to observe how quickly EBM POC tools can change and to see trends in the SCAMeL collections and in tool development. Due to product changes during this time frame, both the literature review and information about the tools were updated multiple times.

Strengths of this review included systematic evaluation of tools' characteristics and quality control processes, as well as in-depth assessment of grading systems. By focusing on those elements that affect the reliability and value of the synthesized evidence, the reviewers highlighted the need for EBM POC tools to be more transparent.

#### Recommendations

The rubrics developed in this study can be used by other librarians to evaluate EBM tools. Because the rubrics themselves do not weigh one element over another, the importance of each element could be adapted according to the priorities and needs of specific libraries. As products change often, these evaluations need to be conducted on a regular basis, to discover the similarities and differences in tools and to make more informed subscription decisions. For example, in this case, the reviewers' recommendation to the library director was to drop at least one of the currently subscribed tools due to redundancy.

#### Future developments

One further area of investigation is to determine how clinicians and students perceive the grading of evidence. How important is it to EBM POC users that the evidence is graded, and how well do they understand the grading scales? If the meaning of the grade is unclear, users may be hesitant to apply the recommendations. What are the mental processes by which users apply the evidence found in EBM POC tools? Focus groups may be helpful to determine users' preferences of tools and impressions of evidence grading.

#### CONCLUSIONS

EBM POC tools remain an important resource for health care practitioners, librarians, and patients. Due to the dynamic nature of these tools, evaluation needs to be continuous. Many tools have similar audiences and content. The grading of the evidence, however, varies among resources and requires standards for evaluation. Tool creators need to more openly communicate guidelines for authorship, reviewers, methods of evidence collection, and grading systems. Medical librarians play an important role in evaluating the quality of POC tools and can develop assessment tools, such as rubrics, to aid in this evaluation.

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#### **AUTHORS' AFFILIATIONS**

Suzanne Shurtz, MLIS, AHIP (corresponding author), sshurtz@library.tamu.edu, Instructional Service Librarian, Medical Sciences Library, Texas A&M University, 4462 TAMU College Station, TX 77843-4462; Margaret J. Foster, MS, MPH, margaretfoster@library.tamu.edu, Social Sciences and Education Librarian, Sterling C. Evans Library, Texas A&M University, 5000 TAMU College Station, TX 77843-5000

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## My contribution to article:

- developed, updated, and managed all search results
- screened portion of articles
- assisted in writing methods
- assisted in editing entire chapter

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# Chapter 17 A Systematic Review of Retirement as a Risk Factor for Mortality

Matthew J. Shim, David Gimeno, Sandi L. Pruitt, Christopher B. McLeod, Margaret J. Foster, and Benjamin C. Amick III

## Introduction

Aging, health, and retirement are closely related in modern industrialized societies such as the United States. Starting in the 1800s and continuing through the early 1900s, old age pensions, fixed age retirement, and government sponsored pension plans were introduced by Germany, France and England, which meant that persons no longer had to work until they died or to rely on friends and family for support in their old age (Streib and Schneider 1971). The aging population in the US is dramatically increasing. The U.S. Census Bureau (2006) estimated that 78.2 million people in the baby boomer generation, those born between 1946 and 1964, were alive, a total that represented 30% of the U.S. population. In 2006, the oldest of this

M.J. Shim, Ph.D., M.P.H., M.A. (🖂)

D. Gimeno, Ph.D. Division of Epidemiology, Human Genetics & Environmental Sciences,

The University of Texas Health Sciences Center at Houston-School of Public Health, San Antonio Regional Campus, San Antonio, TX, USA

Institute for Work & Health, Toronto, ON, Canada email: david.gimeno@uth.tmc.edu

S.L. Pruitt, Ph.D., M.P.H. Department of Clinical Sciences, The University of Texas Southwestern Medical Centere, Dallas, TX, USA email: sandi.pruitt@utsouthwestern.edu

C.B. McLeod, Ph.D. School of Population and Public Health, The University of British Columbia, Vancouver, BC, Canada email: chris.mcleod@ubc.ca

<sup>15</sup>th Aerospace Medicine Squadron, Public Health Flight (15 AMDS/SGPM), Joint Base Pearl Harbor-Hickam, HI, USA e-mail: matthew.shim@us.af.mil

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generation turned 60 years old. The Census also estimates that persons age 65 and older will total about 13% of the U.S. population by 2010, and 19% by 2025 (Campbell 1996). These changes could overwhelm the public and private social security and health care insurance and delivery systems (Gebbie et al. 2005).

Retirement is a change in employment status, from working to non-working, that is usually expected to coincide with a predetermined age (e.g., 65), predetermined length of service (e.g., 20 or 30 years), or health deterioration (e.g., physical disability) (Streib and Schneider 1971). Three basic types of retirement can be defined: (1) on-time retirement, when a worker stops working on or after a predetermined age or length of service; (2) health-related retirement, when a worker stops working either on, after, or prior to a predetermined age or length of service because of ill-health and/ or disability; and, (3) early retirement, when a worker stops working prior to a predetermined age or length of service where ill-health and disability are not factors.

The relationship between retirement and health is not well defined (Kasl and Jones 2000). There is no consensus on the definition or measurement of retirement as an exposure or risk factor for mortality. Current social research tends to focus on the association between unemployment, job loss, and/or job transition and health outcomes (Breeze et al. 2001; Gallo et al. 2004; Henriksson et al. 2003; Kasl 1996; vanAmelsvoort et al. 2003) with only a cursory mention of retirement. When retirement is the exposure of interest, the focus has been on the relationship between retirement and mortality without discussing retirement types (Gallo et al. 2004; Marmot and Shipley 1996; Moen 1996).

Two conflicting health beliefs are associated with retirement: (1) retire early and live longer and (2) retire and die sooner (Anderson 1985; Padfield 1996). To date, no research has provided any definitive evidence to support or refute either belief (Anderson 1985; Ekerdt et al. 1983; Haynes et al. 1978; Herzog et al. 1991; Marmot and Shipley 1996; Mein et al. 2003; Ohrui et al. 2004; Quaade et al. 2002; Rosenkoetter and Garris 1998; Ross and Drentea 1998; Schnurr et al. 2005; Sorlie and Rogot 1990).

The role of retirement and its effect on health and mortality is dependent on how retirement is defined and measured. In contrast to the ambiguous results of the relationship between early and on-time retirement as risk factors for illness, both ill-health and disability appear to be strong risk factors for retirement (Krause et al. 1997; Pransky et al. 2005; Siebert et al. 2001). Without considering health-related retirement, it is possible to mistakenly assume that retirement is the risk factor. This systematic review addresses the following research question: "Does the research literature support the view that type of retirement is a risk factor for mortality?"

B.C. Amick III, Ph.D.

M.J. Foster, M.S.

Client Services, Texas A&M University Libraries, College Station, TX, USA email: margaretfoster@library.tamu.edu

School of Public Health Southwest Center for Occupational and Environmental Health, The University of Texas Health Sciences Center at Houston, Houston, TX, USA

Institute for Work & Health, Toronto, ON, Canada email: benjamin.c.amick@uth.tmc.edu

## Methods

Research related to retirement and mortality was systematically reviewed adapting a Cochrane review protocol (Higgins and Green 2006) and following Slavin's (1995) 'best evidence synthesis' approach and the systematic review protocols of the Institute for Work and Health (IWH) (Brewer et al. 2006). The review team included six researchers from the United States, Canada, and the United Kingdom. Web-based SRS, version 4.0 software (Mobius Analytics 2009) was used for article organization, review, data extraction, and tracking. Team members did not review or extract data from articles they had consulted on, authored, or co-authored.

## Eligibility Criteria

Studies were included if they: (1) were written in English; (2) were published or in-press in a peer-reviewed journal; (3) reported data from a longitudinal primary study (i.e., not a review or editorial); (4) measured retirement as an independent variable, main effect, co-variable, or confounder; (5) did not combine retirement with unemployment status or "other" employment categorizations; and (6) measured either all-cause or cause-specific mortality as an outcome.

## Literature Search

As of December 2008, no systematic reviews of this literature were identified. A preliminary literature review identified search terms covering three broad areas: (1) retirement, (2) mortality/survival, and (3) epidemiologic study methods. Search and exclusion terms were adapted for six electronic databases that index social, economic, and health related journals published through 2008. The databases, search platforms, and beginning coverage dates included: Academic Search Premier (via EBSCO) 1887, CINAHL (via OVID and EBSCO) 1982, EconLit (via OCLC FirstSearch) 1969, MEDLINE (via OVID) 1950, PsycInfo (via OVID) 1887, and Sociological Abstracts (via CSA) 1967. For all articles eligible for data extraction, we used the Scopus<sup>™</sup> web-based database (Elsevier 2007) to identify any additional articles 'cited by' or 'citing' the article that may have been overlooked or missed. Content area experts were also surveyed for potentially eligible articles. The complete search strategy is available from the first author.

## Selection for Relevance

First, title and abstract screening (TAS) was conducted to quickly identify and exclude non-relevant studies. Second, full text screening (FTS) was completed for the

	Quality assessment question	Weights
1.	Is retirement (or type of retirement) grouped together with non-retirement related categories?	Yes=exclude
2.	The primary research question/objective is clearly stated.	Yes = 1
3.	Is the primary research question/objective related to the systematic review study question thattype of retirement is a risk factor for mortality?	Yes=2
4.	Were study sample methods (including sample size, inclusion/exclusion criteria and power) adequately described?	Yes=2
5.	Was non-response to participation in the study addressed and/or adequately described?	Yes = 1
6.	Is retirement the primary exposure or main independent variable in the study?	Yes=2
7.	Is retirement a main effect, co-variable, confounder or interaction in the study?	Yes = 1
8.	Is mortality a measured outcome in the study? If cause-specific is selected, enter the cause(s) in the text box.	Yes = 1
9.	Did the study measure retirement (exposure) before mortality (outcome)?	Yes=3
10.	Is the comparison group (or reference group) appropriate? (i.e. does it make sense?)	Yes = 1
11.	Did the study make comparisons between similarly employed/retired populations?	Yes = 1
12.	Were covariates/potential confounders for mortality (e.g. gender, age, pre-existing health conditions) appropriately used to adjust or stratify the analysis and/or adequately described?	Yes=2
13.	Was loss to follow-up appropriately addressed and/or adequately described in the study?	Yes = 1
14.	Were statistical methods appropriately used and/or adequately described to examine the retirement/mortality relationship?	Yes=3

Table 17.1 Quality assessment questions, exclusionary response and weights

remaining studies. One review team member evaluated each article at each step. To reduce agreement bias, reviewers were assigned different articles for TAS and FTS.

To address potential bias due to a single reviewer conducting the TAS, an independent reviewer completed a quality control check by reviewing titles and abstracts of 5% (n=39) of the 758 excluded articles and 5% (n=11) of the 210 articles forwarded to FTS. Concordance was high and the team considered the quality of the TAS process acceptable.

## Quality Assessment and Ranking

After FTS, articles were forwarded to Quality Assessment (QA) and Ranking (QR) review. Prior to QA, the team developed 14 criteria to assess methodological quality and statistical validity. Following Brewer et al. (2006), the team decided on a three-point weighting scale ranging from "important" (1 point) to "moderately important" (2 points) to "highly important" (3 points) (Table 17.1). A non-weighted exclusionary

question (Table 17.1, Item 1) addressed the definition of retirement in each article. Grouping retirement with unemployment status or "other" employment categories was inadequate to assess the study question. Each article was independently reviewed by two team members who were required to reach consensus.

The QR for each article was based on a weighted sum of 13 quality criteria (highest score=21). This QR denominator was reduced by one for each "non applicable" answer. Each article received a QR by dividing the weighted score by the QR denominator and multiplying by 100. Articles were grouped into three categories (Appendix A) determined by consensus following the review methodology literature (Higgins and Green 2006; Slavin 1995): (1) high (90–100%), (2) medium-high (75–89%) and (3) medium-low (£74%).

## Data Extraction

To retain only those studies with adequate validity to answer the research question, studies with medium-low quality (MLQ) rankings (£74%) were excluded. Differences between medium-low (MLQ) and medium-high (MHQ) QR studies (Appendix A) varied. The main reasons for lower rankings were: (1) inappropriate use and/or description of statistical methods (MLQ=66%, 19/29 vs. MHQ=0%, 0/9); and (2) lack of statistical adjustment for potential confounders (MLQ=62% 21/29 vs. MHQ=44% 4/9). Also, 44.8% (13/29) of the MLQ studies, but only 22% (2/9) of the MHQ studies, did not compare similarly employed and/or retired populations. Thus, many MLQ studies did not address the healthy worker effect, when lower mortality is observed in employed populations when compared to the general population.

Full data extraction and evidence synthesis was completed on all studies in the "high" (n=4) and "medium-high" (n=9) categories using standardized data extraction questions (Appendix B). Two reviewers performed independent data extraction on each article. The data collected were used to build summary tables and to form the 'best evidence' synthesis basis for the team's conclusions. When studies presented multiple statistical analysis models adjusting for different confounders, data extraction is presented for the fully adjusted models only.

## Evidence Synthesis

The studies reviewed were heterogeneous and differed by country, study designs, exposure definitions, mortality outcomes, and statistical methods used. This required a research synthesis approach using Slavin's (1995) 'best evidence synthesis' methodology. Based on quality ranking, quantity of evidence, and consistency among articles, we used the criteria in Table 17.5 to classify evidence as strong, sufficient, mixed, or insufficient (Brewer et al. 2006; Briss et al. 2000; Slavin 1995).



Fig. 17.1 Flowchart of systematic review process

## Results

We identified a total of 1,126 articles (Fig. 17.1); 1,084 were excluded during TAS (n=897), FTS (n=149) and QA (n=38). Out of the 42 articles ranked, 29 articles were excluded based on their medium-low quality rankings. Thus, evidence synthesis was conducted on the remaining 13 articles (Table 17.2). These studies were published between 1976 and 2008 and covered the time period of 1953–2006. Cohort sample sizes ranged from 1,235 (Olsen and Jeune 1980) to 170,749 (Munch and Svarer 2005); 54% of the studies had more than 12,000 individuals.

Table 17.3 shows the main study characteristics and illustrates the heterogeneous nature of the studies. The studies included mostly Caucasian men in both white- and blue-collar occupations, and spanned over Asia/Middle-East, Europe, and North America. Study designs were either prospective or retrospective cohort and employed and reported multiple statistical techniques: standardized mortality ratios, survival analysis with hazard ratios (HRs), or logistic regression with relative risks (RRs). All-cause mortality was measured in all studies and six studies provided additional cause-specific mortality. Study results are presented in Table 17.4 and evidence synthesis in Table 17.5.

				Time period (years)		
				Study location	Sample size	Employment classifications
		Author (year)	Primary research question/objective	Study design	(% female)	definitions (see notes below)
		Jeune (1982)	Estimate the survival prognosis of semi-skilled disability pensioners	1975–1978 Denmark Retrospective cohort	4,439 (0%)	<ol> <li>High disability</li> <li>Intermediate disability</li> <li>Low disability</li> <li>Employed</li> </ol>
ity ranking	High	Litwin (2007)	Address the association between early retirement and seven-year all-cause mortality in a sample of 2,374 older Jewish Israelis	1997–2004 Israel Prospective cohort	2,374 (39.2%)	<ol> <li>Still at work – not retired</li> <li>Left work young – before age 50</li> <li>Early retirement – women age 50–59; men age 60–64</li> <li>On time retirement – women age 60+; men age 65+</li> <li>Missing – failed to date exit from work</li> </ol>
Qual		Olsen (1980)	Compare mortality rates of male pensioners to a matched reference group of employed workers from the same union	1969–1979 Denmark Retrospective cohort	1,235 (0%)	<ol> <li>Disability/early old-age pension – received between 10/1/69 – 9/30/73</li> <li>Active worker – present at work 4/1/71 and alive on 9/30/73</li> </ol>
		Tsai (2005)	Assess whether there is any survival advantage of early retirement among employees of the petrochemical industry in the United States who retired at 55, 60, and 65	1973–2003 United States Prospective cohort	26,781 (11%)	<ol> <li>Retired at 55</li> <li>Retired at 60</li> <li>Retired at 65</li> <li>Working at 55</li> <li>Working at 60</li> </ol>

## Table 17.2 Study descriptions

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Table	17.2	(continue)	d)
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			Time period (years)		
			Study location	Sample size	Employment classifications –
	Author (year)	Primary research question/objective	Study design	(% female)	definitions (see notes below)
	Amick (2002)	A person's lifetime exposure to psychosocial work conditions was modeled over the working life course, and its relationship to mortality was assessed in a representative sample of U.S. workers	1968–1992 United States Prospective cohort	25,413 (55.1%)	<ol> <li>Retired – self-report for the year preceding the current interview year</li> <li>Working – self-report of working<sup>a</sup> in the past year</li> <li>Unemployed – self-reported unemployment status</li> </ol>
Medium-high	Arrich (2005)	Investigate the association between socioeconomic status and mortality of patients with acute ischemic stroke and transient ischemic attack	1998–2002 Austria Prospective cohort	3,607 -47%	<ol> <li>Currently unemployed at the time of the event</li> <li>Working in own household at the time of the event</li> <li>Retired early before normal retirement age</li> <li>Retired women = age 60; men = age 65</li> </ol>
	Bamia (2008)	Determine whether early retirement is a risk factor for all-cause and cause-specific mortality in apparently healthy retirees	1994–2006 Greece Prospective cohort	16,827 (47%)	<ol> <li>Employed – at enrollment in the study</li> <li>Early retired – retired at enroll- ment in the study and before age 65</li> </ol>
	Collins (1976)	Describe what would occur in a large scale historical study of steelworkers if retirees only were used for mortality findings instead of all workers in the industry	1953–1966 United States Prospective cohort	58,828 (0%)	<ol> <li>Retirees over age 65<sup>b</sup></li> <li>Nonretirees over age 65 who left plant before 65<sup>c</sup></li> </ol>

	Morris (1994)	Assess the effect of unemployment and early retirement on mortality in a group of middle aged British men using measures of health and health related behavior made before the loss of employment	1979–1990 United Kingdom Prospective cohort	6,191 (0%)	<ol> <li>Employed full time – continuously employed during follow-up</li> <li>Retired early for reasons other than illness</li> </ol>
	Munch (2005)	Describe the association between socio-economic status and mortality at the individual level	1992–1997 Denmark Prospective cohort	170,749 (50.5%)	<ol> <li>Early retirement – at age 60</li> <li>Retired – through all the years 1988, 1992–1997</li> </ol>
Medium-high	Pensola (2004)	Quantify the contribution of living conditions in the parental home and life-events and trajectories in youth to adult social class differences in mortality from various causes of death	1970–1998 Finland Prospective cohort	186,408 (0%)	<ol> <li>Steady employment – up to end of 1990, with the exception of national service</li> <li>Short unemployment – &lt;6 months during 1986–1990 or one spell at the time of the census</li> <li>Long unemployment – ≥6 months during 1986–1990, or repeated at the time of ≥2 censuses</li> <li>Fragmental employment - occa- sional exclusion<sup>d</sup> from labor force</li> </ol>
	Wagner (2006)	Establish the life expectancy and standardized mortality ratios of firefighters of the Fire Department of the City of Hamburg, Germany compared to Hamburg and the national reference population with special emphasis on disentangling the suspected strong healthy worker effect in this cohort from the effects of potential chemical exposures and heavy work load	Germany Retrospective cohort	4,557 (0%)	<ol> <li>Dead</li> <li>Active firefighter- full-time professional employees</li> <li>Left by own request – left the department for instance to move to a different city</li> <li>Early retirement - left for health reasons/disability</li> <li>Regular retirement</li> </ol>

(continued)

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				Time period (years) Sudy location	Sample size	Employment classifications -
		Author (year)	Primary research question/objective	Study design	(% temale)	definitions (see notes below)
Quality ranking	Medium-high	Wen (1984)	Present the mortality experience of active, terminated and retired groups from a large refinery cohort	1937–1978 United States Prospective cohort	12,526 (0%)	<ol> <li>Active – employed during the study</li> <li>Terminated – left employment with no further financial linkage to the company</li> <li>Regular retired – at or after age 65</li> <li>Early retired-regular – at 55°; at 50°; before 65<sup>g</sup> with length-of- service criteria</li> <li>Early retired-disability – 15 years of service + medical disability (initiated in 1957)</li> </ol>

Notes

<sup>a</sup>Full time, part-time, or temporary; annual working hours >500 h or individual labor income was >\$1,000 Management = age  $\geq 65$ ; union = age  $\geq 65$  and minimum 15 years at the company

<sup>e</sup>Left plant after usual retirement age, still employed, died while employed

Other than unemployment, retirement, or education

'Between 1944–1963

<sup>1</sup>Between 1963–1974

<sup>g</sup>1975-present

## Table 17.3 Study characteristics

	Qu	ality	ranl	cing									
	Hig	gh			Me	diun	n-hig	h					
Author, year	Jeune (1982)	Litwin (2007)	Olsen (1980)	Tsai (2005)	Amick (2002)	Arrich (2005)	Bamia (2008)	Collins (1976)	Morris (1994)	Munch (2005)	Pensola (2004)	Wagner (2006)	Wen (1984)
Study location													
Europe	Х		Х			Х	Х		Х	Х	Х	Х	
Middle-East		Х											
United States				Х	Х			Х					Х
Study design													
Prospective cohort		Х		Х	Х	Х	Х	Х	Х	Х	Х		Х
Retrospective cohort	Х		Х									Х	
Study demographics													
Males only	Х		Х					Х	Х		Х	Х	Х
Males and females		Х		Х	Х	Х	Х			Х			
Caucasian only	*	Х	*	*		*	Х		*	*	×	*	Х
Multiple ethnicities					$\mathbf{X}^{\mathrm{a}}$			$\mathbf{X}^{\mathrm{b}}$					
Retirement data source													
Census data											Х		
Employee/retiree records				Х				Х					Х
Municipal records	Х		Х							Х		Х	
Self-report		Х			Х	Х	Х		Х				
Analysis type													
Logistic Regression					Х						Х		
Standardized Mortality Ratio (SMR)								Х			Х		Х
Survival Analysis	Х	Х	Х	Х		Х	Х		Х	Х		Х	
Mortality outcome(s)													
All-cause mortality	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
Cause-specific mortality							Х	Х	Х	Х	Х		Х
Mortality outcome measure													
Hazard ratio		Х		Х	Х	Х	Х			Х			
Relative Risk	Х		Х						Х		Х	Х	
Standardized Mortality Ratio (SMR)								Х				Х	Х
Occupational category													
White-collar				Х					Х		Х		
Blue-collar	Х			Х		Х		Х	Х		Х	Х	
White/Blue-collar Combined		Х	Х		Х		Х			Х			Х

Note:

\*Race/ethnicity of study population not explicitly stated \*Ethnicities included white and black

<sup>b</sup>Ethnicities included white and non-white

	Author (Year)	Exposure(E)/Referent(R) groups	Number of events
	Jeune (1982)	E1. All disability pensioners $(n = 1,353)$	E1. 234 deaths
		R1. Employed ( <i>n</i> = 1,353)	R1.41 deaths
	Litwin (2007)	E1a. Still at work $(n = 486)$ E1b. Left work young $(n = 164)$ E1c. Early retirement $(n = 540)$ E1d. Missing $(n = 219)$ R1. On time retirement $(n = 965)$	NP
High			
	Olsen (1980)	E1. Disability pensioners ( $n = 64$ ) R1. Active workers ( $n = 121$ )	E1. 13 deaths R1. 4 deaths
	Tsai (2005)	E1. Retired at 55 ( <i>n</i> = 839) E2. Retired at 60 ( <i>n</i> = 1,929) R1-2. Retired at 65 ( <i>n</i> = 900)	E1. 173 deaths E2. 581 deaths R1. 462 deaths

 Table 17.4
 Study results and interpretation by quality ranking, author and exposure/referent groups

Measure of association; 95% CI; p value	Statistical Adjustment for Covariables/Confounders	Interpretation
E1. Relative death rate = 1.85; 95% CI NP R1. Relative death rate = 0.28; 95%	Age	Disability pensioners have 6.8 times the risk of dying than those currently employed.
$\frac{RR (Crowley method) = 6.8;}{p < 0.05^{a,b}}$		YES – Health-related retirement is a risk factor for mortality
E1a. HR = 0.65; 95% CI 0.48-0.88; p < 0.01 E1b. HR = 0.75; 95% CI 0.48-1.19 E1c. HR = 0.93; 95% CI 0.74-1.16 E1d. HR = 1.17; 95% CI 0.91-1.51	Reason for retirement Gender Age Income Education Diagnosed illness	<ul> <li>Those currently employed are 35% less likely to die than those who retire on-time. Although it appears that leaving work while young or retiring early offers some decreased risk of dying, the 95% confidence intervals which include 1.0 do not support the association.</li> <li>YES – On-time retirement is a risk factor for mortality</li> <li>NO – Early retirement is not a risk factor for mortality</li> </ul>
<u>RR = 7.2; p&lt;0.001</u>	NP	Disability pensioners have 7.2 times the risk of dying than active workers. YES-Health-related retirement is a risk factor for mortality
E1. <u>HR = 1.37; 95% CI 1.09-1.73</u> E2. HR = 1.06; 95% CI 0.92-1.22	Gender SES Calendar year of entry to study	<ul> <li>Employees that retired at age 55 had a 37% increase in mortality when compared to employees that retired at age 65.</li> <li>YES – Early retirement is a risk factor for mortality</li> </ul>

(continued)

Table 17.4 (continued)

	Author (Year)	Number of events	
	Amick (2002)	5-year lag <u>(Karasek job strain)</u> El a. Retired ( <i>n</i> = 7,591) El b. Age × retired ( <i>n</i> = 7,591)	<u>5-year lag</u> 10,008 retirements 571 deaths
		10-year lag <u>(Karasek Job Strain)</u> E2a. Retired ( <i>n</i> = 7,746) E2b. Age × retired ( <i>n</i> = 7,746)	<u>10-year lag</u> 10,959 retirements 726 deaths
		5-year lag <u>(Job strain quotient)</u> E3a. Retired E3b. Age × retired	
		10-year lag <u>(Job strain quotient)</u> E4a. retired E4b. Age × retired R1-4. Not retired	
Quality ranking Medium-high			
	Arrich, (2005)	E1a. Early retired $(n = 328)$ E1b. Retired $(n = 1,478)$ R1. Employed $(n = 512)$	E1a. 57 deaths E1b. 351 deaths R1. 18 deaths

Measure of association; 95% CI; p value	Statistical Adjustment for Covariables/Confounders	Interpretation
$5-year lag (Karasek job strain)E1a. HR = 5.92; 95% CI 3.40-10.30;p < 0.05^{a,b}E1b. HR = 0.92; 95% CI 0.90-0.94;p < 0.0510-year lag (Karasek job strain)E2a. HR = 2.85; 95% CI 1.56-5.11;p < 0.05E2b. HR = 0.95; 95% CI (0.93-0.97;p < 0.05E2b. HR = 5.90; 95% CI 0.93-0.97;p < 0.05E3a. HR = 5.90; 95% CI 0.90-0.94;p < 0.05E3b. HR = 0.92; 95% CI 0.90-0.94;p < 0.05I0-year lag (Job Strain Quotient)E4a. HR = 2.83; 95% CI 1.58-5.08;p < 0.05E4b. HR = 0.95; 95% CI 0.93-0.97;p < 0.05$	Psychosocial work conditions Age Black race/ethnicity Sex Study year Family income Family size Not working Age × black Age × retired Baseline disability	<ul> <li>When compared to those NOT retired, retirees were 5.9 times as likely to die in the 5 year post retirement transition period.</li> <li>When compared to those NOT retired, retirees were 2.8 times as likely to die in the 10 year post retirement transition period.</li> <li>YES – On-time retirement is a risk factor for mortality</li> </ul>
E1a. HR = 1.76; 95% CI 0.93-3.36 E1b. HR = 1.45; 95% CI 0.79-2.67	SES Age Sex Stroke severity History of stroke Ischemic heart disease Hypertension Elevated plasma lipids Diabetes Peripheral vascular disease Smoking status	<ul> <li>When compared to those employed, those that retired and retired early showed an increased risk of dying, however 95% confidence intervals for both measures included 1.0 and offer no conclusive evidence to support the association.</li> <li>NO – On-time retirement is not a risk factor for mortality</li> <li>NO – Early retirement is not a risk factor for mortality</li> </ul>

(continued)

	Author (Year)	Exposure(E)/Referent(R) groups	Number of events
	Bamia (2008)	E1. Early retired $(n = 3,874)$ R1. Employed $(n = 12,953)$	E1. 404 deaths R1. 215 deaths
e -high	Collins (1976)	E1. Retirees over 65 ( $n = 9,688$ ) E2. Nonretirees over age 65 ( $n = 391$ ) R1. Allegheny county males ( $n = NP$ )	E1. 2,637 deaths E2. 97 deaths
Medium	Morris (1994)	<ul> <li>E1. Retired early not due to illness (n = 479)</li> <li>R1. Continuously employed (n = 4,112)</li> <li>E2a. Retired early not due to illness – Manual workers</li> <li>E2b. Retired early not due to illness – Non-manual workers</li> <li>R2a. Continuously employed – Manual workers</li> <li>R2b. Continuously employed – Non-manual workers</li> </ul>	E1-2. 59 deaths R1-2. 174 deaths
	Munch ( 2005)	E1a. Early retirement-women $(n = NP)$ E1b. Retired-women $(n = NP)$ R1. Skilled-women $(n = NP)$ E1a. Early retirement-men $(n = NP)$ E1b. Retired-men $(n = NP)$ R1. Skilled-men $(n = NP)$	NP
Medium-High			

Pensola (2004)	E1. Retired on disability $(n = 4,767)$	E1. 422 deaths
	R1. Steady employed ( $n = 139,716$ )	R1. 1,493 deaths

Measure of association; 95%	Statistical Adjustment for Covariables/Confounders Interpretation					
E1. <u>HR = 1.51; 95% CI 1.16-1.98;</u> $p = 0.002^{a, b}$	Age at enrollment Education Smoking status Waist-to-hip ratio Physical activity Body mass index Total energy intake Ethanol intake	When compared to those still employed at study enrollment, early retirees (persons that were £ age 65 and already retired at study enrollment) in the study had a 51% increase in all-cause mortality.				
	Stratified by gender	YES – Early retirement is a risk factor for mortality				
E1. <u>SMR = 0.851; p &lt; 0.05</u> E2. <u>SMR = 1.769 ; p &lt; 0.05</u>	Age (men > age 65 only)	Retirees over age 65 were 15% less likely to die than their community counterparts. <b>NO – On-time retirement is not</b> a risk factor for mortality				
E1. <b>RR =1.86; 95% CI 1.34-2.59</b> E2a. <b>RR = 1.57; 95% CI 1.00-2.47</b> E2b. <b>RR = 2.51; 95% CI 1.50-4.19</b>	Age Town Social class Smoking Alcohol intake Pre-existing disease	<ul> <li>Those that retire early (not due to illness) are 86% more likely to die than those employed.</li> <li>Those that retire early (not due to illness) are 86% more likely to die than those employed.</li> <li>White collar workers (non-manual) that retire early (not due to illness) are 2.5 times as likely to die as those white collar workers who are employed.</li> <li>YES – Early retirement is a risk factor for mortality</li> </ul>				
E1a. $HR = -0.82^{\circ}(-55.96\%^{d});$ $p = 0.05^{a,b}$ E1b. $HR = -0.01^{\circ}(-0.995\%^{d});$ p > 0.05 E2a. $HR = -0.22^{\circ}(-19.75\%^{d});$ p = 0.05 E2b. $HR = 0.22^{\circ}(24.61\%^{d});$ p = 0.05	City Education Skill level Sector Homeownership	<ul> <li>When compared to female skilled workers, women that retire early have a 56% decrease in mortality rate.</li> <li>When compared to male skilled workers, men that retire early have about a 20% decrease in mortality rate.</li> <li>When compared to male skilled workers, men that are retired have about a 25% increase in mortality rate.</li> <li>YES – On-time retirement is a risk factor for mortality (men only)</li> <li>NO – Early retirement is not a risk factor for mortality</li> </ul>				
<u>RR = 4.72; p &lt; 0.05</u>	Age Social class Parental class Family type Number of siblings Language Region Education Marital path Early parenthood Employment path	<ul> <li>Disability retirees have 4.7 times the risk of dying than those steadily employed.</li> <li>YES – Health-related retirement is a risk factor for mortality</li> </ul>				

Author (Year)	Exposure(E)/Referent(R) groups	Number of events
 Wagner (2006)	E1a. Early retirement-disability $(n = 469)$	E1b. 131 deaths
(14Eiler (2000)	E1b. Regular retirement $(n = 1,419)$	Elc. 644 deaths
	R1. German population $(n = NP)$	E2. NP
	E2. Early retirees-disabled $(n = NP)$	R2. NP
	R2. All other retirees $(n = NP)$	

#### Table 17.4 (continued)

	Wen, 1984	E1a. Active $(n = 12,526)$	E1a. 855 deaths
5		E1b. Terminated $(n = 6, 199)$	E1b. 1,306 deaths
Hig		E1c. Retired $(n = 2,837)$	E1c. 1,280 deaths
Ē		E2a. Retired-regular $(n = 1,053)$	E2a. 246 deaths
liu		E2b. Retired-early $(n = 1,784)$	E2b. 485 deaths
Чес		R1-2. White males in the US by cause	
~		of death $(n = NP)$	

#### Note:

Quality Ranking

<sup>a</sup>Meaningful measures of association and interpretations are highlighted in **bold** <sup>b</sup>statistically significant effects are <u>underlined</u> <sup>c</sup>Hazard rate coefficient <sup>d</sup>% change =  $100 \times (\exp(\beta)-1)$ Abbreviations *NP* not provided, *HR* hazard ratio, *RR* relative risk, *SMR* standardized mortality ratio

Measure of association; 95%	Statistical Adjustment for	
CI; p value	Covariables/Confounders	Interpretation
E1a. SMR = $1.35$ ; 95% CI 1.13 - $1.60^{\mu, b}$ E1b. SMR = $0.79$ ; 95% CI $0.73 - 0.85$ E2. <u>RR = <math>1.71</math>; 95%</u> <u>CI 1.18 - 2.50</u>	Age-specific SMR Rank group Age at employment Year of employment Duration of employment	Firefighters that retired early on disability were 1.7 times more likely to die than all other firefighter retirees. YES – Health-related retirement is a risk factor for mortality
E1a. SMR = 0.68; 95% CI 0.64 – 0.73; p <.01 E1b. SMR = 1.04; 95% CI 0.99 – 1.10 E1c. <u>SMR = 0.89; 95% CI 0.84 –</u> 0.94; p <.01 E2a. <u>SMR = 0.87; 95% CI 0.76 –</u> 0.98; p <.05 E2b. <u>SMR = 0.89; 95% CI 0.82 –</u> 0.98; p <.05	Cause-specific mortality Age-specific mortality Calendar time-specific mortality	<ul> <li>Retirees were 11% less likely to die than the general US white male population</li> <li>Among those that retired, regular retirees were 13% less likely to die than the general US white male population</li> <li>Among those that retired, early retirees were 11% less likely to die than the general US white male population.</li> <li>MO – On-time retirement is not a risk factor for mortality</li> <li>NO – Early retirement is not a</li> </ul>

<b>Table 17.5</b>	Evidence	synthesis <sup>a</sup>
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			Is retirement a risk factor	Is type of retirement a	risk factor for mortality?	
Author, year			for mortality?	On-time	Early	Health-related
		Jeune (1982)	Yes			Yes
	gh	Litwin (2007)	Mixed	Yes	No	
	Ηi	Olsen and Jeune (1980)	Yes			Yes
		Tsai et al. (2005)	Yes		Yes	
ality ranking		Amick et al. (2002)	Yes	Yes		
		Arrich et al. (2005)	No	No	No	
	gh	Bamia et al. (2008)	Yes		Yes	
	Ĥ	Collins and Redmond (1976)	No	No		
ð	ġ	Morris et al. (1994)	Yes		Yes	
	edii	Munch and Svarer (2005)	Mixed	Yes	No	
	М	Pensola and Martikainen (2004)	Yes			Yes
		Wagner et al. (2006)	Yes			Yes
		Wen et al. (1984)	No	No	No	
Evidence synthesis results		synthesis results	Strong and sufficient evidence FOR	Mixed evidence (inconclusive)	Mixed evidence AGAINST	Mixed evidence FOR

Following guidelines set forth by Brewer et al. (2006), **strong** evidence in this review requires a minimum of three high quality studies to converge on the same finding; **sufficient** evidence requires convergence of seven medium-high to high studies; and **mixed** evidence requires a minimum of three medium-high to high studies

Given our primary research question, "Does the research literature support the view that type of retirement is a risk factor for mortality?", we first examined the general question about retirement as a mortality risk factor and then summarized evidence based on three specific types of retirement: (1) on-time (regular) retirement, (2) early retirement (not health-related), and (3) health-related retirement.

