The Coca-Cola Company

COCA-COLA PLAZA
ATLANTA, GEORGIA

11530-JA07

RESEARCH AGREEMENT

This Research Agreement ("Agreement") is effective on the last date of execution of this Agreement ("Effective Date") between THE SOUTH CAROLINA RESEARCH FOUNDATION ("SCRF"), the university-affiliated research foundation for THE UNIVERSITY OF SOUTH CAROLINA ("University"), Dr. Steven Blair, Professor, Arnold School of Public Health, having his principal office located at Room 225, 921 Assembly Street, Columbia, SC 29208 ("Study Director"), Dr. Greg Hand, Professor, Arnold School of Public Health, having his principal office located at Room 102, 800 Sumter Street, Columbia, SC 29208 ("Study Co-Director"), and THE COCA-COLA COMPANY, a Georgia corporation with offices located at One Coca-Cola Plaza, Atlanta, GA 30313 (hereinafter "Sponsor"). University, Study Director, Study Co-Director, and Sponsor are also referred to herein individually as a "Party" and collectively as "Parties".

RECITALS

WHEREAS, the research study contemplated by this Agreement is of mutual interest and benefit to the Parties;

WHEREAS, the Parties to this Agreement share a common mission of improving the public health by engaging in research relating thereto;

WHEREAS, in connection with this mission, Sponsor desires to have further clinical research conducted evaluating the key components of energy balance via the protocol attached hereto as **Exhibit A** ("Protocol"); and

WHEREAS, SCRF, Study Director, and Study Co-Director having particular expertise and opportunity in the Protocol, desire to provide this research.

NOW, THEREFORE, in consideration of the mutual promises contained herein, the Parties agree as follows:

1 Research Protocol

1.1 IRB Review. University shall commence performance of the Protocol subject to prior receipt of necessary approvals from its Human Investigational Review Committee ("IRB"). The IRB must operate in accordance with the U.S. Code of Federal Regulations ("CFR"), Title 21 CFR, Part 56 (Institutional Review Boards), as promulgated under the Federal Food, Drug and Cosmetic Act. The Parties agree that no changes will be made to the Protocol without the Sponsor's prior written consent, which consent shall not be unreasonably withheld or delayed.

1.2 Study Director and Study Co-Director. The Protocol will be conducted by the Study Director, Dr. Steven Blair, and by the Study Co-Director, Dr. Greg Hand, each of whom has expertise in the field of research involving body mass index, physical activity, physical fitness, energy balance, and other factors necessary to execute the Protocol. If, for any reason, Study Director, and Study Co-Director become unavailable, SCRF shall promptly advise Sponsor. If Sponsor and SCRF cannot agree on a qualified replacement scientist or an appropriate solution within thirty (30) days after the Study Director and Study Co-Director cease to be available to work on the Protocol, either Sponsor or SCRF may terminate this Agreement on ten (10) business days' written notice to the other Party.

1.3 Standards, Conflicts and Integrity.

1.3.1 Standards. The study (including without limitation the study execution, Protocol, data collection, analysis and interpretation thereof) (hereinafter "Study") shall be conducted in a professional and competent manner, in accordance with generally accepted sound scientific research techniques, methods and principals, and be consistent with good clinical practice as defined and outlined in the United States Code of Federal Regulations, and in strict adherence to the Protocol.

1.3.2 Conflicts and Integrity. Sponsor and SCRF will each fulfill its respective obligations with respect to the Study in accordance with the Eight Guiding Principles enumerated at page 4 of attached **Exhibit D,** *"Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity".*

1.4 Research Site. SCRF will conduct the Study at the following research site(s) [the "Research Site(s)"]:

Arnold School of Public Health
The University of South Carolina
921 Assembly Street,
Columbia, SC 29208

1.5 Personnel and Equipment. SCRF will at all times furnish and devote the necessary and agreed qualified personnel, facilities and equipment to perform the Study and carry out the Protocol as set forth in this Agreement. SCRF acknowledges that all personnel involved in the Study shall be employees of University or Research Site and not of Sponsor, and that University or Research Site shall be responsible for their compensation and benefits, shall make all payments required to be made by any taxing or governmental authority with respect to their employment and shall maintain any necessary workers compensation insurance with respect to such employees. University or Research Site personnel who perform or work on the Study under Study Director and Study Co-Director, together with any other direction, shall be referred to as "Investigators". All Investigators will be subject to all terms and conditions, particularly confidentiality and inventions, as set forth in this Agreement herein.

1.6 Consultants. University will make all necessary contract arrangements with the consultants identified in the portion of **Exhibit B** titled "Budget Justification" ("Consultants") who are providing guidance with respect to the Study.

1.7 Sponsors' Representative. Sponsors' Technical/Scientific representatives on the Study shall be Dr. Susan Roberts and Dr. Karen Cunningham and/or such other representative(s) as Sponsors may subsequently designate in writing from time to time ("Sponsors' Technical/Scientific Representative(s)").

1.8 Informed Written Consent and Confidentiality for Participants. SCRF represents that informed, executed, written consents will be obtained from each Study participant ("Research Subject") prior to his/her participation in the Study in exchange for the consideration they are to receive. SCRF shall be solely responsible for the preparation and content of the informed, written consent. The consent form shall also be approved by the IRB prior to its use in the Study. SCRF shall certify in writing to Sponsor that the informed, written consent has been executed by each Research Subject no later than 10 days after the last Research Subject is randomized.

1.9 Record Keeping, Reporting and Access. SCRF, Study Director, and Study Co-Director agree as follows:

1.9.1 Record Keeping. Study Director and Study Co-Director will keep and maintain adequate records containing data generated in the course of the Protocol to enable Study Director and Study Co-Director to furnish complete and accurate information to Sponsor regarding the Protocol results; provided, however, that the Parties agree that SCRF, Study Director, and Study Co-Director shall not disclose to Sponsor any personal information relating to Research Subjects.

1.9.2 Access and Inspection. Sponsor's authorized representative(s), and governmental or regulatory authorities, to the extent required by law, may, at mutually agreed upon times and upon reasonable notice to SCRF, Study Director, and Study Co-Director, arrange to: (i) examine and inspect University's facilities used for performance of the Protocol; and (ii) audit, inspect and copy all data and work products relating to the Study, (other than confidential Research Subject records as provided in Article 1.8), to verify compliance by SCRF, Study Director, and Study Co-Director with the terms of this Agreement.

1.9.3 Government Inspections. If any governmental or regulatory authority conducts or gives notice to SCRF of its intent to conduct an inspection at the Research Site or to take any other regulatory action with respect to the Study, SCRF will promptly give Sponsor written notice thereof, including all information pertinent thereto;

provided that it shall not be a breach of this Agreement for SCRF to comply with the demands and requests of a governmental or regulatory authority in accordance with SCRF's reasonable judgment and subject to the other terms and conditions of this Agreement.

1.9.4 Records Retention. All records of Study Director and Study Co-Director related to the Protocol shall be maintained for a minimum retention period of five (5) years following the natural expiration or termination of this Agreement, except with regard to Confidential Information, as defined in Article 3.1, which shall be handled in accordance with Article 3.

1.9.5 Reporting procedures. Once per month during the execution of the Protocol, SCRF shall send Sponsor a brief progress report (3-4 sentences). Once in the first 3 calendar quarters, SCRF shall send Sponsor a more detailed progress report (1-2 pages). Once per calendar year, in December, SCRF shall send sponsor a comprehensive progress report summarizing all work performed that year in the execution of the Protocol. Each quarterly report shall take the place of the report for the month in which the quarterly report is sent. The annual progress report shall take the place of a quarterly report for the fourth quarter.

1.10 Material Error. If SCRF commits a material error in the conduct of the Study or Protocol that adversely affects the Study's validity or results, University will either repeat the Study in a timely manner without additional cost to the Sponsor, or refund to Sponsor the cost of the Study, by mutual agreement.

2 Protocol Funding

2.1 Budget and Payment Schedule. Sponsor agrees to support this Study and shall pay SCRF as set forth in the Budget and Payment Schedule attached hereto as **Exhibit B** and **Exhibit C**, respectively. In the event that SCRF unexpectedly learns that certain other expenses need to be considered, SCRF must seek the prior written approval of Sponsor before taking steps that would incur additional costs. SCRF shall send an invoice to the responsible Party for Sponsor, as set forth in Article 10.4, no earlier than one day after execution of the Agreement by both Parties. Sponsor shall pay each invoice within forty-five (45) days of receipt. Payments will be made by wire transfer to:

Bank Name:	Wachovia Bank, NA
Bank Address:	1525 West WT Harris Boulevard Charlotte, NC 28262
Name on Account:	SC Research Foundation
Routing Number:	053207766
Account Number:	2003233007079
SWIFT Code:	PNBPUS33

2.2 Use of Funds. SCRF shall monitor expenditures to ensure that the funds provided by Sponsor are spent in accordance with this Agreement, and as set forth in **Exhibit B**, and will maintain complete and accurate accounting records in accordance with generally accepted accounting principles, which shall be available for inspection, review and audit at reasonable times by Sponsor. Minor variances (not to exceed 10%) of expenditures from the established budget shall not require prior approval of the Sponsor.

2.3 No Government Funding. Unless otherwise agreed to in writing by Sponsor, SCRF agrees that it will not accept any funding for the Study from the United States Government or any agency thereof. Accordingly, unless Sponsor has agreed in writing to permit partial funding of the Study by the United States Government or an agency thereof, SCRF represents that the United States Government shall obtain no rights under 35 U.S.C. § 200-212 to any Inventions resulting from this Study.

3 Confidential Information

3.1 In preparation of and during the course of the Protocol, it may be necessary for the Sponsor to disclose to Study Director, Study Co-Director, and University, orally or in writing, technical and business information regarding the Sponsor's products, marketing plans, public relations plans, or Protocol thereto (hereinafter referred to as "Confidential Information"). Any Confidential Information that is disclosed orally must be reduced to writing within 30 days of disclosure. All Confidential Information is considered to be highly confidential by the Sponsor. Study Director, Study Co-Director, and SCRF agree to take all reasonable precautions to prevent disclosure of Confidential Information and to others and to not use Confidential Information without the express written consent of the Sponsor. These restrictions upon disclosure and use of Confidential Information shall extend beyond the term of the Agreement and any extensions herein for a period of five (5) years, but shall cease to apply to any specific portion of Confidential Information which:

3.1.1 is already in Study Director, Study Co-Director, or the SCRF's possession at the time of disclosure thereof as established by relevant documentary evidence;

3.1.2 is or later becomes available to the public other than by Study Director, Study Co-Director, or SCRF's default;

3.1.3 is received by the Study Director, Study Co-Director, or SCRF from a third party having no obligation of confidentiality to the Sponsor;

3.1.4 is independently developed by University personnel who are not aware of the Confidential Information, as established by relevant documentary evidence; or

3.1.5 is required to be disclosed by law or government regulation.

4 Publication Rights and Use of Project Results

4.1 Publication. SCRF shall prepare one or more manuscripts suitable for publication in a peer-reviewed scientific journal, reporting the results obtained through execution of the Protocol. SCRF shall exercise its best efforts to obtain the acceptance and publication of all such manuscripts in peer-reviewed scientific journals.

4.2 Review Rights. Each Party agrees to submit to the other Party, for review, the draft of any proposed oral or written disclosure of the results, including any abstract of the results, or any manuscript at least ten working days (10) days in advance of any disclosure of the results. The Party preparing such disclosure shall consider any suggestions from the other Party concerning the disclosure, but is not bound to incorporate such suggestions in any oral or written publications, except for redaction of Confidential Information as necessary for SCRF to fulfill its obligations of confidentiality under Article 3. At the expiration of the ten (10) working day period, SCRF, Study Director, and/or Study Co-Director may proceed with the disclosure (e.g. publication of a manuscript) unless it has received written notice from Sponsor that it wishes to cease or delay publication due to:

a.) Sponsor reasonably believes a patent application claiming a new invention should be filed prior to such publication;
b.) Sponsor's confidential and/or proprietary Confidential Information is contained in the proposed manuscript; or
c.) Sponsor reasonably believes a risk exists to the protection of proprietary rights.

If a potentially patentable invention results from the Protocol and Sponsor wishes to file a patent application covering such invention pursuant to Article 5 herein; the Parties agree to negotiate in good faith to determine and agree upon a reasonable delay of any oral or written disclosure of the results, in order to allow the Sponsor to complete development necessary for filing and to file such patent application. Such delay shall not exceed one hundred twenty (120) days.

4.3 Public Acknowledgement. Publication shall acknowledge authorship according to those significantly involved in the Study. SCRF agrees that if Sponsor so requests, and only if Sponsor requests, substantive releases and/or written reports contemplated by this Article 4 may include language to the effect that "The Study was funded by The Coca-Cola Company".

4.4 Company name. Without Sponsor's prior written approval, SCRF will not publish or use any advertising, sales promotion or publicity matter relating to services, equipment, materials, products and reports furnished by SCRF wherein the names of Sponsor, its subsidiaries, affiliates and/or authorized bottlers are mentioned or their identity implied.

5 Invention Rights

5.1 Study Director, Study Co-Director, and University agree to disclose promptly and fully in writing to the University Intellectual Property Office , all creative ideas, developments and inventions, whether or not patentable, conceived or reduced to practice by Study Director, Study Co-Director, or University as a result of the Study (herein referred to as the "Inventions"). The Parties agree to hold all information regarding any Invention in confidence until a patent application covering the Invention has been filed, or the Parties have agreed in writing that no patent application covering the Invention is to be filed, or publication of the Invention occurs pursuant to Article 4 herein.

5.2 All Inventions shall be the sole property of Sponsor, and SCRF, Study Director, and Study Co-Director hereby transfer and assign to Sponsor any and all of their and the other investigators' rights, title and interests in the Inventions. Each of SCRF, Study Director, and Study Co-Director agrees to cooperate with Sponsor and to assist Sponsor in protecting any Inventions and related Confidential Information and Sponsor's rights therein, including by promptly executing and delivering to Sponsor any documents reasonably requested by Sponsor to perfect or evidence Sponsor's rights therein, whether by patent, copyright, trade secret or otherwise.

5.3 If Sponsor determines that it wishes to have a patent application or application for other intellectual property protection filed with respect to any Invention, each of SCRF, Study Director, and Study Co-Director shall promptly assist Sponsor in Sponsor's preparation, filing and prosecution of such U.S. and/or foreign application(s). Accordingly, Study Director, Study Co-Director, and SCRF agree to assign outright to the Sponsor the entire right, title and interest, both in the United States and abroad, to any Inventions developed as a result of the Protocol and/or Study, without payment other than the fees provided for herein. Sponsor shall bear all costs incurred in connection with the preparation, filing, prosecution and maintenance of U.S. and foreign application(s) directed to the Inventions. Each of SCRF, Study Director, and Study Co-Director shall cooperate with Sponsor to assure that such application(s) will cover, to the best of their knowledge, all items of commercial interest and importance. Sponsor alone shall be responsible for making decisions regarding scope and content of the application(s) to be filed and the prosecution thereof, but Study Director, Study Co-Director, and SCRF will be given an opportunity to review and provide input thereto. The Study Director, Study Co-Director, and the SCRF further agree to execute any and all documents which the Sponsor determines are necessary or convenient to fully implement Sponsor's proprietary rights in such Inventions.

6 Termination

6.1 Term. This Agreement shall take effect as of the Effective Date and shall remain in effect until completion of the Protocol, including delivery by SCRF to Sponsor of all relevant reports and manuscripts, which shall be

no later than December 31, 2013, unless sooner terminated in accordance with Article 6.2 or otherwise agreed to by the parties in writing.

6.2 Termination. Sponsor may terminate this Agreement, without cause, upon prior 15 days written notice to SCRF. Either Party may terminate this Agreement upon thirty (30) days prior written notice to the other Party in the event the other Party is in breach of its material obligations hereunder. The breaching Party may cure such default prior to the expiration of the same thirty (30) day notice period, at which point this Agreement shall continue in full force and effect. If the breaching Party does not cure the breach during the notice period, the Agreement will be terminated.

6.3 Effect of Termination.

6.3.1 Termination of this Agreement by either Party for any reason shall not affect the rights and obligations of the Parties accrued prior to the effective date of termination of this Agreement.

6.3.2 Articles 1-5, 7, and 10 shall survive the natural expiration or termination of this Agreement.

6.3.3 Upon early termination of this Agreement, Sponsor will be responsible for compensating SCRF for all authorized, non-cancelable commitments for costs incurred or to be incurred as a result of the performance of the Protocol under this Agreement as of the date of termination; provided, however, that Sponsor will in no event be obligated to compensate SCRF more than the total amount set forth in **Exhibit B**. If the amount Sponsor has paid to SCRF prior to the date of termination exceeds the amount of cancelable commitments for costs incurred or to be incurred at the date of termination, SCRF will reimburse Sponsor for the excess.

6.3.4 Upon termination of this Agreement, SCRF shall immediately discontinue any work and shall take such precautions as requested by Sponsor, including returning to Sponsor or certifying in writing to Sponsor that it has destroyed all documents and other tangible items containing Sponsor Confidential Information.

6.3.5 Neither Party shall be liable to the other for damages of any kind relative to termination of this Agreement in accordance with this Article 6, even if advised of the possibility of such damages.

7 Indemnification

7.1 Liability of SCRF. SCRF hereby agrees that it shall be solely responsible, to extent allowed by South Carolina law, where found liable by a court of competent jurisdiction, for any and all damages, deficiencies, actions, suits, proceedings, demands, assessments, judgments, claims, losses, costs, expenses (including medical expenses incurred by participants

enrolled in the Study to the extent such medical expenses are not covered by the participants' medical or hospital insurance or governmental programs providing such coverage), obligations and liabilities (including expenses and reasonable experts' and attorneys' fees) arising from or relating to (i) the intentional misconduct, recklessness or negligent act or omission by University, any of its employees or agents as it relates to the performance of the Protocol; or (ii) the failure of Study Director, Study Co-Director, or his co-investigators, and assistants to adhere to the terms of the Protocol or to employ reasonable care in the performance of the Protocol in conformity with the generally accepted standards of the medical and scientific communities or to adhere to any local or national laws in any material respect.

7.2 Insurance. University shall maintain, at all times during the performance of the Protocol, sufficient liability insurance to adequately protect the respective interests of Sponsor hereunder.

8 Representations and Warranties

8.1 University Representations. SCRF hereby represents to the best of its ability that: (i) University is, and shall continue to be throughout the period of the Study, in compliance with all of University's internal rules and regulations applicable to: (a) it or its activities; and (b) the Study; (ii) other than those which have already been obtained, no consents or approvals of, and no filings with, any governmental entity or any other person are needed to enable the Study to be conducted; (iii) other than those which have already been obtained, no approvals or consents of any person or body at University is required for University, Study Director, or Study Co-Director to conduct the Study; (iv) University obtained from all the Investigators and University's faculty, staff, employees or students that will be working on the Study, all rights necessary to grant the rights granted to Sponsor in this Agreement; (v) the informed written consent form has been approved by the IRB; (vi) University has the experience and ability in the fields and related disciplines as may be necessary to perform all required services with a high standard of quality; (vii) University's services will be performed in a workmanlike and professional manner and all services, equipment, materials and reports furnished will be as represented by University, suitable for Sponsor's business purposes; (viii) the individual signing this Agreement on its behalf is duly authorized to do so and to bind SCRF by this Agreement; (ix) SCRF is a duly organized and validly existing corporation in good standing under the laws of South Carolina and is duly qualified and authorized to do business and is in good standing in all jurisdictions where it is required to be so qualified; and (xi) SCRF has the power and authority (a) to own its property and assets and to transact the business in which it is engaged and presently proposes to engage, and (b) to execute, deliver and perform this Agreement.

8.2 Sponsor Representations. Sponsor hereby represents and warrants that the individual signing this Agreement on its behalf is duly authorized to do so and to bind Sponsor by this Agreement. EXCEPT AS SET FORTH IN

THIS AGREEMENT, SPONSOR MAKES NO EXPRESS OR IMPLIED REPRESENTATIONS OR WARRANTIES AND THE WARRANTY OF MERCHANTABILITY OR FITNESS FOR PURPOSE OR USE IS EXPRESSLY DISCLAIMED AND WAIVED BY UNIVERSITY, STUDY DIRECTOR, AND STUDY CO-DIRECTOR.

9 Conduct, Principles, Minority and Women-Owned Business Enterprises

9.1 Supplier Guiding Principles and Code of Business Conduct for Suppliers. It is well understood that SCRF is not a "Supplier" as defined by the industry. SCRF, however, shall review and abide by Sponsor's Supplier Guiding Principles and the Code of Business Conduct for Suppliers and will, at a minimum, meet the principle standards with respect to its operations as a whole as the same principles will apply to SCRF. Sponsor's Supplier Guiding Principles and the Code of Business Conduct for Suppliers are available at http://www.thecoca-colacompany.com/citizenship/supplier_code.html SCRF will implement appropriate internal business processes to ensure compliance with these standards. Sponsor has the right to use independent third parties to audit SCRF's compliance with these standards, including, but not limited to, conducting interviews with employees and on-site personnel. If SCRF fails to uphold any aspect of these standards, SCRF will implement immediate corrective actions. Sponsor has the right to terminate this Agreement if SCRF cannot demonstrate that it is in compliance with these standards.

9.2 Minority and Women-Owned Business Enterprises. Sponsor is committed to the ongoing growth and development of Minority and Women-Owned Business Enterprises ("MWBE"). Sponsor is further committed to providing equal opportunity to diverse suppliers of goods and services and makes every effort to use MWBE to the maximum extent possible. In this regard, Sponsor is interested in establishing contractual agreements with suppliers of goods and services that share our vision and are dedicated to supplier diversity principles. For more information, please visit www.coke.net, link to Supplier Diversity.

10 Miscellaneous

10.1 Relationship of Parties. Each Party shall be deemed to be an independent contractor and not an agent or employee of the other Party. Neither Party shall have the authority to make any statements, representations nor commitments of any kind, nor take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized in writing.