Considering *all types of retirement combined*, three high quality studies (Jeune 1982; Olsen and Jeune 1980; Tsai et al. 2005) and five medium-high quality studies (Amick et al. 2002; Bamia et al. 2008; Morris et al. 1994; Pensola and Martikainen 2004; Wagner et al. 2006) found specified categories of retirees with higher risk when compared to either current employees or other retirees. Two studies, one high quality study (Litwin 2007) and one medium-high quality (Munch and Svarer 2005), found mixed evidence. Three medium-quality studies (Arrich et al. 2005; Collins and Redmond 1976; Wen et al. 1984) found no increased risk. *These results suggest both strong and sufficient evidence that retirement (all types combined) is a risk factor for mortality*.

## **On-Time Retirement**

One high quality study (Litwin 2007) found on-time retirement to be associated with an increased risk of dying when compared to current employees. Mediumhigh quality studies found higher mortality risk among retired men and women, both, when compared to non-retired workers (Amick et al. 2002), higher risk when compared to non-retired workers only among men (Munch and Svarer 2005), lower risk when compared to the general population (Collins and Redmond 1976; Wen et al. 1984), and no evidence of association when compared to those still employed (Arrich et al. 2005). These results suggest a mixed—and inconclusive—level of evidence neither for nor against on-time retirement as a risk factor for mortality.

## Early Retirement

Two high quality studies showed contradictory results. When compared to on-time retirees, Tsai and colleagues (2005) found an increased mortality risk for early retirees, while Litwin (2007) found no association. The medium-high quality studies results include the following : three studies found no association: Munch and Svarer (2005) and Wen and colleagues (1984) found lower mortality risk when compared to their skilled/employed counterparts in both men and women; Arrich and colleagues (2005) found an inconclusive association; two other studies reported higher mortality risk: Bamia and colleagues (2008) found early retirees (Ll65 years-old and

already retired at study enrollment) to have higher all-cause mortality when compared to those still employed at study enrollment and, finally, Morris and colleagues (1994) found higher mortality risk among retired male white-collar workers when compared to actively employed male white-collar workers. *These results suggest a mixed level of evidence against early retirement (not health-related) as a risk factor for mortality.* 

## Health-Related Retirement

Two of the high quality studies found that disability retirement was shown to increase the risk of dying when compared to current employees (Jeune 1982; Olsen and Jeune 1980). These results were consistent with the medium-high quality studies that showed disability retirees with a higher risk than persons currently employed (Pensola and Martikainen 2004) or than other, non-disability, retirees (Wagner et al. 2006). *These results suggest a mixed level of evidence for health-related retirement as a risk factor for mortality*.

## Discussion

Our review suggests that there is strong and sufficient evidence for considering all-type retirement as a risk factor for mortality. However, there is mixed evidence for on-time retirement, early retirement (not health related), and health-related retirement as risk factors for mortality.

These dissimilar findings are not surprising since retirement is commonly used as a general descriptor of employment status—a worker who has permanently stopped working. However, this definition is too broad and includes, at a minimum, three different conceptualizations of retirement. Moreover, there is very little research in this area and the lack of standardized measures of mortality related to retirement makes it difficult to synthesize.

Not only were different outcome measures used, but different exposure groups and numerous operational definitions of retirement make results interpretation more difficult. We identified three main measures used to examine the relationship between retirement and mortality: relative risk, hazard rate, and standardized mortality ratio (SMR). The use of SMR, for instance, may not be the best risk measure since SMRs are usually adjusted for age only and mortality rates of the general population are used as the comparison group. Both Wen and colleagues (1984) and Collins and Redmond (1976) showed the protective effects of retirement on mortality, but using the general population as the comparison group of a workrelated population overlooks the healthy worker effect bias. Because there is a mixed level of evidence for health-related retirement as a risk factor for mortality, special attention is needed to avoid misclassifying health-related retirees as early or on-time retirees. Also if ill-health and disability are strong risk factors for retirement, then it is necessary to differentiate between health and non-health related reasons of early and on-time retirement. This may help clarify the relationship between early/on-time retirement and mortality by controlling for possible confounding of the ill-health and disability risk factors.

Because of the limited number of studies, we were not able to examine in detail the possible roles of gender, race, and/or culture on retirement and mortality. The studies included in the review spanned nine countries over three continents with less than 50% including women and only one study adjusting for ethnicity. Retirement may represent something different for men and women, given different labor market experiences for women compared to men, including lower rates of pay for similar jobs, greater familial obligations outside work, and lower labor force attachment. A focus on how gender affects the relationship between retirement and health should be included in future studies on the relationship between retirement and health.

Retirement is also a life transition that may be influenced by the social and institutional environment. While there were too few studies to examine the relationship between retirement and health by country, welfare state regime, or market economy orientation, these broader based structural factors may play a role in determining who is able to retire and the effect on health. For example the higher rate of healthrelated retirement in European countries compared to the United States and Canada may mean that the relationship between health-related retirement and health could vary substantially across country clusters. Further, health insurance is tied to employment for most working Americans and creates a selection pressure and pathway though which early retirement could influence health in the U.S. that is not present in other high-income countries that have universal health insurance.

Clearly a gap exists in the current research. If ill health and disability are reasons why people retire, future research will need to identify employee health histories and health status prior to retirement measurements. Health may be a confounder in the relationship between retirement and mortality and retirement may not be a risk factor for mortality when pre-retirement health is considered. More research is needed to determine if health selection into retirement (i.e. people retire based on their health) is the driver of mortality post retirement or if the retirement transition itself is the risk factor.

We consider it important to continue to develop the retirement/mortality literature with an eye toward the complexity—and reality—of the multiple circumstances surrounding the exit of workers from the workforce. Regrettably, the lack of translation resources required the exclusion of 12 non-English language articles that may or may not have been valuable to the evidence synthesis process. There is very little research on retirement as a risk factor for mortality, so development and identification of the grey literature in this area may not be yet possible. Since no comprehensive systematic reviews that addressed the retirement/mortality relationship were identified, the review team decided to focus on the broader research question using the best evidence synthesis versus comparing specific effects using meta-analysis techniques.

The current peer-reviewed literature provides very few high quality studies on the effect of retirement on mortality. Given the large and increasingly growing retired population, there is a critical need for more research in this area.

The views expressed in this paper are those of the authors and do not reflect the official policy or position of the United States Air Force, Department of Defense, or the U.S. Government.

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Criteria #	2	3	4	5	6	7	8	9	10	11	12	13	14	Ouality
Criteria weight	1	2	2	1	2	1	1	3	1	1	2	1	3	Ranking (%)
High quality ranking			*** *** *** *** *** ***											
Jeune (1982)	1	2	2	N/A	2	1	1	3	1	1	2	N/A	3	100
Litwin (2007)	1	2	2	N/A	2	1	1	3	1	1	2	N/A	3	100
Olsen and Jeune (1980)	1	2	2	N/A	2	1	1	3	1	1	2	N/A	3	100
Tsai et al. (2005)	1	2	2	N/A	2	1	1	3	1	1	2	N/A	3	100
Criteria Met	4/4	4/4	4/4	N/A	4/4	4/4	4/4	4/4	4/4	4/4	4/4	N/A	5/5	
% Criteria Met	100	100	100	N/A	100	100	100	100	100	100	100	N/A	100	
Medium-high quality ranking	-													
Bamia et al. 2008	1	2	2	N/A	2	N/A	1	3	1	1	0	1	3	89
Collins and Redmond (1976)	1	2	2	N/A	2	N/A	1	3	1	0	0	1	3	84
Amick et al. (2002)	1	0	2	1	0	1	1	3	1	1	2	1	3	81
Morris et al. (1994)	1	2	2	0	2	N/A	1	3	1	1	0	0	3	80
Pensola and Martikainen (2004)	1	0	2	N/A	0	1	1	3	1	1	2	1	3	80
Wagner et al. (2006)	1	0	2	N/A	0	1	1	3	1	1	2	1	3	80
Arrich et al. (2005)	1	0	2	N/A	0	1	1	3	1	1	2	N/A	3	79
Wen et al. (1984)	1	2	2	N/A	2	1	1	3	0	0	0	N/A	3	79
Munch and Svarer (2005)	1	0	2	1	0	1	1	3	1	1	2	0	3	76
Criteria Met	9/9	4/9	9/9	2/3	4/9	6/6	9/9	9/9	8/9	7/9	5/9	5/7	9/9	
% Criteria Met	100	44	100	67	44	100	100	100	89	78	56	71	100	

# Appendix A: Methodological Quality Assessment Ordered by Quality Ranking and Author

(continued)

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(continued)

Criteria #	2	3	4	5	6	7	8	9	10	11	12	13	14	Ouality
Criteria weight	1	2	2	1	2	1	1	3	1	1	2	1	3	Ranking (%)
Medium-low quality ranking														
Collins and Redmond (1978)	1	0	2	N/A	0	N/A	1	3	1	0	2	1	3	74
Haynes et al. (1977)	1	2	2	N/A	2	1	1	3	1	1	0	N/A	0	74
Haynes et al. (1978)	1	2	2	N/A	2	1	1	3	1	1	0	N/A	0	74
Sweeney et al. (1985)	0	2	2	N/A	0	1	1	3	0	0	2	N/A	3	74
Morris et al. (1994)	1	2	2	N/A	2	N/A	1	3	1	1	0	N/A	0	72
Boaz (1990)	1	2	0	1	0	1	1	3	1	1	0	1	3	71
Ostamo (2001)	1	0	2	1	0	1	1	3	1	1	0	1	3	71
Wolfson (1993)	1	0	2	1	0	1	1	3	1	1	0	N/A	3	70
Baker (1982)	1	2	2	N/A	2	1	1	3	1	0	0	N/A	0	68
McMahan (1955)	1	2	2	N/A	2	1	1	3	0	1	0	N/A	0	68
Wong (1985)	0	0	2	N/A	0	1	1	3	1	0	2	N/A	3	68
Herttua (2008)	1	0	2	N/A	0	1	1	0	1	1	2	N/A	3	63
May (2002)	1	0	2	1	0	0	1	3	1	1	2	1	0	62
Quaade et al. (2002)	1	2	2	0	2	N/A	1	0	1	0	0	0	3	60
Rushing (1992)	1	0	2	1	0	1	1	3	0	0	2	1	0	57
Enterline (1972)	1	0	2	N/A	2	N/A	1	3	0	1	0	N/A	0	56
Kingson (1982)	0	2	0	N/A	2	N/A	1	3	1	1	0	N/A	0	56
Gamble (2000)	0	2	2	0	2	N/A	1	3	1	0	0	0	0	55
Beck (1981)	1	0	2	N/A	2	1	0	3	1	0	0	N/A	0	53
Lidgren (2007)	1	0	2	N/A	0	1	1	0	1	1	0	N/A	3	53
Studznski (2003)	1	2	2	0	0	0	1	3	1	1	0	0	0	52
Weiland (1996)	1	0	2	1	0	1	1	3	1	0	0	1	0	52
Saarela (2002)	1	0	2	N/A	0	1	0	0	1	0	2	0	3	50
Enterline(1975)	1	0	0	N/A	2	N/A	1	3	1	1	0	0	0	47

Criteria Met % criteria Met	24/29 83	12/29 41	23/29 79	6/10 60	13/27 45	17/20 85	26/27 90	21/29 72	23/29 79	16/29 55	8/29 28	6/12 50	10/29 34	
Heikkinen (1992)	0	0	0	0	0	0	1	0	0	0	0	N/A	0	5
Thomas (1985)	- 1	Ô	0	$N/\Delta$	0	1	1	ñ	1	0	ñ	$N/\Delta$	Ô	21
Clarke (1972)	1	0	2	N/A	2	N/A	0	0	1	1	0	N/A	0	39
Pinto (1977)	1	2	0	N/A	2	N/A	1	3	0	0	0	0	0	47
Pavia (2005)	1	0	2	N/A	0	1	1	0	1	1	2	N/A	0	47

## **Appendix B: Data Extraction Questions**

- 1. Write the last name of the first author and the year of publication
- 2. State the primary research question(s)/objective(s) related to the systematic review study question
- 3. State the primary hypothesis related to the systematic review study question that
- 4. State additional hypotheses related to the systematic review study question that are not listed in question #3
- 5. In what country was the study conducted?
- 6. In what region/province was the study conducted?
- 7. In what state was the study conducted?
- 8. In what city was the study conducted?
- 9. What is the overall time period covered by the study?
- 10. What is the study design? (Select only one)
- 11. What is the main statistical analysis method used? (Select only one)
- 12. What is the overall study sample size and description?
- 13. List the detailed characteristics of the study population/study participants/ subjects.
- 13a. Sample size
- 13b. Follow-up time period
- 13c. Mean/median age (report stated measure of central tendency and its value to one decimal place)
- 13d. Standard deviation of age (report to one decimal place)
- 13e. Age range
- 13f. Number of males
- 13g. Number of females
- 13h. Ethnicities included (separate by comma)
- 13i. Percent non-white (report as a number to one decimal place)
- 13j. Occupation
- 13k. Percent blue-collar workers (manual or technical laborer -report as a number to one decimal place)
- 131. Mean/median of employment tenure—years employed at job (report stated measure of central tendency and its value to one decimal place)
- 13m. Standard deviation of employment tenure (report to one decimal place)
- 13n. Employment tenure range (include the unit of time days/months/years)
- 14. Describe any additional notable/unique characteristics of the study population/study participants/subjects not listed above in Q13
- 15. For each data type, list the associated data source
- 16. List the inclusion criteria described in the study
- 17. List the exclusion criteria described in the study
- 18. List each employment classification used in the study

- 19. List associated definition of each employment classification used in the study
- 20. List the criteria for handling those study participants which are lost to follow-up
- 21. Select the mortality outcome measured in the study
- 22. List the location of data in the article
- 23. List/describe each exposure/referent group related to the systematic review study question
- 24. List the associated number of people for each exposure/referent group
- 25. List the mean of age for each exposure/referent group
- 26. List the SD of age for each exposure/referent group
- 27. List the age range for each exposure/referent group
- 28. List the number of females for each exposure/referent group
- 29. List/describe each exposure/referent group related to the systematic review study question that (from question #23)
- 30. List the number of events for each exposure/referent group
- 31. List the outcome measure for each exposure/referent group
- 32. List the measure of association value for each exposure/referent group
- 33. List the 95% confidence interval/p-value for each exposure/referent group
- 34. List the adjustment for each exposure/referent group
- 35. Describe any additional outcome measures and their associated 95% CIs and p-values not listed in Q29 Q34 above
- 36. Describe the significant differences in covariates/confounders between those that participated in the study vs. those that were lost to follow-up
- 37. State the overall conclusion(s) of the study
- 38. Please provide YOUR interpretation of the study results plus any noteworthy strengths and limitation of the study. You can also provide any comments, remarks or insights on the study/findings, comparability of the exposure/ referent groups or enter other information that is unique about the study that may not be adequately captured elsewhere on the data extraction form
- 39. Check the names of both data extraction reviewers for this study
- 40. Is this the consensus-final-version of the data extraction form?

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Listed below are potential Phase 2 projects that are referred to in the current proposal. We are prepared to discuss any of these potential projects with ILSI. It is difficult to put a dollar value on these at this time since we don't yet know the extent of the database until we do the searches.

**1.** New project on animal, ex vivo, and in vitro studies. Our laboratory is capable of doing a 'Phase 2' project that would be similar but include animal, ex vivo and in vitro studies for each of the Vahouny health benefits, and although this could provide important mechanistic information our primary interest is translating good science into public policy, and this effort would be unlikely to influence public policy. We would suggest instead generating more in depth publications using the database that we will have created.

**2.** Evaluating each manuscript for quality and adding numerical values for health benefits. The Phase One proposal does not evaluate each manuscript and score it for quality. If the sponsors would like us to do this in Phase Two we could do this, but we may wish to have others use and database and do this for themselves in order to save considerable time and money. We also have the capacity to add quantitative information as to the degree of change from baseline for the health benefit studies together with P values, etc.

**3.** *Advanced Evidence Maps*. Due to time and budget restrictions on Phase 1 we will not have the opportunity to do more advanced evidence maps or look at the data in several different ways to generate more manuscripts on human studies. This could be considered for phase 2.

**4.** *Separating fibers into Codex Type 1, 2, and 3.* The RFP calls for categorizing fibers into each of the three Codex defined categories, and if this is important to the sponsors we are prepared to do this, but it would require the addition of a researcher specifically trained to contact authors of the studies, food manufacturers and food ingredient companies to assure that the distinction between types 2 and type 3 can be accurately assessed. We estimate that it would take a full time individual who is familiar with the types of fibers and can contact Principal Investigators, Food Manufacturers and ingredient suppliers. Our experience is that many researchers do not know or accurately describe in their manuscripts whether the fiber they are using is synthesized or extracted (which are two separate categories). The sponsors might consider, however, that "added or functional" fibers which by the Codex definition have to show a beneficial effect to health, whereas fibers that are endogenous to the plant do not, does not require a distinction between categories 2 and 3, and would be much easier and thus less expensive to combine these two groups. In addition, there are some circumstances in which even separating Type 1 from types 2 and 3 would be difficult. For example, since by the Codex definition resistant starch is considered a "fiber" it may be unclear whether the resistant starch in a trial was naturally occurring, if it was synthesized or if it was extracted and added to the food product.

**5.** *Grouping fibers*. This is an exercise in and of itself. There are many potential ways to group fibers, but all of those ways need to be justified. For the present proposal we have listed each fiber separately. If we want to consider groups we need to do a separate study as to how to classify a group of fibers.

**6.** Database maintenance. Annual updates. Our laboratory would be interested and is capable of updating this annually. A proposed budget for that would be ~\$20,000 per year. This would include adding newly published articles to the database twice a year. In addition we have the ability to make a new database and put it online from Texas A&M and make it more searchable than the current AHRQ@ database.

#### Development of a Comprehensive Fiber Database and Evidence Map

Submitted by: Joanne R. Lupton, PhD, Principal Investigator Margaret J. Foster, MS, MPH, Co-Principal Investigator Texas A&M University

#### Introduction

This proposal follows the format of the RFP from the ILSI Technical Committee on Carbohydrates to facilitate the sponsor evaluation of whether or not we are appropriately responding to their needs.

#### 1. Methods

a) Methods for generating the list of fibers to be included. There will not be an *apriori* list of dietary fibers, as we feel that it is important to be inclusive at the outset. Preselecting fibers and only using the selected fibers in the search has the potential to overlook important studies. After the initial search we will meet with the sponsors to discuss potential groupings of fibers before they are entered in the final database.

#### *b* & *c*) Study search criteria and methodology.

<u>1. Types of studies included.</u> The only observational studies included will be prospective cohort studies and the only intervention studies will be randomized clinical trials (RCTs), clinical trials with concurrent controls, and clinical trials with a "crossover" design. The rationale for this decision is that prospective cohort studies are considered the type of observational study with the least bias [1] and the RCTs, those with concurrent controls, and those with a "crossover" design are the highest quality study types within the category of intervention studies [1]. We considered limiting the intervention studies to RCTs but decided that would unnecessarily eliminate solid smaller studies that make a contribution to the literature. The reason for setting study design as a limiting factor is because cost and time constraints prohibit doing a review of each selected manuscript for *quality* using accepted quality criteria [2]. Evaluation of study quality could be conducted in a Phase 2 proposal, if desired. (See addendum on Phase 2.)

<u>2. Years of studies included</u>. We will include all studies that meet our inclusion/exclusion criteria from 1980 onward. The rationale for not limiting this to more recent studies is that there is a potential for bias towards the Codex type 2 and 3 studies, which are more recent, at the expense of the earlier studies which focused on "high fiber diets" and type 1 fibers (e.g. wheat bran and oat bran). The rationale for not going earlier than 1980 is a practical one in that it would likely involve retrieving articles that are not available online, and thus add to the time and expense of the project.

<u>3. Specific search criteria.</u> The search will be limited to human studies, English language and only those studies that have both a stated fiber and one of the Vahouny health outcomes [3]. Specifically, the search criteria will be: any article that has a keyword/thesaurus term about dietary fiber; one of the 9 health benefits; and has a keyword, publication type or subject heading that indicates it is a prospective cohort study or a clinical trial. In addition, systematic reviews and meta-analyses will be included in the search so that bibliographies can be backreferenced.

<u>4. Databases to be searched</u>. These include: Medline, Embase, CAB Abstracts, BIOSIS, Food Safety and Technology Abstracts, AGRIS, Agricola, CINAHL, Sport Discus, and Cochrane Central Register of Controlled Trials. Medline search will be designed following *Cochrane Handbook* requirements [2] of using both keywords and thesaurus terms. Previous systematic reviews that have sought to find similar studies, either about dietary fiber or one of the Vahouny health benefits [3], will be reviewed to evaluate if part of the search could be included in this search. Validated search filters for study types from groups like the Cochrane Collaboration will be used. The Medline search will be adapted for all of the other databases.

5. Selection. After retrieving articles and placing into a RefWorks database [4], articles will be screened by abstract. RefWorks will allow the TAMU team to collaborate online as it is a web based system and freely available to us as TAMU faculty and staff. RefWorks has an unlimited reference size and an unlimited maximum number of references. If an abstract is not available and the article is of potential interest, it will move to full text screening. Each abstract will be randomly assigned to 2 screeners who will determine independently if it should be included. Reasons for exclusion will be recorded, as per PRISMA guidelines [5]. The following questions will be used: Is it in English; Does it involve a study of humans; Does it involve a study of a fiber; Is it a prospective cohort study or a RCT, or a clinical trial that has either concurrent controls or is of a crossover design; Does it discuss one of the 9 health benefits? We will do an evaluation of primary screening to calculate inter-rater reliability. All disagreements will be settled with a third screener. This information will be part of the manuscript describing the process of establishing the database.

# e & g) A description of the data that will be extracted for each study; and a method for labeling the direction and assessing the consistency of findings.

<u>1. Content of abstraction forms.</u> Data extracted will include citation information, categorization as to type of study, type of fiber studied (name of fiber and category 1 or categories 2&3) and type of endpoint (one or more of the 9 Vahouny criteria). See section 2 (Potential challenges) for rationale of combining CODEX types 2 and 3 [6]. In addition, length of the intervention, information on the subject population (gender, age, number of individuals, and country where the study was done) will be extracted. Two team members will each conduct five abstractions and compare them to each other. When they routinely produce five abstractions with all entries the same they will work independently.

2. Method of labeling the direction and assessing the consistency of findings. Also included on the abstraction form will be an entry for whether or not there was a beneficial effect of the fiber on the health outcome. This will be scored by selecting the relevant endpoint (e.g. decrease in blood pressure, attenuation of blood glucose, increase in satiety, etc.) and determining from the manuscript whether there was a significant health benefit, a negative effect or no statistically significant effect of the fiber on the health benefit. The entry on the abstraction form will list a (+) for positive benefit, a ( $\emptyset$ ) for no statistically significant benefit and a (-) for a negative effect on health benefit. The abstraction forms will explain this process. Although not possible to include numerical values for the health benefits (i.e. P values and % change, etc.) a phase 2 project could be designed to do this. The consistency of findings on health effects of the fibers could be stated as "in 8 out of 10 clinical trials fiber "X" had a beneficial effect on blood pressure". **d,f & h**) *Data organization, approach for summary tables and an evidence map, approach for describing findings regarding a particular health benefit.* 

<u>1. Data organization.</u> The public database will be created on the AHRQ Systematic Review Data Repository Site (AHRQ SRDR). See Sections 3 and 4 for further details. The extracted data will be uploaded as they are completed. Data will then be exported from the AHRQ database into excel spreadsheets so that we can sort it in a variety of ways for both presentation to the sponsor and for our utility in writing the manuscripts, and, importantly, so that we can store a backup of the database.

2. Approach to developing summary tables and an evidence map(s) and approach regarding a particular health benefit for an individual fiber. Summary tables will be developed using the AHRQ SRDR Project Tools and Excel spreadsheets imported from the fiber database on the AHRQ website. This will afford us the ability to sort by any field on the abstract forms (authors, date of publication, type of study (prospective cohort, clinical trial), type of fiber, type of health benefit, whether or not the health benefit was achieved in the study (positive, negative, null). For example, we could ask: "How many manuscripts involve the effect of dietary fiber on Vahouny criterion 3 (reduced blood pressure)? Of those manuscripts, how many showed a beneficial, null, or negative effect on blood pressure? Of those studies showing a beneficial effect how many were prospective cohort studies and how many were clinical trials? How many were with type 1 fibers versus type 2 & 3 fibers? We can do the same thing in terms of specific dietary fibers and ask "How many different fibers have been tested for one of the 9 Vahouny health effects? Which fiber has been tested the most? For which fibers are there the most randomized clinical trials? Which health outcome has the most beneficial health effects associated with it?" Simple evidence maps will be prepared to illustrate the summary table findings, as appropriate. These maps will be helpful both for presenting the database to the ILSI committee and also for the manuscript. These could take the form of a figure which would show numbers of manuscripts abstracted; then how many different fibers (with number of studies attached to each) then a breakout of the types of studies, and which of the 9 health criteria are addressed. It could also take the form of overlapping circles including the summary data described above. The summary tables will determine the best format for the evidence mapping. It should be noted that evidence mapping is a considerable task in and of itself [7] and given the very short turnaround time this task will be approached in a very simple way. We would be pleased to consider a more sophisticated approach for a Phase 2 study. i) Format we will use to present the information to the committee.

Our format will be whatever is most useful to the committee. As we see it (and as you have listed in the RFP) there are several times where conference calls will be needed to decide on "next steps." We would like ILSI to schedule these calls, taking our schedules into consideration (see Timeline section). In presenting the database we would use a combination of slides describing what we have done, how we did it, and what the results are and show the committee the actual AHRQ online database. In presenting the summary data we feel this should be by a web based system so that we can show data and also discuss it by phone. The call discussing the summary data should result in an approach/overall theme for the manuscript.

*j) Approach we will take to communicate the findings in a summary manuscript.* The approach we will take is as follows: We should select a target journal up front in consultation with the ILSI committee. This will help to develop the overall theme of the manuscript. Relevance, citation factor, and turnaround time will be important factors that need to be considered, e.g. quick publication versus journal quality may need to be discussed. The TAMU conversations with ILSI as we move through this process should establish our major themes for the manuscript which we need to capture in the introduction. For example, we could suggest that this is targeted to the 2015 Dietary Guidelines Committee and draw from the ILSI statement that they need to consider "added or functional fibers" and that we have created a database to facilitate this process. It is difficult to say in advance how the summary tables should be arranged before we know what the results are. The methods section would go over exactly what we did and why and how and will emphasize the quality factors for the inclusion criteria and the efforts we have made to minimize bias. It will also explain the ILSI desire to make all of this transparent and available to the public and that this should be very useful information for others. We do not envision in this manuscript coming to any conclusions on different types of fibers or their efficacy in promoting health. That could be the subject of a future manuscript. This manuscript would be designed to make future researchers knowledgeable with how the data were collected and abstracted so that they would be comfortable using the data for future manuscripts.

## 2. Potential challenges

There are a number of challenges, but none that can't be met. Since we are limited to 5 pages we need to be brief but are happy to discuss these issues with the sponsors, if desired.

<u>1) Colonic fermentation and short chain fatty acid production</u>. Admittedly this is a significant challenge, but fortunately Dr. Lupton is an expert on colonic fermentation and short chain fatty acid production (See CV). We do not recommend using animal studies or ex vivo or in vitro studies in support of this "beneficial effect." We also recommend that fermentation *per se* should not be evaluated as a beneficial effect nor should an increase in butyrate or "good" bacteria. For deciding on what constitutes a positive endpoint we would recommend a functional, not merely descriptive endpoint.

<u>2) Separating fibers into Codex Type 1, 2, and 3.</u> The time and effort required to separate fibers in manuscripts into the three Codex definition types is considerable. We are prepared to put them into two categories (those that are endogenous to the plant (Type 1) and those that are synthesized and/or extracted (types 2 and 3). We will not be able to separate types 2 and 3 without a significant increase in time and money. See addendum on Phase two studies

<u>3) Fiber rich diets versus specific dietary fibers.</u> The issue here is how to deal with a "fiber rich diet" as compared to a specific dietary fiber. This is an important issue to come to consensus on up front. There are a number of key studies in which participants are instructed to increase the amount of fiber in their diets by eating high fiber foods but the specific fibers they choose to eat are not necessarily delineated. The argument is that "it's not the fiber that's important, but rather all of the other nutrients that come along with eating high fiber foods".

<u>4) Grouping fibers.</u> Grouping fibers is not a simple process. They can be grouped by physiological effect, chemical composition, health benefit, etc. This requires a discussion with the ILSI committee if we need to group the fibers.

5) The AHRQ website and system. From what we can see, the AHRQ SRDR system does not allow the public to create their own reports by selecting a field (fiber or health benefit) then sorting the studies. The public will be able to review extraction forms and view individual studies. In Phase 2 we could create a University housed database that would allow more flexible searching.

## 3 & 4. Database Maintenance and Access

The primary way in which the public will access the database is through the AHRQ Systematic Review Data Repository Site (AHRQ SRDR). The TAMU team will become certified data contributors. Margaret Foster (our TAMU process expert) discussed setting up training with Nira Hadar from AHRQ SRDR on June 27, 2013 and we will complete the training and certification by webinar. We do not anticipate any problems with the certification. First the database will be created in the AHRQ SRDR. Data will then be exported from the AHRQ database into excel spreadsheets so that we can sort it in a variety of ways for both presentation to the sponsor and for our utility in writing the manuscript, and importantly, so that we can store a backup. These spreadsheets will be stored in the TAMU Digital Library as a backup. The TAMU Digital Repository (repository.tamu.edu) is built on the open source DSpace system, developed by MIT and Hewlett Packard and now with more than 900 installations worldwide.

#### 5. Investigators and their role in the project

Joanne R. Lupton, Ph.D., Principal investigator. Dr. Lupton is the content expert. She will assume ultimate responsibility for all phases of the project working closely with Ms. Foster. She will devote 10% of her time to this effort. She will train/advise on all content related decisions such as categorizing fibers, grouping fibers, interpretation of the Vahouny endpoints, and she will do the first draft of the manuscript. She is an expert on dietary fiber, on its definition and what the health benefits of specific fibers may be. She chaired the Institute of Medicine DRI process for determining the definition of dietary fiber and she also chaired the Institute of Medicine DRI process for determining intake values for Macronutrients which included dietary fiber. She was awarded the Vahouny medal (June 2010) for her research in dietary fiber which is awarded ~ every four years by peers in dietary fiber. She is a member of the Institute of Medicine, is currently on the Food and Nutrition Board, and she is a past President of ASN. Her CV and 2 relevant articles are attached.

*Margaret J. Foster*, MS, MPH, Co-Principal Investigator. Margaret Foster will serve as the process expert for this proposal. She will devote 8% of her time to this project and will do database searches, remove duplicate results, establish a final set of articles, configure Refworks for support of database entry, list and explain screening protocols, train all participants to screen articles, develop abstraction forms, and will oversee the preparation of the evidence map. She has a Masters in Library and Information Science and a Masters in Public Health and is currently working as the Systematic Review and Research Coordinator at the Medical Sciences Library at Texas A&M University. Working in medical libraries for over 10 years and consulting on systematic reviews for the past 7 years, she has contributed to over 200 systematic review projects. She is currently one of 15 team leaders for the Medical Library Association Research Agenda Systematic Review group. Her CV and 2 relevant articles are attached.