10.2 Publicity. Sponsor and SCRF shall consult with each other and reach agreement regarding and prior to the issuance of any press release or the making of any public statements with respect to this Agreement and the transactions contemplated hereby (inclusive of the Protocol) and shall not issue any such press release or make any such public statement unless approved in writing by an authorized representative of Sponsor and

University. Notwithstanding the foregoing, University may publish general information about this project in its standard reports of sponsored program activity.

10.3 Work for Competitors. SCRF agrees that during the period in which University is actively performing the Protocol under this Agreement, the Study Director, Study Co-Director and any University personnel working under them for performance of this study will not perform a similar study to the one described in the Protocol, or use the same study Protocol, for PepsiCo, Cadbury Schweppes, Cott, Danone, Kraft, Nestlé, Unilever, or any entity, including any subsidiary thereof, the primary business of which is the marketing of food or beverage products, including, but not limited to soft drinks, coffee, tea, sports beverages, bottled water, and fruit or vegetable juice concentrates or beverages, except as Sponsor may, in its sole discretion, expressly authorize in writing. Study Director, Study Co-Director, and SCRF further agree not to make any public presentation regarding the results of this study on behalf of or at the request of any such entity without prior written approval of Sponsor.

10.4 Notices. All notices required or permitted hereunder will be in writing and delivered personally, sent by facsimile transmission, mailed by overnight courier, or sent by certified or registered mail to the following addresses:

if to SCRF, the notice shall be addressed to:

R. Steven Etheredge, Asst. Director
Sponsored Awards Management
901 Sumter St., Suite 501
Columbia, SC 29208
Telephone No.: 803-777-4457
Facsimile No.: 803-777-4136
E-mail: steven@mailbox.sc.edu

Notices relating exclusively to medical or scientific issues shall be sent to the Study Director and Study Co-Director, with a copy to SCRF at the address below if such notices regard a change in the Protocol.

if to Study Director and Study Co-Director, the notice shall be addressed to:

Dr. Steven Blair, Study Director
Arnold School of Public Health
The University of South Carolina
921 Assembly Street,
Columbia, SC 29208

Telephone No.: 803-777-0567
Facsimile No.: 803-777-2504
E-mail: sblair@mailbox.sc.edu

And

Dr. Greg Hand, Study Co-Director
Arnold School of Public Health
The University of South Carolina
800 Sumter Street,
Columbia, SC 29208

Telephone No.: 803-238-6960
Facsimile No.: 803-777-2504
E-mail: grehand@mailbox.sc.edu

If to Sponsor, the notice shall be addressed to:

Dr. Susan Roberts
Principal Scientist, SRA
The Coca-Cola Company
NAT 342C
One Coca-Cola Plaza N.W.
Atlanta, Georgia 30313
Telephone No.: 404-676-3586
Facsimile No.: 404-598-3586
E-mail: suroberts@na.ko.com

And

Dr. Karen Cunningham
Principal Scientist, SRA
Beverage Services Ltd
1 Queen Caroline Street
London, W6 9HQ
Great Britain
Telephone No.: +44-208-237-3327
Facsimile No.: 011-44-189-584-4870
E-mail: kacunningham@eur.ko.com

With a copy to:

John M. Packman
Senior Counsel
The Coca-Cola Company
NAT 2038
One Coca-Cola Plaza, N.W.
Atlanta, Georgia 30313
Telephone No.: 404-676-2663
Facsimile No.: 404-598-2663
E-mail: jopackman@na.ko.com

or to such other place as any Party may designate by written notice to the other Party.

10.5 Integration; Amendments. This Agreement constitutes the entire agreement of the Parties pertaining to the Protocol and supersedes all prior agreements and understandings, whether oral or written. In the event of any inconsistency between the body of the Agreement and the Exhibits, the terms of the body of the Agreement shall govern. No modification, amendment or waiver of this Agreement shall be binding unless executed in writing by the Parties. The waiver by Sponsor or SCRF of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

10.6 Force Majeure. Except as specifically provided to the contrary herein, the inability or failure of SCRF or Sponsor to perform any of their obligations pursuant to this Agreement will not be the basis of claims for damages sustained by SCRF or Sponsor or for breach of contract when due to causes or contingencies reasonably beyond the control of SCRF or Sponsor. If either SCRF or Sponsor suffers the event of force majeure, the suffering Party shall give notice of such event of force majeure in reasonably full particulars to the non-suffering Party as soon as reasonably possible.

10.7 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of South Carolina, USA, without giving effect to any choice or conflict of law provisions to the extent such provisions would apply the law of another jurisdiction.

10.8 Counterparts. This Agreement may be executed in counterparts (including without limitation execution via facsimile or e-mail transmission of signatures in the spaces indicated below), each of which shall be deemed an original, but all of which taken together shall constitute one single agreement between the parties. The person signing on behalf of each party represents that he or she is authorized to execute this Agreement on behalf of such party and has the authority to bind such party to the terms and conditions of this Agreement.

IN WITNESS WHEREOF SCRF and Sponsor have caused this Agreement to be duly executed on their behalf by their respective representatives as of the date below.

SOUTH CAROLINA RESEARCH FOUNDATION

By: _____
R. Steven Etheredge
Assistant Director
Sponsored Awards Management

Date: 11/4/10

THE COCA-COLA COMPANY

2010-10-28

By: _____
Rhona Applebaum, PhD
VP, Chief Scientific & Regulatory Officer

Date: 10/28/2010

STUDY DIRECTOR
Acknowledged as read and understood:

By: _____
Dr. Steven Blair

Date: 11/4/10

STUDY CO-DIRECTOR
Acknowledged as read and understood:

By: _____
Dr. Greg Hand

Date: 11/4/10

EXHIBIT A

PROTOCOL

Energy Balance Study Design and Protocol
Steven N. Blair, Study Director, and Gregory Hand, Study Co-Director
Department of Exercise Science, University of South Carolina

Background

It is indisputable that the world is experiencing an epidemic of obesity. Although the prevalence of obesity has been increasing for approximately 30 years, we have little evidence of the specific causes. It is clear that the general cause is too many people being in positive energy balance on too many days. However, no studies have properly measured energy intake and energy expenditure, and evaluated each as separate and independent causes of the obesity epidemic. Most of the attention given to the obesity epidemic focuses on the intake side of the equation rather than on the expenditure side. A report from the U.S. Institute of Medicine, "Bridging the Evidence Gap in Obesity Prevention," gives much more attention to energy intake than energy expenditure. A rough estimate from scanning the document is that diet/nutrition is mentioned three times more often than physical activity/fitness. This continued imbalance in attention from the highest levels of scientific thinking does not augur well for success. It is difficult, and in fact impossible, to develop strategies and tactics to stem or reverse this epidemic until we better understand the specific causes.

We propose to conduct a large-scale, comprehensive energy balance study. This study will measure energy balance more accurately than it has ever been measured in a large sample followed for at least one year, using a number of sophisticated measures of energy intake and energy expenditure. Data and findings from this study will lead to high-impact publications that will have a profound effect on how clinicians, public health officials, and lay people view the obesity epidemic, its causes, and what can be done to address it.

A group of expert advisors (Drs. Allison, Hill, Jakicic, Hamilton, Katzmarzyk, Church, and Blundell) has provided guidance in developing a proper energy balance study and will continue to provide expertise throughout the study. This group of scientists is among the best in the world in the fields of energy balance, obesity, physical activity, and nutrition. The expert advisors and key personnel in this study are among the most highly-cited individuals in the world on topics related to energy balance.

Specific Aims

Prefatory Aim 1. To examine the extent to which variation in total energy expenditure and variation in total energy intake contribute to changes in body weight and fat among young adults.

Primary Aim 1. To examine the extent to which changes in body weight and fat are driven by changes in energy expenditure, changes in energy intake, or both.
Secondary Aim 1. To examine the extent to which changes in body weight and fat during specific time intervals are driven by changes in energy expenditure, changes in energy intake, or both.
Secondary Aim 2. To examine the specific components/attributes of energy expenditure and energy intake that drive changes in body weight and fat.
Secondary Aim 3. To determine to what extent demographic characteristics modify the relationship between variance in the changes in energy expenditure and energy intake and variance in the changes in body weight and fat.
Tertiary Aim 1. To study the feasibility of examining the temporal sequence of changes in energy expenditure and changes in energy intake.

Hypotheses

1. Changes in body weight and fat will be positively associated with increases in total energy intake.
2. Changes in body weight and fat will be positively associated with decreases in total energy expenditure.

Testing these two hypotheses will allow us to determine the specific contributions of energy intake and energy expenditure to changes in body weight and fat.

Depending on the results, at the end of this study we will be able to make statements such as:
1. The proportion of body weight change that is explained by changes in total energy expenditure is X.
2. The proportion of body weight change that is explained by changes in total energy intake is X.
3. Decreases in occupational physical activity contributed to XX% of the decrease in total energy expenditure.
4. Decreases in light intensity physical activity contributed to XX% of the decrease in total energy expenditure.
5. The study of body weight change is complex and should always contain an evaluation of **both energy intake and energy expenditure**

Overview of Study Timeline

The study will take a total of 3 years. The first six months of the study will be dedicated to project start-up to obtain equipment, complete detailed planning, recruit and train staff, and begin initial recruitment of participants. The final six months of the study will be dedicated to cleaning data, running analyses, and preparing papers and reports for publication.

Table 1. Energy Balance Study Timeline

Activity	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	Oct-Dec 2010	Jan-Mar 2011	Apr-June 2011	July-Sept 2011	Oct-Dec 2011	Jan-Mar 2012	Apr-June 2012	July-Sept 2012	Oct-Dec 2012	Jan-Mar 2013	Apr-June 2013	July-Sept 2013
Start-Up	XXX											
Recruitment		X	XXX	XXX	XXX	XXX						
Baselines		XXX	XXX	XXX	XXX	XXX						
Follow-ups			XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX		
Data Clean, Analyses, Publications											XXX	XXX

* Note: each x refers to a month in the quarter

Recruitment

400 men and women between the ages of 21-35 years will be recruited to take part in the Energy Balance study. A variety of recruitment strategies will be used, including advertising to the general population (newspapers, radio, TV, flyers), in addition to more targeted approaches (listserves at worksites and universities, social media). Participation in the study will be open to all comers; however, the goal is to recruit 50% women and 50% men. Inclusion and exclusion criteria for enrollment into the study are listed in Table 2 below.

Table 2. Inclusion and Exclusion Criteria.

Inclusion Criteria	Exclusion Criteria
• BMI: 25-30 • 21-35 years of age • Fasting Plasma Glucose <126 mg/dl	• Currently on medications to lose weight • Planning to have weight loss surgery • Weight loss > 10 lbs in last 3 months
• Current medications must have been prescribed for three or more months and stable • Internet access (home or other; agreement by participant that they will comply with the extent of internet use required). We are experienced with using internet interventions and are aware that we must be certain that participants have regular internet access, and have the ability to use it as instructed. We will conduct training sessions during the run-in period in order to insure that this will not be a barrier for participants.	• History of depression, anxiety or panic with medications started within last 3 months (include if stable on medications) • Medical history with presence of significant conditions or disease that may interfere with study - e.g., cancer within past 5 yrs of diagnosis (except non-melanoma skin cancer), recent surgery • Pregnant or actively trying to become pregnant • Gave birth in last 12 months • <6 months post-lactation

	• >90th percentile on the Brief Symptom Inventory (BSI) • Planning to move from the area in the next 12 months • Other medical, psychiatric or behavioral factors that in the judgment of the principal investigator may interfere with study participation or the ability to follow the intervention protocol.