**Stella Taddeo**, BS in Food Science and Technology, **Coordinator**, will work with J. Lupton and M. Foster to 1) select the manuscripts to be abstracted; 2) abstract the manuscripts; 3) be the primary liaison to the ILSI sponsors at each step of the project. She will devote 25% of her time. She has worked with Dr. Lupton for over 22 years, and is very familiar with fiber research and the protocols for systematic reviews. Her background in the laboratory and BS in Food Science & Technology give her a useful expertise and perspective when it comes to the understanding of papers that will need to be evaluated for this review.

*Chelsea Bishop Smith MPH,* Research Associate, will devote 17% of her time working with J. Lupton and M. Foster to 1) select the manuscripts to be abstracted; 2) abstract the manuscripts. She has a Masters in Public Health and has worked with Dr. Lupton for 4 years in various aspects preparing, reviewing and conducting literature searches and reviews. Her background in public health and her current experience in systematic reviews have provided the necessary tools to be a valued asset to this team.

## 6. Resources

The most significant resource is that all investigators are either faculty or staff of Texas A&M University. The University has licenses for all faculty and staff to download RefWorks and EndNote free of charge as well as training and tutorial assistance to customize data procurement and storage. Also, University Libraries have an inter-library loan program through which affiliates have full, free access to all journal articles and publications. The use of AHRQ as the host site for the database is of no charge.

#### 7. Budget

Personnel	% Effort	Fringe Benefits	Salary Total
PI: Joanne Lupton	10%	\$3,680	\$17,879
Co-PI: Margaret Foster (Sub-Contract)	8%	\$1,207	\$4,288
Coordinator: Stella Taddeo	25%	\$3,693	\$13,051
Research Associate: Chelsea Smith	17%	\$2,195	\$7,168
Total Salaries			\$42,386
Total Benefits			\$10,775
Total Personnel Costs			\$53,161
Publication Costs			\$1,384
Total Direct Costs			\$54,545
Total AgriLife Indirect Costs			\$4,905
Total Sub-Contract Indirect Costs			\$550
Total Project Costs			\$60,000

## 8. Timeline

The table depicts the timeline including the deadline dates set by ILSI and the anticipated deliverables that were outlined in the proposal. It is important to note that each of these deliverables is related to the next so if there is delay in ILSI approval then the timeline will need to be adjusted accordingly.

Project Activities		Month in which Project Activities will be completed								
FIDJECT ACTIVITIES	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY
Initial call with ILSI project objectives and	Х									
Begin work on literature search	Х									
Create abstraction forms	Х									
Submit to ILSI committee for approval	v									
(Search Criteria; database)	^									
Identify studies for database		Х								
Send draft list of studies to ILSI for review		Х								
Work on entering studies into the AHRQ databas			Х	Х						
Complete AHRQ Database and submit to ILSI				30th						
Revisions/edits to database from ILSI review					Х					
Database Published on AHRQ					31st					
Work on summary tables of studies					Х	Х				
Work on Evidence Map of studies					Х	Х				
Completed Summary Tables Submit to ILSI						31st				
Evidence Map Completed Submit to ILSI						31st				
Outline of publication sent to ILSI for review					Х					
Complete writing of publication					Х	Х				
Submit draft publication to ILSI for review							Х			
Publication Submitted							28th			
Responses and edits to journal submission								Х	Х	
Revised manuscript for re-submission									Х	Х

## References

- 1. Academy of Nutrition and Dietetics, *Evidence Analysis Manual: Steps in the Academy Evidence Analysis Process*, 2012. p. module 2.
- Cochrane Collaboration, Cochrane Handbook for Systematic Rreviews of Interventions. Cochrane Book Series. Vol. 5. 2008, West Sussex, England: Wiley-Blackwell.
- 3. Howlett, J.F., V.A. Betteridge, M. Champ, S.A. Craig, A. Meheust, and J.M. Jones, *The definition of dietary fiber discussions at the Ninth Vahouny Fiber Symposium: building scientific agreement*. Food Nutr Res, 2010. **54**.
- 4. ProQuest, *Refworks*, 2001. http://www.refworks.com/
- 5. Moher, D., A. Liberati, J. Tetzlaff, D.G. Altman, and The PRISMA Group, *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. PLoS Medicine, 2009. **6**(7): p. e1000097.
- 6. Lupton, J.R., V.A. Betteridge, and L.T.J. Pijls, *Codex final definition of dietary fibre: issues of implementation.* Quality Assurance and Safety of Crops & Foods, 2009. **1**(4): p. 206-212.
- 7. Parkhill, A.F., O. Clavisi, L. Pattuwage, M. Chau, T. Turner, P. Bragge, and R. Gruen, *Searches for evidence mapping: effective, shorter, cheaper.* Journal of the Medical Library Association: JMLA, 2011. **99**(2): p. 157.

## Joanne R. Lupton, Ph.D. Curriculum Vitae

## **POSITION:** Distinguished Professor, Regents Professor, University Faculty Fellow and William W. Allen Endowed Chair in Human Nutrition Texas A&M University

Mailing Address: Department of Nutrition and Food Science 213 Kleberg Center, MS 2253 Texas A&M University College Station, Texas 77843-2253 Telephone (979) 845-0850 Fax (979) 862-1862 Email: Jlupton@tamu.edu

EDUCATION: Institution	<u>Degree</u>	Year Conferred	Field of Study
Mt. Holyoke College	B.A.	1966	Philosophy
California State University	M.S.	1980	Foods and Nutrition
University of California, Davis	Ph.D.	1984	Nutrition (Minor, Physiological Chemistry)
Post Doctoral Fellow/ UC Davis Medical School		1984	Clinical Nutrition

## **PROFESSIONAL APPOINTMENTS:**

2000-2008	Program Leader, Nutrition, Physical Fitness and Rehabilitation, National Space
	Biomedical Research Institute (NASA/NSBRI)
2003-2004	Visiting Scholar, Food and Drug Administration, Center for Food Safety and
	Applied Nutrition, College Park, MD
2009-present	Elected to the Institute of Medicine, National Academies

## ACADEMIC APPOINTMENTS

1980-1984	Post-Graduate Research Associate, Associate Instructor, Post-Doctoral Fellow
	University of California, Davis
1984-1989	Assistant Professor of Nutrition, Department of Animal Science
	Texas A&M University, College Station, Texas
1989-present	Cross-appointed Department of Veterinary Anatomy and Public Health,
	College of Veterinary Medicine, now Veterinary Integrative Biosciences, Texas
	A&M University
1989-1996	Associate Professor of Nutrition, Department of Animal Science,
	Texas A&M University
1990-1993	Founding Chair, Faculty of Nutrition, Texas A&M University
1995-2005	Section Leader, Human Nutrition, Dept. of Animal Science
1995-present	William W. Allen Endowed Chair in Human Nutrition

7/2/2013

1996-present Professor, Texas A&M University
1999-present Regents Professor, Texas A&M University
2000-present University Faculty Fellow, Texas A&M University
2008-present Distinguished Professor, Texas A&M University
2010-present Joint Appointment with Texas A&M Health Science Center School of Rural Public Health

## PROFESSIONAL SOCIETY MEMBERSHIPS

American Institute of Nutrition, American Society for Nutritional Sciences, American Society for Nutrition (ASN) 1980 - present American Association for Cancer Research, 1997 - present American Physiological Society, 1987 - present Sigma XI, 1987 – present

Associate Editor, Nutrition and Cancer, an International Journal, 1999-present Associate Editor, The Journal of Nutrition, 1994 - 2004. Established office for the Journal at Texas A&M University. Appointed to (3) 3-year terms. Regional Associate Editor, American Institute of Nutrition Notes, 1989-1993 Editorial Board, The Journal of Nutrition, 1991-1994 Editorial Board, Current Nutrition Reviews, 2004-present

Ad hoc reviewer for: American Journal of Clinical Nutrition, American Journal of Physiology, Cancer Epidemiology and Biomarkers, Cancer Research, Carcinogenesis, Cell Growth and Differentiation, Cereal Chemistry, Comparative Biochemistry and Physiology, Gastroenterology, Journal of the American Dietetic Association (Reviewer for their position statements on dietary fiber and wheat bran and colon cancer), Journal of Nutrition, Journal of Nutritional Biochemistry, Journal of Parenteral and Enteral Nutrition Metabolism, Nutrition, Nutrition and Cancer

Reviewer of a text book on Nutrition in the Life Cycle, Times Mirror Mosby Publishers Reviewer of a chapter in Advanced Nutrition, West Publishing, 1989

Reviewer for the Institute of Medicine Report titled "Child and Adult Care Food Program:

Aligning Dietary Guidance for All", August, 2010.

Reviewer for the Front of Pack Labeling

## PATENTS

United States Provisional Patent, "Non-invasive stool-based detection of infant gastrointestinal development using gene expression profiles from exfoliated epithelial cells". <u>R.S. Chapkin</u>, J.R. Lupton, L.A. Davidson and E. Dougherty (In process).

United States Provisional Patent, "Methods for detecting colorectal diseases and disorders." November 5, 2008. <u>R.S. Chapkin</u>, L.A. Davidson, E. Dougherty and J.R. Lupton (PCT/US09/05966).

United States Provisional Patent, "Gene expression profiles from colonocyte mRNA isolated from feces." August 29, 2005 (TAMU 1014). <u>R.S. Chapkin</u>, L.A. Davidson, N. Wang and J.R. Lupton.

United States Provisional Patent Application, "Noninvasive detection of colonic biomarkers using fecal messenger RNA." July 10, 2001 (6,258,541). <u>R.S. Chapkin</u>, L.A. Davidson and J.R. Lupton.

## PUBLICATIONS

## **Refereed Papers**

- 1. Jacobs LR and <u>Lupton JR</u>. Dietary wheat bran lowers colonic pH in rats. J. Nutr. 112:592-594, 1982.
- 2. Jacobs LR and <u>Lupton JR</u>. Effect of dietary fibers on rat large bowel mucosal growth and cell proliferation. Am. J. Physiol. 246:G378-G385, 1984.
- 3. Lupton JR. Colon epithelial cell kinetics. Gastroenterology 80:251-252, 1984.
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- 185. Turner ND, Sanders LM, Wu G, Davidson L, Ford J, Braby L, Carroll R, Chapkin RS, and <u>Lupton JR</u>. Relationship between oxidative damage and colon carcinogenesis in irradiated rats: influence of dietary countermeasures (F24-0004-08). 37<sup>th</sup> COSPAR Scientific Assembly, Montreal, Canada, July 13-20, 2008.
- 186. Chapkin, RS, Davidson, LA, McMurray, DN, and Lupton, JR. Omega-3 fatty acids and
- 187. cancer prevention. American Institute for Cancer Research Meeting, Washington, DC, November 6-7, 2008.
- 188. Chapkin RS, Davidson LA, Colburn N, Lanza E, Hartman T, <u>Lupton JR</u>, Dougherty E, Zhao C, and Ivanov I. Non-invasive detection of candidate molecular biomarkers in patients at high risk for colorectal adenoma recurrence. NCI Translational Science Meeting, Washington, DC, November 7-9, 2008.
- 189. Turner, ND, Taddeo SS, Davidson LA, Chapkin RS, Carroll RJ, Ford JR, Braby LA, and <u>Lupton JR.</u> 2009. Radiation responsiveness of colonic mucosa detected from initiation through tumor development. NASA HRP Investigator's Workshop. February 2-4, League City, TX.

- 190. Fan Y-I, Callaway ES, Ran Q, <u>Lupton JR</u>, and Chapkin RS. The proapoptotic effects of n-3 fatty acids are enhanced in oxidatively stressed transgenic mouse models. Frontiers in Cancer Research Meeting, Houston, TX, March 26-27, 2009.
- 191. Chapkin RS, Davidson LA, Wang N, Ivanov I,Goldsby j and <u>Lupton JR</u>. Identification of actively translated mRNA transcripts in a rat model of early stage colon carcinogenesis. Presented at the Frontiers of Cancer Research Conference, Houston, TX, March 26-27, 2009.
- 192. Cho Y, Turner ND, Taddeo SS, Davidson LA, Wang N, Vannuci M, Carroll RJ, Chapkin RS and <u>Lupton JR</u>. Chemoprotective fish oil/pectin diets temporally alter gene expression profiles in exfoliated colonocytes. Experimental Biology 2009, FASEB Meeting, New Orleans, LA, April 18-22, 2009.
- 193. Turk HR, Kolar SS, Fan Y, Cozby CA, <u>Lupton JR</u> and Chapkin RS. Linoleic acid and butyrate synergize to increase Bcl-2 pevels in colonocytes. Frontiers in Cancer Research, Houston, Texas, March 26-27, 2009.
- 194. Chapkin RS, Wang N, Ivanov I, Goldsby JS, <u>Lupton JR</u>, Davidson LA. Identification of actively translated mRNA transcripts in a rat model of early stage colon carcinogenesis. Frontiers in Cancer Research, Houston, Texas, March 26-27, 2009.
- 195. Zhao C, Ivanov I, Dougherty ER, Hartman TJ, Lanza E, Colburn NH, <u>Lupton JR</u>, Davidson LA and Chapkin RS. Ranked molecular biomarkers for patients at high risk for colorectal adenoma recurrence. Presented at the MidSouth Computational Biology and Bioinformatics Society (MCBIOS) meeting, Starkville, Mississippi, February 20, 2009.
- 196. Turner, ND, Taddeo SS, Davidson LA, Chapkin RS, Carroll RJ, Ford JR, Braby LA, and <u>Lupton JR</u>. Radiation-induced gene expression changes in colonic mucosa detected at initiation through tumor development. Frontiers in Cancer Research, Houston, Texas, March 26-27, 2009.
- 197. Paulhill, KJ, Taddeo SS, Wu G, Carroll RJ, Chapkin RS, <u>Lupton JR</u>, and Turner ND. Dietary lipids and quercetin alter endogenous antioxidant enzyme activities and colonocyte redox balance. Frontiers in Cancer Research, Houston, Texas, March 26-27, 2009.
- 198. Davidson LA, Zhao C, Ivanov I, Dougherty ER, Hartman TJ, Lanza E, Colburn NH, <u>Lupton JR</u> and Chapkin RS. Non-invasive identification of ranked molecular markers for patients at high risk of colorectal adenoma recurrence. Frontiers of Cancer Research Conference, Houston, TX, March 26-27, 2009.
- 199. Turner ND, Paulhill KJ, Taddeo SS, Wu G, Carroll RJ, Chapkin RSand <u>Lupton JR</u>. Dietary lipids and Quercetin alter endogenous antioxidant enzyme activities and colonocyte redox balance. Presented at the Frontiers of Cancer Research Conference, Houston, TX, March 26-27, 2009.
- 200. Turk HF, Kolar SS, Fan YY, Cozby CA, <u>Lupton JR</u>, and Chapkin RS. Linoleic acid and butyrate synergize to increase bcl-2 levels in colonocytes. Presented at the Frontiers of Cancer Research Conference, Houston, TX, March 26-27, 2009.
- 201. Kim H, Turner ND, Taddeo SS, Davidson LA, Wang N, Vannuci M, Carroll RJ, Chapkin RS, and <u>Lupton JR</u>. A fish oil/pectin diet suppresses radiation-enhanced folon carcinogenesis via down-regulation of the β-catenin signaling pathway. Experimental Biology 2009, FASEB Meeting, New Orleans, LA, April 18-22, 2009.
- 202. Paulhill KJ, Taddeo SS, Davidson LA, Carroll RJ, Chapkin RS, <u>Lupton JR</u>, Turner ND. Dietary lipid source alters quercetin effects on antioxidant enzyme/phase I and II gene

expression in rat colon. Experimental Biology 2009, FASEB Meeting, New Orleans, LA, April 18-22, 2009.

- 203. Jia Q, Weeks BR, Goldsby JS, <u>Lupton JR</u>, Chapkin RS, and McMurray DN. Dietary lipids and curcumin interact to affect gene expression in a mouse model of DSS induced chronic colitis. Experimental Biology 2009, FASEB Meeting, New Orleans, LA, April 18-22, 2009.
- 204. Shah MS, Davidson LA, Ivanov I, Wang N, Lupton JR and Chapkin RS. Establishment of a cell culture model to examine dietary regulation of microRNA expression in the colon. Presented at the Keystone Symposia on "MicroRNA and Cancer", Breckenridge, CO, June 10-15, 2009.
- 205. Ferguson CM, Pokusaeva K, Zorych I, Thomas LN, Taddeo SS, Callaway ES, Fan YY, Turner ND, Chapkin RS, <u>Lupton JR</u>, and Sturino JM. Resistant Starch Differentially Stimulates the Proliferation of Native Gastrointestinal Bifidobacteria. Presented at the United States National Academy of Sciences Sackler Symposium on Microbes and Health (Irvine, CA), October, 2009.
- 206. Donovan SM, Davidson LA, Zhao C, Ivanov I, Goldsby J, <u>Lupton JR</u>, Mathai RA, Monaco MH, Rai D, Russell M, Dougherty ER, and Chapkin RS. Non-invasive stool-based detection of newborn infant gastrointestinal development using gene expression profiles derived from exfoliated epithelial cells. Experimental Biology 2010, Anaheim, CA, April, 2010.
- 207. Turner ND, Taddeo SS, Callaway Es, Fan Y, Davidson LA, Thomas LA, Ferguson CM, Sturino JM, Chapkin RS, and <u>Lupton JR</u>. Differential activation of NF- κB in colonic mucosa of DSS-challenge rats consuming fermentable fiber sources. Experimental Biology 2010, Anaheim, CA, April, 2010.
- 208. Fan YY, Toyokuni S, Callaway ES, Ran Q, <u>Lupton JR</u>, and Chapkin RS. n-3 polyunsaturated fatty acids promote apoptosis in oxidatively stressed transgenic mouse models. To be presented at the Annual American Association for Cancer Research Meeting, Washington, D.C., April, 2010
- 209. Turk HF, <u>Lupton JR</u>, and Chapkin RS. Docosahexaenoic acid alters the spatio-temporal segregation and activation of the EGF receptor. Presented at the Annual American Association for Cancer Research Meeting, Washington, D.C., April, 2010.
- 210. Donovan SM, Davidson LA, Zhao C, Ivanov I, Goldsby J, <u>Lupton JR</u>, Mathai RA, Monaco MH, Rai D, Russell M, Dougherty ER, and Chapkin RS. Noninvasive assessment of the intestinal transcriptome of breast and formula-fed infants. To be presented at the 15<sup>th</sup> International ISRHML Conference, Lima, Peru, October 8-12, 2010.
- 211. Donovan SM, Davidson LA, Zhao C, Ivanov I, Goldsby J, <u>Lupton JR</u>, Mathai RA, Monaco MH, Rai D, Russell M, Dougherty ER, and Chapkin RS. Non-Invasive assessment of intestinal gene expression profiles in breast- and formula-fed human infants using exfoliated epithelial cells collected from stool. Milk Genome and Human Health meeting. To be presented at the 7<sup>th</sup> International Symposium: Milk genomics & Human Health Meeting, University of California-Davis, October 20-22, 2010.
- 212. Chapkin RS, Shah M, Ivanov I, <u>Lupton JR</u> and Davidson LA. Identification of dietary modifiers of crypt stem cells the cells of origin of intestinal cancer. Presented at the Cancer Prevention and Research Institute of Texas (CPRIT) Conference, November 17-19,2010 Austin, Texas.

- 213. Cho Y, Turner ND, Davidson LA, Chapkin RS and <u>Lupton JR</u>. A chemoprotective fish oil/pectin diet regulates the expression of bcl-2 oncogene by altering CpG island methylator phenotype (CIMP) in colon cancer. Presented at the Annual Experimental Biology Meeting, Washington, D.C., April, 2011.
- 214. Field LB, Cunningham RL, Elliott AL, Maloney TG, Luna SV, <u>Lupton JR</u>. A Systematic Literature Review of Front-of-Pack Labeling. Experimental Biology 2011, April 9-13, 2011, Washington, DC.
- 215. Turk HM, Barhoumi R, <u>Lupton JR</u> and Chapkin RS. A novel role for n-3 polyunsaturated fatty acids in inhibition of EGFR signal transduction. Presented at the Annual Experimental Biology Meeting, Washington, D.C., April 11, 2011. \*Winner of the 2011 American Society of Nutritional Sciences (ASN) Graduate Student Award.
- 216. Shah MS, Schwartz SL, Zhao C, Davidson LA, Zhou B, <u>Lupton JR</u> and Chapkin RS. Integrated microRNA and mRNA expression profiling in a rat colon carcinogenesis model: Effect of a chemoprotective diet. Presented at the 102<sup>nd</sup> American Association for Cancer Research annual meeting, Orlando, FL, April 2-6, 2011.
- 217. <u>Lupton, JR</u>. Dietary Fiber and its Effect on Health From a Science\Physiological Perspective. Presented at the International Conference on Food Factors, Taipei, Taiwan, November 22, 2011.
- 218. <u>Lupton, JR</u>. From basic science to dietary guidance: Dietary Fiber as an example. Presented at the International Conference on Food Factors, Taipei, Taiwan, November 23, 2011.
- 219. Turner ND, Smith CB, and <u>Lupton JR</u>. The graduate training program in Space Life Sciences at Texas A&M University. NASA HRP Investigator's Workshop, Houston, TX February 14, 2012.

# GRANT HISTORY

 Title: Alterations in human intestinal mucosal glycoconjugates in colon cancer and preneoplastic disease
 Investigators: J.R. Lupton, PI (50% effort)
 Agency: Office of Graduate Studies, University of California, Davis
 Type: Graduate Research Grant: Period 7/1/81-6/30/82

Project Direct Costs: \$2,000

Specific Aims: To determine differences in mucosal glycoconjugates in preneoplastic disease that predict for future tumor development.

 Title: The effect of soluble and insoluble fibers on experimentally-induced gastric cancer Investigators: J.R. Lupton, PI (50% effort) Agency: Office of Graduate Studies, University of California, Davis Type: Graduate Research Grant: Period 7/1/82-6/30/83 Project Direct Costs: \$2,000 Specific Aims: To determine how diet relates to gastric cancer and if the effect is mediated by gastric pH.

3. Title: *Stimulation of rat colonic epithelial cytokinetics by dietary acidification of luminal contents* Investigators: J.R. Lupton, PI (50% effort)

Agency: Office of Graduate Studies, University of California, Davis Type: Graduate Travel Grant: Period 4/15/84 Project Direct Costs: \$1,200 Specific Aims: To present research findings at national meeting.

4. Title: *Exploration of a possible link between diet and colon cancer* Investigators: J.R. Lupton, PI (50% effort) Agency: Office of University Research, Texas A&M University Type: Organized Research Development Grant: Period 9/15/84-8/31/85 Project Direct Costs: \$4,776 Specific Aims: To explore a potential link between fiber and colon cancer.

5. Title: Dietary fiber/fat interactions and their relationship to colon cancer Investigators: J.R. Lupton, PI (50% effort)
Agency: Office of University Research, Texas A&M University
Type: Organized Research Development Grant: Period 9/15/85-8/31/86
Project Direct Costs: \$5,000
Specific Aims: To investigate a fat/fiber interaction with respect to colon cancer.

6. Title: *A practical nutrition experiment* 

Investigators: J.R. Lupton, PI (10% effort) Agency: Center for Teaching Excellence, Texas A&M University Type: Teaching incentive grant: Period 9/15/85-8/31/86 Project Direct Costs: \$1,000 Specific Aims: To test the effectiveness of a diet intervention in the classroom.

7. Title: A possible protective role of calcium in colon carcinogenesis
Investigators: J.R. Lupton, PI (10% effort)
Agency: Office of University Research, Texas A&M University
Type: Interdisciplinary Improvement Research: Period 9/15/85-8/31/86
Project Direct Costs: \$700
Specific Aims: To test the effectiveness of calcium to decrease colon tumorigenesis.

8. Title: Fermentation of dietary fiber from common foods by human colonic microflora Investigators: J.R. Lupton, PI (50% effort) Agency: Office of University Research, Texas A&M University Type: Organized Research Development Grant: Period 9/15/86-8/31/87 Project Direct Costs: \$4,000 Specific Aims: To develop a fiber fermentation system to test relative fermentability of different fibers.

9. Title: Statistical Evaluation for Research
Investigators: J.R. Lupton, PI (10% effort)
Agency: Office of University Research, Texas A&M University
Type: Computer grants for statistical analysis: Period 9/15/86-8/31/91
Project Direct Costs: \$1,000

Specific Aims: To statistically evaluate data from research projects.

10. Title: The effect of exercise and dietary fiber on the rate of gastrointestinal transit Investigators: J.R. Lupton, PI (10% effort) Agency: National Institutes of Health Type: Biomedical Research Support Grant: Period 9/15/86-8/31/87 Project Direct Costs: \$8,500 Specific Aims: To investigate a potential interactive effect between fiber and exercise on gastrointestinal transit rate.

11. Title: Molecular mechanisms underlying dietary fiber/fat interactions in the etiology of colon cancer

Investigators: J.R. Lupton, PI (20% effort), T.R. Irvin, Co-PI Agency: Milheim Foundation for Cancer Research Type: Research Grant: Period 9/15/86-8/31/87 Project Direct Costs: \$12,000. Specific Aims: To determine the metabolism of the carcinogen dimethylhydrazine in colon cells

12. Title: Protein/fiber interactions: effect on colon carcinogenesis
Investigators: J.R. Lupton, PI (5% effort)
Agency: Houston Livestock Show and Rodeo
Type: Research Grant: Period 9/15/86-8/31/87
Project Direct Costs: \$1,800.
Specific Aims: To determine if dietary fiber can ameliorate the potentially promotive effects of high protein diets against colon cancer.

# 13. Title: Calcium soap formation: a possible mechanism by which calcium protects against colon cancer Investigators: J.R. Lupton, PI (20% effort)

Agency: Wisconsin Milk Marketing Board, administered by the National Dairy Council Type: Research Grant: Period 9/15/86-8/31/88 Project Direct Costs: \$35,228. Specific Aims: To determine if calcium protects against colon cancer by forming calcium soaps.

14. Title: Nutrient substitutions from animal products
Investigators: J.R. Lupton, PI (5% effort)
Agency: Houston Livestock Show and Rodeo
Type: Research Grant: Period 9/15/87-8/31/88
Project Direct Costs: \$1,800.
Specific Aims: Fiber and meat ratios to achieve the best bulking effect.

15. Title: *Physiological effects of dietary amaranth* Investigators: J.R. Lupton, PI (10% effort) Agency: Health Valley Foods Type: Research Grant: Period 9/15/88-8/31/89 Project Direct Costs: \$13,503.

Specific Aims: To test potential benefits of dietary amaranth.

16. Title: Mechanisms by which amaranth lowers serum cholesterol
Investigators: J.R. Lupton, PI (10% effort)
Agency: Health Valley Foods
Type: Research Grant: Period 9/15/88-8/31/89
Project Direct Costs: \$9,954
Specific Aims: To test how dietary amaranth lowers serum cholesterol.

17. Title: The effects of processed oat bran products on serum cholesterol levels of hypercholesterolemic individuals
Investigators: J.R. Lupton, PI (20% effort)
Agency: Health Valley Foods
Type: Research Grant: Period 9/15/88-8/31/89
Project Direct Costs: \$27,414
Specific Aims: Clinical trial to determine the efficacy of various oat bran products to lower cholesterol.

18. Title: Protein/fiber interactions: effect on colon cytokinetics
Investigators: J.R. Lupton, PI (5% effort)
Agency: Houston Livestock Show and Rodeo
Type: Research Grant: Period 9/15/88-8/31/89
Project Direct Costs: \$2,000
Specific Aims: How protein and fiber combinations affect colon cell kinetics

19. Title: Data analysis for oat bran products study
Investigators: J.R. Lupton, PI (5% effort)
Agency: Health Valley Foods
Type: Research Grant: Period 9/15/89-8/31/90
Project Direct Costs: \$4,499.
Specific Aims: To statistically evaluate data from the oat bran clinical trial.

20. Title: Effect of barley on serum lipids and gastrointestinal transit Investigators: J.R. Lupton, PI (20% effort) Agency: Miller Brewing Company Type: Research Grant: Period 9/15/89-8/31/90 Project Direct Costs: \$103,089
Specific Aims: Clinical trial to determine the effect of barley in individuals.

21. Title: *Physiological effects of dietary fibers*Investigators: J.R. Lupton, PI (30% effort)
Agency: USDA
Type: Hatch Grant: Period 9/15/89-present
Project Direct Costs: Variable amounts each year, supports technician, partial salary of JRL
Specific Aims: Determine the physiological effects of dietary fibers on health.

22. Title: *Testing high-fiber products in a model system*Investigators: J.R. Lupton, PI (10% effort)
Agency: Health Valley Foods
Type: Research Grant: Period 9/15/89-8/31/90
Project Direct Costs: \$32,405.
Specific Aims: In vitro tests to measure potential benefits of dietary fibers.

23. Title: *Effect of soluble fibers on colonic physiology*Investigators: J.R. Lupton, PI (10% effort)
Agency: American Institute for Cancer Research
Type: Research Grant: Period 9/15/89-8/31/90
Project Direct Costs: \$11,000
Specific Aims: Rodent study to test the effects of fibers on colon cell kinetics

24. Title: *Health and nutritional factors and food consumption*Investigators: J.R. Lupton, Co-PI (20% effort); Oral Capps, Co-PI
Agency: Texas Agricultural Experiment Station
Type: Research Grant, Expanded Research Area: Period 9/15/89-8/31/91
Project Direct Costs: \$49,896
Specific Aims: To use dietary intake data from NHANES to determine food consumption patterns and nutritional value

25. Title: *Physiological effects of sorghum, corn, rice*Investigators: J.R. Lupton, Co-PI (20% effort); Lloyd Rooney, Co-PI
Agency: Texas Agricultural Experiment Station
Type: Research Grant, Expanded Research Area: Period 9/15/89-8/31/91
Project Direct Costs: \$62,998.
Specific Aims: To use our rodent model to determine the physiological effects of sorghum, corn, and rice.

26. Title: *Mechanisms by which fibers lower cholesterol*Investigators: J.R. Lupton, PI (20% effort)
Agency: Texas Agricultural Experiment Station
Type: Research Grant, Expanded Research Area: Period 9/15/89-8/31/91
Project Direct Costs: \$63,000.
Specific Aims: To determine mechanisms by which fibers lower cholesterol.

27. Title: Interaction of dietary fat and fiber
Investigators: J.R. Lupton, Co-PI (20% effort); RS Chapkin, Co-PI
Agency: Texas Agricultural Experiment Station
Type: Research Grant, Expanded Research Area: Period 9/15/89-8/31/91
Project Direct Costs: \$68,000.
Specific Aims: To determine mechanisms by which fat and fiber interact to protect against colon

cancer.

28. Title: Dietary interactions between fats, calcium, and fiber
Investigators: J.R. Lupton, PI (20% effort)
Agency: Norwegian Dairies Association
Type: Research Grant: Period 9/15/89-8/31/91
Project Direct Costs: \$60,865.
Specific Aims: To determine mechanisms by which fat, fiber and calcium interact to protect against colon cancer.

29. Title: A culturally sensitive weight loss program for Texans Investigators: J.R. Lupton, PI (5% effort); B.A. Witcher and K. Dettwyler Co-PIs Agency: Office of University Research, Texas A&M University Type: Interdisciplinary research award: Period 9/15/91-8/31/92 Project Direct Costs: \$12,000. Specific Aims: To determine mechanisms by which Texans may lose weight.

30. Title: *Fat, fiber, calcium interactions*Investigators: J.R. Lupton, PI (20% effort)
Agency: Norwegian Dairies Association
Type: Research Award: Period 9/15/91-8/31/93
Project Direct Costs: \$25,000.
Specific Aims: To determine mechanisms by which fat, fiber and calcium interact to protect against colon cancer.

31. Title: *Effect of calcium in ileostomy patients*Investigators: J.R. Lupton, PI of subcontract, (20% effort), G Steinbach, PI overall grant Agency: National Institutes of Health, subcontract from MD Anderson Cancer Hospital, Houston, TX
Type: Research Award: Period 9/15/91-8/31/93
Project Direct Costs: \$8,500.
Specific Aims: To determine the physiological effects of calcium on the large intestine in individuals with ileostomies.

32. Title: *Fat/fiber interactions: effect on colon cytokinetics*Investigators: J.R. Lupton, Co-PI, (20% effort), RS Chapkin, Co-PI
Agency: American Institute for Cancer Research
Type: Research Award: Period 9/15/91-8/31/93
Project Direct Costs: \$110,000.
Specific Aims: To determine how fat and fiber interact to protect against colon cancer

33. Title: *Phase I calcium trial*Investigators: J.R. Lupton, Collaborator, subcontract (20% effort), R Winn, PI, MD Anderson Cancer Center, Houston, TX
Agency: National Institutes of Health, National Cancer Institute
Type: Research Award subcontract: Period 9/15/91-8/31/94

Project Direct Costs: \$46,000.

Specific Aims: To determine the safety of calcium supplements on the large intestine in a Phase I trial.

34. Title: *Physiological effects of acarbose*Investigators: J.R. Lupton, Collaborator, subcontract (5% effort), P. Holt, PI, Columbia College of Physicians and Surgeons, New York, New York
Agency: National Institutes of Health, National Cancer Institute
Type: Research Award subcontract: Period 9/15/91-8/31/94
Project Direct Costs: \$9,700.
Specific Aims: To determine the effect of the starch blocker acarbose on colon physiology.

35. Title: *Fat/fiber effects on colonocytes*Investigators: J.R. Lupton, Co-PI (10% effort), R.S. Chapkin, Co-PI, R. Burghardt, Co-PI
Agency: Office of University Research, Texas A&M University
Type: Interdisciplinary Research Funds: Period 9/15/93-8/31/94
Project Direct Costs: \$25,000.
Specific Aims: To determine fat/fiber effects on colonocytes.

36. Title: Noninvasive detection of colonic cellular markers: modulation by diet and carcinogen Investigators: J.R. Lupton, Co-PI (20% effort), R.S. Chapkin, Co-PI Agency: American Institute for Cancer Research Type: Research Award: Period 9/15/93-8/31/95 Project Direct Costs: \$110,000.
Specific Aims: To test a noninvasive technique to predict for colon tumor development.