Study Design & Methods

This study will follow participants for 1 year, with repeated measures conducted across the study period. Recruitment will continue over a 1-year period of time so that baseline and follow-up measures are staggered across the calendar year.

Prior to the baseline visit, all interested and eligible participants will be scheduled to take part in a 3-week run-in period. During week 1, participants will be asked to complete the informed consent form and some questionnaires, have their height and weight assessed, and complete the DXA measure. During week 2, participants will be asked to complete the basal metabolic rate assessment (BMR) and some questionnaires, and have their blood drawn. During week 3, another DXA measure will be conducted, a sub-maximal fitness test will be administered, and doubly labeled water (DLW) will be started on a sub-sample. We also will instruct participants on internet use and evaluate their ability to adhere to these instructions. The run-in period will help screen out participants who are less likely to adhere to the study requirements.

Table 3. Run-in Timeline

Week 1	Week 2	Week 3
• Informed consent • Questionnaires • DXA #1	• BMR • Blood draw • Questionnaires	• Sub-maximal fitness test • Start DLW on sub-sample • DXA #2

Laboratory Measures

Participants will complete laboratory measures 5 times throughout the study. At each visit, body fat (DXA), height, weight, and waist circumference will be measured in all participants, in addition to a blood draw to measure lipids and glucose. Although blood draws will be done at all time points, analyses will be done only on baseline and post-test measures for this study, and samples from all time points will be frozen and stored. BMR and fitness will be measured on all participants at baseline. Doubly-labeled

water on the subsample will be measured at baseline and again at 12 months. See Table 4 for a summary of the measurement protocol.

A number of other demographic, health, and lifestyle-related factors will be measured in all participants at each time point. Prior to each scheduled laboratory visit, participants will receive a packet of questionnaires to be completed and returned at the laboratory visit.

Of the total budget, 90% will be used for recruitment, retention, and collecting the primary and secondary outcome measures. We are measuring many additional variables that directly affect the exposures (energy intake, energy expenditure), and therefore are crucial to explain our study findings. A number of other valuable questions, following our primary and secondary questions, can be examined/answered with our proposed study design and measures.

Energy Expenditure and Energy Intake Measures

Participants will wear the SenseWear Armband for 10 consecutive days at baseline and during each subsequent quarterly follow-up period (5 times x 10-days during entire study). During this same time, participants will complete 3 random 24-hour dietary recalls (5 times x 3 recalls during entire study). Participants also will weigh themselves daily using a WIFI/web-connected scale. To prevent the armband and daily weighing from becoming an 'intervention,' feedback from the armband and scale will not be available to participants (screened/blinded). See Table 4 for a summary of the measurement protocol.

Table 4. Measurement Timeline.

Baseline	Quarter 1	Quarter 2	Quarter 3	Quarter 4 (POST VISIT)
• Armband 10 days • 3 random 24-hr dietary recalls	• Armband 10 days • 3 random 24-hr dietary recalls	• Armband 10 days • 3 random 24-hr dietary recalls	• Armband 10 days • 3 random 24-hr dietary recalls	• Armband 10 days • 3 random 24-hr dietary recalls
• LAB VISIT & questionnaires • BMR • DLW on sub-sample	• LAB VISIT & questionnaires	• LAB VISIT & questionnaires	• LAB VISIT & questionnaires	• LAB VISIT & questionnaires • BMR • DLW on sub-sample

Retention

Upon enrollment into the study, participants will be asked to provide their contact information, as well as the names and contact information of two additional people (who do not live with them) that we could contact in the event we cannot get in touch with the participant. In addition, retention mailings (emails and/or postcards) will be sent one time a month. In the event that a participant moves, this will allow him/her to provide new contact information to study staff.

Incentives

In an effort to increase adherence and compliance, participants will receive an incentive upon completion of baseline and quarterly measures. A total of $500 will be given to each subject throughout the 1-year study period, with cash payments increasing as participants progress through the study (e.g. $50 after completion of the baseline measurement, $75 after the Q1 measurement, etc.).

Publication Plan

Upon completion of the study, a number of manuscripts will be prepared and submitted to top peer-reviewed journals for publication (e.g. Journal of the American Medical Association, New England Journal of Medicine). Study findings will also be presented at national meetings (e.g. American College of Sports Medicine, Experimental Biology, The Obesity Society, American Nutrition Society) and released to the press/media (e.g. New York Times, Washington Post, USA Today).

Examples of publication titles include:

1. What drives the increase in body weight/fat – energy intake or energy expenditure? Findings from a prospective energy balance study.
2. Changes in energy intake and energy expenditure: What components contribute to these changes?
3. Do demographic factors moderate the relationship between energy intake, energy expenditure and weight/fat gain?
4. Re-thinking the obesity epidemic: Implications for clinicians, public health officials, and policy makers.
5. The importance of energy balance design elements in future obesity research studies.

EXHIBIT B

BUDGET

Budget Summary

	Q4 2010	2011	2012	Q1-3 2013	Total
Total Direct Costs	$366,935	$850,062	$8881,849	$192,765	$2,291,611
USC Indirect Costs	$36,693	$85,006	$88,185	$19,277	$229,161
Total Costs	$403,628	$935,068	$970,033	$212,042	$2,520,772

Attached to this **Exhibit B** are budget details by calendar year.

BUDGET 4th QUARTER 2010												
PERSONNEL	ROLE	APPOIN	PERCENT	MONTHS	BASE SALARY	Q4 SAL REQ	FB	FB%	INS	INS COST	TOTAL FRING	TOTAL COST
Steven Blair	PI	12	10%	1.20	$250,480	$6,262	$1,390	22.19%	6360	$159	$1,549	$7,811
Gregory Hand	Co-PI	10.5	10%	1.05	$111,248	$2,781	$617	22.19%	6360	$159	$776	$3,557
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$10,000	$2,219	22.19%	6360	$1,590	$3,809	$13,809
James Hebert	Investigator	11	5%	0.55	$178,511	$2,232	$495	22.19%	6360	$80	$575	$2,806
James Hardin	Investigator	12	5%	0.60	$108,356	$1,355	$301	22.19%	7414	$93	$394	$1,748
Mei Sui	Investigator	12	10%	1.20	$69,960	$1,749	$388	22.19%	7414	$185	$573	$2,322
Tom Hurley	Investigator	12	10%	1.20	$72,000	$1,800	$399	22.19%	0	$0	$399	$2,199
TOTAL PERSONNEL COSTS:												$34,253
CONSULTANT COSTS:												
TOTAL CONSULTANT COSTS:												$0
EQUIPMENT:												
TOTAL EQUIPMENT COSTS:												$0
SUPPLIES:												
Electronic scales (400 @ $150)												$60,000
Armbands (300 @$200)												$60,000
Computers (5 @ $1500)												$7,500
Project-specific office/computer supplies												$2,500
Doubly labeled water												$110,000
TOTAL SUPPLIES COSTS:												$240,000
TRAVEL EXPENSES:												
Local travel for recruitment												$2,000
TOTAL TRAVEL EXPENSES:												$2,000
OTHER EXPENSES:												
Printing												$30,000
Recruitment costs												$5,000
TOTAL OTHER EXPENSES:												$35,000
TOTAL DIRECT COSTS FOR Q4 2010												$311,253
USC INDIRECT COSTS FOR Q4 2010												$43,575
TOTAL COSTS FOR Q4 2010												$354,828

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BUDGET 2011														
PERSONNEL	ROLE	APPO	PERCENT E	MONTHS	BASE SALA	SALARY ESCA	SAL. REQ	FB	FB%	INS	INS COST	TOTAL FRINGE	FRINGE ESCA	TOTAL COST
Steven Blair	PI	12	10%	1.20	$250,480	$257,994	$25,799	$5,725	22.19%	6360	$636	$6,361	$6,552	$32,351
Gregory Hand	Co-PI	10.5	15%	1.58	$111,248	$114,585	$17,188	$3,814	22.19%	6360	$954	$4,768	$4,911	$22,099
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$41,200	$41,200	$9,142	22.19%	6360	$6,360	$15,502	$15,967	$57,167
James Hebert	Investigator	11	5%	0.55	$178,611	$183,969	$9,199	$2,040	22.18%	7414	$571	$2,611	$2,689	$11,877
James Hardin	Investigator	12	5%	0.60	$106,356	$111,667	$5,583	$1,238	22.19%	7414	$571	$1,809	$1,857	$7,238
Mei Sui	Investigator	12	10%	1.20	$69,960	$72,059	$7,206	$1,599	22.19%	7414	$741	$2,340	$2,410	$9,616
Tom Hurley	Investigator	12	15%	1.80	$72,000	$74,160	$11,124	$2,468	22.19%	0	$0	$2,468	$2,542	$13,666
TBN, Project Manager	Project Manage	12	100%	12.00	$60,000	$61,800	$61,800	$13,713	22.19%	7414	$7,414	$21,127	$21,761	$83,561
TBN, Web Site Manage	Web Manager	12	20%	2.40	$45,000	$46,350	$9,270	$2,057	22.19%	7414	$1,483	$3,540	$3,646	$12,816
TBN, Laboratory Tech	Lab Tech	12	100%	12.00	$45,000	$46,350	$46,350	$10,285	22.19%	7414	$7,414	$17,699	$18,230	$64,580
TBN, Laboratory Tech	Lab Tech	12	100%	12.00	$30,000	$30,900	$30,900	$6,857	22.19%	7414	$7,414	$14,271	$14,699	$45,599
TBN, Statistician	Statistician	12	10%	1.20	$80,000	$82,400	$8,240	$1,828	22.19%	7414	$741	$2,569	$2,646	$10,885
TBN, Data Manager	Data Manager	12	50%	6.00	$50,000	$51,500	$25,750	$5,714	22.19%	7414	$3,707	$9,421	$9,704	$35,454
Recruitment/Retention	R/R Coordinator	12	100%	12.00	$50,000	$51,500	$51,500	$11,426	22.19%	7414	$7,414	$18,842	$19,407	$70,907
TBN, Graduate Researc	GA	12	100%	12.00	$18,000	$18,540	$18,540	$185	1.05%	0	$0	$195	$201	$18,741
TBN, Graduate Researc	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TBN, Graduate Researc	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TBN, Graduate Researc	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TOTAL PERSONNEL COSTS:														$524,567
CONSULTANT COSTS:														
Consultants (8 @ $5000)														$40,000
TOTAL CONSULTANT COSTS:														$40,000
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
Project-specific office/computer supplies														$2,500
TOTAL SUPPLIES COSTS:														$2,500
TRAVEL EXPENSES:														
Meeting with consultants														$5,000
Local travel for recruitment														$2,000
TOTAL TRAVEL EXPENSES:														$10,000
OTHER EXPENSES:														
*Lab costs (200 @ $45)														$9,000
Printing														$5,000
Recruitment costs														$20,000
GA tuition														$30,000