37. Title: Fat effect on colonic mucosal phospholipids, arachidonic acid cascade, cell proliferation
Investigators: J.R. Lupton, PI (20% effort)
Agency: Norwegian Dairies Association
Type: Research Award: Period 9/15/93-8/31/95
Project Direct Costs: \$43,000.
Specific Aims: To test if dairy fats inhibit the arachidonic acid cascade.

38. Title: Butyrate metabolism in transformed vs normal cells
Investigators: J.R. Lupton, PI (20% effort)
Agency: Office of University Research, Texas A&M University
Type: Research Enhancement Funds: Period 9/15/93-8/31/95
Project Direct Costs: \$85,480
Specific Aims: To determine why butyrate has a protective effect against colon cancer in vitro, and a promotive effect in vivo.

39. Title: *Fiber, short chain fatty acids and colon cancer*Investigators: J.R. Lupton, PI (20% effort)
Agency: National Institutes of Health, National Cancer Institute
Type: RO1 CA 61750 research grant: Period 9/15/94-8/31/99

Project Direct Costs: \$588,088

Specific Aims: To determine the relationship between fiber, short chain fatty acid production and colon cancer.

40. Title: *Colonic cytokinetics and cell signaling: dietary effect* Investigators: J.R. Lupton, Co-PI (20% effort); RS Chapkin, PI Agency: National Institutes of Health, National Cancer Institute Type: RO1 CA 59034 research grant: Period 12/94-11/97 Project Direct Costs: \$449,314 Specific Aims: To study the mechanism(s) by which dietary fat modulates protein kinase C

expression and colonic cell proliferation in rats.

41. Title: Butyrate initiation of gene transcription: differential PCR
Investigators: J.R. Lupton, Co-PI (10% effort); RS Chapkin, Co-PI, N Ing Co-PI, L Jaeger, Co-PI
Agency: Office of University Research, Texas A&M University
Type: Interdisciplinary Research Funds: Period 9/15/95-8/31/96
Project Direct Costs: \$25,000
Specific Aims: To determine genes that are turned on or off in response to butyrate

42. Title: Butyrate mediated signal transduction on colonocytes: role of cAMP-dependent protein kinase.

Investigators: J.R. Lupton, Mentor (10% effort); H Aukema, PI, RS Chapkin, mentor Agency: American Institute for Cancer Research Type: Post Doctoral Award: Period 9/15/95-8/31/96 Project Direct Costs: \$16,500 Specific Aims: To determine how butyrate mediates signal transduction in colonocytes

43. Title: *Effect of dietary fat source on phospholipase C gamma I activation in early stages of carcinogenesis.* 

Investigators: J.R. Lupton, Mentor (10% effort); YH Jiang, PI, RS Chapkin, Mentor Agency: American Institute for Cancer Research Type: Post Doctoral Award: Period 9/15/97-8/31/98 Project Direct Costs: \$26,500 Specific Aims: To determine how fat source affects phospholipase C gamma I activation

44. Title: *Effect of a chemopreventive diet on carcinogen induced colonic ras activation* Investigators: J.R. Lupton, Co-PI (20% effort); RS Chapkin, Co-PI Agency: American Institute for Cancer Research Type: Research Award: Period 9/15/98-6/30/02 Project Direct Costs: \$164,565 Specific Aims: To determine how fat source affects ras activation

45. Title: *Phytate promotes apoptosis in colonocytes via inhibition of the PI3 kinase/Akt signaling pathway* Investigators: J.R. Lupton, Mentor (10% effort); ND Turner, PI, RS Chapkin, Mentor

Agency: American Institute for Cancer Research Type: Post Doctoral Award: Period 9/15/97-8/31/98 Project Direct Costs: \$16,500 Specific Aims: To determine if phytate promotes apoptosis by inhibiting PI3 kinase.

46. Title: Use of a transgenic rat model to determine the mechanisms by which diet influences colon tumor development
Investigators: J.R. Lupton, Co-PI (10% effort); W. Foxworth, Co-PI; A. Kier, Co-PI Agency: Office of University Research, Texas A&M University
Type: Interdisciplinary grant: Period 9/15/98-8/31/99
Project Direct Costs: \$24,817
Specific Aims: To develop a rat transgenic model for Protein Kinase C overexpression.

47. Title: Mechanisms by which select dietary lipids reduce colon cancer risk
Investigators: J.R. Lupton, Co-PI (20% effort); RS Chapkin, Co-PI, R Burghardt, Co-PI.
Agency: Office of University Research, Texas A&M University
Type: Interdisciplinary grant: Period 9/15/98-8/31/99
Project Direct Costs: \$32,010.
Specific Aims: To determine how dietary lipids reduce colon cancer risk.

48. Title: Communication techniques for health professionals
Investigators: J.R. Lupton, PI, (2% effort); ND Turner, Co-PI
Agency: Office of University Research, Texas A&M University
Type: V.F. and Gertrude Neuhaus Teaching Scholars Program: Period 9/15/98-8/31/99
Project Direct Costs: \$3,000.
Specific Aims: To purchase a computer projection system to enhance student presentations in senior seminar.

49. Title: Dietary fibers/phytoestrogens and colon carcinogenesis
Investigators: J.R. Lupton, Co-investigator, (2% effort); ND Turner, PI
Agency: National Institutes of Environmental Health Sciences
Type: P30 (ES09106, Years 1-4); pilot project grant: Period: 9/1/99 - 8/31/00.
Project Direct Costs: \$15,000.
Specific Aims: To develop preliminary data on phytoestrogens and colon cancer for application for external funding.

50. Title: *Honors Section of Senior Seminar* Investigators: J.R. Lupton, Co-PI, (2% effort); ND Turner, Co-PI Agency: Office of University Honors, Texas A&M University Type: Funds to support the development of honors courses: Period 9/15/99-8/31/00 Project Direct Costs: \$2,000. Specific Aims: To develop an honors senior seminar class.

51. Title: *Influence of docosahexaenoic acid (DHA 22:6n-3) on p21 ras membrane binding and function.* 

Investigators: J.R. Lupton, Co-PI (10% effort), R.S. Chapkin, PI

Agency: American Institute for Cancer Research Type: Research Grant, 7/31/00 - 7/30/02 Project Direct Costs: \$75,000 Specific Aims: To determine the effect of docosahexaenoic acid on colonic membrane interaction with oncogenic p21 ras.

52. Title: Noninvasive mRNA-based detection of colon cancer markers
Investigators: J.R. Lupton Co-PI, (5% effort), R. S. Chapkin, PI
Agency: National Institutes of Health/National Cancer Institute
Type: R01 (CA59034; Supplemental Funding): Period 8/1/00 – 7/30/01
Project Direct Costs: \$116,808
Specific Aims: To determine the ability of exfoliated cell mRNA markers to detect colon cancer in humans.

53. Title: Colonic cytokinetics and cell signaling: dietary effect
Investigators: J.R. Lupton, Co-PI (20% effort); RS Chapkin, PI
Agency: National Institutes of Health, National Cancer Institute
Type: RO1 CA 59034-05 Years 4-8: Period 9/15/98-8/31/03
Project Direct Costs: \$883,641.
Specific Aims: Experiments are designed to elucidate the role of specific PKC isozymes in
colon tumor development by using a targeted pharmacological inhibitor *in vivo* in combination
with overexpression and antisense strategies *in vitro*.

54. Title: *Nutritional countermeasures to radiation exposure* Investigators: J.R. Lupton, PI (20% effort), N.D. Turner, Co-PI Agency: National Space Biomedical Research Institute Type: Research Grant: Project Dates: 7/01/01 – 09/30/04 Project Direct Costs: \$1,175,000 Specific Aims: The overall goal of this project is to design diets that protect against radiationenhance colon carcinogenesis.

55. Title: Generalized linear measurement error models in nutrition and cancer.
Investigators: J.R. Lupton, Collaborator (10% effort), R.J. Carroll, PI.
Agency: National Institutes of Health/National Cancer Institute
Type: R01 (CA57030) Period: 7/1/00-6/30/05
Project Direct Costs: \$650,000
Specific Aims: The long-term objective of this research project is to develop new statistical methods for problems involving nutrition, cancer, and related areas.

56. Title: *Gene Expression in Radiation-Enhanced Colon Cancer* Investigators: J.R. Lupton, PI, (10% effort), N.D. Turner; Co-PI Agency: National Aeronautics and Space Administration (NASA) Washington Type: NAG-91523 Period: 5/15/2003-5/30/2005 Project Direct Costs: \$240,552 Specific Aims: The goal of this project is to determine if gene expression patterns, using mRNA from fecal material, are predictive of aberrant crypt development, and whether radiation treatment or a dietary intervention influences the relationships.

57. Title: Response to DNA damage: Colon vs Small Intestine
Investigators: J.R. Lupton, PI (15% effort)
Agency: National Institutes of Health/National Cancer Institute
Type: RO1 (CA61750): Period: 8/01/1994 – 5/30/2005
Project Direct Costs: \$157,500/year
Specific Aims: The goal of this project is to determine the differences in DNA damage, DNA repair, apoptosis, and reactive oxygen species generation that exist between the small vs large intestine that may explain the difference in small vs large intestinal cancer rates.

58. Title: A Graduate Education Program Focusing on Space Life Sciences
Investigators: J.R. Lupton, PI, N.D. Turner, Co-PI
Agency: National Space Biomedical Research Institute
Type: EO00604 (NASA NCC 9-58): Period: 11/1/04 - 5/31/06
Project Direct Costs: \$90,661
Specific Aims: The goal of this Phase I project is to develop a graduate education program that
emphasizes training and research for future scientists engaged in the challenges associated with safe, long-duration spaceflight.

59. Title: Center for Environmental and Rural Health.
Investigators: J.R. Lupton, Director, Nutrition Research Core (5% effort), P. Mirkes, PI. Agency: National Institutes of Environmental Health Sciences
Type: P30 (ES09106) Period: 5/1/02 - 3/31/07.
Project Direct Costs: \$5,000,000
Specific Aims: NIEHS Center for the study of Environmental and Rural Health.

60. Title: *Diet, apoptosis and colon carcinogenesis*Investigators: J.R. Lupton, PI (20% effort)
Agency: National Institutes of Health/National Cancer Institute
Type: R01 (CA82907): Period 2/01/01 – 1/31/2007
Project Direct Costs: \$1,000,000
Specific Aims: To determine the effects of dietary fiber and fat on colon cancer incidence, Cox-2 expression and induction of apoptosis.

61. Title: Fish oil and pectin enhances apoptosis in colonocytes via inhibition of PGE2 and PPAR delta signaling and promotion of death receptor pathway Investigators: J Vanamala, PI, JR Lupton (1% effort) Co-investigator Agency: American Institute for Cancer Research Type: Post Doctoral Grant; Period: 2006-2007 Project Direct Costs: \$25,000/year Specific Aims: To delineate the signaling pathway by which fish oil and pectin enhance colonic cell apoptosis. 62. Title: Adaptive Methodology for Functional Biomedical Data
Investigators: J. Morris, PI, (MD Anderson Cancer Center) J.R. Lupton, (1% effort) Coinvestigator
Agency: National Institutes of Health/NCI
Type: RO1 CA107304; Period: 3/01/2004 – 4/30/2008
Project Direct Costs: \$175,000/year

Specific Aims: The major goals of this project are to develop new methodology for functional data that provides a unifying framework for performing nonparametric function estimation and inference for functional data.

63. Title: *Colonic cytokinetics and cell signaling: dietary effect* Investigators: J.R. Lupton, Co-PI (5% effort); RS Chapkin, PI Agency: National Institutes of Health, National Cancer Institute Type: RO1 CA 59034: Period 5/01/03-6/03/08 Project Direct Costs: \$185,000/year for 5 years = \$1,125,000. Specific Aims: To elucidate the role of n-3 PUFA in reducing colon cancer risk. Specifically, determine if n-3 PUFA down-modulate tumor formation at the initiation stage of colon carcinogenesis.

64. Title: *Nutritional countermeasures to radiation-enhanced colon cancer* Investigators: J.R. Lupton, PI (10% effort), N.D. Turner, Co-PI Agency: National Space Biomedical Research Institute Type: Research Grant: NPFR00402 (NASA NCC 9-58): Project Dates: 10/01/04 – 09/30/08 Project Direct Costs: \$1,175,000 Specific Aims: The primary goal of this competitive renewal is to develop a set of colonocyte

Specific Aims: The primary goal of this competitive renewal is to develop a set of colonocyte gene expression profiles that accurately characterize the radiation-enhancing effect on colon carcinogenesis and the chemoprotective effect of dietary countermeasures.

65. Title: *Ability of n-3 fatty acids to influence colon tumor formation by modulating estrogen action* 

Investigators: C Allred, PI, JR Lupton, Co-PI Agency: American Institute for Cancer Research Type: Research Grant; Period: 1/1/2008 – 12/31/2009 Project Direct Costs: \$165,000 Specific Aims: To determine the ability of n-3 fatty acids to influence colon tumor development as a function of estrogen administration.

66. Title: Dietary Fibers as Potential Anti-Inflammatory Agents
Investigators: JR Lupton, PI, RS Chapkin, Co-Investigator, J Sturino, Co-Investigator
Agency: Tate & Lyle Ingredients Americas, Inc.
Type: Private Profit Corporation Research; Period: 12/1/2007 – 05/30/2009
Project Direct Costs: \$215,340
Specific Aims: To determine if ingestion of specific Tate & Lyle fibers reduces chronic inflammation, using the dextran sulfate sodium (DSS) inflammatory bowel disease rate model.

67. Title: Bayesian Models for Gene Expression with Microarray

Investigators: B. Mallick, PI, J.R. Lupton, (5% effort) Co-investigator Agency: National Institutes of Health/NCI Type: RO1 CA104620: Period: 6/10/05 – 5/31/2009 Project Direct Costs: \$197,500/year Specific Aims: Specific aim is to develop models for colon gene expression profiles of microarray data.

68. Title: *Measurement error, nutrition and breast/colon cancer*Investigators: R.J. Carroll, PI, J.R. Lupton, Co-investigator, (7% effort)
Agency: National Institutes of Health/National Cancer Institute
Type: 5 R37 CA057030-21: Period 7/08/2005 – 4/30/2010
Project Direct Costs: \$309.549 per year, \$1,387,671.19.
Specific Aims: The long-term objective of this research project is to develop new statistical methods for problems involving nutrition, cancer and related areas.

69. Title: Allen Foundation Graduate Program In Critical Evaluation of Nutrition Research Investigators: JR Lupton, PI Agency: Allen Foundation, Inc Type: Private Foundation Period: 06/1/2009 – 06/1/2011 Project Direct Costs: \$124,208 Specific Aims: To train students trained in evaluating nutrition research proposals, studies, and manuscripts, and help to develop skills that are highly marketable in academics, government, and private industry.

70. Title: Gene Expression Analysis of Coding and Non-coding RNAs in Colon Cancer Prevention
Investigators: RS Chapkin, PI, JR Lupton, Co-investigator
Agency: National Institutes of Health
Type: R01 CA129444; Period: 8/1/2009 – 7/31/2011
Project Direct Costs: \$300,000; Total Costs: \$439,500
Specific Aims: To use well established colitis-associated colon cancer models, i.e., the
azoxymethane (AOM)-dextran sodium sulfate (DSS) treated mouse and AOM treated
Interleukin-10 (IL-10) null mouse models in combination with a chemoprotective diet
extensively studied in our laboratory, i.e., n-3 polyunsaturated fatty acids (PUFA). These
experimental models will be used to test our hypothesis that n-3 PUFA suppression of oncogene-directed

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# **Current Support**

71. Title: Nutrition, Biostatistics, and Bioinformatics
Investigators: J.R. Lupton, Co-Investigator, (8% effort) R.J. Carroll, PI
Agency: National Institutes of Health/National Cancer Institute
Type: R25 (CA90301): Period: 8/1/01 - 6/30/11, refunded 8/1/11 - 7/31/16.
Project Direct Costs: \$2,286,848, refunded for 493,574/year

Specific Aims: Our goal is to train statistically oriented individuals to function as independent researchers in a multidisciplinary environment focusing on Nutrition and cancer. To achieve this goal we have assembled a team of researchers specializing in Statistics/Biostatistics, Bioinformatics and the biology of Nutrition and cancer.

72. Title: *PhD training program in critical areas of space life sciences*Investigators: J. R. Lupton, PI, (10% effort) N.D. Turner, Co-PI
Agency: National Space Biomedical Research Institute
Type: Education Grant: Period: 7/1/06-6/30/12
Project Direct Costs: \$1,031,630
Specific Aims: To train future space life scientists in a coordinated PhD program

73. Title: Simultaneous gene expression analysis of coding and non-coding RNAs in colon cancer prevention
Investigators: RS Chapkin, PI, JR Lupton, Co-investigator
Agency: National Institutes of Health, NCI
Type: RO1 CA129444-01 Period: 10/1/07-9/30/11
Project Direct Costs: \$200,000/year
Specific Aims: To quantify the number and spatiotemporal location of stem cells in the colonic crypt in response to inducers of chronic inflammation and carcinogenesis following exposure to a chemoprotective diet. And to investigate the effects of disease progression and microRNAs and their post-transcriptionally regulated mRNA targets by evaluating both coding and non-coding transcripts in colonic stem cells following AOM/DSS or saline exposure.

74. Title: Colonic cytokinetics and cell signaling: dietary effects
Investigators: RS Chapkin, PI, JR Lupton, Co-investigator
Agency: National Institutes of Health, NCI
Type: 2RO1 CA0595034: Period: 12/01/2007-11/30/2012
Project Direct Costs: \$1,785,880
Specific Aims: To determine the mechanisms by which n-3 PUFA modulate intrinsic
(mitochondria-mediated) cell death signaling. And to determine the mechanisms by which n-3 PUFA modulate extrinsic (non-mitochondrial) cell death signaling.

75. Title: Measurement error, nutrition and breast/colon cancer
Investigators: R.J. Carroll, PI, J.R. Lupton, Co-investigator, (5.91% effort)
Agency: National Institutes of Health/National Cancer Institute
Type: 5 R37 CA057030-21: Period 5/01/2010 – 4/30/2015
Project Direct Costs: \$318,171 per year, \$1,058,390.
Specific Aims: The long-term objective of this research project is to develop new statistical methods for problems involving nutrition, cancer and related areas.

76. Title: *Comparative Biomedical Research Training for Veterinarians* Investigators: AB Kier, PI, JR Lupton, Co-investigator Agency: National Institutes of Health Type: T32 RR031229-01; Period: 7/01/2010 – 07/01/2015

#### Project Direct Costs: \$892,704

Specific Aims: To provide veterinarians with post-doctoral research training to assume important roles in biomedical research. These comparative medicine researchers are critical to the translation of basic biomedical research into new treatments and management of human disease conditions.

## **INVITED PRESENTATIONS**

#### National/International

- 1. Diet induced cell proliferation changes in the gastrointestinal tract and their relationship to gastrointestinal cancer. Memorial Sloan Kettering Cancer Research Center, New York, NY. July, 1983.
- 2. *Dietary Fiber FASEB Conference*. Invited participant in the conference, sponsored by the Federation of American Societies for Experimental Biology. Saxons River, VT, July, 1986.
- 3. *The physiological effects of dietary fiber in the large intestine*. Food and Drug Administration. Washington, DC, 1987.
- 4. *Fiber and cardiovascular health*. National Conference: Nutrition and Cardiovascular Health, sponsored by the American Heart Association, Austin, TX, 1987.
- 5. *Effect of calcium on calcium soap formation*. Part of a conference on "Calcium and Cancer", National Dairy Council, Chicago, IL., 1988.
- 6. *Effect of fiber type on colon carcinogenesis*. Special symposium on diet and cancer as part of the American Association for Cancer Research Meetings, New Orleans, LA, 1988.
- 7. *Dietary fiber and carbohydrates in cancer prevention*. Designer Foods in Cancer Prevention. A two day symposium. Rutgers, New Brunswick NJ, 1989.
- 8. *Does dietary fiber reduce the risk of cancer?* Nutrition and Cancer Prevention Conference. Sponsored by the American Cancer Society. Austin, TX, November 9,10, 1989.
- 9. *Effect of barley on serum cholesterol*. Presented to Miller Brewing special cereal chemist conference. Milwaukee, WI, November 14, 1989.
- 10. *Dietary fiber: current trends*. Presentation to the research scientists at General Foods, Tarrytown, NY, January 10, 1990.
- 11. *Controversies over fiber*. National Conference sponsored by the American Cancer Society, Partners in Prevention. Houston, TX, October 11, 1990.
- 12. *Dietary fiber, short chain fatty acids and colon carcinogenesis*. Invited presentation and participation in an international conference on short chain fatty acids: metabolism and clinical importance. Sanibel Island, Fl, December 2-4, 1990.
- 13. *Effect of dietary fiber on the colonic luminal environment and epithelial cytokinetics.* Invited presentation as part of a symposium on dietary fiber and epithelial cytokinetics at the annual FASEB meeting. Atlanta, GA, April 23, 1991.
- 14. Co-chair, fiber minisymposium at the annual FASEB meeting, Atlanta, GA, April, 1991.
- 15. *Dietary fiber and colon carcinogenesis*. Symposium on diet and cancer. M&M Mars, Hacketstown, NJ, June 13, 1991.

- 16. *Fat/fiber interactions: effect on colon cytokinetics*. Vahouny Conference on Dietary Fiber (held every four years), Washington, DC, April 13, 1992.
- 17. *Effect of fiber fermentability on colonic physiology*. Workshop on the "Physiological effects of complex carbohydrates." Sponsored by the International Life Sciences Institute, Washington, DC April 15-16, 1992.
- 18. *Fat/fiber/calcium: bile acids and cell proliferation*. Norwegian Dairies Association. Oslo, Norway, July 21, 1992.
- 19. *Fat/fiber interactions: effect on colon cytokinetics*. Nutrition Institute. University of Oslo, Oslo, Norway. July 30, 1992.
- 20. Amount and type of calcium, fat and fiber, effect on fecal bile acids and colonic proliferation. Invited presentation representing the USA, sponsored by Norway, to the Utrecht Group. International Workshop on Dairy Products and Prevention of Colon Cancer. November 10, 1992. Utrecht, The Netherlands.
- 21. *Dietary fiber and colon carcinogenesis*. Symposium on Diet and Carcinogenesis, Rutgers University, College of Medicine, and Cancer Center. New Brunswick, NJ, June 11, 1993.
- 22. *Fat/fiber interactions: effect on colon carcinogenesis*. "Advances in the Biology and Therapy of Colorectal Cancer," an International Conference, MD Anderson Cancer Center, November 4-7, 1993.
- 23. *Dietary fiber and colon cancer*. Panel Member, FDA-initiated public conference on dietary fiber and cancer and coronary heart disease, to determine if enough scientific evidence exists to make health claims for dietary fibers. Arlington, Virginia, May 12-13, 1994.
- 24. *Colon cancer: The fat/fiber connection*. The Allen lecture, Cedar Crest College, Allentown, PA, October 15, 1994.
- 25. *Dietary fiber and colon cancer*. American Society of Preventive Oncology, Annual meeting, Houston, TX. March 8-11, 1995.
- 26. *Fiber fermentability is key to its effect on colon tumor development*. Symposium speaker. Symposium on Future Directions in nutrition research at the International Food Technologists annual meeting, Anaheim, CA, June 7, 1995.
- 27. *Presentation of the FDA's opinion on the gastrointestinal effects of Olestra* at the public hearing for Olestra approval. Food and Drug Administration, Washington, DC, November 14, 1995.
- 28. *Dietary Fiber: An Evolving Perspective*. The Boyd O'Dell Lecture at the University of Missouri-Columbia, March 25, 1996.
- 29. *Obtaining funding in an unfriendly world*. University of Missouri-Columbia, March 26, 1996.
- 30. *The FDA's conclusion on the gastrointestinal effects of Olestra*. The Toxicology Forum, Aspen, Colorado, July 8, 1996.
- 31. *Co-chair and summary of presentations*, Diet and Carcinogenesis minisymposium at Experimental Biology, News Orleans, LA, April, 1997.
- 32. *Dietary fiber and colonic cytokinetics*. University of Illinois, Champaign-Urbana, IL, October 31, 1997.
- 33. *Mechanisms by which wheat bran protects against colon cancer*. Conference on "Primary Prevention of Colorectal Cancer and Polyps: The Role of Fiber." Sponsored by

the American Health Foundation, New York, New York, and organized by Memorial Sloan Kettering, December 2, 1997.

- 34. *Chair, and overview presentation*, Diet and Carcinogenesis minisymposium at Experimental Biology, San Francisco, April 18-22, 1998.
- 35. *Diet, apoptosis and colon carcinogenesis*. International symposium on apoptosis and cancer, Studenica, Yugoslavia, Institute of Oncology Sremska Kamenica, Novi Sad. Given in absentia due to political unrest in Yugoslavia, June/July, 1998.
- 36. *Wheat bran protection against colon cancer- role of butyrate*. 6th International Conference on Mechanisms of Antimutagenesis and Anticarcinogenesis, Arcachon, France, October 25-29, 1998.
- Dietary fiber, colonic cytokinetics and colon carcinogenesis. Satellite Vahouny Conference. International Meeting on Dietary Fiber. Adelaide, Australia, November 29 -December 1, 1998.
- 38. *Fat/fiber interactions on colonic cytokinetics: relationship to colon cancer*. Nutritional Sciences Seminar. University of Florida, Gainesville, Florida, March 21-22, 1999.
- 39. Butyrate and Colon Cancer: A controversy in need of resolution. The Millennium (Sixth) Vahouny Fiber Symposium. Washington, DC, March 20, 2000.
- 40. *The business of eating right*. The Allen Lecture. Northwood University Business School, Midland, Michigan, April 10, 2000.
- 41. Chair, programmer, and overview speaker for the carbohydrates minisymposium, Experimental Biology 2000, San Diego, April 16, 2000.
- 42. Co-Chair, Energy density minisymposium. Experimental Biology 2000, San Diego, CA, April 16, 2000.
- 43. Co-Chair, Functional Food minisymposium. Experimental Biology 2000, San Diego, CA, April 17, 2000.
- 44. *Structure/function claims. How much science is enough?* National Academy of Sciences, Washington, DC, April 26, 2000.
- 45. *Outcomes of dietary fiber clinical trials: where is the science taking us*. Mars Nutrition Research Council, Strasbourg, France, May 2, 2000.
- 46. *Fat/fiber interactions and their effect on colon carcinogenesis*. ISSFAL 2000, 4<sup>th</sup> Congress of the International Society for the Study of Fatty Acids and Lipids. Tsukuba, Japan, June 4-9, 2000.
- 47. *Nutritional Countermeasures to radiation exposure*. NASA Bioastronautics Meeting. Galveston, Texas, January 18, 2001.
- 48. *Presentation of the Food and Nutrition Board's Proposed Definition of Dietary Fiber.* Experimental Biology 2001, Orlando, Florida, April 3, 2001.
- 49. *Dietary fiber: what is it, what does it do for us, is it protective against colon cancer.* Mars Nutrition Research Talks, University of Illinois, Champaign-Urbana, Illinois, May 29, 2001.
- 50. *Dietary fiber: The science behind the recommendations*. Mars Nutrition Talks, University of Illinois, Champaign-Urbana, Illinois, May 30, 2001.
- 51. *Fat/fiber interactions: Effect on colon cytokinetics*. Mars Nutrition Talks, University of Illinois, Champaign-Urbana, Illinois, May 30, 2001.
- 52. *Mechanisms by which specific fats and fibers protect against colon cancer*. Mars Nutrition Talks, University of Illinois, Champaign-Urbana, Illinois, May 31, 2001.

- 53. *Mechanisms by which specific fats and fibers protect against colon cancer*. Colorectal Cancer Prevention Meeting, Rockville, MD. National Cancer Institute's Division of Cancer Prevention, November 3, 2001.
- 54. *Nutrition as a countermeasure to radiation-enhanced colon cancer*. NSBRI, Bioastronautics Meeting. Del Lago, Texas, January 15, 2002.
- 55. *Nutritional countermeasures to radiation exposure*. Kongress Medizin und Mobilitat Munich, Germany, Sept. 12-14, 2002.
- 56. *New recommendations on dietary fiber*. American Dietetic Association Annual Meeting, Philadelphia, PA, Oct. 21, 2002.
- 57. *Dietary Fiber recommendations from the DRI Process*. Presentation to the Food and Nutrition Board, National Academy of Sciences, Washington, DC, Nov. 6, 2002.
- 58. *Carbohydrate recommendations from the DRI Process*. Presentation to the Food and Nutrition Board, National Academy of Sciences, Washington, DC, Nov. 6, 2002.
- 59. Overview of all of the Macronutrient Report Recommendations. Presentation to the Food and Nutrition Board, National Academy of Sciences, Washington, DC, Nov. 6, 2002.
- 60. *Recent recommendations on Carbohydrates and Fiber*. Presentation to the General Mills Nutrition Research Board. Minneapolis, MN, Nov. 7, 2002.
- 61. Overview of the key Macronutrient Report Recommendations. Presentation to the General Mills Nutrition Research Board. Minneapolis, MN, Nov. 7, 2002.
- 62. *Nutrition as a possible countermeasure to radiation exposure.* Bioastronautics Investigators' Workshop, Galveston, TX, Jan. 13-15, 2003.
- 63. *Challenges in Developing Dietary Reference Intakes for Energy and Macronutrients*. ILSI annual meeting, Miami, FL, Jan. 22, 2003.
- 64. *Dietary fiber and colon cancer: What's the real story?* Thirtieth Annual Texas Human Nutrition Conference, College Station, TX, Feb. 7, 2003.
- 65. *Carbohydrates: Fiber*. Part of the National Academy Symposium on DRIs at Experimental Biology, San Diego, April 11, 2003.
- 66. *Carbohydrates: Starches and Sugars.* Part of the National Academy Symposium on DRIs at Experimental Biology, San Diego, April 11, 2003.
- 67. Evidence that Microbial Degradation Products influence Colon Cancer Risk: The Butyrate Controversy. Part of the Symposium on Diet Induced Changes in the Colonic Environment and Colorectal Cancer, Experimental Biology, San Diego, April 14, 2003.
- 68. Individualized Nutrition and its Potential Impact on the Food Supply: Future Applications of Metabolomics. Chair of the symposium and summary speaker. Food Forum, National Academy of Sciences, Washington, DC, May 6, 2003.
- 69. *Introduction to the DRI Process*. American College of Sports Medicine, San Francisco, CA, May 28, 2003.
- 70. Development, Interpretation, and Application: Dietary Carbohydrate Recommendations. American College of Sports Medicine, San Francisco, CA, May 28, 2003.
- 71. *How to integrate teaching, running a laboratory and committee work and remain sane.* Danon Institute Mentoring Project, Wye Center, MD, June 9,10, 2003.
- 72. Potential Updates to the 2000 Dietary Guidelines on carbohydrates: new research. Open meeting of the Dietary Guidelines Committee, Washington, DC, September 24, 2003.

- 73. *Applying evidence-based science review methodology to the 2005 Dietary Guidelines.* Open meeting of the Dietary Guidelines Committee, Washington, DC, September 24, 2003.
- Diet and Colon Cancer: Fat/Fiber interactions and their effect on colon cancer incidence. Distinguished Scientist Lecture Series. University of Maryland, College Park, MD, September 25, 2003.
- 75. *Dietary Fiber: What it is, what it does and doesn't do for you, how much you need to eat.* FDA/CFSAN/OFAS, Food and Drug Administration, Washington, DC, October 28, 2003.
- 76. *Diet and Colon Cancer: Fat/fiber interactions*. Cancer Prevention and Control Colloquia Lecture Series. National Institutes of Health, Rockville, Maryland, December 10, 2003.
- 77. *Fat/Fiber interactions and their effect on colon cancer incidence*. The Linus Pauling Institute, Oregon State University, Corvallis, OR, February 26, 2004.
- 78. Determining the strength of the relationship between a food, food component or dietary supplement ingredient and a disease or health-related condition. Part of the Symposium on Nutrient Disease Relationships: Closing the Scientific Knowledge Gap, Experimental Biology, Washington, DC, April 19, 2004.
- 79. *Is fiber protective against colon cancer?* Korean Nutrition Society Symposium, Muju, Korea, May 14, 2004.
- 80. The US and Canadian DRIs for carbohydrate and fiber: Science behind the recommendations. Korean Nutrition Society Symposium, Muju, Korea, May 15, 2004.
- 81. Dietary fiber update: what fiber does and doesn't do for you. Lecture for freshmen class College of Human Ecology, Seoul National University, Seoul, Korea, May 18, 2004.
- 82. *Fat/fiber interactions and their effect on colon carcinogenesis*. Lecture for faculty and graduate students, Department of Food and Nutrition, Seoul National University, Seoul Korea, May 18, 2004.
- 83. The Institute of Medicine, Food and Nutrition Board, National Academy of Sciences Definition of Fiber. Dietary Reference Intakes: Implications for Fiber Labeling and Consumption. ILSI NA Fiber Workshop, Washington, DC, June 1-2, 2004.
- 84. New promises require new criteria: Evaluating and regulating foods/substances that claim to decrease risk of a disease. The Future of Food: Five, Twenty-Five and Fifty-Year Visions A Mars MDRU\* Conference MARS Incorporated, McLean, Va., June 7, 2004.
- 85. *The Mission to Mars: Food challenges for the astronaut. Benefits and lessons for those still on earth.* The Future of Food: Five, Twenty-Five and Fifty-Year Visions A Mars MDRU\* Conference MARS Incorporated, McLean, Va., June 7, 2004.
- 86. *Dietary Guidelines Advisory Committee: From molecules to dietary patterns.* The Food Guide Pyramid: A Call-to Action. Society for Nutrition Education, Salt Lake City, UT, July 18-19, 2004.
- 87. *Current status of the definition of dietary fiber in the U.S. and the science behind the recommendation for fiber.* Symposium on Dietary Fiber, Japanese Association for Dietary Fiber Research, Osaka, Japan, September 17, 2004.
- 88. *Dietary fiber and colon cancer: Where do we stand now?* Current topics of dietary fiber and the prospects for the future, Japanese Association for Dietary Fiber Research, Tokyo, Japan, September 21, 2004.

- 89. *Dietary fiber update: What fiber does for you and how much we should eat.* ADA Media spokespersons' Breakfast meeting, American Dietetic Association Annual Meeting, Anaheim, CA., October 4, 2004.
- 90. *Dietary fiber: From molecules to public policy*. 2004 Lucille Hurley Lecture, University of California at Davis, CA. October 18, 2004.
- 91. The new dietary guidelines Part 2, Energy balance, fats, whole grains and carbohydrates, fruits and vegetables. Fall Corporate Affiliates Meeting at Purdue University, October 22, 2004.
- 92. Steps to a national nutrition policy: translating nutrient recommendations and food intake data into food pattern recommendations. Symposium on Nutrition Monitoring and Health Policy Development. Taipei, Taiwan, December 3, 2004.
- 93. *Dietary fiber and colon cancer: where do we go from here.* Sonia Wolf Wilson Lectureship at the University of Texas at Austin, December 10, 2004.
- 94. The importance of optimal nutrition to long duration spaceflight. Johnson Space Center, Space Medicine Grand Rounds, Houston, Texas, January 18, 2005.
- 95. Current status of the definition of dietary fiber in the US and the major issues of disagreement worldwide on the definition of dietary fiber. Symposium on the definition of dietary fiber, analytical methods, and energy values. Chinese Center for Disease Control and Prevention, and Department of Health, Beijing, China, June 15, 2005.
- 96. *The importance of optimal nutrition to long duration spaceflight: Foods for the future.* Conference on the future of food, MDRU, Washington, DC, June 22, 2005.
- 97. *The 2005 Dietary Guidelines perspective on: Glycemic carbohydrates and sugar.* Symposium on the complexity of carbohydrates. Annual Meeting of the Institute of Food Technologists (IFT), New Orleans, LA, July 17, 2005.
- 98. *The 2005 Dietary Guidelines for carbohydrates and fiber*. Symposium on the science behind the 2005 Dietary Guidelines. Annual Meeting of the Institute of Food Technologists (IFT), New Orleans, LA, July 18, 2005.
- 99. Health implications for dietary fiber: Guidelines for the clinical practice on the role of fiber in the prevention of cardiovascular disease. Symposium on Nutraceuticals and Medicine. Annual Meeting of The American Nutraceutical Association, Nashville, TN, October 15, 2005.
- The 2005 Dietary Guidelines: Science behind the carbohydrate recommendations. Annual Meeting of the American Dietetic Association (ADA), St. Louis, MO, October 23, 2005.
- 101. *The 2005 Dietary Guidelines: What's new?* 2005 Nutrition Symposium, Texas State Extension Agents and Specialists, San Antonio, TX, November 15, 2005.
- 102. *Carbohydrates: The Science behind the recommendations.* The Texas Human Nutrition Conference, College Station, TX, February 3, 2006.
- 103. Discussion of Research Recommendations: DRIs for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein and amino acids. Dietary Reference Intake Research Synthesis Workshop. National Academy of Sciences, Washington, DC, June 7, 2006.
- 104. *Dietary Fiber: Definition, functions, current recommendations, potential health benefits.* Grain Processing Corporation, Muscatine, Iowa, June 22, 2006.
- 105. *From molecules to meals: Constructing the 2005 Dietary Guidelines.* Friedman School Symposium, Tufts University, Boston MA, September 20, 2006.

- 106. A combination of omega-3 fatty acids and a butyrate-producing fiber mitigates colon cancer development. International Astronautical Congress. Valencia, Spain, October 3, 2006.
- 107. Rationale for the Institute of Medicine's total fiber definition and the requirement that functional fibers demonstrate physiological efficacy. Scientific Workshop on Dietary Fiber. Toronto, CA, November 15, 2006.
- 108. *How might the food label, pyramid and Guidelines be better aligned to send consistent messages.* Keystone Food and Nutrition Roundtable. Washington, DC, January 9, 2007.
- 109. From molecules to food patterns: The challenge of developing a national nutrition policy. University Distinguished Lecture. Texas A&M University, College Station, TX, March 20, 2007.
- 110. *Scientific substantiation of claims in the USA: Focus on functional foods.* International symposium on functional foods. Malta, May 9, 2007.
- 111. Detection of radiation exposure and countermeasure responses in vivo using exfoliated rat colonocytes collected over time. International Astronautical Congress. Beijing, China, May 22, 2007.
- 112. *The importance of optimal nutrition to long duration spaceflight*. Streaming video produced for NASA/NSBRI for their distribution. Baylor College of Medicine, Houston, TX . <u>http://www.bioedoline.org</u>. May 29, 2007.
- 113. *Current recommendations for fiber intake:* the science behind them and practical applications for children. Nutrition Center Seminar Series at the Children's Hospital of Philadelphia. May 14, 2008.
- 114. *Good carbs\bad carbs: The science behind the recommendations and guidelines for clinical practice.* ANA CME Conference. Memphis, Tennessee, October 25, 2008.
- 115. Current status of the definition of dietary fiber in the US and the major issues of disagreement worldwide on a definition for dietary fiber. Pre-Codex Workshop, Current Issues in Nutrition and Health Oils, Micronutrients, and Dietary Fiber: Health Benefits, Recommended Intakes and Definitions. Capetown, South Africa, November 2, 2008.
- Diet and colon carcinogenesis: Using mRNA from exfoliated colon cells to predict tumor outcome. Cancer Prevention Grand Rounds, MD Anderson Cancer Center, February 20, 2009.
- 117. *Notes from the crypt: What statistics can tell us about colon cancer*. Statistical Methods for Complex Data" to honor and celebrate Raymond Carroll's 60<sup>th</sup> birthday and his distinguished career. March 14, 2009
- 118. *Where is the science*? Smart choices program. Experimental Biology 2009, New Orleans, LA, April 20, 2009.
- 119. Financial conflicts and scientific integrity: Perspective from an academic research scientist. Experimental Biology 2009, New Orleans, LA, April 21, 2009.
- 120. ASN and the Smart Choices Program. Industry Forum Meeting. Experimental Biology 2009, New Orleans, LA, April 17, 2009.
- 121. *Smart Choices Program: Science behind the nutrition criteria*. Institute of Medicine Food Forum Meeting. Washington, DC, May 14, 2009.
- 122. *Fiber is a nutrient of need in the diet*. Institute of Food Technologists Annual Meeting. Anaheim, CA, June 7, 2009.
- 123. Codex Step 8 Definition of Dietary Fibre and Issues Requiring Resolution. Dietary Fibre Conference, Vienna, Austria, July 2, 2009.

- 124. *Smart Choices Program: Science Behind it and Comparison to other programs.* Panel on the Smart Choices Program; Purdue Fall Corporate Affiliates. Purdue University West Lafayette, Indiana, August 28, 2009.
- Perspectives from an Academic Research Scientist. 2010 ILSI North America Scientific Session Financial Conflicts of Interest and Scientific Integrity, Puerto Rico, January 25, 2010.
- 126. *Public Policy in Nutrition: Where Does Science Fit In?* The National Academy of Sciences and Engineering, Distinctive Voice Lecture Series at the Beckman Center, Irvine, CA, , February 16, 2010.
- 127. Front-of-Pack Labeling: Health claims, nutrient content claims and point of purchase claims. International Conference on Food Labeling: Opening the Doors to the United States Market. Texas A&M University Mexico City, March 26, 2010
- 128. *Smart Choices Program: Rationale behind the nutrition criteria.* Committee on Examination of Front-of-Package Nutrition Rating systems and Symbols Institute of Medicine. Washington DC, April 9, 2010.
- 129. Added Sugars Recommendations: From the DRIs to the current US Dietary Guidelines. American Heart Association Added Sugars Conference. Washington DC, May 5, 2010.
- Overview of CODEX definition and future implementation and summation of implementation issues with CODEX fiber definition. 9<sup>th</sup> Vahouny Fiber Symposium. Washington DC, June 10, 2010.
- 131. *The science behind the claims and why the product that bears a claim needs to be* "*healthy*". NABC22 conference on "Promoting Health by Linking Agriculture, Food and Nutrition", University of California, Davis, June 17, 2010.
- 132. Updating the DRIs in China: Key elements to consider from the US Institute of Medicine DRI process. Chinese Nutrition Society, DRIs Symposium Beijing, China November 10-11, 2010.
- 133. "Is there still a place at the table for refined grains post the 2010 Dietary Guidelines Advisory Committee Report? Rice as a Case Study". Institute of Food Technologist's Annual Meeting. New Orleans, LA, June 14, 2011.
- 134. *"When Earning an "F" in School is a Good Thing"*. Annual National Conference for the School Nutrition Association. Nashville, TN, July 10, 2011.
- 135. "Dietary Fiber and its Effect on Health From a Science\Physiological Perspective". 2011 International Conference on Food Factors. Taipei, Taiwan, November 22, 2011.
- 136. *"From basic science to dietary guidance: Dietary Fiber as an example".* 2011 International Conference on Food Factors. Taipei, Taiwan, November 22, 2011.
- 137. "Global challenges in dietary bioactive substances today and in the future". 11<sup>th</sup> China Nutrition Science Congress & International Nutrition Sciences and DRIs Summit. Hangzhou, China. May 15-17<sup>th</sup>, 2013.
- 138. "USA Experience-DRIs for the Macronutrients". 11<sup>th</sup> China Nutrition Science Congress & International Nutrition Sciences and DRIs Summit. Hanzhou, China. May 15-17<sup>th</sup>, 2013.

# TEACHING

Developed and taught the following courses at Texas A&M University:

<u>Course</u>	Description	Years Taught
Nutrition 202	Basic Nutrition. Proteins, carbohydrates, lipids vitamins and minerals.	1985-1988 1990-1992
Nutrition 203	Basic Nutrition for majors.	1992-2001
Nutrition 444	Nutrition in the Life Cycle. How physiological changes at different stages of the life cycle manifest themselves in changing nutritional requirements.	1984-1991
Nutrition 470	Physiological Chemistry. Tissue specific metabolism of proteins, carbohydrates and lipids and the controls on metabolism.	1990-present
Nutrition 481	Senior Seminar. How to review the current literature and give a seminar using Power Point.	1996-present
Nutrition 485	Undergraduate Research Problems. Teach every semester.	1985-present
Nutrition 485	Undergraduate Research Honors. Have had three Honors University Fellows.	
Nutrition 489	Diet, heart disease and cancer.	1988, 1989
Nutrition 489/689	Critical Evaluation of Nutrition & Food Science Literature: Evidence based reviews.	2008-present
Nutrition 681	Nutrition Seminar. Started the seminar series and	1986-1993
Nutrition 685	Graduate Problems. Teach most semesters.	1985-present
Nutrition 690	Graduate Course. How to give a scientific presentation.	1989-1996
Nutrition 691	Graduate Research. Teach every semester.	1985-present
Meid 981	Nutrition for Medical Students. Helped to develop the course and taught one to two lectures each year.	1993-2000

# EDUCATION OF GRADUATE STUDENTS AND POST DOCTORAL FELLOWS:

#### Major advisor or Co-major advisor:

- Christin Forest Aymond. MS, 1997. (Co-major advisor with Dr. R. S. Chapkin). Detection of putative colon cancer biomarkers in exfoliated colonocytes.
- Laura Bancroft. MS, 2002. (Co-major advisor with Dr. R. S. Chapkin). *Dietary fish oil reduces* oxidative DNA damage in rat colonocytes.
- Cherie Byler. MS, 1987. The effect of a computerized nutrition education activity on the knowledge and applied use of information by college students.
- Wen-Chi L. Chang. MS, 1992. Effect of different amounts and type of fat on colonic cell proliferation and fecal bile acid concentrations.
- Wen-Chi L. Chang. PhD, 1997. *Modulation of colonic biomarkers by different types of dietary fat and fiber during tumorigenesis.*
- Wen-Chi L. Chang. Post Doctoral Fellow, 1998. Apoptosis in colonocytes during the tumorigenic process.
- Xiao-Qing Chen. *MS*, 1991. Effect of different amounts and types of calcium on colonic cell proliferation and fecal bile acid concentrations.
- Youngmi Cho, PhD student. Current
- Susan Marie Clay (Maier). MS, 1989. The effect of oat bran and amaranth products in men and women.
- Esther Dick Collett. MS, 2000. (Co-major advisor with Dr. Robert Chapkin). *Effect of docosahexaenoic acid on ras post-translational processing and localization in a transgenic mouse colonic cell line.*
- Kristi Lynn Covert (Crim). MS, 2005. Dietary fish oil and butyrate increase apoptosis and decrease aberrant crypt foci in colon cancer by cnhancing histone acetylation and  $p21^{Waf1/Cip1}$  expression.
- Ruth Ann Danz. MS, 1988. Physiological effect of dietary amaranth.
- Suzanne Dorr. MS, 1987. The effect of exercise and dietary fiber on the rate of gastrointestinal transit time in the rat.
- Christine Economopolous. MS, 1993. Dietary fiber consumption in the US population.
- Lindsey Briggs Field. MS, Current
- Jeanne Gazzaniga (Moloo). MS, 1985. The bulking effect of dietary fiber in the rat large intestine: an in vivo study of cellulose, guar, pectin, wheat bran and oat bran.
- Jolene Gibson. MS, 1987. *Applying adult education techniques in a nutrition education program about dietary fiber.*
- Anna Glagolenko. MS, (Health Physics) 2004. (Co-major advisor with Dr. John Ford). *Effect of HZE radiation and diets rich in fiber and n-3 polyunsaturated fatty acids (n-3 PUFA) on colon cancer in rats.*
- Susan Renee Haynes. MS, 1988. Cellulose and psyllium supplementation in 10 females; the effect on food intake and in vitro fermentation variables.
- Valerie Hebert. MS, 1999 (Co-major advisor with Dr. W. Sampson). *Changes in bone* morphology and composition following long-term alcohol consumption.
- Cara Everett Henderson. MS, 2001. *Effect of aging on oxidative damage to DNA in the small intestine vs the large intestine.*
- Mee Young Hong. PhD, 1999. Effect of lipid source on initiation of colon tumorigenesis: Apoptosis, DNA damage and DNA repair.

Mee Young Hong. Ph.D. Post Doctoral Fellow 1999 - 2005.

- Yi-Hai Jiang. PhD, 1996. (Co-major advisor with Dr. R. S. Chapkin). Signal transduction and colon carcinogenesis.
- Elizabeth Anne Kahlich. MS, 2006.
- Mihae Kim. MS, 1996. *Mechanisms by which butter fat may be protective against colon carcinogenesis.*
- Hyemee Kim. PhD student. Current
- Dong-Yeon K. Lee. PhD, 1992. (Co-major advisor with Dr. R. S. Chapkin). Dietary modulation of biomarkers of colon carcinogenesis: interactive effect of different types of fiber and fat.
- Tety Leonardi. MS, 2005. (Co-major advisor with Dr. N.D. Turner). *Dietary apigenin and naringenin protect against colon carcinogenesis by lowering high multiplicity aberrant crypt foci and enhancing apoptosis in axoxymethane-treated rats.*
- Michelle McNichol. MS, 1992. A culturally sensitive weight loss program for Texans.
- John Clifford Mann. MS, 2005. (Co-major advisor with Dr. N.D. Turner). *The effects of diet and ionizing radiation on azoxymethane induced colon carcinogenesis.*
- Linda Jean Marchant. MS, 1986. *The effect of dietary protein and fiber on in vivo ammonia concentration.*
- Elizabeth Gonzalez May. MS, 1993. Effect of different amounts and types of dietary fiber on colonic cell proliferation and fecal bile acid concentrations.
- M. Melanie Meacher. MS, 1986. A radiographic analysis of the effect of dietary fiber on transit time through the rat large intestine.
- Janet Louise Morin. MS, 1990. The effects of barley bran flour on colonic physiology.
- Anne Henry Newton, MS, 2004. *Effects of fish oil and butyrate on diet-mediated apoptosis at the promotion stage of colon carcinogenesis.*
- Pamela Denise Parish (Kurtz). MS, 1985. The effect of wheat bran and pectin supplementation on luminal pH and short chain fatty acid production in the rat large intestine.
- Jennifer Pickering. MS, 1996. (Co-major advisor with Dr. R. S. Chapkin). *Prostaglandins, dietary lipids and colonic cytokinetics.*
- Natasa Popovic. MS, 2003. Nutritional countermeasures to radiation exposure.
- Daniela Radulovich (Knight). MS, 1988. In vivo calcium soap formation with two levels of fat and calcium and three types of fiber.
- Michael Clayton Robinson. MS, 1991. The effects of barley bran flour and barley oil on hypercholesterolemic men and women.
- Lisa Sanders. PhD, 2005. *Effect of dietary fat and fiber on the oxidative status of the small intestine and colon of rats.*
- Susan Walker Sharp. PhD, 1992. *The effect of dietary fiber on colonic cell proliferation and serum and tissue cholesterol levels.*
- Dana R. Smith. PhD, 1992. (Co-major advisor with Dr. H. R. Cross). Use of palmitoleic acid to establish the effects of fatty acid chain length and saturation on serum cholesterol levels.
- Heather Lynae Spears. MS, 1999. (Co-major advisor with Dr. H. W. Sampson). Level of osteopenia and bone recovery in alcohol-fed rats.
- Xiao-Qing Sun. MS, 1991. Determination of mechanisms by which soluble fibers lower serum cholesterol.
- Colleen Tracey. MS, 1991. Dietary fiber and food energy intakes of women and their children at breakfast, snacks, and food away from home.

Jairam Vanamala, Post Doctoral Fellow, 2004-2006. Phytochemicals and colon cancer.

- Nonita Villalba. MS, 1990. Fermentation of pectin and cellulose to short chain fatty acids: A comparative study with humans, baboons, pigs, and rats.
- Cynthia Ann Warren. MS, 2003. (Co-major advisor with Dr. N.D. Turner). An assessment of the ability of quercetin to inhibit colon carcinogenesis.
- Henrietta Wolf. MS, 1992. Effect of meal frequency and dietary fiber on plasma glucose, insulin and cholesterol.
- Kit-Ying Yung. MS, 1990. Development of a model system for testing the physiological effects of high fiber products.
- Jianhu Zhang. MS, 1993. Fiber type, meal frequency and colonic cytokinetics.
- Jianhu Zhang. PhD, 1997. Effect of dietary fiber and carcinogen on metabolism in isolated colonocytes during tumorigenesis.
- Jianhu Zhang. Post Doctoral Fellow, 1999. *Relationship of colonocyte metabolism, colonic cytokinetics and mitochondrial function.*
- Debra L. Zoran. DVM, PhD, 1997. Butyrate and the colonocyte: Effect on cellular events and role in protection against colon cancer.

#### **COMMITTEE MEMBER:**

Kyunghwa Baek, PhD, 2007 Lisa Barker, MS, 2000 Dawn Blaschke, MS, 1999 Julie Bowlin, MS, 2001 Roxanne Brown, MS, 1999 Cynthia Kay Edwards Bohac, MS, 1987 Julie Bowlin, MS, 2001 Deborah Jean Brown, MA, 1986 Susan Chan, MA, 1987 Suhasani Chitla, MS, 1994 Amy Clark, MS, 1997 Maria Cobos, MS, 1988 Diane T. Cohill, MS, 1987 Rachel Condie, PhD, current Juan I. Corujo, MS, 1991 Mou Dasgupta, MS, 2004 Paula Davis, MS, 1997 Tina Davros, MS, 1990 Chris Dekaney, MS, 1996 Bart Roberts Dunsford, PhD, 1990 Laura Cruz y Celis Ehlinger, MS, 1993 Connie Jo Swenson Elliff, PhD, 1992 Yang Yi Fan, PhD, 1996 Anne Ford Gilmore, PhD, current Denise Garcia, PhD, 1990 Mary Beth Georghiades, MS, 1988 Stephanie Green, MS, 1989

Kevin Lykins, MS, 1992 Deborah Marie Madden, MS, 1995 Sudeep Majumdar, PhD, 2001 Juan Ignacio Corujo Martinez, MS, 1991 Amy J. Maslowski, PhD, Current Rodolfo Mercado Navga, Jr., PhD, 1991 Sibyl Miller, MS, 2007 Sibyl Miller Swift, PhD, 2010 Veronica Alejandra Molina, MS, current Katherine Newberry, MS, 2002 Yee Voon Ng, MS, 2004 Kimberly Paulhill, MS, 2008 Ann Marie Petkoff, MS, 1985 Scott Peterson, MS, 1996 Monica De La Torre Pineda, MS, current Lauren Ritchie, MS, current Lauren Ritchie, PhD, current Lorraine Reck, MA, 1986 Liat Lauren Scharf, MA, 1987 John David Schmitz, PhD, 1991 Jeongmin Seo, PhD, 2005 Manasvi Shah, MS, Current Susie Shipley, MS, 1998 Tina Shipley, PhD, 1987 Christine M. Spinka, PhD, 2004 Jorg M. Steiner, DVM, PhD, 2001 Kirsten Switzer, PhD, 2004

Chenxiang Ha, MS, 1995 Saijuan Hang, PhD, current Tony Haynes, MS, 2005 Katherine Ideno, MS, 1987 Poorni Iyer, PhD, 1989 Abagail Kennedy, MS, 1997 Nancy King, PhD, 1990 Satya Sree Kolar, PhD, 2009 Margaret Lerma, MS, 1987 Jaime Lewis, MS, 2008 Hui Li, PhD, 2001 Wei-Ann Lin, MA, 1985 Iryna Lobach, PhD, 2006 Laura Thomas, PhD, current Karen Triff, PhD, current Harmony Turk, PhD, current Jairam Krishna Prasad Vanamala, PhD, 2004 Juliann Walker, MS, 1992 Cynthia A Warren, PhD, 2010 Andrew Murphy Welch, MA, 1988 Charles Conan Weige, PhD, current Elizabeth Willingham, MS, 1988 Dean Xu, MS, current Dolores Anderson Yarosz, MS, 1990 Karen Elizabeth Zern, MA, 1986

## EDUCATION OF UNDERGRADUATE STUDENTS IN THE LABORATORY:

Kara Best, Biochemistry. 1985-1987. University Fellow Zach Bohanan, Nutrition/Genetics. 2007. Apoptosis detection using ethanol fixed tissue. Melissa Boyle, Animal Science. Howard Hughes Fellow Lara Broemmer, Genetics. 1997-1998. Howard Hughes Fellow Jennifer Burford, Biochemistry. Howard Hughes Fellow Emillia Cristina, Biology. Howard Hughes Fellow Jon Courand, Biochemistry. 1987-1988. Calcium soaps and colon cancer. Heather Donahoe, Biochemistry. 1991-1992. University Fellow Cynthia Elizondo, Biomedical Sciences. Howard Hughes Fellow Cara Everett, Nutrition. 1999. Lori Lynn Finch, Nutrition. 2004. Theresa Garcia, Biochemistry. 1995-1998. Howard Hughes Fellow Alexandria Hill, Nutritional Sciences. 2001. Shameka Hodge, Prairie View A&M University, Undergraduate Summer Research Program. 1998. Meng Chao Lee, Biochemistry. 1993-1995. Bile acids and colon cancer. John Mann, Nutritional Sciences. 2002-2003. Melinda Jo-Mar Morris, Nutritional Sciences. 2001. Stephanie Osborn, Nutritional Sciences. 2000. Kimberly Paulhill, Nutritional Sciences. 2002-2003. Carol Perez, Nutrition. 1998. Howard Hughes Fellow Melissa A. Pujazon, Biochemistry. 1994. How diet affects colon microbial populations. Jason Ramsey. 2001. Kathleen Roney. 2001. Tammy K. Rooney, Food Science. 1990-1991. University Fellow Jennifer Schaefer, Biochemistry. 1996-1997. Howard Hughes Fellow Elizabeth Travis Spoede, Biology. 2004. Tara Tomlin, 2004.

Harmony Turk, Nutrition. Bioinformatics and nutrition. 2007.

Timothy D. Wagner, Biochemistry.1994. How diet affects colon microbial populations. Stephanie Wilks, NSF Foundation summer intern (MS student). 2004-2005. Effects of fish oil on oxidative DNA damage in the colon of rats.

# SERVICE TO TEXAS A&M UNIVERSITY

# **Local/State Invited Presentations**

- 1. *Effect of diet on cell proliferation in the large intestine*. O.E. Teague Veterans' Center, Scott & White Memorial Hospital and Clinic, and Medical Sciences, Texas A&M University, November, 1984.
- 2. *Dietary fiber: facts and fallacies.* Texas Human Nutrition Conference, College Station, TX. February, 1985.
- 3. *Dietary fiber and cell proliferation*. Food Science and Technology Seminar Series, December, 1985.
- 4. *Role of dietary fiber in the protection against colon carcinogenesis*. Environmental Toxicology and Pharmacology Seminar Series. Texas A&M University, January 1986.
- 5. *Dietary fiber, cell proliferation and colon carcinogenesis*. Texas Carcinogenesis Meeting. MD Anderson Cancer Center, Houston, TX November 11, 1986.
- 6. *Dietary fiber and colon carcinogenesis*. Presented as part of a joint seminar series on "Nutrition, Immunology and Cancer" sponsored by the University of Texas at Austin and the University of Texas System Cancer Center, Austin, TX, 1987.
- 7. *The role of fiber in cancer and heart disease*. Two hour seminar as part of a graduate class on "Nutritional aspects of disease". University of Texas at Austin, Austin, TX, 1987.
- 8. *Dietary fiber and colon carcinogenesis*. Part of a seminar series on cancer prevention and control. The University of Texas System Cancer Center. Houston, TX, 1987.
- 9. *Update on dietary fiber*. University of Texas Health Science Center's Teleconference Network of Texas. Broadcast throughout Texas, 1987.
- 10. *Fiber supplements: use and abuse*. Texas Human Nutrition Conference, College Station, TX, February, 1987.
- 11. *The physiological effects of diet on the large bowel*. Presented to the Medical Physiology Group, Texas A&M University, as part of their seminar series, 1987.
- 12. *The physiological effects of diet on the large bowel: update.* Presented to the Medical Physiology Group, Texas A&M University, as part of their seminar series, 1988.
- 13. Update on dietary fiber. Presentation to the Statewide annual conference of Texas Nutrition Extension Agents and Specialists, College Station, TX.
- 14. Fiber supplements: use and abuse. Texas Department of Mental Health, Brenham, TX.
- 15. Update on dietary fiber. San Antonio Health Fair, San Antonio, TX, March 3, 1989.
- 16. *The effects of nutrition on colonic physiology*. Clinical Nutrition Symposium, College of Veterinary Medicine. Texas A&M University. September 10-12, 1989.
- 17. *Mechanisms by which fibers lower serum cholesterol*. Medical Physiology Seminar. Texas A&M University, September 1, 1989.
- 18. *Dietary fiber and colon carcinogenesis*. Texas Carcinogenesis Meeting. September 15, 1989, Austin, TX.

- 19. *Nutrition for the modern woman*. American Association of University Women, College Station, TX, September 18, 1989.
- 20. *Mechanisms by which fibers protect against colon carcinogenesis*. Nutrition Seminar Series, Texas A&M University, September 25, 1989.
- 21. *Health aspects of dietary fibers*. Medical School, Texas A&M University. Televised on KAMU-TV. September 28, 1989.
- 22. *Research in dietary fiber*. Department of Veterinary Anatomy and Public Health, Texas A&M University. October 10, 1989.
- 23. *Dietary fiber and cancer risk reduction*. Texas Agricultural Extension Service and the American Cancer Society. Teleconference. January 24, 1990.
- 24. *Effect of dietary fibers on serum lipids*. Seventeenth Annual Texas Human Nutrition Conference. College Station, TX, February 16, 1990.
- 25. *Fiber: friend or foe.* Scott and White Clinic, public forum. College Station, TX, March 22, 1990.
- 26. *Dietary fiber and gastrointestinal physiology*. Comparative Gastroenterology Group, Texas A&M University, May 23, 1990.
- 27. *Nutrition and dietary fiber*. The Eureka Rebels Older Adult Discussion Group. Community service. August 27, 1990.
- 28. *Dietary fiber and colon carcinogenesis*. M.D. Anderson, Gastroenterology Group, Houston, TX, November 7, 1990.
- 29. *Effect of dietary fiber on colon carcinogenesis*. Environmental Toxicology and Pharmacology Seminar Series, Texas A&M University, November 26, 1990.
- Carbohydrate chemistry and function. Two hour invited lecture to Texas A&M University's Department of Food Services Management Team, Chefs and Supervisors as well as local chefs and Food service professionals. January 7, 1991.
- 31. *Effects of dietary fiber on serum lipids*. Research address for the 10th Anniversary of The Institute for Nutritional Sciences, Texas Tech University, Lubbock, TX, March 13, 1991.
- 32. *How to give a scientific presentation*. Minority High School Student Research Apprentice Program and Lab Start Program. Department of Biochemistry and Biophysics. Texas A&M University, July 11, 1991.
- Dietary fiber type and colon carcinogenesis. Invited speaker, Prevention and screening: Science vs Practicality. Physician Oncology Education Program. San Antonio, TX, August 3, 1991.
- 34. *How diet affects colonic contents: how colonic contents affects colonic cell proliferation.* Seminar to Faculty of Nutrition. September 18, 1991.
- 35. *How to give a scientific presentation*. Biochemistry Club. Texas A&M University. October 8, 1991.
- 36. *Chair, overview, introductions, Texas Human Nutrition Conference*, College Station, TX, February 7, 1992.
- 37. *Dietary fiber, issues in the food supply*. Food Science Seminar, Texas A&M University, October 12,1992.
- 38. *Chair, overview, introducer, coordinator* of the Texas Human Nutrition Conference, College Station, TX, February, 1993.
- 39. *How to give a scientific presentation*. Minority High School Student Research Program and Lab Start Program, Texas A&M University, July 1, 1993.

- 40. *Nutrition for the health conscious consumer*. Department of Health and Safety, Texas A&M University, July, 1993.
- 41. *Fat and fiber and their relationship to colon cancer, the science and practical recommendations.* Televised presentation for the Texas Agricultural Extension Service and the American Cancer Society. January 14, 1994.
- 42. *How to give a scientific presentation*. Minority high school student research program and lab start program. Texas A&M University, July, 1994.
- 43. Dietary fiber and colon cancer: do the data justify a health claim for a protective effect? Texas Human Nutrition Conference. Texas A&M University, College Station, TX, February 3, 1995.
- 44. *Dietary fiber and colon cancer*. Kinesiology Seminar series. Texas A&M University, March 3, 1995.
- 45. *How to give a scientific presentation*. To the minority and lab start programs at Texas A&M University, June 29, 1995.
- 46. *How to present a scientific talk*. To the participants in the summer enrichment program of ALPS, Texas A&M University, July 5, 1996.
- 47. *Current nutrition research at Texas A&M*. To the emeritus faculty of the Animal Science Department. June 5, 1997.
- 48. *How to give a scientific presentation*. To the minority and lab start programs at Texas A&M University, July 3, 1997.
- 49. *Managing a research group*. A panel discussion for the Women's Faculty Network. Texas A&M University, October 22, 1997.
- 50. *How to give a scientific presentation*. To the minority and lab start programs at Texas A&M University, November 17, 1997.
- 51. *Effects of dietary fiber*. Leadership in Medicine, Texas A&M Medical School, January 27, 1998.
- 52. *How to give a scientific talk*. Spring General Meeting of the University Undergraduate Research Fellows, Texas A&M University, March 3, 1998.
- 53. *Diet and colon physiology*. Leadership in Medicine, Texas A&M Medical School, March 10, 1998.
- 54. *Nutrition: the link between agriculture and medicine*. To members of the European Parliament, at Texas A&M University, College Station, TX, June 25, 1998.
- 55. *Diet, nutrition and health.* To members of the Dupont Agricultural Biotechnology Research Team. Texas A&M University, December 16, 1998.
- 56. *Is fiber protective against colon cancer? It depends*. First annual Ethel Ashworth-Tsutsui Memorial Lecture and Award Ceremony. January 22, 1999.
- 57. *Effects of dietary fiber*. Leadership in Medicine (MEID 901), Texas A&M Medical School. January 26, 1999.
- 58. Facilitator, organizer and speaker. *Texas Food For Health Industry/Academic Roundtable*. Hilton Hotel and Conference Center. College Station, TX. February 12, 1999.
- 59. Fiber and unabsorbed, modified foods -- effects on the colon. Leadership in Medicine (MEID 901), Texas A&M Medical School. March 9, 1999.
- 60. *Fat-fiber interactions and their effects on colon cancer*. First Annual Scientific Symposium of the Center for Environmental and Rural Health, College Station, TX, May, 25, 1999.
- 61. *Prevention and early detection of colon cancer*. The Vannie E. Cook Jr. Foundation, McAllen, Texas, June 7, 1999.