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Incentives (200 @ $500)													$100,000
Shipping of blood samples to PBRC													$5,000
24-hour dietary recalls (200 @ $750)													$150,000
DLW													$55,000
TOTAL OTHER EXPENSES:													$374,000
TOTAL DIRECT COSTS FOR 2011													$951,067
USC INDIRECT COSTS FOR 2011													$133,149
TOTAL COSTS FOR 2011													$1,084,217

BUDGET 2012														
PERSONNEL	ROLE	APPOINT	PERCENT	MONTHS	BASE SAL	SALARY E	SAL REQ	FB	FB%	INS	INS COST	TOTAL FRING	FRINGE eSCA	TOTAL COST
Steven Blair	PI	12	10%	1.20	$250,480	$285,734	$28,573	$5,897	22.19%	6360	$636	$6,533	$6,831	$33,504
Gregory Hand	Co-PI	10.5	10%	1.05	$111,248	$118,023	$11,802	$2,619	22.19%	6360	$636	$3,255	$3,453	$15,255
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$42,436	$42,436	$9,417	22.19%	6360	$6,360	$15,777	$16,738	$59,174
James Hebert	Investigator	11	5%	0.55	$178,511	$189,382	$9,469	$2,101	22.19%	7414	$371	$2,472	$2,623	$12,092
James Hardin	Investigator	12	5%	0.60	$108,356	$114,955	$5,748	$1,275	22.19%	7414	$371	$1,646	$1,746	$7,494
Mei Sui	Investigator	12	10%	1.20	$69,960	$74,221	$7,422	$1,647	22.19%	7414	$741	$2,388	$2,533	$9,955
Tom Hurley	Investigator	12	10%	1.20	$72,000	$76,385	$7,638	$1,695	22.19%	7414	$741	$2,436	$2,584	$10,222
TBN, Project Manager	Project Manag	12	100%	12.00	$60,000	$63,654	$63,654	$14,125	22.19%	7414	$7,414	$21,539	$22,851	$86,505
TBN, Web Site Manag	Web Manager	12	15%	1.80	$45,000	$47,741	$7,161	$1,589	22.19%	7414	$1,112	$2,701	$2,865	$10,026
TBN, Laboratory Tech	Lab Tech	12	100%	12.00	$45,000	$47,741	$47,741	$10,594	22.19%	7414	$7,414	$18,008	$19,105	$66,846
TBN, Laboratory Tech	Lab Tech	12	50%	6.00	$30,000	$31,827	$15,914	$3,531	22.19%	7414	$3,707	$7,238	$7,679	$23,593
TBN, Laboratory Tech	Lab Tech	12	50%	6.00	$30,000	$31,827	$15,914	$3,531	22.19%	7414	$3,707	$7,238	$7,679	$23,593
TBN, Statistician	Statistician	12	25%	3.00	$80,000	$84,872	$21,218	$4,708	22.19%	7414	$1,854	$6,562	$6,962	$28,180
TBN, Data Manager	Data Manager	12	50%	6.00	$50,000	$53,045	$26,523	$5,885	22.19%	7414	$3,707	$9,592	$10,176	$36,899
Recruitment/Retention	R/R Coordinato	12	40%	4.80	$50,000	$53,045	$21,218	$4,708	22.19%	7414	$2,966	$7,674	$8,141	$29,359
TBN, Graduate Reseal	GA	12	100%	12.00	$18,000	$19,096	$19,096	$201	1.05%		$0	$201	$213	$19,309
TBN, Graduate Reseal	GA	12	100%	12.00	$18,000	$19,096	$19,096	$201	1.05%		$0	$201	$213	$19,309
TBN, Graduate Reseal	GA	12	50%	6.00	$18,000	$19,096	$9,548	$100	1.05%		$0	$100	$106	$9,654
TBN, Graduate Reseal	GA	12	50%	6.00	$18,000	$19,096	$9,548	$100	1.05%		$0	$100	$106	$9,654
TOTAL PERSONNEL COSTS:														$510,424
CONSULTANT COSTS:														
Consultants (8 @ $5000)														$40,000
TOTAL CONSULTANT COSTS:														$40,000
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
Project-specific office/computer supplies														2000
TOTAL SUPPLIES COSTS:														$2,000
TRAVEL EXPENSES:														
Meeting with consultants														$8,000
Local travel for recruitment														$2,000
TOTAL TRAVEL EXPENSES:														$10,000
OTHER EXPENSES:														
*Lab costs (200 @ $45)														$9,000
Printing														$5,000

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Recruitment costs	
GA tuition	$10,000
Incentives (200 @ $500)	$48,000
24-hour dietary recalls (200 @ $750)	$100,000
DLW	$150,000
TOTAL OTHER EXPENSES:	$55,000
	$377,000
TOTAL DIRECT COSTS FOR 2012	
	$939,424
USC INDIRECT COSTS FOR 2012	$131,519
TOTAL COSTS FOR 2012	$1,070,943

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BUDGET 1st - 3rd QUARTERS 2013														
PERSONNEL	ROLE	APPOIN	PERCENT	MONTHS	BASE SAL	SALARY E	SAL REQ	FB	FB%	INS	INS COST	TOTAL FRI	FRINGE ES	TOTAL COST
Steven Blair	PI	12	10%	1.20	$250,480	$273,706	$20,528	$4,555	22.19%	6360	$477	$5,032	$5,499	$26,027
Gregory Hand	Co-PI	10.5	10%	1.05	$111,248	$121,564	$9,117	$2,023	22.19%	6360	$477	$2,500	$2,732	$11,849
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$43,709	$32,782	$7,274	22.19%	6360	$4,770	$12,044	$13,161	$45,943
James Hebert	Investigator	11	15%	1.65	$175,511	$195,084	$21,945	$4,870	22.19%	7414	$834	$5,704	$6,233	$28,178
James Hardin	Investigator	12	10%	1.20	$108,356	$118,404	$8,880	$1,971	22.19%	7414	$556	$2,527	$2,761	$11,641
Mei Sui	Investigator	12	20%	2.40	$89,960	$76,447	$11,467	$2,545	22.19%	7414	$1,112	$3,657	$3,995	$15,463
Tom Hurley	Investigator	12	20%	2.40	$72,000	$78,676	$11,801	$2,619	22.19%	0	$0	$2,619	$2,862	$14,663
TOTAL PERSONNEL COSTS:														$153,764
CONSULTANT COSTS:														
Consultants (8 @ $5000)														$40,000
TOTAL CONSULTANT COSTS:														$40,000
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
TOTAL SUPPLIES COSTS:														$0
TRAVEL EXPENSES:														
Consultant travel to meeting														$8,000
TOTAL TRAVEL EXPENSES:														$8,000
OTHER EXPENSES:														
TOTAL OTHER EXPENSES:														$0
TOTAL DIRECT COSTS FOR Q1-3 2013														$201,764
USC INDIRECT COSTS FOR Q1-3 2013														$28,247
TOTAL COSTS FOR Q1-3 2013														$230,011

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Budget Justification
Energy Balance Study

Introduction

It is indisputable that the world is experiencing an epidemic of obesity. Although the prevalence of obesity has been increasing for approximately 30 years, we have little evidence of the specific cause. A proper energy balance study with appropriate measures of both energy intake and energy expenditure has never been done before. We are proposing to conduct a large-scale, comprehensive energy balance study. This study will measure energy balance more accurately than it has ever been measured in a large sample over one year, using a number of sophisticated measures of energy intake and energy expenditure.

The total budget for this project is $2.5 million over a three-year period. This budget allows for the detailed and extensive measurements described in the project outline and allows for a sample size of 400 participants. We are confident that a sample size of 400 will be adequate to detect changes in weight and fat mass in the current study. Assuming a weight gain of 2 pounds over the 1-year study period, power calculations indicate that 300 participants will be needed in order to detect a small change in weight (ES=0.2), so 400 participants will provide greater power and allow for drop-outs. Preliminary data from 52 individuals are available from the INSIGHT study (Dr. Katzmarzyk), which targeted adults ages 20-35 years with a BMI range of 19-27 at baseline. The investigators found a mean weight gain of 1.85 pounds (range -15.4 to +21.1 pounds) over a 1-year study period. Our population will have higher baseline BMI and will likely gain more weight than participants in the INSIGHT study, so we are confident that we will have adequate power to test our primary hypotheses. By obtaining doubly-labeled water (DLW) measurements on 100 participants at the beginning and end of their one-year study period, we will obtain data that will be useful in addressing additional important questions, such as validation of energy balance determined by 24-hour recalls and armband data.

Personnel

The extensive set of measures and multiple follow-up measurement periods throughout the study will require significant time and effort by study personnel. A large study staff will be needed during 2011 and 2012, when most of the data will be collected, to conduct laboratory measures and collect energy intake (24-hour recalls) and energy expenditure (armbands, DLW, basal metabolic rate) data, and considerable effort will be required to maintain contact and insure good adherence to the study protocol.

The investigators will provide expertise in key aspects of this study. Dr. Steven Blair has expertise in conducting large-scale prospective studies and randomized trials, and extensive background in physical activity/fitness research in areas related to overweight and obesity. Dr. Blair has used the armband to measure energy expenditure in previous

studies. Dr. Greg Hand has expertise in all laboratory measures being conducted in this study, which include body fat measurement (DXA), physiological assessments (i.e. blood draws for lipid and glucose analysis), waist circumference, basal metabolic rate, and DLW. Dr. James Hebert has expertise in dietary intake assessment and has used the 24-hour recall in a number of his studies. Dr. Meghan Baruth has expertise in program/study evaluation. She will be responsible for protocol development and will oversee the daily tasks of program initiation and implementation. Dr. Tom Hurley will oversee conducting the 24-hour recalls at the USC Cancer Prevention and Control Center. He has supervised work in this area for over 125,000 dietary recalls in various studies funded by the National Cancer Institute. He also has expertise in analyzing the dietary data. Dr. James Hardin has statistical expertise in longitudinal data analysis. Dr. Mei Sui has expertise in data management and coordination, in addition to data analysis. Each investigator will provide guidance in his/her area of expertise during program development and throughout the study period. This set of investigators is among the leaders in the field of energy balance and dietary and physical activity assessment.

A number of individuals, including the Project Coordinator, Web Manager, Recruitment/Retention Specialist, Data Manager, Statistician, Lab Technicians, and Graduate Research Assistants will be hired to conduct the daily operations of the project.

The Project Coordinator will manage the day-to-day aspects of this study and will coordinate laboratory visits and energy intake and expenditure assessments. The Project Coordinator will also be available to participants to answer questions about the scales, armbands, and other measures (e.g. surveys). He/she will meet regularly with the investigators and will supervise the work of the other project staff members.

The Web Manager will develop and maintain the study Web site, oversee and troubleshoot the Web-based data collection (electronic scales and armbands), work with the Data Manager to ensure the accuracy and integrity of the Web-based data collection, and assist participants who have questions about or difficulty with the scales or armbands.

The Data Manager, working with Drs. Sui, Hardin, and Hurley, will be responsible for cleaning, storing, and ensuring the security of the data. Study data will be collected from several measures: survey data, dietary recall data (USC Nutrition Center), and laboratory measures (USC laboratory). The Data Manager will coordinate the data from all of these sources and develop datasets that are clean and properly formatted.

The Statistician will work with Drs. Sui, Hardin, and Hurley and the Data Manager to conduct statistical analyses of the data, assist with design adjustments as needed, develop and implement new and complex analyses as warranted by the data and emerging questions, and help to maintain data quality control.

Recruiting a large number of participants and retaining those participants for the entire one-year study period will be crucial for the success of this project. The Recruitment/Retention Specialist will be responsible for recruiting participants into the

study and for executing the retention plan to ensure participants return for follow-up visits.

The Laboratory Technicians will be responsible for collecting all laboratory measures (DXA, blood draws, DLW, fitness, basal metabolic rate, etc). The large sample size and multiple study visits will require multiple technicians to be available.

The Graduate Research Assistants will assist the Project Coordinator, Recruitment/Retention Specialist, and Laboratory Technicians with a wide variety of research and administrative tasks.

Consultants

A group of world-renowned experts (Drs. Allison, Hill, Jakicic, Hamilton, Katzmarzyk, Church, and Blundell) in the area of energy balance will serve as consultants and advisors to this project. These scientists have provided guidance in the development of the study protocol and will continue to provide their expertise throughout the study. The consultants will meet with study personnel annually, in person or by teleconference, to provide guidance and expertise, problem solve, and help disseminate study findings. Additional discussions with the advisors will be conducted at least quarterly by teleconference and email.

Equipment

A laboratory freezer will be purchased in Year 1 to store blood samples for future analyses.

Supplies

Previous energy balance studies have relied on self-report measures to assess energy intake and energy expenditure, and many of these approaches are not accurate or precise enough to get a valid assessment of energy balance. A major purpose of this study is to obtain the most accurate and precise measures of body fat, energy intake, and energy expenditure. Therefore, it is important that the best measures available are used in this study.

Electronic scales that can directly upload weight to an internet site will be given to all participants to measure daily weight.

All participants will wear SenseWear Armbands, which automatically monitor energy expenditure and physical activity, for 10 days on a quarterly basis to measure energy expenditure. The armbands have been shown in a number of validation studies to provide an accurate assessment of energy expenditure.

Computers will be used for data entry, data management, and participant retention activities.

Project-specific office and computer supplies will include shirts that staff will wear during recruitment and data collection activities, data storage supplies, and other project supplies.

Doubly-labeled water (DLW) will be purchased for use in a sub-sample of 100 participants to assess total energy expenditure. Total energy expenditure can be derived from DLW assessments and is considered the gold standard for assessing total energy expenditure in free living conditions.

Laboratory supplies, including glassware and disposables, will be purchased in Year 1.

Travel

Funds for one in-person meeting of the consultants and several teleconference meetings are included. Recruitment efforts will also require some local travel (e.g. delivering flyers, presentations, attending events where a booth can be set up, etc). In addition, travel funds for the PI and investigators to present the study results at scientific meetings are included.

Other Costs

Laboratory costs include the cost to draw, process and store blood, to conduct fitness assessments, and to test basal metabolic rate. The Clinical Exercise Research Laboratory at USC has a DXA machine, and there will be no equipment costs to obtain DXA data. Technicians to perform these tests are included in the budget.

Printing costs will include recruitment materials (flyers, brochures), project letterhead and envelopes, and signage.

Recruitment costs will include advertising on radio, in newspapers, and through Web-based and social media.

Graduate assistant tuition is required by the University when graduate students are included in a research study.

Incentives – As previously mentioned, retaining participants will be very important in this study. In order to encourage ongoing participation in the study, participants will receive a cash incentive after each laboratory and/or energy expenditure and intake assessment period.. Incentives will increase as the study progresses. Participants completing the study will receive a total of $500.

Random 24-hour dietary recalls are the gold standard for assessing dietary intake. Three, random 24-hour dietary recalls will be conducted on all participants at baseline and on a quarterly basis (3 recalls x 5 measurement periods = 15 total recalls) by the Diet Assessment Research Unit of the University of South Carolina Cancer Prevention and

Control Center. Three assessments per quarter will provide an accurate assessment of each participant's dietary habits. The Center will collect the data, process it, and analyze it. The Center has provided 24-hour dietary recall services for a number of large scale nutrition studies.

EXHIBIT C
PAYMENT SCHEDULE

Payment Schedule

Sponsor will pay University based on completion of the following milestones:

- **2010 Payment:**

  Total payment of $403,628:
  Total 2010 amount of $403,628 paid upon execution of this agreement

- **2011 Payments:**

  Total payment of $935,068:
  ½ the total 2011 amount of $467,534 paid upon completion of the start-up (scheduled for early January 2011)
  ½ the total 2011 amount of $467,534 paid on delivery of status report by University to Sponsor at the end of July 2011

- **2012 Payments:**

  Total payment of $970,033:
  ½ the total 2012 amount of $485,016.50 paid upon completion of recruitment (scheduled for March 2012)
  ½ the total 2012 amount of $485,016.50 paid on delivery of status report by University to Sponsor at the end of the 3rd Quarter of 2012

- **2013 Payments:**

  Total payment of $212,042:
  ½ the total 2013 amount of $106,021 on delivery of results and analyses
  ½ total 2013 amount of $106,021 on delivery of one or more manuscripts suitable for publication.

EXHIBIT D

Attached to this **Exhibit D** are the Eight Guiding Principles enumerated at page 4 of *"Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity"*.

AJCN. First published ahead of print April 8, 2009 as doi: 10.3945/ajcn.2009.27604.

Special Article

Funding food science and nutrition research: financial conflicts and scientific integrity[1–4]

Sylvia Rowe, Nick Alexander, Fergus M Clydesdale, Rhona S Applebaum, Stephanie Atkinson, Richard M Black, Johanna T Dwyer, Eric Hentges, Nancy A Higley, Michael Lefevre, Joanne R Lupton, Sanford A Miller, Doris L Tancredi, Connie M Weaver, Catherine E Woteki, and Elaine Wedral for the International Life Sciences Institute North America Working Group on Guiding Principles

ABSTRACT

There has been significant public debate about the susceptibility of research to biases of various kinds. The dialogue has extended to the peer-reviewed literature, scientific conferences, the mass media, government advisory bodies, and beyond. Whereas biases can come from myriad sources, the overwhelming focus of the discussion to date has been on industry-funded science. Given the critical role that industry has played and will continue to play in the research process, the International Life Sciences Institute (ILSI) North America Working Group on Guiding Principles has, in this article, proposed conflict-of-interest guidelines regarding industry funding to protect the integrity and credibility of the scientific record, particularly with respect to health, nutrition, and food-safety science. Eight principles are enumerated, which specify the ground rules for industry-sponsored research. This article, which issues a challenge to the broader scientific community to address all bias issues, is only a first step; the document is intended to be dynamic, prompting ongoing discussion and refinement. In the conduct of public/private research relationships, all relevant parties shall *1*) conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome; *2*) require control of both study design and research itself to remain with scientific investigators; *3*) not offer or accept remuneration geared to the outcome of a research project; *4*) ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame; *5*) require, in publications and conference presentations, full signed disclosure of all financial interests; *6*) not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations; *7*) guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers; *8*) require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO. *Am J Clin Nutr* 2009;89:1–7.

INTRODUCTION

It has been said that "scientific 'truth' is the primary aim that all should pursue in the jungle of academic-industry interactions" (1). The point of scientific endeavor, in the first place, is and should be, the pursuit of truth—nothing more, nothing less—irrespective of financial or other interactions. It goes without saying that seekers of truth must not impose preconceptions on the method or result of their search: they must not have ulterior motives. Throughout modern history, scientists have been guided by rules that ensure the integrity of the pursuit of truth, rules that continue to evolve as the research and communication landscapes change. The purpose of this article is to articulate, in the sophisticated, industrialized, modern world in which we find ourselves, principles defining and protecting the integrity and maintaining the credibility of the scientific record, particularly that part of it devoted to health, nutrition, and food-safety science.

The agricultural, food, and nutrition sciences have come to be a crucial part of evolving health research, which, in turn, plays an ever-growing role in improving the human condition. Although regarded as important determinants of human health, agricultural practices, food processing and safety, and nutritional status do not

[1] From SR Strategy LLC, Washington, DC (SR and NA); the University of Massachusetts at Amherst, Food Science Policy Alliance, Amherst, MA (FMC); the Coca-Cola Company, Global Scientific and Regulatory Affairs, Atlanta, GA (RSA); McMaster University, Department of Pediatrics, Hamilton, Canada (SA); Kraft Foods Global Inc, Glenview, IL (RMB); the Frances Stern Nutrition Center, New England Medical Center, Boston, MA (JTD); ILSI North America, Washington, DC (EH and EW); PepsiCo Inc, Scientific & Regulatory Affairs, Valhalla, NY (NAH); Utah State University, Center for Advanced Nutrition, Logan, UT (ML); Texas A&M University, College of Agriculture and Life Sciences, Department of Nutrition and Food Science, College Station, TX (JRL); the University of Maryland Center for Food, Nutrition and Agriculture Policy, College Park, MD (SAM); Cadbury Adams USA LLC, Science & Technology, Whippany, NJ (DLT); Purdue University, Department of Foods & Nutrition, West Lafayette, IN (CMW); and Mars Inc, McLean, VA (CEW).

[2] Originally published in: Nutrition Reviews® 2009;Vol. 66(5). DOI: 10.1111/j.1753-4887.2009.00188.x.

[3] Supported in part by educational grants from Cadbury Adams USA LLC, the Coca-Cola Company, ConAgra Foods Inc, General Mills, Kraft Foods, Mars Snackfoods US LLC, PepsiCo Inc, Procter & Gamble, Sara Lee, and Tate & Lyle.

[4] Address reprint requests and correspondence to E Hentges, ILSI North America, 1156 15th Street, NW, Suite 200 Washington, DC 20005-1743. E-mail: ehentges@ilsi.org.

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receive the same attention and funding from the federal research agencies as biomedical research does. Federal funds allotted to agricultural, food, and nutrition research amount to ≈$1.8 billion annually (out of a total US Department of Agriculture research budget of $2.3 billion), with most of this focusing on agricultural production; in contrast, $28.6 billion is appropriated to the National Institutes of Health (2). Industry-funded research projects, large and small, account for a large proportion of all food science and nutrition research (3–5), both for obvious and nonobvious reasons.[†] United States' law places the responsibility for product safety and for the truthfulness of label claims on the manufacturer. Clearly, it is in the food industry's interest to conduct the research necessary to meet the legal requirements as well as to improve food-product healthfulness, safety, accessibility, taste, cost, attractiveness, etc. Most of this research falls outside the mission of traditional federal funding agencies and would not be done without food industry support. Pursuant to an extensive web of laws and regulatory requirements concerning food and food ingredients that have evolved over the past century, industry scientists and academic researchers who work with industry strive to enhance food quality, studying everything from the safety of ingredients to the evidence in support of health claims that appear on food packaging.