- 62. *How to give a scientific presentation*. To the minority and lab start programs at Texas A&M University, July 7, 1999.
- 63. *Speaking to a scientific or technical audience*. Texas A&M University presentation, sponsored by Women in Science and Engineering. October 20, 1999.
- 64. *Effect of dietary fiber on the gastrointestinal tract.* Texas A&M University presentation at the Medical School. February 22, 2000.
- 65. *How to give a presentation*. Talk for the Office of University Research for all students participating in the Texas A&M Research Week. March 3, 2000.
- 66. *Opportunities in human nutrition*. Talk for High School Science Students at Texas A&M University. March 4, 2000.
- 67. *Effect of diet on colon physiology*. Texas A&M University presentation at the Medical School. March 7, 2000.
- 68. *How to live to an old age and feel great about it.* Talk with Dr. Ray Bowen, President, Texas A&M University, to the annual meeting of the Houston Texas Aggie Club, Houston, TX, March 25, 2000.
- 69. *Nutrition for the intelligent woman*. Talk with Don Powell, Chair of the Board of Regents, Texas A&M University, First National Bank of Amarillo, Amarillo, TX, April 6, 2000.
- 70. *Nutrition Research Core*. Presentation to the External Advisory Board of the Center for Environmental and Rural Health. May 22, 2000.
- 71. *Nutrition, Physical Fitness and Rehabilitation*. Documentation of the NSBRI budget for 2000, 2001, Johns Hopkins University, August 24-25, 2000.
- 72. Nutrition research at Texas A&M. Talk to incoming graduate students about research in nutrition. Biochemistry, August 29, 2000.
- 73. *Nutrition, Physical Fitness and Rehabilitation*. Biannual presentation of research program to the external advisory committee of the National Space Biomedical Research Institute. Johns Hopkins University, September 12, 13, 2000.
- 74. Current controversies in nutrition: The science behind them. Using Nutrition in the classroom to teach basic science. Cast 2000, Plenary Lecture, College Station, TX, October 14, 2000.
- 75. *Nutrition, Physical Fitness and Rehabilitation*. Defense and explanation of program. Mock Site Visit, Houston, TX, November 10, 2000.
- Nutrition, Physical Fitness and Rehabilitation. Defense and explanation of program. Site visit for 5 year Renewal of the entire NSBRI program. Houston, TX, November 29-Dec. 1, 2000
- 77. *Dietary fiber: What is does and doesn't do for you*. Texas A&M Medical School, College Station, TX. February 13, 2001.
- 78. *Nutrition, Physical Fitness and Rehabilitation*. Biannual presentation of research program to the external advisory committee of the National Space Biomedical Research Institute. Houston, TX. March 1-2, 2001.
- 79. *Mock site visit for actual site visit.* Center for Environmental and Rural Health. Nutrition Research Program. Texas A&M, April 17, 2001.
- 80. *Mock site visit for actual site visit.* Center for Environmental and Rural Health. Nutrition Research Program. Texas A&M, May 18, 2001.
- 81. Site visit for competitive renewal of the Center for Environmental and Rural Health. Texas A&M, May 24, 2001.

- 82. *Nutrition, Physical Fitness and Rehabilitation*. Biannual presentation of research program to the external advisory committee of the National Space Biomedical Research Institute. Houston, TX. October 17,18, 2001.
- 83. *Butyrate and colon cancer: a controversy in need of resolution*. Presentation to Department of Health and Kinesiology, Redox Biology and Cell Signaling Laboratory, Texas A&M University, November 9, 2001.
- 84. How to give a scientific presentation. Texas A&M University, February 5, 2002.
- 85. *Nutrition, Physical Fitness and Rehabilitation.* Biannual presentation of research program to the external advisory committee of the National Space Biomedical Research Institute. San Jose, CA. March 12, 2002.
- 86. How to design diets for animal studies. Texas A&M Vet School, March 21, 2002.
- 87. *The place of nutrition and physical fitness on the International Space Station.* Rice University, March 29, 2002.
- 88. Nutrition Research as a Career. Texas A&M University, April 8, 2002.
- 89. *Macronutrient Report from the DRI Process*. Presentation to the Faculty of Nutrition, Seminar Series, Texas A&M University, October 1, 2002.
- 90. *The Nutrition Research Program*. Presentation for the CERH Competitive Renewal, Texas A&M University, October 31, 2002.
- 91. *What are the DRIs and how are they used*. Presentation to the Nutrition Club, Texas A&M University, November 19, 2002.
- Note: On sabbatical in Washington, DC during all of 2003.
- 92. National Public Policy in Nutrition: The DRIs; Dietary Guidelines; and the Food Label. Texas A&M, February 2, 2004.
- 93. *Health Claims and the Rules*. Presentation to the Institute of Food Technologists Alamo Section Meeting, Texas A&M University, February 11, 2004.
- 94. *National Nutritional Policy: How does it work?* Presented at Sigma XI Spring Symposium, Texas A&M University, March 25, 2004.
- 95. *National Public Policy in Nutrition: The DRIs; Dietary Guidelines; and the Food Label.* Presented to Nutrition 430 Class, Texas A&M University, July 7, 2004.
- 96. *Nutrition, Physical Fitness and Rehabilitation*. Biannual presentation of research program to the external advisory committee of the National Space Biomedical Research Institute. Conroe, Texas. September 23, 2004.
- 97. *The Dietary Guidelines and the DRI Process: From molecules to foods to dietary patterns.* Community Nutrition. Texas A&M University, College Station, TX. September 27, 2004.
- 98. *The 2005 Dietary Guidelines: Departures from the past.* Presentation to The Alamo Section Institute of Food Technologists (IFT) at its mid-year meeting at Texas A&M University, October 1, 2004.
- 99. *The Nutrition Research Core*. Presentation at the CERH annual retreat. Conroe, Texas, October 8, 2004.
- 100. *Public Policy in Nutrition*. Presented at the 30<sup>th</sup> Annual Texas Student Dietetic Association Conference, Texas A&M University, College Station, Texas, November 20, 2004.
- 101. *The 2005 Dietary Guidelines: Departures from the past.* Faculty of Nutrition Seminar Series, Texas A&M University, College Station, Texas, January 25, 2005.

- 102. The Dietary Guidelines and the DRI Process: From molecules to foods to dietary patterns. Presented to the Community Nutrition Class at Texas A&M University, College Station, Texas, January 28, 2005.
- 103. *Graduate Education: Is it for you?* Presented to Nutrition 289 Class at Texas A&M University, College Station, TX, March 3, 2005.
- 104. Panel on how to obtain funding from the National Institutes of Health. Office of the Vice President for Research, Texas A&M University, March 3, 2005.
- 105. You can be what you want to be (with a few caveats). Invited by the graduating seniors to address them, their families, and fellow students at their first "graduation brunch". Texas A&M University, College Station, Texas, Parents Weekend, April 9, 2005.
- 106. What to eat and why and when you can substitute a supplement for a food: Messages from the 2005 Dietary Guidelines Committee. Presentation to members of the Aggie Hostel (returning former students). Texas A&M University, College Station, TX, June 6, 2005.
- 107. *The DRI process and the Dietary Guidelines*. Presentation to the Community Nutrition class. Texas A&M University, College Station, TX, July 8, 2005.
- 108. *From DRI's to Dietary Guidelines*. Presentation to the Community Nutrition class. Texas A&M University, College Station, TX, September 2, 2005.
- 109. *Methylation and oxidative DNA damage to colon cells:* Diet as a countermeasure (from basic science to translational research). Center for Environmental and Rural Health annual membership workshop, Del Lago, TX, October 7, 2005.
- 110. *Nutrition, Physical Fitness and Rehabilitation*. Presentation to the 5-year review team for the National Space Biomedical Research Institute, Houston, TX, December 6, 2005.
- 111. *Birth of a patent: the Scientists' Perspective*. Texas Science Partnership (Advisory group to the Department of Nutrition and Food Science), April 12, 2006.
- 112. *The Importance of Optimal Nutrition to Long Duration Spaceflight*: Food for the Future. Presentation to students who are part of a summer research program in biology at Texas A&M. July 20, 2006.
- 113. Goals of the Nutrition, Physical Fitness and Rehabilitation Team and using Diet and Exercise as Countermeasures against Long Duration Space Flight. Half day interactive session with PhD students in the NSBRI Fellows program. Baylor College of Medicine, Houston, TX. May 30, 2007.
- 114. *Carbohydrates: The Science behind the recommendations.* College Station Rotary, August 23, 2007.
- 115. The Importance of Nutrition to Long Duration Space Flight and Why Depressed Food Intake in Space is Not a Good Idea. Half day interactive session with PhD students in the NSBRI Fellows program. National Space Biomedical Research Institute Bioastronautics Summer Program. Baylor College of Medicine, Houston, TX. June 6, 2008.
- 116. The importance of optimal nutrition to long duration spaceflight and Depressed food intake and the catabolic state: consequences for astronaut health. Half day interactive session with PhD students in the NSBRI Fellows program. National Space Biomedical Research Institute Bioastronautics Summer Program. Baylor College of Medicine, Houston, TX. June 6, 2009.
- 117. Nutrient Profiling Systems and the science behind them. Faculty of Nutrition Seminar Series. Texas A&M University November 16, 2009.
- 118. *Whole grains, added sugar and fortification, the future of front of pack labeling.* General Mills Agricultural Research. Texas A&M University February 18, 2010
- 119. *National Nutrition Policy: From molecules to front-of-pack labeling*. College of Agriculture Development Annual Meeting. Texas A&M University February 25, 2010
- 120. *Carbohydrates: The good, the bad and the ugly*. Texas A&M University System Board of Regents' spouses day. May 27, 2010.
- 121. Keynote Speaker. New Faculty Orientation. Texas A&M University. August 23, 2010.
- 122. *How to Eat Healthy After 50*. Retired Faculty and Staff Bi-Annual Meeting. Texas A&M University. April 18, 2011.

## TEXAS A&M UNIVERSITY COMMITTEES

## Search Committees at Texas A&M University (Committee Member unless otherwise noted)

Mark Harris Professorship in Veterinary Clinical Nutrition, 1989-1990 Nutrition Position, Institute of Biosciences and Technology (IBT), several searches, 1991-1995 Department Head, Department of Animal Science, 1991-1992. Chair, Search committee for department head, Veterinary Physiology and Pharmacology, 1992-1993. Assistant Professor, Kinesiology, 1992-1993 Assistant Professor, Poultry Science, 1992-1993 Assistant Professor, Veterinary Anatomy and Public Health, 1992-1993 Director of the Combined MS/Dietetic Internship program, 1994 Chair, Search Committee, Human Nutrition Position in the Animal Science Department, 1994-1995. Director of Laboratory Animal Research Resource (LARR), (two searches) 1995-96, 1996-1997. Chair, Search Committee, Associate Vice President for Research, 1995-1996. Assistant Professor of Nutrition, Poultry Science, 1998-1999. Dean of Faculties, Texas A&M University, 1998-1999. Dean of the Bush School of Public Service, (two searches) 1999-2000, 2000-2001 Associate Director, Texas Agricultural Experiment Station, 1999-2000 Assistant Professor, Kinesiology, 1999-2000 Instructor Position, Human Nutrition, Department of Animal Science, 1999-2000 Endowed Chair in Parks and Recreation, 1999-2000 Assistant Professor, Kinesiology, 2000-2001 Associate Vice Chancellor, College of Agriculture and Life Sciences, 2000-2001 Director, Dietetic Internship, Department of Animal Science, 2000-2001 Assistant Professor of Nutrition, Department of Animal Science, 2000-2001 Dean, College of Agriculture and Life Sciences, Director Texas A&M Experiment Station and Vice Chancellor, Texas A&M System, 2004-2005 Department Head, New Department of Nutrition and Food Science, 2005-2006 Assistant Professor of Nutrition, Department of Nutrition and Food Science, 2005-2006 Co-chair with Dr. Jimmy Keeton of the search for four faculty positions for the Department of Nutrition and Food Science, 2006-2007 Chair, Vice President for Research, Texas A&M University, 2008-2009 Department Head and Professor, Department of Nutrition and Food Science, 2008-2009 Professor and Holder of the Charles R. Parencia, Jr. Chair in Entomology, 2009-present

Department Head, Department of Physics and Astronomy, 2010

## **University Wide Committees**

College of Agriculture and Life Sciences Representative to the Council of Principal Investigators, 1988-1992 Co-chair, Comparative Gastroenterology Group, TAMU, 1989-1992 Member, University Laboratory Animal Care Committee, 1989-1992 Member, Health Promotion Program Advisory Committee, 1989-1994 Appointed TAMU's representative to the American Association of University Women, attended the National Meetings, 1990-1994 Initiated and chaired the Womens' mentoring project for TAMU women faculty members, 1990-1993 On the steering committee of the women's faculty network, 1990-1994 Mentor to women faculty, 1996-present. Appointed to the University Committee on the status of women, Dr. W. Perry, Chair, 1990-1992. Committee to write the TAMU recruitment and retention handbook, appointed by Provost Dean Gage, 1991-93. Revised in 1994. Council for Women in Higher Education, appointed by Provost Dean Gage, 1991-1995 Member, Graduate Program Council, 1990-1994 Director of Nutrition for the Center for Environmental Health, TAMU, planned the Nutrition Core, have directed it since its inception, and defended it in two competitive renewals, (planning started 1998). Center began in 1999, Director of the Nutrition Research Core and Member of the Executive Committee – present. Member, Committee to assess new human subjects requirements for NIH, TAMU, 1999-2000. Distinguished Achievement Awards Selection Committee, 2000-2001 Chair, internal review of the Reproductive Biology Faculty Member, Huffines' Institute, 2005-present Research Roadmap Committee, 2008-2009 Texas A&M University Press Faculty Advisory Committee, 2009-present Elected, Executive Committee for Distinguished Professors, 2010-2013 Member, President Loftin's Development Strategy Council, 2011-Present Member, Texas A&M University Institute for Advanced Study Administrative Council, 2011-Present **Intercollegiate Faculty of Nutrition** Elected Founding Chair, 1990-1993 Elected to the Executive Committee, 1993-1995, elected again 2001 - 2004

Member committee on graduate curriculum 1084 present (currently chair)

- Member, committee on graduate curriculum, 1984-present (currently chair)
- Member, Human Nutrition Conference Committee, 1984-89, Chair, 1990-1993, member 1993-98.
- Chair, external/internal review of Food Science and Nutrition at Texas A&M University, 1987-1988.

Chaired, organized and was responsible for the Texas Coordinating Board Review of the PhD program in Nutrition.

# College of Agriculture and Life Sciences Committees

## 7/2/2013

Member, Scholarships Committee, 1985-1989

- Member, Committee to select distinguished Texan in Agriculture, 1996-7.
- Member, Scientific Advisory Board, Link Equine Funds Committee, 1999-2002
- Member, Committee to assist in developing a formal proposal for the establishment of a new Department of Food and Nutritional Sciences (2001-3)
- Elected as a member of the faculty advisory committee on the proposed department of food and nutritional sciences as representing the Department of Animal Science (2001-2002).
- Elected member of the Advisory Committee to the Dean, College of Agriculture and Life Sciences, 2006- 2009.

Review Panelist, Regents Professor Award Texas A&M AgriLife, 2010

## **Department Committees (Animal Science and Nutrition and Food Science)**

Faculty advisory responsibilities to the student Nutrition Club, 1984-2008.

Committee member, undergraduate curriculum committee in nutrition, 1984-2005.

- Section Leader for Human Nutrition in the Department of Animal Science, 1994 until the establishment of the Department of Nutrition and Food Science in 2005.
- Member, Tenure and Promotion, Department of Animal Science (2000-present, now in Department of Nutrition and Food Science).
- Chair, Faculty Advisory Committee to the Department Head, Department of Nutrition and Food Science, 2006-present.
- Member of mentoring committees for two new faculty members in the Department of Nutrition and Food Science, 2006-present.
- Elected, Transition Committee. To assist in the transition of the Faculty of Nutrition into the Department of Nutrition and Food Science, 2011, member.

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# Codex definition of dietary fibre and issues requiring resolution<sup>1</sup>

## J.R. Lupton

Texas A&M University, College Station, TX 77843-2253, USA; Jlupton@tamu.edu

# Abstract

On November 4, 2008, the 30th session of the Codex Committee on nutrition and foods for special dietary uses (CCNFSDU) was held in South Africa and here a definition of dietary fibre was agreed upon. This was an important major accomplishment, and the result of many individuals, organisations and countries working towards a collaborative effort over a ten year time period. Although many aspects of what can be called 'dietary fibre' were resolved, still the application of this definition requires further discussion. This paper notes the major issues that were resolved for the definition of dietary fibre and discusses three issues in need of resolution going forward: (1) the footnote that countries can decide whether or not they accept the degree of polymerisation 3-9 in the definition or not; (2) what will be the process to certify that a fibre added to the food supply rather than intrinsic to foods can be called 'fibre'? To do this will require both agreed upon endpoints (e.g. increases faecal bulk, lowers blood cholesterol, attenuates glycemic response) and agreed upon standards for the types of studies that will be necessary. (3) What affect does the new definition have on food labels and analytical methods? Although none of these issues is simple, resolution of them will move the entire dietary fibre research agenda forward as it will inform government regulatory agencies, companies with fibre products, academics desiring to do research on dietary fibre, non profit organisations which promote fibre, and consumers who need to know the science behind the recommendations.

Keywords: oligosaccharides, physiological effects of fibres, dietary fibre labelling

# Introduction

The 30<sup>th</sup> session of the Codex Committee on Nutrition and Foods for special Dietary Uses (CCNFSDU) met in South Africa on November 4, 2008 and agreed on a definition of dietary fibre (Codex Alimentarius Commission, 2009) (Box 1). The definition will be forwarded to the 2009 Session of the Codex Alimentarius Commission for adoption at Step 8, the final step in the eight-step approval process of Codex. This was an important

<sup>&</sup>lt;sup>1</sup> For the sake of clarity the five key definitions of fibre discussed in this paper will be abbreviated as follows. The definition agreed to in South Africa on November 4, 2008 at the 30<sup>th</sup> session of the Codex Committee on Nutrition and Foods for Special Dietary Uses – and adopted as Codex definition of dietary fibre July 2009 – is abbreviated Codex. The Institute of Medicine Definition will be abbreviated as IOM. The FAO/WHO Consultation will be abbreviated as FAO/WHO. The Codex Step 6 definition will be called CCNFSDU. The.definition from the European Union will be called EU.

Box 1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (Codex): definition of dietary fibre (adopted as Codex definition July 2009).

#### Definition

Dietary fibre means carbohydrate polymers<sup>1</sup> with ten or more monomeric units<sup>2</sup>, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed.
- Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic
  or chemical means and which have been shown to have a physiological effect of benefit to health as
  demonstrated by generally accepted scientific evidence to competent authorities.
- Synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

<sup>1</sup>When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis: fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately 'associated' with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligosaccharide fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of analysis and sampling).

major accomplishment, and the result of many individuals, organisations and countries working towards a collaborative effort over a ten year time period. There are a number of reasons why it is critical to have a worldwide definition of fibre. Some countries have an official definition of dietary fibre whereas others have accepted analytical assays for fibre that if one adheres to the accepted assay then the product can be called 'dietary fibre.' Which countries have definitions, and which use accepted assay protocols are listed in the IOM fibre definition report (IOM, 2001). The IOM report also provides a rationale for a formal definition in that without a definition compounds not currently analysed by accepted methods but which may have physiological fibre-like benefits cannot be termed 'dietary fibre.' In contrast, compounds that do analyse as 'dietary fibre' but for which there are no known beneficial physiological effects can be termed 'dietary fibre' (IOM, 2001). The conclusion of this report was that with a definition the definition determines the methodology rather than the methodology determining what fibre is and is not. In a recent report on the new CCNFSDU definition other benefits of a worldwide definition of fibre were enumerated and included that a Codex definition would 'be used for measurement, food labelling, setting reference nutrient values, and health claims' (Cummings *et al.*, 2009).

At the time of the November 4 meeting there were essentially four different definitions, each of which had a certain amount of support. Those definitions included one from the Institute of Medicine, National Academy of Sciences in the US (IOM, 2001); The CCNFSDU Step 6 definition (Codex Alimentarius Commission, 2007); the definition from the European Union (2008) and the FAO/WHO consultation definition (Cummings and Stephen, 2007) These definitions can be viewed as being on a continuum (Figure 1, 1a) in that all four definitions would include that of the FAO/WHO consultation: 'Dietary fibre consists of intrinsic plant cell wall polysaccharides' (Cummings and Stephen, 2007), but the IOM definition adds that the polysaccharides do not have to be limited to the cell wall, and also includes oligosaccharides, resistant starch and lignin (Panel 1b). Both the CCNFSDU and EU definitions also allow nondigestible polysaccharides from animal products. The CCFNSDU at step 6 definition would accept everything the IOM definition includes but add nondigestible polysaccharides from animal products (Panel 1c). Panels 1d, 1e and 1f show the continuum on how each of the four definitions deal with 'fibre' that is added to the food supply. According to the FAO/WHO consultation if fibre like substances are shown to produce beneficial effects then the fibre like substance should be called by its scientific name and the particular benefits described (Panel 1d). The IOM report states that fibres added to the food supply could be called 'functional fibre' if they are shown to have a health benefit (Panel 1e). Both The Codex and EU definitions



state that once 'added fibre' shows a health benefit it can then be considered 'dietary fibre' (Panel 1f).

Of importance is how each definition deals with 'fibres' that are added to the food supply. This would include isolated, extracted or synthesised nondigestible carbohydrates. As shown in Figure 1, if fibre-like substances were shown to provide beneficial physiological effects in humans then the FAO/WHO consultation would conclude that they should be able to describe their beneficial effects but the substances should be called by their scientific name, not termed 'fibre.' The IOM decision would be for these 'fibres' to be called 'functional fibre' rather than 'dietary fibre' after they have shown to produce a beneficial physiological effect. Both CCNFSDU and the EU definitions would include fibres added to the food supply and showing a beneficial physiological effect as 'dietary fibre', not insisting that they be called 'added fibre' or 'functional fibre'. The final Codex definition accepted on November 4, 2008 was a blending of these four definitions were resolved. However, there still remain unresolved issues which will be addressed below.

# Major differences among the four definitions (IOM, CCNFSDU, FAO/ WHO and EU) and how they were resolved in the Codex definition

The major issues that needed to be resolved among different proposed definitions of dietary fibre and were resolved at the November 4, 2008 meeting (Codex Alimentarius Commission 2009) were whether or not to include: animal sources; oligosaccharides; mono- and disaccharides; lignin; resistant starch; fibres extracted; synthesised, etc. and whether or not there was a requirement for a specific physiological benefit. Resolution of these issues and the outcome in the final document are shown below.

The Codex definition includes fibre from animal sources. The issue here was whether or not animal sources of fibre should be included. Traditionally, the definition of dietary fibre has included only plant substances. In addition, some felt that consumers expect fibre to be from plants, so it would be confusing if it were from animals. In contrast, others argued that the key attribute of dietary fibre is its nondigestibility. In other words it should not matter if it is of plant or animal origin. Both the FAO/WHO definition and the IOM definition are limited to plant sources for their definition of 'dietary fibre.' However, the IOM report would accept animal sources of fibre as 'functional fibre' if they would show a specific physiological benefit. Specifically the IOM report states that there is an extensive literature on health benefits of high fibre food from plants, but little data from animals. The Codex definition includes animal sources of fibre, and according to the wording of this document, if the nondigestible substance were endogenous to the food and of animal origin it would not have to prove a physiological benefit. This aspect of the new Codex definition was not thoroughly discussed at the meeting and may surface again in future discussions. The Codex definition does not include mono- and disaccharides. Interestingly, the only point on which all four proposed definitions (IOM; FAO/WHO; Codex; and EU) agreed was that mono- and disaccharides should not be included in the definition of dietary fibre. In many countries, mono and disaccharides are regulated differently as sugars. The Codex definition excludes mono- and disaccharides.

The Codex definition does include lignin, but only when it is associated with plant poly-oroligo-saccharides. Although lignin is not a carbohydrate it can be covalently bound to fibre carbohydrates or associated with these carbohydrates and alter their physiological effects. The Codex definition includes lignin when derived from a plant origin and intimately 'associated' with plant poly-or oligosaccharides. However, the definition does not include lignin if it has been extracted or re-introduced into a food (Codex Alimentarius Commission, 2009). The FAO/WHO definition did not include lignin, but the IOM, CCNFSDU and EU definitions did include it under the same set of criteria espoused in the Codex definition.

The Codex definition includes resistant starch. If resistant starch is endogenous to the food source it will be included as dietary fibre. However, if the resistant starch has been obtained from the food raw material by physical, enzymatic or chemical means or synthesised then it will have to show a physiological benefit. Although the FAO/WHO definition did not include resistant starch as fibre, the other three definitions (IOM; EU; and CCNFSDU) did, under the same set of criteria as in the *Codex* definition. There is likely to be further discussion on resistant starch as amounts are affected by processing of the food. More specification as to what is meant by 'processing' may be required.

The Codex definition states that fibre does not have to be intact and naturally occurring in food but if it has been obtained from food raw material by physical, enzymatic or chemical means or synthesised then it has to show a physiological benefit. The FAO/WHO definition only accepts as dietary fibre intrinsic plant cell wall polysaccharides. The EU and Codex definitions both accept extracted and synthesised fibre as long as a physiological benefit is shown. The IOM report separates 'dietary fibre' which is relatively intact from 'functional fibre' and calls them by two different names. 'Functional fibre' has to show a physiological benefit.

The Codex definition contains a footnote that states: 'Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.' The issue here is that there is an ethanol precipitation step in AOAC 985.29 in which those substances that do not precipitate are not analysed as fibre. The commonly accepted methods include this ethanol precipitation step. Including substances that do not precipitate in ethanol requires adding procedures to regulations, and in some cases developing and approving new procedures. In addition, some say that the lower molecular weight substances do not have the same mechanism of action (e.g. for laxation) as higher molecular weight substances.

Others say that some of these substances would be considered dietary fibre by most formal definitions, e.g. fructo-oligosaccharides. They also state that many of these methods have already been developed. The final decision is that the definition of dietary fibre should predominate over methodological considerations. The IOM conclusion was that 'dietary fibre' should include oligosaccharides and fructans that are endogenous in foods and that 'functional fibre' should include these substances it they show a physiological benefit. The Codex and EU definitions included carbohydrates from 3 to 9 monomeric units. The FAO/WHO consultation definition does not include oligosaccharides.

The Codex definition calls out three categories of dietary fibre and two of those categories require fibre to show a specific physiological benefit. Most agree that fibre must have a physiological benefit. The disagreement comes as to whether or not they have to prove it. The reasoning is that the phrase 'dietary fibre' has a positive association with it. Consumers expect dietary fibre to offer physiological benefits. If the fibre is endogenous to the food there exists a long history of the physiological benefits of 'high fibre foods' and thus no reason to re-prove these benefits (IOM, 2002). However, if the fibre is extracted from food or synthesised then it cannot take advantage of the long history of high fibre foods as the resulting fibre may be more beneficial to health than endogenous fibre or it may be less. For this reason the Codex definition states that these two latter categories must show a physiological effect of benefit to health 'as demonstrated by generally accepted scientific evidence to competent authorities.' Both the EU and Codex definitions are consistent with the Codex definition. The FAO/WHO definition would not call the latter two categories 'fibre', but rather by their biochemical names, and the IOM report would call them 'functional fibre' as compared to 'dietary fibre.'

# Issues requiring further resolution

Despite the importance of coming to an agreement on a worldwide definition of dietary fibre, issues remain for the interpretation and implementation of this definition. The three primary issues are: (1) how to resolve the compromise footnote 2 which states: 'Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities' (Codex Alimentarius Commission, 2009); (2) how carbohydrate polymers isolated from food raw material or synthesised can 'prove' to have a physiological effect of benefit; and (3) the effect of the new definition on food labels and analytical methods. Two other issues are of lesser significance but are still important: (4) agreement on the extent and effect of processing on endogenous fibre as to when/if the fibre may be so altered that it needs to 'prove' a physiological effect of benefit; and (5) the interpretation of the Codex definition with respect to endogenous fibres of animal origin.

How to resolve the compromise footnote 2 which leaves the decision on whether to include carbohydrates from 3 to 9 monomeric units up to national authorities. It was clear to most at the CCNFSDU meeting in South Africa on November 4, 2008 that the only way to

get consensus from voting members was to compromise on whether or not carbohydrates from 3 to 9 monomeric units would be included in the definition by adding a footnote that this decision should be left to national authorities. While necessary for consensus purposes, it poses real problems for implementation, and fails to establish one worldwide definition since definitions can vary from country to country on this issue. This in turn means that food labels will need to vary depending upon the decision of the national authority; analytical procedures for measuring dietary fibre would have to have an 'add on' for total fibre which includes the measurement of 3 to 9 monomeric units for countries that include them as part of the definition. Clearly the most straightforward choice would be to not have the footnote and make a decision that is either pro or con for their inclusion. Although most countries have not gone on record subsequent to the November 4, 2008 meeting, the status of this decision making process is available for several countries. The United States delegation did not endorse the Codex definition in part because the FDA had issued a Federal Register Advance Notice of Proposed Rulemaking (FDA, 2007) that contained a discussion and questions posed about the definition of dietary fibre as reported in the IOM proposed fibre definition document (IOM, 2001) and the comments submitted to FDA had not been analysed by the time of the meeting in South Africa. The FDA has not decided whether or not it will adopt the IOM definition. Currently FDA accepts specific AOAC analytical methods for the measurement of dietary fibre (a value that is required on the Nutrition Facts Panel). These methods do not measure oligosaccharides that do not precipitate in alcohol and thus would not count as dietary fibre. However, the recommendation from the IOM was that nondigestible carbohydrates consisting of 3 to 9 monomeric units should be included in the definition of dietary fibre. Australia and New Zealand include carbohydrates from 3 to 9 monomeric units according to the definition of dietary fibre offered by Food Standards Australia and New Zealand (FSANZ). In addition, the European Union will stay with its previously published definition which includes 3-10 monomers (European Union, 2008). It is interesting that the CCNFSDU definition at step 6 stated that 'Dietary fiber means carbohydrate polymers with a degree of polymerisation (DP) not lower than 3, which are neither digested nor absorbed in the small intestine. A DP not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture...' (Codex Alimentarius Commission, 2007). Why the Codex definition at step 8 changed to read 'Dietary fibre means carbohydrate polymers with ten or more monomeric units is unclear, since the emphasis had always been on three or more. It would seem more likely that the final step 8 definition should have read: 'Dietary fibre means carbohydrate polymers with three or more monomeric units (see Box 1). In other words, the exception for footnote 2 might have read 'Decision on whether to include only carbohydrates from ten and above monomeric units should be left to national authorities'. The fact that there was considerable debate at step six as to whether three or more monomeric units was an average or a cut off suggests that the CCNFSDU had decided on three as the lower limit, not ten.

Towards agreement on the endpoints and procedures for establishing the health benefits of isolated and synthesised fibres. The single most important obstacle to successful application of the new Codex definition is establishing the accepted endpoints and procedures for determining whether or not an isolated or synthesised fibre can be proven to have a physiological benefit. These endpoints and procedures are stated as being 'demonstrated by generally accepted scientific evidence to competent authorities' (Codex Alimentarius Commission, 2009). One has only to review the petitions and decisions of the European Union health claims to realise how difficult it is to characterise either 'generally accepted scientific evidence' or 'competent authorities.' Certainly the FDA has struggled with this since the adoption of NLEA, first for health claims based on significant scientific agreement and more recently on qualified health claims. Allowing each country to decide for itself as to what constitutes generally accepted scientific evidence or competent authorities, while perhaps a practical solution, will negate the opportunity for a worldwide definition as what would be accepted by one country as having generally accepted scientific evidence for a beneficial physiological effect of fibre might not be accepted by other countries. In fact, since it has taken over ten years to agree on a definition it could easily take another ten to agree on the criteria that need to be met to establish proposed fibres as 'dietary fibres.'

There are a few lessons that can be learned from previous efforts to establish health benefits of dietary fibres. For example, the Institute of Medicine, in establishing the dietary reference intake values for dietary fibre, reviewed the major human studies on dietary fibre and decreased risk of disease or increased benefit to physiological function (IOM, 2002). This report based its final recommendation for intake on the totality of the evidence but came up with the reference values based on three prospective epidemiological studies which determined the amount of fibre necessary to decrease risk of coronary heart disease, since the science base behind fibre intake and decreased incidence of heart disease was stronger than the other endpoints (IOM, 2002). The IOM report on the definition of dietary fibre wrestled with the process for determining the endpoints and processes involved in establishing 'added fibres' as 'dietary fibres' (IOM, 2001) and concluded that such determinations should be made by a separate committee and should also be open to new endpoints rather than just the traditional ones of increasing faecal bulk, decreasing blood cholesterol values and modulating blood glucose levels (IOM, 2001). A recent report (Mann and Cummings, 2009) lists a table which rates the strength of the evidence for a preventive or therapeutic role of dietary fibre in frequently occurring chronic diseases. This could also be a starting point. They go on to ask important questions such as, 'which authorities should be regarded as competent? What are meaningful physiological effects likely to benefit human health? And who determines the level of evidence? (Mann and Cummings, 2009). These are all important issues. It would seem appropriate to establish a committee through Codex to make these determinations. We have come so far, and this is so important, we need to go the extra effort to (1) determine if we can come to agreement on the number of monomers required to be called 'dietary fibre' and (2) if we can establish a worldwide committee to establish the guidelines and endpoints for establishing prospective fibres as dietary fibres.

Health Canada put a major emphasis on establishing rules and regulations for 'novel fibres' and we can benefit from their outcomes and from the experiences in how their guidelines have influenced the introduction of fibres into the Canadian food supply. According to these guidelines, novel fibre sources refer to a food that is manufactured to be a source of dietary fibre, and (a) that has not traditionally been used for human consumption to any significant extent, or (b) that has been chemically processed, e.g. oxidised, or physically processed, e.g. very finely ground, so as to modify the properties of the fibre contained therein, or (c) that has been highly concentrated from its plant source (Health Canada Revised, 1997). It would be of interest to talk with the original committee members for this definition and qualifications for dietary fibre to ask how they feel now if their initial suggestions for qualifying as a novel fibre were too lenient or too restrictive and how this contributed to their ultimate decisions on which fibres should be included in the food supply. One thing that should be kept in the back of our minds is establishing criteria for what is or is not considered a 'dietary fibre' is that we need to go forward so that research can be done that uses an accepted definition of dietary fibre and that amounts of fibre in food products can be put on food labels so that we know if we can set intake guidelines and conform to them.

Other issues are: the effect of the new definition on food labels and analytical methods; effect of processing on endogenous fibre; and the interpretation of the Codex definition with respect to endogenous fibres of animal origin. The effect of the new definition on food labels and analytical methods will be dealt with in other chapters in this book. The issue of processing food and its effect on fibre is of interest and needs to be considered further. For example, the amount of resistant starch in a food can be increased or decreased by processing. Will the starch still have the same physiological benefits? The Codex definition breaks fibre down into three categories (see Box 1) with the first category being edible carbohydrate polymers naturally occurring in the food as consumed, and this is the only category that does not require showing a physiological effect of benefit. The other two categories are carbohydrate polymers obtained from food raw material and synthetic carbohydrate polymers. The effect of processing is not delineated in any of these three categories and requires further discussion. Likewise, the first category of edible carbohydrate polymers naturally occurring in the food as consumed does not restrict these polymers to plant sources. The rationale for not requiring proven benefits for the first category is that there is a long and deep history and literature of high fibre foods and health benefits. This is not true for fibre from animal sources.