The rationale for food industry funding of research may be less obvious in areas such as microbiology (6),[‡] toxicology (7–9),[§] nutrient bioavailability (10, 11), and fortification (12)—all of which lead to enhancement of human health and to research on animal breeding and agricultural efficiency, which helps to feed more people. Some such research will be conducted by industry, in-house, whereas other projects will be contracted out to academic institutions or government or contract research laboratories. Scientists, especially novice researchers, conducting investigations in any of these settings need principles on which to rely while conducting their research ethically and with integrity. Clearly, it is essential to preserve the integrity and credibility of food and nutrition science for the benefit of public health and understanding.

In recent years, a growing body of literature has evolved on the subject of conflicts of interest and their potential influence on the integrity of researchers and the scientific record. In these discussions, conflicts are typically treated as disqualifying factors in scientific papers and research; that is, scientists with conflicts of interest are viewed in the literature as being at least partially integrity-compromised, and, even with complete and open disclosure, are regarded, at least to some extent, as of suspect scientific credibility. It is hoped that this article will define and clarify the highly complex issues involved in questions of conflict and scientific bias, particularly with regard to the portion of research funding that originates from the food industry.

In the interest of beginning this crucial dialogue in a sharply defined and dispassionate manner, the focus of this article will be limited to only one very specific issue and its relation to bias: financial conflicts of interest, specifically funding-based conflicts. It must be pointed out that there is a potential for all funding, regardless of source (eg, public, private, government, or industry), to bias behavior, unconsciously or otherwise. The focus of the current article will be on the management of potential bias from industry funding of science. Our goal is to separate monetary considerations from the science—including research design, execution, reporting, publishing, and other factors.

HISTORICAL CONTEXT

From its beginning, the food industry has concerned itself with researching food products and ingredients from the perspective of safe and efficient delivery of food to a rapidly expanding population. Before World War II, the overwhelming bulk of food research was funded and carried out by food-industry scientists; there has been little public funding of food safety and nutrition research. It was the evolution of American society from the laissez faire environment that existed during the industrial revolution to the complex public/private sector mixed economy of the more recent past that transformed research funding and higher education in general.

Although the food industry first entered the era of managing financial conflicts in the late 18th century, with the development of proprietary technologies to enhance food preservation and safety, the post-World War II period saw an exponential increase in the administrative challenges of research funding. For example, the number of patents awarded to universities or academic researchers increased by a factor of 10 in the past 2 decades of the last century (13). Similarly, federal funding of research increased from $405 million to $1.7 billion in a single decade (1960–1970) after the launch of the space race between the United States and the Soviet Union (14).

In the decades after World War II, in addition to the significant increases in government funding of university research, the United States experienced, in general, rapid evolution of science and technology, transformation and consolidation of agricultural production, and the steady growth of industry, especially those companies involved in public health, eg, medical/pharmaceutical, chemical, and food industries. In late 1980, the US Congress passed the Bayh-Dole Act, with the specific intention of stimulating the transfer of technology from government-funded university research to the private sector (15). This legislation has not been without controversy—both over issues concerning the diversion of university faculty from basic research and conflict of interest concerns due to the resulting university-industry partnerships.

The research community and individuals involved in health communications and public policy advocacy became increasingly concerned about the possibility that exogenous interests might influence published results of scientific research (16, 17).[‖] By late 2000, this concern had become heightened around medical/pharmaceutical practice: a number of articles appeared in the major medical journals (18, 19) that explored the financial relations of the pharmaceutical industry and physicians and their possible effect on physicians' decisions about patient treatment, researchers' decisions concerning study design, companies' interference in publication, and public health policy in general. Medical and other scientific journals began establishing rules for disclosure of financial conflicts in an attempt to manage them.

In succeeding years, concern broadened to include other industries, more recently the food industry, with authorities questioning how financial conflicts might impinge on the outcomes of health, nutrition, and food-safety research. It was generally acknowledged that the issue was complex and not susceptible to narrow or inflexible remedies, but that has not deterred some groups from concluding that industry-funded science is inherently biased (20, 21). These groups demanded that all industry-funded research, whether conducted at contract research facilities or at universities, be denied consideration in

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the formulation of public policy and that scientists who have conducted industry-funded research be barred from serving on public policy advisory committees (22). It is this article's contention that such efforts are helpful neither to the public nor to the scientific community. Industry funding, although a major component of the scientific landscape, is only one piece of an extremely complex research environment. The twin issues of financial conflict and bias demand a more reasoned approach and skillful management.

DEFINING THE ISSUE

First, conflicts of interest are not inherently determinants of bias. Even a massive multiplicity of conflicts, in and of itself, carries with it no certainty of bias. Although many definitions exist for *conflict of interest* and *bias*, the simplest of definitions suffice.

Conflict of interest

"A conflict of interest is 'a conflict between the private interests and the official responsibilities of a person in a position of trust.' A conflict of interest thus arises when a person has to play one set of interests against another" (23).

Bias

Per the online Oxford English Dictionary, bias is an "inclination or prejudice in favour of a particular person, thing, or viewpoint" (24). "A cognitive bias is something that our minds commonly do to distort our own view of reality" (25).

Or, more rigorously, bias is a deviation of either inferences or results from the truth, or any process leading to that kind of systematic deviation. This includes tendencies by which data are reviewed or analyzed or interpreted or published in a way that yields conclusions that deviate systematically from the truth (26, 27).[¶]

For example, for researchers, a conflict might describe a situation in which a funder has offered financial incentives for research and hopes for a particular research result; it might also describe a situation in which the researcher, for philosophical, religious, or professional reasons, wishes to achieve a certain result. Neither situation necessarily results in a biased result, which would depend on a measurable deviation of research results from "the truth," although much of the literature regrettably confounds bias and conflict. For that matter, much of the literature confuses conflict with a particular kind of conflict—financial. Unfortunately, even if all conflicts were banished forever, there would still be myriad sources of bias.

For example, the following well-known forms of scientific and publication bias exist (28):[#] sample-selection bias, sample-size bias, data-collection bias, data-quality bias, statistical-analysis bias (29), confounding-variable bias, and publication bias (30). These are just a few of the more commonly encountered pitfalls leading to skewed research conclusions, but these scientific sources of bias may be easier to identify than other cognitive and emotional causes that have nothing to do with the formal research process. Consider the following possible sources of bias: one's previous body of work; one's desire for fame and respect among peers (or, alternatively, the desire to achieve iconoclastic stature); religious bias; ethical or values-based bias; philosophical bias; political bias; one's nationality or ethnicity; pressure to publish (31);[**] pressure to win prizes; fear of losing one's job or position; highly personal matters, such as one's physical or mental health issues or one's family's health; the pernicious effect of pack behavior or "group think" facilitated by social or professional networks, either in the physical world or in cyberspace (blogs, websites, chat rooms, list serves, and other communication tools of the Internet); financial or funding bias resulting from all kinds of financial incentives, including gratuities, bribes, grants, free trips, gifts, and cash prizes; and the desire to please one's source of funding, either unconsciously or deliberately.

The multiplicity and variety of sources of bias in research and in public health communications generally are extensive, complex, and yet of major importance to scientific research, the integrity of individual study, and the body of scientific literature as a whole. Strategies must be developed to address and manage all sources of bias, whether technical, statistical, cognitive, or emotional in origin. These are critically necessary, not just for the scientific community, but also for the well-being of the public. The interpretation of health research and the promotion of public policies resting on that research are far too important to be based on formulas that would address conflicts at the price of excluding the input of a large proportion of food-safety and nutrition scientists.

EXISTING CHECKS ON BIAS

As far as scientific research and communications are concerned, several checks exist to ensure adherence to good practice and to avoid biased conclusions. Of course, replication and coherence of scientific findings are the major mechanism by which bias in research is controlled. This section is intended to summarize postresearch control mechanisms. First and foremost is the system of scientific peer review that is built not only into publication in scientific journals, but also into the promotion and tenure decisions for individual faculty conducting research at colleges and universities. Governance and review processes of academe exercise oversight, particularly on industry-funded research projects. Charges of irregularities, errors, and outright scientific fraud are usually investigated by the academic institutions where the research is conducted. However, in one recent noteworthy case, a distinguished nutrition researcher resigned his university position 9 y after initial charges of fraud were filed in connection with his infant-formula study. In the university's subsequent report, the authors recommended that the government monitor scientific misconduct through a new national agency "charged with all aspects of science, *irrespective of funding sources, public or industry* [emphasis added]" (32).

Most importantly, peer pressure serves as a check on bias, ie, the peer pressure of meetings, conferences, e-mail listservs, and discussion boards run by scientific colleagues and, especially, the process of peer review, particularly relied on by the thousands of scientific journals around the world and other organizations (33).[††] For more than a century, peer review has served to provide a rigorous framework by which research papers and articles can be evaluated before their general dissemination—although not foolproof, scientists regard the process as a reliable safeguard against errors, biases, and scientific misconduct. However, in recent months, a robust debate has been generated about peer

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review and whether it needs to be refined (34, 35). Donald Kennedy, the former Editor-in-Chief of Science for the Journal of the American Association for the Advancement of Science (AAAS), has offered an eloquent defense of the current peer review process as "a fair system of evaluating and publishing scientific work—one that offers high confidence in, though not an absolute guarantee of, the quality of the product" (36).

If all of these checks fail, a governmental oversight structure exists within the granting agencies. For example, the Office of Research Integrity in the Department of Health and Human Services sets policies for government research grants, establishes reporting standards, and investigates misconduct (37). National and local volunteer health organizations review health science as it unfolds. Finally, the following checks on bias exist: science writers and journalists, who attend scientific conferences, digest new studies, and communicate them to the public; science associations, such as the National Science Foundation and the National Academies of Science, which regularly review new research and publish articles that are, in turn, read and commented on by member scientists; Congressional hearings reveal and publicize the real or perceived biases arising from too-close relations between industry and academia; and, ultimately, public disgrace occurs when research is revealed as deeply flawed.

In any case, given the increasingly broad and complex nature of scientific research and communications, additional recommendations are appropriate for managing the extremely complex issues of financial conflicts and potential bias.

PROPOSED GUIDELINES ON INDUSTRY FUNDING OF RESEARCH

Although funding, whether through the private or public sector, does not automatically introduce bias into scientific research, it is nonetheless prudent to address both the possibility of bias and the perception of it through explicit guidelines. On the basis of work commissioned by the ILSI North America Working Group on Guiding Principles, a series of proposals was developed to manage potential biases resulting from conflicts of interest between research investigators and companies wishing to fund their work.

It is our view that disclosure is an essential, but no longer a sufficient, measure to safeguard research from undue influence exerted by funding organizations. Managing conflicts, case by case, is the requisite step, ie, procedures need to be established, such as the following guidelines, to ensure research integrity. This should apply across the array of mechanisms through which research is funded currently: in intramural industry and government laboratories; in sponsored grants and contracts; and in cooperative agreements, Cooperative Research and Development Agreements (CRADAs), and "platforms" funded jointly by governments and industry, as is the case in the European Union and Australia. Whereas there may be a multitude of mechanisms by which research is funded, designed, conducted, and communicated, these guidelines should be adhered to by all parties, in all respects, in the spirit of openness and honesty that are the aim of this article (*see* the footnote to guideline 2 below).