# Conclusions

Coming to consensus on a Codex definition is a major accomplishment, and once officially accepted by Codex and implemented around the world will make a significant difference to food manufacturers, consumers, educators, researchers and regulatory agencies. It should encourage more research on fibre (now that we have a definition of what fibre is) and it should allow food manufacturers to renovate and innovate products to make them healthier. Although setting guidelines for 'proving' the physiological benefits of fibres will be a difficult and time consuming process, it is critical that we not stop now when we have come so far.

# References

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- IOM (Institute of Medicine), 2002. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. National Academies Press, Washington, DC, USA.
- Mann, J. and Cummings, J., 2009. Possible implications for health of the different definitions of dietary fibre. Nutrition, Metabollism and Cardiovascular Diseases 19: 226-229.

From: Sent: To: Cc: Subject: Joanne Lupton Tuesday, June 18, 2013 6:58 PM Courtney Gaine Margaret Foster; Chelsea L. Bishop RE: RFP for fiber database

1

Thanks Courtney, you have been very helpful. I appreciate it. If we have more questions I'll call you. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Courtney Gaine [mailto Sent: Tuesday, June 18, 2013 6:05 PM To: Joanne Lupton Subject: RE: RFP for fiber database

Hi Joanne,

Apologies for the delay in getting back to you. I put my responses in red following your questions. Feel free to call or email if I don't sufficiently answer them.

Courtney

From: Joanne Lupton [mailto:jlupton@tamu.edu] Sent: Tuesday, June 18, 2013 11:21 AM To: Courtney Gaine Subject: RFP for fiber database

Hi Courtney:

I have a couple of questions on the ILSI RFP for the fiber database.

The RFP states: "Studies included should be well-designed, clinical trials (retrospective, prospective, and RCTs) in humans". The words "retrospective and prospective" are usually used to describe epi studies, not clinical trials. Also, I'm confused about RCTs in the same sentence as well-designed, clinical trials. I would think that a well-designed clinical trial is a RCT. Are you excluding epidemiological studies? Wow, of all the versions and people that have read this, I can't believe none of us picked up on this. It should read "well-designed studies (retrospective, prospective, and RCTs) in humans. So no, we did not mean to exclude epi studies. However, see below on time/\$.

Second question is the characterization into type 1, type 2 and type 3. It will be very difficult to separate out type 2 and 3 from each other. Many of the papers I've read have failed to characterize their fiber as to whether it was synthesized or extracted. Has this been considered? Is it critical to have each characterized into 1,2, or 3? Would it be possible to

put a placeholder for that and have companies or PIs send information which can be added over time (but most probably not in time for your deadline). Again, a great point. I think that this could be addressed in the potential challenges section of the proposal. We should have mentioned that if you think of other challenges, please describe. Maybe there could be a category of non-type 1. If the information became available at a future point, those studies could be re-tagged, or moved. This is a great point that industry needs to be aware of in terms of complicating research.

Last question: Is the committee aware that this is an extremely low amount of money, and a fast timeline to do what is said in the proposal, including producing and getting the database online and writing the paper evaluating the studies and providing quantitative information. Yes, we do! A few things on this: first, the paper is intended to describe the methodology in developing the database and really highlight the breadth of research (and any obvious gaps) on a large number of fiber types and varied health benefits. The intent is not to truly summarize the available information other than basic quantitative descriptors and tables that hopefully speak for themselves. All of this being said, there are two approaches that I could see working – 1) narrow the scope of the database [i.e., exclude epi or limit to top 15 fibers in the US marketplace (although the latter may not be too popular)] and justify it in the budget, 2) propose additional funds for a qualitative analysis (possibly a second paper) to increase the overall budget, but there would be a more substantial deliverable to the committee (I think they could be persuaded to fund a systematic review answering a needed question using this database). I hope this helps.

I'd appreciate some help as it will definitely determine whether or not my EBR colleague and I will write the proposal. Thanks, Joanne

#### 

Joanne R. Lupton, Ph.D.

Distinguished Professor Regents Professor and University Faculty Fellow William W. Allen Endowed Chair In Nutrition Staff Assistant: Chelsea Bishop (<u>clbishop@tamu.edu</u>) E-mail: <u>jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From:	Joanne Lupton
Sent:	Wednesday, June 05, 2013 6:46 PM
То:	Gwen Twillman; Courtney Gaine
Cc:	Chelsea L. Bishop; Joanne Lupton
Subject:	RE: FNB results from call today re: DRI process for bioactives

Great Gwen, I'm really looking forward to working with you and Courtney to actually get this vision accomplished. I'm so excited to be chairing the planning committee since I'm directly related to FNB, ASN and ILSI. Without all of this support we will not be able to accomplish this goal. Please start thinking about ASN and ILSI membership on the planning committee so we can discuss. Ann will be preparing an outline of the goals of the symposium and also the costs. Once we have everything in front of us that we need to discuss we will get back to the two of you. Since our call with the government people is Monday we should try to set up a call after that time. Probably the best time for the three of us to talk would be after Ann outlines the costs and other IOM issues. If either of you contact me for dates please include my staff assistant Chelsea who keeps my calendar. Her email address is shown in the cc line above. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Gwen Twillman [mailto]Sent: Wednesday, June 05, 2013 6:23 PM]To: Joanne Lupton; Courtney Gaine]Subject: RE: FNB results from call today re: DRI process for bioactives

Many thanks, Joanne. I'll share your note with my ASN colleagues.

I am traveling tomorrow but could be available Friday or anytime next week to continue discussions regarding logistics.

Many thanks for your efforts to move this forward -- It is very exciting!

Chat soon, Gwen

## **Gwen Twillman**

Managing Director, Education & Professional Development American Society for Nutrition 9650 Rockville Pike Bethesda, MD 20814 301-634-7282 direct 301-634-7894 fax From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Wednesday, June 05, 2013 7:15 PM
To: Courtney Gaine; Gwen Twillman
Subject: FNB results from call today re: DRI process for bioactives

## Hi Courtney and Gwen:

We managed to get Ann Yaktine, Suzanne Murphy and myself on a TC this afternoon and came to some conclusions. IOM would like to take the lead and have this be an IOM meeting and an IOM report as we feel that this will be the most effective in the long run for achieving the goal of having a DRI-like process for bioactives. Having said that we are very excited about partnering with ILSI and ASN. IOM would put together the planning committee and, I'm excited to say, I will chair that committee, but we will get input from ILSI and ASN for other members of that committee. I don't think this will be an issue because many of the key people who are most active in this area are on the ILSI flavonoids/bioactives? Committee and the same holds true for ASN. There are still logistical issues to be worked out, and of course financial issues to discuss but FNB is committed to this and Ann Yaktine will staff this from the FNB. The conference report will come out from the FNB which is very fortuitous since their reports are now available globally online and for free.

Also up for discussion is whether this should be at the Hilton or at NAS. I thought there was a good discussion on this yesterday, we should discuss further. Another decision to be made is whether we have a  $\frac{1}{2}$  day in advance of Dec 5 or  $\frac{1}{2}$  day after Dec 5 or just have a 1 day meeting.

There are a number of things that are "required" when IOM is the organizer. One is that no fees can be charged for coming to the meeting. However, if ASN feels that they need to collect fees to pay for the hotel there could be a "gift" (not from IOM) to cover the fees so that anyone who wanted to come could come. Also, lunches, receptions, etc. could not be paid for by IOM. However, we could use corporate money to sponsor a lunch, dinner, or reception. We can discuss all of these things.

Courtney and Gwen, I'm happy to work with the two of you to achieve the goals of this conference. Once we work out who is paying for what I'd like to work with the sponsors to get their suggestions for planning committee members, so that we can move forward.

Suzanne, Ann and I have a call on Monday with the DRIs subcommittee of the FNB and the Government DRIs subcommittee. I'll also keep you informed as to how that goes. Needless to say we are actively looking for "government" money for this. If either of you have any ideas they are most welcome.

#### Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 From: Courtney Gaine [ Sent: Wednesday, June 05, 2013 1:53 PM To: Joanne Lupton Subject: RE: Information for Doug and others

#### Hi Joanne,

Thank you, thank you, for joining the committee meeting yesterday! Your enthusiasm was infectious and everyone is thrilled at the forward progress. I hope that your call with Suzanne and Ann went well this morning and I'd love an update when you get the chance, if there is one.

And, thank you for this information on the meeting in China. I will pass it on to Doug and if he doesn't have quick success, I will reach out to the ILSI Focal Point in China.

Thank you for everything and I'm excited about what's to come!

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121

From: Joanne Lupton [mailto:jlupton@tamu.edu] Sent: Tuesday, June 04, 2013 12:32 PM To: Courtney Gaine Subject: Information for Doug and others

## Hi Courtney:

Doug asked for info on the 11<sup>th</sup> China Nutrition Science Conference and International DRIs Summit which was held in Hangzhou China from May 15 – 17, 2013. I believe the easiest way to access the site for the conference is through the Chinese Nutrition Society website which is <u>http://www.cnsoc.org/en/news.asp</u> The Chinese Nutrition Society was the organizer of the conference and the main sponsor was Danone China. The person most knowledgeable about the Chinese DRIs for bioactives is Professor Yuexin Yang who is the new President of the Chinese Nutrition Society. She also gave the presentation on the Chinese DRI process for bioactives. She would be the best person to contact to get further information. If you need more information please let me know. Thanks, Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

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Subject:	FNB results from call today re: DRI process for bioactives

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Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862 From: Courtney Gaine [ Sent: Wednesday, June 05, 2013 1:53 PM To: Joanne Lupton Subject: RE: Information for Doug and others

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Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862 From: Sent: To: Subject:

Joanne Lupton Monday, May 06, 2013 5:48 PM Courtney Gaine RE: Availability on June 4 - ILSI Flavonoids Meeting

Courtney:

Thanks for contacting me. I was just going to contact you. At this time I am available on June 4. if you pick a time for me to be on the phone that would be fine. My calendar has a way of changing quickly (with grad students trying to take exams and me trying to go on a vacation) so the sooner we pick a time the better. Things are actually moving ahead on a workshop for bioactives. I have a call with Sarah tomorrow, and today Suzanne Murphy (the head of the FNB) and I also talked with the small government committee on the DRIs. ASN is interested in having a satellite meeting on bioactives before its symposium in DC on December 5, and the FNB is also interested in having the workshop (either at that time if we can do it, or later). We also have some support from the government for a workshop. I am out of pocket for most of the rest of May but I'm also getting nervous about not taking advantage of the enthusiasm right now to get something planned. I haven't talked with John, but I've been pretty sick for a week so I may have missed an email. If you think it would be good to have a quick talk we could try for a time later this week. I leave Sunday for China.

Thanks for staying in touch Courtney, I appreciate it and look forward to working with you. Joanne

Joanne R. Lupton, Ph.D. Distinguished Professor Regents Professor and University Faculty Fellow William. W. Allen Endowed Chair in Nutrition Staff Assistant: Chelsea Bishop Smith (<u>clbishop@tamu.edu</u>) E-mail: <u>Jlupton@tamu.edu</u> Mailing Address: Texas A&M University 213 Kleberg Center, MS 2253 College Station, TX 77843-2253 Phone: (979) 845-0850 Fax: (979) 862-1862

From: Courtney GaineSent: Monday, May 06, 2013 4:04 PMTo: Joanne LuptonSubject: Availability on June 4 - ILSI Flavonoids Meeting

Hi Joanne,

Thank you for the insights you provided at the ASN Public Policy meeting at EB. It is clear that the ILSI Flavonoids committee needs to be aware of how FNB is progressing and how we may be able to support your efforts without duplicating them.

Our annual in-person meeting is on Tuesday, June 4 and I think it would be incredibly valuable if you were able to participate for part of this meeting. Are you available to call in at any point during the day? The meeting is from 8:30-4:00 ET and I can work the agenda around your availability.

Please let me know when you get a chance. I can also share all that the committee is working on with you prior to this meeting.

Also, I spoke with John Erdman last week and filled him on the ASN mtg and he may be reaching out to you, if he hasn't already.

## Thank you in advance!

Courtney

P. Courtney Gaine, Ph.D., R.D. Senior Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121

From: Sent: To:		Suzanne Harris Thursday, April 18, sushilachang@sutc Lupton; Rodriguez,	2013 2:54 PM I.edu.sg; goodman3@msu. Felipe {PI}	edu;	Joanne ; Smith, Lewis L. (Prof.)
Cc:		Lagerquist	; Chelsea L. Bishop;	); Beth Bruegge	; Christine meyer; Beth-Ellen Berry;
Subject: Attachments:		Snawn Suilivan; Schedule of quarte FOC 2013-04-25 ag 03312013.pdf; ILSI	erly ILSI Financial Oversight gd.doc; FOC 2012-12-14 m Reserve Policy FINAL.PDF;	t Committee conf inutes.docx; ILSI I Portfolio Returns	Ference calls Financial Statements .pdf
TO:	ILSI Board of Trustees Financial Oversight Committee				
FROM:	Suzie Harris				
A conference ca beginning at 9:0	ll for the ILSI Boar <b>)0 a.m. Eastern D</b> a	rd of Trustees Financ aylight Time. The ca	cial Oversight Committee i all will not last longer than	s scheduled for <b>T</b> one hour.	hursday, April 25, 2013,
The proposed ag	genda for the con	ference call is attach	ned here.		
Agenda Item II.	Draft minutes froi	m the December 14,	, 2012 conference call		
Agenda Item III.	2013 Year-to-dat	te financial report			
Agenda Item V.	Current reserve f	und investment poli	icy; examples of portfolio i	eturns	
Please let me kn	now if you have ar	ny questions.			
Dial-in Instruction	ons				
If you are call	ing from:	Please	dial this toll-free numb	er	
Australia		1-800-2	21-2361		
Germany		0800-1	82-9571		
Mexico		001-88	8-706-6468		
Singapore		800-11	0-1778		
United Kingdo	m	0808-2	34-3676		
USA	1-888-706-6468				

The access code for everyone is 4498699 #.

*Suzanne S. Harris, Ph.D.* Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: www.ilsi.org

Follow ILSI on: ...

			Jan-13 <u>Balance</u>	Mar-13 <u>Balance</u>	1st QTR Return	
<b>Organization</b>	<u>Equity</u>	Fixed Income			<u>Amount</u>	<u>Percent</u>
ILSI NA LT Portfolio	55%	45%	1,592,767	1,664,361	71,594	4.49%
HESI LT Portfolio	40%	60%	921,172	951,783	30,611	3.32%
ILSI RF Portfolio	35%	65%	11,715,927	12,048,980	333,053	2.84%
ILSI Theoretical Portfolio *	35%	65%	269,608	281,308	11,700	2.84%

\* Return factors in \$300,000 deposit to reserve made in February 2013
1. Purpose

To set the goals for a Board-Designated Reserve and to establish the terms and conditions for its use.

2. Policy

The International Life Sciences Institute (ILSI) will establish and maintain a "Board-Designated Reserve" (Reserve) to sustain financial operations if faced with significant un-budgeted increases in operating expenses and/or losses in operating revenues.

3. Objectives

The objectives of the Reserve are:

- a. To have sufficient funds to carry out the organization's strategic objectives if faced with significant unanticipated decreases in revenue or increases in expenses.
- b. To fortify ILSI's position as an organization that is financially stable.
- c. To provide a funding source for unanticipated opportunities or changes in strategy.
- 4. Reserve Balance

The target amount for the Reserve balance will be set at 50% of unrestricted annual operating expenses.

5. Investment of the Reserve

ILSI will establish a separate investment account for the Reserve. The balance will be shown separately on the Balance Sheet as "Board-Designated Reserve". The reserve will be invested in a diversified portfolio of fixed income securities with a weighted average credit rating of AA and maturity of 3 years.

6. Management of the Reserve

The Reserve balance and policy will be reviewed as part of the Financial Oversight Committee's annual budgeting process. Any significant variations from the target balance will be reported to ILSI's Board of Trustees. The policy will be evaluated each year for any significant changes in ILSI's operations or strategic objectives.

### INTERNATIONAL LIFE SCIENCES INSTITUTE BALANCE SHEET

ASSETS		3/31/2013 <sup>(1)</sup> 12/31/2012 12/31/2011 12/31/2010 12/31/200					12/31/2009	12/31/2008				
Current Assets												
Cash	\$	549 889	\$	491 663	\$	773 370	\$	883 041	\$	817 803	\$	943 779
Short-Term Investments	Ψ	613 700	Ψ	914 298	Ψ	911 040	Ψ	401 663	Ψ	199 533	Ψ	-
Accounts Receivable		86.838		164.011		119,954		257,151		88,442		215.941
Due From ILSI Entities		325,530		174.414		109,126		156.341		220,499		183,944
Prepaid Expenses and Other Current Assets		10,103		16.979		24.342		31.626		41.058		85.345
Total Current Assets		1,586,060		1,761,366		1,937,832		1,729,822		1,367,335		1,429,009
Other Assets												
Inventory Net		-		-		-		-		30 364		71 933
Rent Receivable under Shared Space Agreement		363.283		364,147		356,748		334,566		299.076		202,732
Board-Designated Reserve		570,516		269,608		268,446		264,897		256,466		234,356
Total Other Assets		933,800		633,755		625,194		599,463		585,906		509,020
Fixed Assets												
Computer Software and Equipment		613,448		594,523		510.315		282.834		263,103		247,482
Office Furniture		114.075		114.075		114.075		116.075		116.075		118.621
Leasehold Improvements		723,761		723,761		703,909		703,909		703,909		703,909
Accumulated Depreciation		(672,454)		(672,454)	)	(508,231)		(376,494)		(344,971)		(291,591)
Total Net Fixed Assets		778,830		759,905		820,069		726,324		738,116		778,421
Total Assets	\$	3,298,690	\$	3,155,025	\$	3,383,095	\$	3,055,609	\$	2,691,357	\$	2,716,450
LIABILITES AND NET ASSETS												
Current Liabilities												
Accounts Pavable	\$	2 789	\$	67 225	\$	140 847	\$	88 347	\$	121 559	\$	249 241
Accrued Liabilities	÷	109.941	Ŧ	103,744	Ŧ	80.695	Ť	79,435	Ť	86.618	Ŧ	75.324
Deferred Revenue		11.315		102.343		86,498		94.645		116,134		104,101
Total Current Liabilities		124,045		273,312		308,040		262,427		324,311		428,666
Long-Term Liabilities												
Denosits - II SI Entities		246 000		246 000		246 000		246 000		246 000		246 000
Deferred Rent		832 374		833 414		891 432		932 650		959 595		914 712
Total Long-Term Liabilities		1,078,374		1,079,414		1,137,432		1,178,650		1,205,595		1,160,712
Total Liabilities		1,202,419		1,352,726		1,445,472		1,441,077		1,529,905		1,589,378
Net Assets												
Beginning Balance		1.802.300		1,937,623		1.614.532		1,161,451		1.127.072		930.509
Current Year Change		293.971		(135.323)		323.092		453.081		34.379		196,563
Total Net Assets		2,096,271		1,802,300		1,937,623		1,614,532		1,161,451		1,127,072
Total Liabilities and Net Assets	\$	3,298,690	\$	3,155,025	\$	3,383,095	\$	3,055,609	\$	2,691,357	\$	2,716,450
Interstricted Operations	¢	167 086	¢	621 222	¢	550 919	¢	110 355	¢	240 460	¢	150 002
Board-Designated Reserve	Ψ	570 516	φ	260 600	φ	209,040	φ	264 207	φ	249,409	φ	224 256
Coca Cola Company Marketing Contribution		3 872		203,000		200,440		204,037		200,400		204,000
PIP/GTF Restricted Funds		125 783		104 0.36		122,210				-		-
International Committees/Branches		1.228 114		743 563		957 905		892 430		655 516		732 813
Total Net Assets	\$	2,096,271	\$	1,802,300	\$	1,937,623	\$	1,614,532	\$	1,161,451	\$	1,127,072
(2)											•	
Current Assets Minus Current Liabilities (Liquidity) <sup>(2)</sup>	\$	1,462,015	\$	1,488,054	\$	1,629,792	\$	1,467,396	\$	1,043,024	\$	1,000,343
		12.79		<b>b.44</b>		6.29		6.59		4.22		3.33

<sup>(1)</sup> The 2013 balances are preliminary and have not been fully adjusted for all accrued revenues and expenses. All balances will be fully adjusted and reported on the 2013 financial statement audit.

<sup>(2)</sup> ILSI's internal balance sheet includes two calculations to show the liquidity of the organization using the subtotals for the current assets and current liabilities. The liquidity is shown by subtracting the current liabilities from the current assets and the difference represents the assets available to meet the organization's short-term obligations. The current ratio is calculated by dividing the current assets by the current liabilities. A current ratio of assets to liabilities of 2:1 is usually considered to be acceptable (i.e.., assets are twice liabilities). Acceptable current ratios vary from industry to industry. If current liabilities exceed current assets, then the company may have problems meeting its short-term obligations. If the current ratio is too high, then the company may not be using its current assets efficiently. A current asset is an asset on the balance sheet which is expected to be sold or otherwise used up in the near future, usually within one year. A current inability is a liability on the balance sheet which is expected to be paid or settled in cash within the near future, usually within one year. The current period current asset and liability balances do not include all accrued revenues and expenses, and accordingly, the liquidity calculations for the current period do not provide a meaningful comparison to the prior year-end liquidity balances.

INTERNATIONAL LIFE SCIENCES INSTITUTE	ILSI GC			COM	MUNICATION	S	IL	SI PRESS		SUBTOTAL ILSI UNRESTRICTED <sup>(1)</sup>		
FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/
For the Three Months Ended March 31, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
		700 000	00/			NI/A			N1/A		700.000	00/
	-	700,000	U%	-	-	N/A	-	-	N/A	-	700,000	0%
	41 021	25 000	1170/	-	-	IN/A	-	-	N/A	41 021	25.000	1170/
CONTRIBUTIONS - RESTRICTED	20,000	35,000	N/Δ	-	-	N/A N/Δ	-	-	N/A N/Δ	20,000	35,000	N/A
EFE FOR SERVICES	21,259	89 000	24%	_	_	N/A	_	_	N/A	20,000	89 000	24%
SHARED SERVICES REIMBURSEMENT			N/A	-	-	N/A	-	-	N/A			N/A
INVESTMENT INCOME	(259)	5.000	-5%	-	-	N/A	1.009	5.000	20%	749	10.000	7%
PUBLICATIONS - BOOKS	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A
PUBLICATIONS - NUTRITION REVIEWS	-	-	N/A	-	-	N/A	141,973	306,300	46%	141,973	306,300	46%
TOTAL REVENUE	82,021	829,000	10%	-	-	N/A	142,981	311,300	46%	225,002	1,140,300	20%
	2 670	0.260	200/	7 700	17 650	440/	401	1 265	200/	11 054	20.275	400/
COMMUNICATIONS	3,670	9,300	39%	1,102	17,050	44 70	401	1,305	29%	11,004	20,375	4270
FINANCIAL/PROFESSIONAL FEES	8.336	29,753	28%	-	-	N/A	100	-	N/A	8.436	29,753	28%
	-,									-,	,	
GENERAL & ADMINISTRATIVE												
Shared Services Overhead	59,426	227,800	26%	-	-	N/A	-	-	N/A	59,426	227,800	26%
Rent	23,822	87,467	27%	-	-	N/A	-	-	N/A	23,822	87,467	27%
Depreciation	-	75,000	0%	-	-	N/A	-	-	N/A	-	75,000	0%
Other	2,803	11,300	25%	2,400	10,500	23%	601	3,590	17%	5,804	25,390	23%
Indirect Reimbursement	(138,225)	(543,456)	25%	45,035	180,212	25%	26,105	106,224	25%	(67,085)	(257,019)	26%
STAFFING	C2 055	050 050	000/	44.045	404 400	050/	00 770	05 400	050/	100 740	500.044	050/
Salaries	63,955	250,250	20%	41,015	161,480	25%	23,776	95,183	25%	128,740	506,914	25%
Benefits Outside Services	10,737	60,060	18%	9,023	38,755	23%	5,231	22,844	23%	24,991	121,659	21%
Outside Services	1,241	400	310%	-	-	N/A	-	-	N/A	1,241	400	310%
CONSULTANTS	13,159	14.100	93%	-	26,500	0%	-	-	N/A	13.159	40.600	32%
	-,	,			-,					-,	-,	
IT SUPPORT SERVICES	-	-	N/A	5,000	50,000	10%	-	-	N/A	5,000	50,000	10%
PUBLICATIONS	4,747	5,625	84%	-	15,000	0%	11,597	62,100	19%	16,344	82,725	20%
MEETINGS												
Travel - Board	30 522	44 000	00%			Ν/Δ			N/A	30 522	44 000	00%
Travel - Staff	504	5 035	10%	6 1 1 0	7 500	82%	1 771	9 300	10%	8 30/	21 835	38%
Travel - Advisors/Speakers/Invitees	13 643	17 830	77%	0,113	7,500	02 /0 N/Λ	1,771	2,300	57%	15 226	21,000	74%
Group Eupctions/Business Meals	03 052	68 530	137%	301	1 500	26%	1,505	2,000	0%	94 344	20,030 71,680	132%
Other Expenses (Audiovisual/Mamt Fee)	48 104	30,530	122%	551	1,500	2070	_	1,000	070 N/A	48 104	11,000	117%
Other Expenses (Audiovisual/Wgmt ree)					1,500					40,104	41,010	
SUBTOTAL MEETINGS	195,725	174,905	112%	6,510	10,500	62%	3,354	13,750	24%	205,590	199,155	103%
										-	-	
OTHER PROGRAM EXPENSES	-	-	N/A	-	-	N/A	-	3,500	0%	-	3,500	0%
TOTAL EXPENSES	240 305	402 564	62%	116 766	510 598	23%	71 165	308 557	23%	437 326	1 221 710	36%
			02 /0			20/0			2070		1,221,713	30 /6
CHANGE IN NET ASSETS	(167,374)	426,436		(116,766)	(510,598)		71,815	2,743		(212,325)	(81,419)	
	1 0 5 7 7 7 7									-	-	
NET ASSETS, BEGINNING OF PERIOD	1,282,250	1,282,250		(1,344,339)	(1,344,339)		1,016,789	1,016,789		954,700	954,700	
NET ASSETS, END OF PERIOD	1,114,876	1.708.686		(1.461.105)	(1.854.937)		1.088.604	1.019.532		742.375	873.281	
	===========	=========		========	=======		===========	=========		===========	========	

<sup>(1)</sup> ILSI Unrestricted operations include the activities of ILSI GC, Communications, and ILSI Press. The revenues and expenses of these functions are shown separately to provide program detail; however, for evaluating the financial activity of ILSI unrestricted operations, a subtotal of the three activities is provided in these columns.

DIMORTONAL ACTIVITY 3TATEMENT (1) CACULA         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013         2013 <th>INTERNATIONAL LIFE SCIENCES INSTITUTE</th> <th>REST</th> <th colspan="2">RESTRICTED: PIP/GTF INT'L BRANCH ACTIVITY</th> <th>IVITY</th> <th>IFBI</th> <th></th> <th>E</th> <th>SHA</th> <th>RED SERVICE</th> <th>ES</th> <th colspan="3">TOTAL</th>	INTERNATIONAL LIFE SCIENCES INSTITUTE	REST	RESTRICTED: PIP/GTF INT'L BRANCH ACTIVITY		IVITY	IFBI		E	SHA	RED SERVICE	ES	TOTAL				
Grin Bartes Machine Stands 3, 2013         YTD ACTUAL         BUDGET	FUNCTIONAL ACTIVITY STATEMENT	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/	2013	2013	% YTD/
DEPENDENT         NEW NOVE	For the Three Months Ended March 31, 2013	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET	YTD ACTUAL	BUDGET	BUDGET
Der Der Der Berner mer mehr er Abstrachter in ausschaften ausschaften ausschaften ausschaften ausschaften ausschaften																
GRAMCHISTUUT ASSESSMENT         -         NM         NM         -	REVENUE															
COMMINIE ASESSMENTS         -         NM         640.00         628.00         1091         -         NM         660.00         628.00         1091           COMMENCE SEGNETS         48.00         96.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00         59.00	BRANCH/INSTITUTE ASSESSMENT	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	-	700,000	0%
COMPENSION RESIDENCE PECISIPATION RESS         -         NM         -         NM         -         NM         -         NM         4.021         3.000         7178           COMPENSION RESTRICTE         -         NM         -         NM         -         NM         -         NM         60.00         757         60.000         757         60.000         757         60.000         757         60.000         757         60.000         756         -         NM         -	COMMITTEE ASSESSMENTS	-	-	N/A	-	-	N/A	680,000	626,000	109%	-	-	N/A	680,000	626,000	109%
CONTRIBUTIONS.RESTRICTED       4.000       96.00       95.00       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50       7.50 <th7.50< th="">       7.50       7.50</th7.50<>	CONFERENCE/ REGISTRATION FEES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	41,021	35,000	117%
PEE POS BENVICES         NNA         ·         ·         ·         NNA         ·         ·         NNA         ·         ·         NNA         ·         ·         NNA         ·         · </td <td>CONTRIBUTIONS - RESTRICTED</td> <td>48.000</td> <td>96.000</td> <td>50%</td> <td>-</td> <td>-</td> <td>N/A</td> <td>-</td> <td>-</td> <td>N/A</td> <td>-</td> <td>-</td> <td>N/A</td> <td>68,000</td> <td>96.000</td> <td>71%</td>	CONTRIBUTIONS - RESTRICTED	48.000	96.000	50%	-	-	N/A	-	-	N/A	-	-	N/A	68,000	96.000	71%
Sind Schulds         I         I         NA         I         NA         I         NA         I         Striktion         St	FEE FOR SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	-	-	N/A	21,259	89.000	24%
NNCSUE         ·         NA         ·         ·         NA	SHARED SERVICES REIMBURSEMENT	-	-	N/A	-	-	N/A	-	-	N/A	351 431	1 455 035	24%	351 431	1 455 035	24%
PUBLICATIONS         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         ·         · <t< td=""><td></td><td>_</td><td>-</td><td>N/A</td><td>_</td><td>-</td><td>N/A</td><td>_</td><td>_</td><td>N/A</td><td></td><td>-</td><td>N/A</td><td>749</td><td>10,000</td><td>7%</td></t<>		_	-	N/A	_	-	N/A	_	_	N/A		-	N/A	749	10,000	7%
PUBLICATIONS         ·         NA         ·         ·         NA         ·         · <td>PUBLICATIONS - BOOKS</td> <td></td> <td>_</td> <td>N/A</td> <td></td> <td>_</td> <td>N/A</td> <td></td> <td></td> <td>N/A</td> <td></td> <td>_</td> <td>N/A</td> <td>145</td> <td>10,000</td> <td>N/A</td>	PUBLICATIONS - BOOKS		_	N/A		_	N/A			N/A		_	N/A	145	10,000	N/A
PERCENCIPACIPALITIES         Image: Percence of the percence o		-	-		-	-		-	-		-	-	N/A	141 072	206 200	16%
TOTAL REVENUE         440.00         96.000         50%         1         NA         660.000         208.000         1.09%         31.44.33         3.17.333         3.98           EXEMUSIS         2.09         1.268         2.9         1.268         2.9         1.267         1.98         2.217         2.18         5.568         4.210         1.8         20.172         44.92         2.8           FINANCIAL/PROFESSIONAL FEES          NA           NA           NA           NA	FUBLICATIONS - NOTRITION REVIEWS	-	-	N/A	-	-	IN/A	-	-	N/A	-	-	IN/A	141,973	300,300	40%
EXPENSES COMMUNICATIONS         29         1.265         20         40         215         100         2.087         12.974         216         5.563         42.100         50,172         64.929         24.96           FINANCIAL/PROFESSIONAL FEES         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .         .	TOTAL REVENUE	48,000	96,000	50%	-	-	N/A	680,000	626,000	109%	351,431	1,455,035	24%	1,304,433	3,317,335	39%
EXPENSE Depresentation         2.9         1.285         2.8         4.0         2.15         1.9%         2.687         1.2974         2.18         5.563         4.2.00         1.9%         20,172         9.4.929         2.485           FINANCIAL/PROFESSIONAL FEES         -         -         NA         -         NA         1.344         50.643         2.258         10.820         60.640         225         10.820         60.303         2.658           GENERAL & ADMINISTRATIVE Stande Grunds Soverhead         -         NA         -         -         NA<																
COMMUNICATIONS         29         1,285         28         40         215         198         2,877         2,780         5,563         4,210         15,78         20,172         64,829         24%           FINANCUAL/PROFESSIONAL/FESS         -         -         N/A         -         -         N/A         -         -	EXPENSES															
FINANCIAL/PROFESSIONAL FEES         .         NNA         .         .         .         NNA         .         .         NNA         .         .         NNA         .         .         .         NNA         .         .         NNA         .         .         .         NNA         .         .         .         NNA         .         .         NNA         .         .         .         NNA         .         .         .         NNA         .         .         .         NNA         .         .         NNA         .         .         .         NNA         .         .         NNA         .         .         .         NNA         .         .         .         NNA         .         .         NNA         .         .         .         NNA         . <th< td=""><td>COMMUNICATIONS</td><td>29</td><td>1,265</td><td>2%</td><td>40</td><td>215</td><td>18%</td><td>2,687</td><td>12,974</td><td>21%</td><td>5,563</td><td>42,100</td><td>13%</td><td>20,172</td><td>84,929</td><td>24%</td></th<>	COMMUNICATIONS	29	1,265	2%	40	215	18%	2,687	12,974	21%	5,563	42,100	13%	20,172	84,929	24%
FINANCLUPRCFESSIONLAFEES         -         N/A         -         N/																
GENERAL & ADMINISTRATIVE Brind         NIA         N	FINANCIAL/PROFESSIONAL FEES	-	-	N/A	-	-	N/A	-	-	N/A	11,384	50,640	22%	19,820	80,393	25%
District Services Overhead Rent         -         -         N/A         -         N/A <th< td=""><td>GENERAL &amp; ADMINISTRATIVE</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	GENERAL & ADMINISTRATIVE															
Bent         I         I         NA         I         NA         I         NA         I         NA         I         NA         I         I         NA         I         I         NA         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I         I <th< td=""><td>Shared Services Overhead</td><td>_</td><td>_</td><td>NI/A</td><td>_</td><td>_</td><td>NI/A</td><td>_</td><td>_</td><td>NI/A</td><td></td><td>_</td><td>NI/A</td><td>59 426</td><td>227 800</td><td>26%</td></th<>	Shared Services Overhead	_	_	NI/A	_	_	NI/A	_	_	NI/A		_	NI/A	59 426	227 800	26%
Depresentation         1         NA         -         NA         -         66.840         005         35.77         17.830         2.05         17.83         2.05         17.83         2.05         17.83         2.05         17.83         2.05         17.83         2.05         17.83         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05         2.05	Pont			N/A			N/A			N/A	33 526	130 565	24%	57 347	227,000	25%
Dipperside         Dippersid         Dippersid         Dippersid	Depreciation	-	-		-	-		-	60.640	0%	55,520	17 920	24/0	57,547	162 470	20%
United Indires Reimbursement         10.085         32,79         31,75         11,057         21,057         54,84         214,059         21,75         10,8,10         20,8,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,2,30         20,3,30	Other	-	-	IN/A	1 750	-	IN/A	1.067	09,040	070	25 772	17,030	20%	44.204	102,470	0%
Indicide Namiousisment         10.065         3.2,99         3.17         2,515         10,21         2.58         54,469         2.400         2.56         -         -         N/A         -         -         N/A           STAFTING Selares         9,185         31,119         30%         2,290         9,069         25%         49,622         191,845         26%         44.471         192,000         26%         401,074         1,538,947         26%           Benefits         2,221         7,469         N/A         -         N/A         -         N/A         -         N/A         24%         84,303         366,347         23%           CONSULTANTS         -         N/A         -         N/A         6,925         54,177         13%         -         -         N/A         24,68         96,909         25%         49,623         18%         -         N/A         24,68         96,909         25%         49,623         191,845         24%         44,77         21%         15%         -         N/A         -         N/A         -         N/A         46,97         5,489         56,000         9%         1,524         19%         5,489         56,000         9%         1,		40.005	-	IN/A	1,750	-	IN/A	1,007	014 000	213%	35,773	176,500	20%	44,394	202,390	22%
StateWing Benefits Outside Services       9 185 3 11.19 2.021       30% 7.469       2.290 2.0%       0.069 504       2.176 2.176       191.845 2.05       2.4% 10.917       46.043 46.047       24% 8.000       211.231       800.000 2.4%       24% 8.4003       309.347 389.347       29% 23% 23%         CONSULTANTS       -       -       N/A       -       -       N/A       6.925       54.177       13%       -       -       N/A       20.01       44.00       309.347       23%       31/19         CONSULTANTS       -       N/A       -       -       N/A       6.925       54.177       13%       -       -       N/A       20.084       94.777       21%         IT SUPPORT SERVICES       -       N/A       -       -       N/A       -       -       N/A       49.922       118.41       43.924       16%       -       -       N/A       20.084       94.777       21%         UBLICATIONS       -       -       N/A       -       -       N/A       -       -       N/A       -       -       N/A       2.44.61       126.649       90%       27.311       44.075       55.00       90       27.311       44.075       55.01       7.37.11       7.37.1	Indirect Reimbursement	10,085	32,799	31%	2,515	10,121	25%	54,484	214,099	25%	-	-	N/A	-	-	N/A
Salaries Benefits Outside Services         9,165         31,19         30% 27%         2200         0,069         25%         49,622         191,845         26%         211,231         800.000         26%         401.074         1538,847         26%           Outside Services         -         -         N/A         -         -         N/A         19,97         46,043         24%         46,71         192,000         26%         410,074         1538,847         26%           CONSULTANTS         -         N/A         -         -         N/A         6,925         54,177         13%         -         -         N/A         20,084         94,777         21%           IT SUPPORT SERVICES         -         N/A         -         -         N/A         6,925         54,177         13%         -         -         N/A         26,98         56,000         9%           PUBLICATIONS         -         -         N/A         8,118         43,924         18%         -         -         N/A         24,461         126,649         19%           Taraet - Advisors/Spackers/Invitees         90         2,370         6,776         8,000         60%         1,574         153,425         11%	STAFFING															
Benefits       2.02       7.469       27%       504       2.1%       2.9%       10.917       46.043       2.4%       46.71       192.00       2.4%       84.903       369.347       23%         CONSULTANTS        NA        NA       6.925       54.177       13%        NA       2.00       NA       2.008       94.777       21%         IT SUPPORT SERVICES        NA        NA        NA        NA       48.923       369.347       22%       94.00       30%       366       31%       31%         USEDPORT SERVICES        NA        NA        NA        NA        NA        NA        NA        NA        NA         NA         NA        NA        NA        NA        NA        NA         NA         NA         NA         NA         NA <td< td=""><td>Salaries</td><td>9,185</td><td>31,119</td><td>30%</td><td>2,290</td><td>9,069</td><td>25%</td><td>49,622</td><td>191,845</td><td>26%</td><td>211,231</td><td>800,000</td><td>26%</td><td>401,074</td><td>1,538,947</td><td>26%</td></td<>	Salaries	9,185	31,119	30%	2,290	9,069	25%	49,622	191,845	26%	211,231	800,000	26%	401,074	1,538,947	26%
Outside Services         Interpretation         N/A         Interpreation         <	Benefits	2.021	7,469	27%	504	2,176	23%	10.917	46.043	24%	46,471	192,000	24%	84,903	369.347	23%
CONSULTANTS	Outside Services	_,		N/A	-	_,	N/A	-		N/A	-	-	N/A	1.241	400	310%
CONSULTANTS														.,		
IT SUPPORT SERVICES        NVA        NVA        NVA       489       8,000       6%       5,489       58,000       9%         PUBLICATIONS        NVA        NVA       8,118       43,924       18%        NVA       24,461       126,699       9%         METINGS         NVA        NVA        NVA       4,535       1.700       267%       6,740       8,400       80%       9%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       97%       93%       93%       97%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93%       93% </td <td>CONSULTANTS</td> <td>-</td> <td>-</td> <td>N/A</td> <td>-</td> <td>-</td> <td>N/A</td> <td>6,925</td> <td>54,177</td> <td>13%</td> <td>-</td> <td>-</td> <td>N/A</td> <td>20,084</td> <td>94,777</td> <td>21%</td>	CONSULTANTS	-	-	N/A	-	-	N/A	6,925	54,177	13%	-	-	N/A	20,084	94,777	21%
IT SUPPORT SERVICES        N/A        N/A       489       8,000       6%       5,489       58,000       9%         PUBLICATIONS        N/A       4,118       43,924       18%        N/A       24,461       126,649       19%         MEETINGS        N/A        N/A       4,3924       18%        N/A       24,461       126,649       19%         MEETINGS         N/A        N/A        N/A        N/A        N/A       24,400       9%         Travel - Board         N/A        N/A        N/A        N/A        N/A       39,522       44,000       9%         Travel - Advisors/Speakers/Invitees       990       2,370       42%       47.76       8,000       66%       17,574       153,426       11%        N/A       38,566       184,426       21%         Other Expenses (Audvisual/Mgm Fee)       1,324       90,023       25%       024       65,70       06%       13,70       65,70       12%       20,000       13,74       13,745																
PUBLICATIONS	IT SUPPORT SERVICES	-	-	N/A	-	-	N/A	-	-	N/A	489	8,000	6%	5,489	58,000	9%
PUBLICATIONS         -         N/A         -         N/A         8,118         43,924         18%         -         -         N/A         24,461         126,649         19%           MEETINGS Travel - Board         -         -         N/A         -         -         N/A         43,924         18%         -         -         N/A         24,461         126,649         19%           MEETINGS Travel - Staff         -         -         N/A         -         -         N/A         4,535         1,700         26%         6,740         8,400         80%         27,341         49,795         55%           Group Functions/Business Meals         1,324         0,024         6,510         139%         8,307         6,500         128%         255         20,000         1%         113,254         105,190         108%         016%         17,714         153,426         11%         -         -         N/A         50,748         43,745         116%         200         16%         225         20,000         1%         43,745         116%         20%         6,995         28,400         269,431         427,156         63%           Other Expenses (Audiovisual/Mgmt Fee)         2,618         27,500 <td></td>																
MEETINGS Travel - board       -       -       N/A       -	PUBLICATIONS	-	-	N/A	-	-	N/A	8,118	43,924	18%	-	-	N/A	24,461	126,649	19%
International Travel - Board       -       N/A       -       -       N/A       39,522       44,000       90%       7672       12,860       60%       4,535       1,700       267%       6,740       8,400       80%       27,341       49,795       55%       55%       777       153,426       11%       267%       78%       30,522       20,000       11%       113,254       105,190       108%       21%       105,190       108%       255       20,000       11%       113,254       105,190       108%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%       21%	MEETINGS															
Inderest - During       -       -       N/A       38,56       17,00       86,740       8,400       80%       27,341       49,705       55%         Travel - Advisors/Speakers/Invitees       990       2,370       42%       4,776       8,000       60%       17,574       153,426       11%       -       -       N/A       38,566       184,426       21%         Group Functions/Business Meals       1,324       500       265%       9,024       6,510       139%       8,307       6,500       128%       255       20,000       1%       113,254       108%       108%       113,254       108%       108%       116%       20,000       1%       113,254       108%       108%       108%       165,655       802,345       21%       6,995       28,400       25,618	Travel Deard			NI/A			NI/A			NI/A			NI/A	20 522	44.000	0.09/
Have - Stath Travel - Advisors/Speakers/Invitees Group Functions/Business Meals Other Expenses (Audiovisual/Mgmt Fee)       -       5,000       0%       1,22,800       60%       1,574       15326       1%       -       -       N/A       38,656       142,62       21%         Group Functions/Business Meals Other Expenses (Audiovisual/Mgmt Fee)       1,324       500       265%       9,024       6,510       139%       8,307       6,500       128%       255       20,000       1%       113,254       105,190       108%         SUBTOTAL MEETINGS       2,314       9,235       25%       22,396       28,740       78%       32,136       161,626       20%       6,995       28,400       25%       269,431       427,156       63%         OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       -       N/A       2,618       52,017       5%         CHANGE IN NET ASSETS       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS, BEGINNING OF PERIOD       104,036	Travel - Board	-	-	N/A	-	40.000	IN/A	4 505	4 700	IN/A	0.740	-	IN/A	39,522	44,000	90%
Travel - Advisors/speakers/invitees       990       2,370       42%       4,776       8,000       60%       11,574       153,426       11%       -       -       N/A       38,366       184,426       215,146       108%         Group Functions/Business       1,324       500       265%       9,024       6,510       139%       8,307       6,500       128%       2255       20,000       161,3254       1018%       1013,254       1018%       1013,254       1018%       1013,254       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1018%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016%       1016% <t< td=""><td>Travel - Staff</td><td>-</td><td>5,000</td><td>0%</td><td>7,072</td><td>12,860</td><td>60%</td><td>4,535</td><td>1,700</td><td>207%</td><td>6,740</td><td>8,400</td><td>80%</td><td>27,341</td><td>49,795</td><td>55%</td></t<>	Travel - Staff	-	5,000	0%	7,072	12,860	60%	4,535	1,700	207%	6,740	8,400	80%	27,341	49,795	55%
Group Functions/Business Meals       1,324       500       265%       9,024       6,510       139%       8,307       6,500       128%       2255       20,000       1%       113,254       105,190       108%         Other Expenses (Audiovisual/Mgmt Fee)       -       1,365       0%       924       1,370       67%       1,720       -       N/A       -       -       N/A       50,748       43,745       116%         SUBTOTAL MEETINGS       2,314       9,235       25%       22,396       28,740       78%       32,136       161,626       20%       6,995       28,400       25%       269,431       427,156       63%         OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       -       N/A       2,618       52,017       5%         CHANGE IN NET ASSETS       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS       21,748       104,036       104,036       104,036       244,640       244,640       498,923 <td>I ravel - Advisors/Speakers/Invitees</td> <td>990</td> <td>2,370</td> <td>42%</td> <td>4,776</td> <td>8,000</td> <td>60%</td> <td>17,574</td> <td>153,426</td> <td>11%</td> <td>-</td> <td></td> <td>N/A</td> <td>38,566</td> <td>184,426</td> <td>21%</td>	I ravel - Advisors/Speakers/Invitees	990	2,370	42%	4,776	8,000	60%	17,574	153,426	11%	-		N/A	38,566	184,426	21%
Other Expenses (Audiovisual/Mgmt Fee)       -       1,365       0%       924       1,370       67%       1,720       -       N/A       -       -       N/A       50,748       43,745       116%         SUBTOTAL MEETINGS       2,314       9,235       25%       22,396       28,740       78%       32,136       161,626       20%       6,995       28,400       25%       269,431       427,156       63%         OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       -       N/A       2,618       52,017       5%         TOTAL EXPENSES       2,612       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS       21,748       (13,387)       (29,494)       (63,821)       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         NET ASSETS, BEGINNING OF PERIOD       104,036       104,036       244,640       244,640       498,923       498,923       -	Group Functions/Business Meals	1,324	500	265%	9,024	6,510	139%	8,307	6,500	128%	255	20,000	1%	113,254	105,190	108%
SUBTOTAL MEETINGS       2,314       9,235       25%       22,396       28,740       78%       32,136       161,626       20%       6,995       28,400       25%       269,431       427,156       63%         OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       NA       2,618       52,017       5%         TOTAL EXPENSES       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS       21,748       (13,387)       (29,494)       (63,821)       514,045       (176,345)       -       -       -       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300	Other Expenses (Audiovisual/Mgmt Fee)	-	1,365	0%	924	1,370	67%	1,720	-	N/A	-	-	N/A	50,748	43,745	116%
OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       -       N/A       2,618       52,017       5%         TOTAL EXPENSES       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%       28%       29,494       (63,821)       514,045       (176,345)       -       -       -       1,010,459       3,652,307       28%       28%       28%       29,494       (63,821)       -       514,045       (176,345)       -       -       -       1,010,459       3,652,307       293,972       (334,972)       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       -       - <t< td=""><td>SUBTOTAL MEETINGS</td><td>2,314</td><td>9,235</td><td>25%</td><td>22,396</td><td>28,740</td><td>78%</td><td>32,136</td><td>161,626</td><td>20%</td><td>6,995</td><td>28,400</td><td>25%</td><td>269,431</td><td>427,156</td><td>63%</td></t<>	SUBTOTAL MEETINGS	2,314	9,235	25%	22,396	28,740	78%	32,136	161,626	20%	6,995	28,400	25%	269,431	427,156	63%
OTHER PROGRAM EXPENSES       2,618       27,500       10%       -       13,500       0%       -       7,517       0%       -       -       N/A       2,618       52,017       5%         TOTAL EXPENSES       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS       21,748       (13,387)       (29,494)       (63,821)       514,045       (176,345)       -       -       N/A       2,618       52,017       5%         NET ASSETS, BEGINNING OF PERIOD       104,036       104,036       104,036       244,640       244,640       244,640       498,923       498,923       498,923       -       -       -       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1																
TOTAL EXPENSES       26,252       109,387       24%       29,494       63,821       46%       165,955       802,345       21%       351,431       1,455,035       24%       1,010,459       3,652,307       28%         CHANGE IN NET ASSETS       21,748       (13,387)       (29,494)       (63,821)       514,045       (176,345)       -       -       293,972       (334,972)       293,972       (334,972)       28%         NET ASSETS, BEGINNING OF PERIOD       104,036       104,036       244,640       244,640       498,923       498,923       -       -       -       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,802,300       1,467,328       1,467,328       1,467,328       1,467,	OTHER PROGRAM EXPENSES	2,618	27,500	10%	-	13,500	0%	-	7,517	0%	-	-	N/A	2,618	52,017	5%
CHANGE IN NET ASSETS     21,748     (13,387)     (29,494)     (63,821)     514,045     (176,345)     -     -     293,972     (334,972)       NET ASSETS, BEGINNING OF PERIOD     104,036     104,036     244,640     244,640     498,923     498,923     -     -     1,802,300     1,802,300       NET ASSETS, END OF PERIOD     125,783     90,649     215,146     180,819     1,012,968     322,578     -     -     2,096,271     1,467,328	TOTAL EXPENSES	26,252	109,387	24%	29,494	63,821	46%	165,955	802,345	21%	351,431	1,455,035	24%	1,010,459	3,652,307	28%
Change in Net Assers       21,746       (13,367)       (29,494)       (05,021)       514,045       (176,345)       -       -       2293,972       (334,972)         NET ASSETS, BEGINNING OF PERIOD       104,036       104,036       244,640       244,640       498,923       498,923       -       -       1,802,300       1,802,300         NET ASSETS, END OF PERIOD       125,783       90,649       215,146       180,819       1,012,968       322,578       -       -       2,096,271       1,467,328	CHANCE IN NET ASSETS		(10 007)		(00.404)	(62 004)		 514 045	(176 345)					202 070	(224 070)	
NET ASSETS, BEGINNING OF PERIOD       104,036       104,036       244,640       498,923       498,923         1,802,300       1,802,300         NET ASSETS, END OF PERIOD       125,783       90,649       215,146       180,819       1,012,968       322,578        2,096,271       1,467,328	CHANGE IN NET ASSETS	21,748	(13,387)		(29,494)	(03,821)		514,045	(176,345)		-	-		293,972	(334,972)	
NET ASSETS, END OF PERIOD 125,783 90,649 215,146 180,819 1,012,968 322,578 2 2,096,271 1,467,328	NET ASSETS, BEGINNING OF PERIOD	104,036	104,036		244,640	244,640		498,923	498,923		-	-		1,802,300	1,802,300	
	NET ASSETS, END OF PERIOD	125,783	90,649		215,146	180,819		1,012,968	322,578		-	-		2,096,271	1,467,328	
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### ILSI Board of Trustees Financial Oversight Committee

## Conference Call December 14, 2012

### **DRAFT MINUTES**

### I. Welcome and Review of Agenda

Dr. Liz Westring, Chairman of the ILSI Board of Trustees Financial Oversight Committee, began the conference call at 9:04 a.m. Eastern Standard Time. In addition to Dr. Westring, the following trustees and staff participated in the call: Dr. Sushila Chang, Dr. Gerhard Eisenbrand, Dr. Jay Goodman, Dr. Joanne Lupton, Mr. Felipe Rodriguez, Ms. Beth-Ellen Berry, Dr. Suzie Harris, and Mr. Shawn Sullivan.

The agenda is attached.

Dr. Goodman asked if a quorum was present and Dr. Harris confirmed that a quorum was present.

### II. Approval of Minutes from the October 30, 2012 Conference Call

Dr. Goodman asked that "approximately" be inserted in second sentence of the first paragraph on page 2 of the draft minutes, so that the sentence reads "Dr. Goodman stated that ...reserve fund that covers approximately a full-year...".

With this change the minutes were approved.

### III. Further Discussion of the Appropriate Size of the ILSI Reserve Fund

A draft policy for the reserve fund was circulated to the committee prior to the conference call. Ms. Berry explained that the policy is the same as the revision that the committee discussed during the October 30 conference call, with a single change that was highlighted in yellow – "Together with the Board Restricted ILSI Press Investment Fund, ILSI's Board-designated Investment reserves represent approximately 47% (or just under 6 months) of unrestricted annual operating expenses." Ms. Berry said that the second footnote was also tweaked to update the Press Fund balance.

A revised 2011 balance sheet was also included to clarify how much is currently available for the reserve. In this iteration of the balance sheet the Press Investment Fund is clearly shown in the unrestricted column. The total undesignated net assets are \$438,705.

Ms. Berry reviewed the history of the ILSI Press Investment Fund which became a Board-restricted fund in 2006. At that time, ILSI had a deficit and the Board adopted a recapitalization policy with \$400,000 as the target for net assets. The Press Investment Fund, which initially was \$250,000 as a signing bonus from Wiley Blackwell, was designated as "Board restricted" to help meet the net asset target. The ILSI Board of Trustees may at any time decide how to use the restricted funds.

Action: The committee approved a motion to combine the Press Investment Fund with the other reserve funds in an ILSI Reserve.

The second guestion before the committee was to decide the size of the ILSI Reserve.

Action: The committee approved a motion to set the target size of the fund at 50 percent of unrestricted annual operating expenses.

#### IV. Adoption of a Reserve Fund Policy

Ms. Berry agreed to revise the policy and send it to the committee for final approval. The revised policy will then be distributed to the ILSI Board of Trustees for approval in January. The context of the committee's decision will be included in the committee's report to the ILSI Board and in the slides that will be used during the presentation to the Board.

#### ν. Next Steps

- Ms. Berry will revise the reserve fund policy and send it to committee for comment.
- The finalized policy will be distributed to the ILSI Board of Trustees with the context of the committee's discussion included in the written report and presentation slides

#### VI. Adjournment

Ms. Berry announced that a joint finance committees (ILSI, ILSI HESI, ILSI North America, and ILSI Research Foundation) meeting will be held again on Sunday, January 20, 2013 during the ILSI Annual Meeting. Representatives from Raffa Wealth Management will join the meeting by conference call. Dr. Goodman asked that the Raffa representatives show how they would respond to a sudden drop in the market. Ms. Berry reminded the committee that Raffa follows the investment policy which calls for rebalancing the portfolio when the investment mix is +/- 20 percent of the target allocation. Raffa recommended an efficient, market following strategy, which forms the investment policy. This policy was approved by the ILSI Financial Oversight Committee earlier in the year.

Dr. Goodman also asked that the joint committees discuss the wisdom of having the auditors conduct the more specific internal controls audit.

As he had done during the October 30 committee conference call, Dr. Goodman asked that ILSI continuing deficit budget be called to the Board's attention. Ms. Berry noted that she had done so in January 2012 and that she would do so again in January 2013.

As there was no further business, Dr. Westring thanked the committee members for their active participation and ended the call at 9:39 a.m. Eastern Standard Time.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

# ILSI Board of Trustees Financial Oversight Committee

# **Conference Call**

Friday, December 14, 2012 9:00 – 10:30 am Eastern Daylight Time

# AGENDA

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the October 30, 2012 Conference Call
- III. Further Discussion of the Appropriate Size of the ILSI Reserve Fund
- IV. Adoption of a Reserve Fund Policy
- V. Next Steps
- VI. Adjournment

# ILSI Board of Trustees Financial Oversight Committee

# **Conference Call**

# Thursday, April 25 9:00 – 10:00 am Eastern Daylight Time

### **PROPOSED AGENDA**

- I. Welcome and Review of Agenda
- II. Approval of Minutes from the December 14, 2013 Conference Call
- III. Review of 2013 Year-to-date Financial Report
- IV. Audit Plans
- V. Investment Policy for Expanded Reserve Funds
- VI. New Business
- VII. Next Steps
- VIII. Adjournment

From: Sent: To:	Suzanne Harris < Monday, March 18, 2013 1:26 PM sushilachang@sutd.edu.sg; Adam Drewnowski; m goodman3@msu.edu ; : Joanne Lupton: john milner@ars.u	; k; narion@vt.edu; eis ; isda.gov: Rodriguez, Felipe {P]}
	,	; Geoff
	; Smith, Lewis L. (Prof.)	) ;
	weavercm@purc Flavio Zambrone; john.c.peters@ucdenver.edu;	; lue.edu;
	; · Coh	en Samuel M (scohen@unmc.edu):
	cputnam@unmc.edu; ; ( linda.reynolds@ars.usda.gov; Christine Lagerquist Beth Brueggemeye	; Chelsea L. Bishop; haan@purdue.edu; tim.goss@ucdenver.edu; er; Fleming, Melinda S
	, Michael Shirreffs: Shawn Sullivan: Beth Bruegger	, beth-Ellen berry, Jever
Subject:	Date for the ILSI Board of Trustees mid-year conf 9:00 a.m. Eastern Daylight Time	erence call Monday, August 5 at

TO: ILSI Board of Trustees

FROM: Suzie Harris

Thank you for sending me your availability so promptly. The best date for the ILSI Board of Trustees mid-year conference call is **Monday, August 5, 2013, beginning at 9:00 a.m. Eastern Daylight Time.** The call will not last longer than two hours.

Please mark this day and time on your calendars. I will send an agenda, briefing materials and the dial-in instructions to you about one week before the conference call.

Please let me know if you have any questions.

### Suzanne S. Harris, Ph.D.

Executive Director International Life Sciences Institute 1156 15<sup>th</sup> Street, NW Suite 200 Washington, DC 20005-1734 T: 202.659.0074 Ext 129 F: 202.659.3859 E: <u>www.ilsi.org</u>

Follow ILSI on: 🖪 토

From:Jacops, LucSent:Thursday, February 21, 2013 9:53 AMTo:Bui, Linh; Joanne Lupton; Hamaker, Bruce R.; De Man, Walter; Chelsea L. BishopSubject:RE: Oldways GI Summit Info - RE: AGENDA & DOCUMENTS: Carbohydrate Quality Call<br/>on 2/19 at 4:00 pm EST

Linh, thanks for clarifying! We are now fully aligned, let's close the can Best regards Luc

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From: Bui, Linh
Sent: donderdag 21 februari 2013 15:55
To: Jacops, Luc; Joanne Lupton; Hamaker, Bruce R.; De Man, Walter; Chelsea L. Bishop
Subject: RE: Oldways GI Summit Info - RE: AGENDA & DOCUMENTS: Carbohydrate Quality Call on 2/19 at 4:00 pm EST

Luc,

I think my understanding was that we were seeking to see if they were still accepting potential sponsor with the opportunity to add onto the agenda to give a more neutral scientific view on Carb Quality, not necessary in support of the general concept of GI. Any how, it doesn't look like they are open to that. I think we can close the discussion.

Linh Bui PhD, MS Scientific & Regulatory Affairs - Research & Development Mars North America Food T: +1 323-394-9495 | M: + 1 323-394-9495 E:



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From: Jacops, Luc
Sent: Thursday, February 21, 2013 6:47 AM
To: Bui, Linh; Joanne Lupton; Hamaker, Bruce R.; De Man, Walter; Chelsea L. Bishop
Subject: RE: Oldways GI Summit Info - RE: AGENDA & DOCUMENTS: Carbohydrate Quality Call on 2/19 at 4:00 pm EST

Hi Linh,

Thanks for going after this. I recall from our previous FSAC conversation Bruce commented the lack of experts on glyceamic carbohydrates and in the discussion that followed we agreed Mars not to sponsor a summit that is going to promote the idea of GI, a concept we have challenged with the FSAC group.

Is there any indication we should change our opinion ? If not, I think we can close the discussion, if yes, we should plan for a discussion slot in the next call.

(Seeing the deck from Felix and John, I think we need to full hour today to go through the flavor work.)

Looking forward to the point of view from Bruce and Joanne.

Best regards Luc

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From: Bui, Linh

Sent: donderdag 21 februari 2013 3:30

**To:** Bui, Linh; Joanne Lupton; Jacops, Luc; Hamaker, Bruce R.; De Man, Walter; Chelsea L. Bishop **Subject:** RE: Oldways GI Summit Info - RE: AGENDA & DOCUMENTS: Carbohydrate Quality Call on 2/19 at 4:00 pm EST

Hi again,

I was reading the letter in more detail, looks like an industry sponsor is only allowed to speak during sessions #5 & #7, which are industrys' perspectives. Not sure we wanted to participate there.

I'd reached out to them twice previously to see if we can provide inputs on the scientific speakers, there were no responses until now.

Linh

From: Bui, Linh
Sent: Wednesday, February 20, 2013 6:22 PM
To: 'Joanne Lupton'; Jacops, Luc; 'Hamaker, Bruce R.'; De Man, Walter; 'Chelsea L. Bishop'
Subject: FW: Oldways GI Summit Info - RE: AGENDA & DOCUMENTS: Carbohydrate Quality Call on 2/19 at 4:00 pm EST

Hello everyone,

I finally received a call from Oldways yesterday (finally) that the opportunity is still open for new sponsors to join and to identify a speaker.

Below I am forwarding to you additional information, now with a much longer list of speakers and developed agenda.

Not sure if we'll have some time to chat on the FSAC call tomorrow or will need to set up something on the side to discuss.

Thanks,

Linh

To: Barbara Winters		Bruce Ray PhD	Daniel G. Steffen PhD
Garrett	; Lagg, Dorothy; ; Jonathan DeVrie Kathryn L. Wiemer	es PhD	; Jennifer L. Julie Miller Jones PhD, CNS eld, David: KURU JCH, Appe C : Bui
Linh; Liska, DeAnn; M	arge Leahy ;	Miller, Kevin;	Nate Matusheski
Suzanne Harris; Theis	; Ron Deis; Satya Jonna , Dr. Stephan, Beneo-Group; Willia : Courtney Kelly: Chor San Kh	ilagadda; Spence, Lisa; Stuar amson-Hughes, Patricia S.; Y 100	t Craig ); Fang Chu
Cc: Christine Pelkman Subject: Oldways GI	( Summit Info - RE: AGENDA & DO	CUMENTS: Carbohydrate Qu	ality Call on 2/19 at 4:00 pm EST
Hello again,			
Chris has provided the blow and in the attac	ne information on the Oldways G hed document for more details.	I summit that she mention	ed on yesterday's call. Please see
International Consen in the Italian Lakes D The Summit will be h	usus Summit on <b>Glycemic Index</b> District, north of Milan, co-organi Held at the Grand Hotel des Iles E	<b>, Glycemic Load and Glyce</b> zed by Nutrition Foundatio Forromees in Stresa. ( <u>http://v</u>	emic Response on June 6-7, 2013 n of Italy and Oldways USA. www.borromees.it/v3/)
Chris will be speakin GI. If any of you are i	g on how GI falls short, but as sh nterested in sponsoring or speal	e mentioned, the conference, chri	ce as of now is slanted toward pro- s is happy to discuss.
Thanks,			
Courtney			
From: Courtney Gaine Sent: Wednesday, Fe	e bruary 20, 2013 11:55 AM		
To: Barbara Winters		); Bruce Ray PhD	; Christine Pelkman
	); Daniel G. Steffen P	hD	; Dot A. Lagg
	); Jonathan DeVries PhD		; Jennifer L. Garrett Julie Miller Jones PhD, CNS
	t; Kathryn L. Wiemer	); Klurf	eld, David; KURILICH, Anne C.;
Nature all' (	Liska, DeAnn; Marge Leahy	); Miller, Kevin	; ; Nate
Matusheski ( (	); Ron Deis; ); Suzanne Harris; Theis, Dr. S	Satya Jonnalagadda; Spence Stephan, Beneo-Group; Willia	, Lisa; Stuart Craig imson-Hughes, Patricia S.; YiFang
Chu (			
Subject: Alfred Aziz S	Nor San Knoo Slides - RE: AGENDA & DOCUMEN	TS: Carbohydrate Quality Cal	l on 2/19 at 4:00 pm EST
Hi Everyone,			
Thanks to all for the p as promised.	roductive call yesterday. Attached	are Alfred Aziz's slides from	the Carbohydrates Forum this year,

A summary of yesterday's call will be coming to you all soon.

Thank you,

Courtney

From: Courtney Gaine Sent: Friday, February 15, 2013 11:49 AM To: Barbara Winters ( ); ); Daniel G. Steffen PhD (

); Bruce Ray PhD

; Jennifer L. Garrett Jonathan DeVries PhD ); Julie Miller Jones PhD, CNS ); Kathryn L. Wiemer ( ); Klurfeld, David; KURILICH, Anne C.; ; Liska, DeAnn; Marge Leahy ( ); Miller, Kevin; ; Nate Matusheski ); Ron Deis; Satya Jonnalagadda; Spence, Lisa; Stuart Craig ; Suzanne Harris; Theis, Dr. Stephan, Beneo-Group; Williamson-Hughes, Patricia S.; YiFang Chu

Cc: Courtney Kelly; Chor San Khoo Subject: AGENDA & DOCUMENTS: Carbohydrate Quality Call on 2/19 at 4:00 pm EST

Dear Carbohydrate Quality Working Group,

Please see the attached documents for our call next Tuesday, 19 February at 4:00 pm EST. The agenda for the call can be found in the 'Call Docs' pdf. If you are unable to make the call, but have suggestions about new projects, please get in touch with me or Jennifer Garrett prior to Tuesday so that we can incorporate these ideas into the discussion.

I look forward to talking with you all next week.

Have a great weekend,

Courtney

P. Courtney Gaine, Ph.D., R.D. Science Program Manager The International Life Sciences Institute, North America 1156 15th St, NW, #200 Washington, DC 20005 202-659-0074 ext. 121

From:	Suzanne Harris
Sent:	Wednesday, January 16, 2013 8:46 AM
To:	Trumbo, Paula; Joanne Lupton
Subject:	RE: Who should I send my slides to? I assume someone will forward the slides for me. Thanks

Friday is fine, Paula. We plan to use a web-based link-up. It is like Go To Meeting, but a different service. I presume you will be at home on Monday. Will you have access to a landline phone? The audio transmission will be clearer, if a landline is used. Will you have internet access? If so, then you will be able to advance your slides.

I will have more details later. Will be happy to have a run through of the system with you as well -- either early Monday morning or sometime over the weekend.

Thanks again for being willing to participate.

Best regards,

Suzie

From: Trumbo, Paula [Paula.Trumbo@fda.hhs.gov]
Sent: Wednesday, January 16, 2013 5:49 AM
To: Joanne Lupton; Suzanne Harris
Subject: RE: Who should I send my slides to? I assume someone will forward the slides for me. Thanks

OK – thanks – I am having the slides reviewed by CDER right now. But will send by Friday.

From: Joanne Lupton [mailto:jlupton@tamu.edu]
Sent: Wednesday, January 16, 2013 8:37 AM
To: Trumbo, Paula; Suzanne Harris
Subject: RE: Who should I send my slides to? I assume someone will forward the slides for me. Thanks

Paula, As a backup please send them to both of us. Yes, someone will advance your slides. Suzie and I will determine who the person shall be (maybe me). Joanne

 From: Trumbo, Paula [mailto:Paula.Trumbo@fda.hhs.gov]

 Sent: Wednesday, January 16, 2013 6:26 AM

 To: Suzanne Harris
 ; Joanne Lupton

 Subject: Who should I send my slides to? I assume someone will forward the slides for me. Thanks