It is also our view that industry participation in the effort to disclose and manage financial conflicts of interest is crucial. Future university-level science students will find their way into either private-sector research occupations or public-sector careers. All need a set of principles to guide their interaction with funding organizations, whether public or private, just as those organizations need principles to guide them in their interactions with academic scientists. Consequently, we propose the following guidelines to serve as a checklist to achieving unbiased research results from industry-funded activities—just as they might be useful guidance in public- or foundation-funded projects (38).[‡‡]

GUIDING PRINCIPLES

In the conduct of public/private research relations, all relevant parties shall:

1) Conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2) Require control of both study design and research itself to remain with scientific investigators;[§§]
3) Not offer or accept remuneration geared to the outcome of a research project;
4) Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;[¶¶]
5) Require, in publications and conference presentations, full signed disclosure of all financial interests;
6) Not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7) Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers;[##]
8) Require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

IMPORT AND IMPLICATIONS OF THE GUIDELINES

Obviously, guidelines are just . . . guidelines. They are not law, but if the research community embraces them, or even embraces their spirit, we believe there will be a profoundly beneficial effect on the quality and integrity of research that will encourage responsible oversight and stewardship of scientific research by all funding organizations. Following the guidelines will undoubtedly lead to closer and more open communication between funding bodies and researchers, resulting in a new spirit of collaboration. Still, it must be stressed that each organization wishing to adopt these guidelines needs to develop its own quality-control mechanism to ensure good compliance.

A strong peer-review system coupled with open declarations of research sponsorship in all scientific communications is a mandatory prerequisite for these guidelines to be effective. The second prerequisite is that university and industry policies be promulgated to address the issues raised in these guidelines regarding control of the design and conduct of the research and its publication. It is the responsibility of both the funding entity and the researchers being funded to adhere to the guidelines; existing oversight structures are also encouraged to endorse and adhere to them. Furthermore, it should be understood that failure to embrace the guidelines will raise serious questions about any research project so conducted.

It has been suggested that, in the past, industry-funded research may have had a bias toward results favored by the food industry (21,

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43). The authors of one publicized study (4) who reached this conclusion proposed several explanations: *1*) food industry companies may wish to demonstrate the superiority of their products to those of their competitors, *2*) investigators are influenced by their funding when formulating their research design and/or hypotheses, *3*) industry sponsors of research may suppress unfavorable results, *4*) authors of scientific reviews may deliberately bias their searches and interpretations to the benefit of their industry funders, and *5*) scientific reviews may disproportionately represent studies "arising from industry-supported scientific symposia." Such criticism overlooks the fact that most university research is basic in nature and that companies frequently enter into research agreements with university faculty at a point at which preliminary experiments (whether conducted in the faculty member's laboratory or in the company's laboratory) have established the proof of concept and, therefore, the likelihood that the research will have positive results is enhanced.

Notwithstanding the obvious observation that scientific reviews conducted by nonindustry-supported authors are also subject to many potential biases, the 8 principles articulated in this article address all of these possible sources of skewed research. Indeed, if these principles are vigorously adopted as the guidelines they are intended to be, there would be virtually no reason to quarrel with a research conclusion except to dispute the science itself.

In fact, the 8 principles articulated herein are intended to provide a clear statement of responsibility on all sides—those that are funding activities as well as those being funded—when academic institutions or academicians are recipients of industry funding for research, publication, or presentation. The principles are intended to offer guidance for the food industry and academic researchers who work with industry, when industry-funded research projects are involved. They may be thought of as a checklist to help ensure insulation of any research project from the provision of the resources enabling the project.

Finally, the guidelines are offered as only a first step in creating a firewall against bias in research: this article is intended to be a dynamic document, prompting ongoing discussion and refinement of the guidelines it presents.

A CHALLENGE TO THE BROADER COMMUNITY

The objectives outlined above may be worthy, though not easy to achieve. However, these principles can also serve as an invitation to the broader scientific, science communications, and public policy communities to embrace similar pledges to immunize their work against the myriad potential sources of bias—nonfinancial as well as financial conflicts. The present article was necessarily confined to one relatively small aspect of an extremely complex issue. However, future discussions could be much wider ranging and much more comprehensive if they embrace all sources of bias and expand the focus from the very narrow issue of potential bias due to financial conflicts of interest.

Consider the extensive list of biases touched on at the end of the section on definitions above: how constructive might it be for the broader scientific, communications, and public policy communities to adopt guidelines to ensure that their work is free from bias? For example, such guidelines might include pledges of transparency (eg, voluntary disclosure of all previous research, published articles, and policy positions that might influence present research, published articles, and policy positions), disclosure of sources of funding (both of the project at hand and overall funding), and disclosure of other potential biases (eg, philosophical, religious, ethical, or political orientation; intention to publish or otherwise garner public or political authority or power through publicity; and previously announced public positions that might be relevant to the work at hand).

Other researchers or groups that are not supported by the food industry (eg, nongovernmental organizations, foundations, and advocacy and consumer groups) might include in their public communications appropriate promises that their work, to the extent possible, is open and objective (not skewed to a particular conclusion or philosophical view) and is controlled by the researcher or cited authority (rather than by a hidden funder or interested party). The checklist provided in the section above on the guidelines' import and implications might prove helpful in designing similar guidelines for other groups.

EXCLUDED ISSUES

It is important to state explicitly what this paper has excluded from consideration. Notwithstanding that all scientific research, whether funded by industry or not, should be subject to the same ethical rules, discussion of all of the following potential institutional sources of bias that can affect the integrity of the published scientific record was specifically excluded from this article: foundation-funded research, government-funded research, and work by academicians on advisory panels to industry, grant panels, government advisory panels, nongovernmental organization panels, and voluntarism on behalf of professional societies.

This is a short list of organizational work and funding situations that routinely pose profound challenges to the independence and integrity of scientific research—the list could certainly be lengthened. All of these potential sources of bias are outside and beyond the scope of this article, but it is suggested that future articles explore the ramifications of inappropriate influence of such organizational bias on research or public policy. It is strongly urged that future investigations into this area be sufficiently broad to include the many nonscientific and other institutions that routinely play a communications role in science-based public policy.

CONCLUSION

We could lament that this entire effort to manage conflicts of interest and to banish bias in science, is, alas, insufficient. It would be easy to complain that the financial and other pressures on research are too great to channel them neatly. Furthermore, some will argue that a mere set of guidelines cannot immunize science from error, misinterpretation, or deliberate miscalculation. We deliberately left aside, for the time, the matter of enforcement mechanisms for these or any guidelines, believing instead that achieving a consensus on best practices in managing conflicts must certainly come before establishing sanctions for failing to adhere to best practices. As professional scientific societies, industry groups, and other organizations that engage regularly with researchers adopt a common set of rules by which to manage these difficult issues, enforcement of guidelines will automatically become increasingly less problematic.

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In the end, management of conflicts of interest, and, for that matter, management of scientific biases altogether, is a matter of consensus building, not enforcement. Should we indulge in more of the self-recriminations that have gone on for far too long or should we construct a workable start to a solution? The choice is obvious: it is time to act. The interpretation of health research and the promotion of public policies resting on that research are far too important for us not to address and manage the myriad potential biases that can intrude. Let this effort be a start.

This article is the product of a working group on conflict of interest/scientific integrity organized by the North American branch of the International Life Sciences Institute (ILSI North America). ILSI North America is a public, nonprofit, scientific foundation with branches around the world that provides a forum to advance the understanding of scientific issues related to the nutritional quality and safety of the food supply. ILSI North America carries out its mission by sponsoring relevant research programs, professional education programs and workshops, seminars, and publications as well as by 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. The programs of ILSI North America are supported primarily by the ILSI North America industry membership. For more information about the working group or ILSI North America, contact Heather Steele at 202-659-0074 or by E-mail at hsteele@ilsi.org. This article underwent independent scientific review by more than 25 reviewers. Authors Sylvia Rowe and Nick Alexander served as consultants to this project and received funds from ILSI NA for their work on this article.

[†] *See* Fuglie et al (3). Also *see* Lesser et al (4), which asserts that roughly 29% of beverage research was fully or partially funded by industry. A study by Thomas et al (5) concluded that roughly 60–65% of long-term (≥1 y) weight-loss trials were funded by industry.

[‡] For industry-funded research that enhanced the microbiological safety of food, *see* Tanaka et al (6). This research, which concerns the safety of cheese products, was the precursor to the field of microbiological predictive modeling, which is now widely used by food processors and regulatory agencies to predict the safety of formulated foods.

[§] For beneficial food-industry toxicological research (ie, research promoting better public health), which was incidentally shared with the US Food and Drug Administration (FDA) prior to journal publication, *see* Velasco (7) and Pittet (8). For FDA aflatoxin information, *see* the *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook* (9).

[‖] Case in point: the FDA's refusal in the early 1960s to approve the drug thalidomide, which was marketed in Europe as a tranquilizer for use in pregnant women, despite the German manufacturer's "scientific" assurances of its safety. *See* Burkholz (16) and Silverman (17) for a case history.

[¶] For a discussion of bias and the distinction between *bias* and *conflict of interest*, *see* publications by the National Academy of Sciences (26) and the Federation of American Societies for Experimental Biology (FASEB) (27).

[#] The sample may not be representative of the population—may be too small. The data may be inaccurate because of self-reporting or inaccurate recording, the sample groups may be inappropriately grouped for analysis, the confounding variables may be misjudged or unidentified, or the journals may refuse to publish null or negative results or research on issues judged unpopular—all of these issues may result in biased conclusions, without the researchers even being aware. For a more complete discussion, *see* Bulgar et al (28).

[**] Pressure to publish can also lead to journal-promoted biases, as cited in a recent article by Butler (31).

[††] For an organizational example of applied peer review, visit the website of the National Institutes of Health (NIH) Office of Extramural Research (33), where the process is used to sift through the many funding applications received by the NIH.

[‡‡] Note the issues raised in the public health research community over a perceived disproportionate influence of one foundation's funding, documented in recent media coverage (38).

[§§] This guideline, separating the science from the funding of it, will be fulfilled in a variety of ways, depending on the specific funding mechanism used in a given research project. For descriptions of the significant variety of research arrangements currently used, *see* guidance offered by the NIH (39); an excellent analysis of conflict of interest management with respect to the varied research funding mechanisms is also offered by FASEB (40–42).

[‖‖] For the purposes of this guideline, the investigative team may include employees of the sponsoring entity; researchers should agree or commit to publish findings on the key questions/hypotheses they investigate in their studies.

[¶¶] This guideline is intended to apply to investigators not associated with the funding entity and appropriate scientific auditors: it is not intended to guarantee availability of research data to the general public.

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BUDGET SUMMARY

	Q4 2010	2011	2012	Q1-3 2013	Total
Total Direct Costs	$366,935	$850,062	$881,849	$192,765	$2,291,611
USC Indirect Costs	$36,693	$85,006	$88,185	$19,277	$229,161
Total Costs	$403,628	$935,068	$970,033	$212,042	$2,520,772

Budget 4th Quarter 2010												
PERSONNEL	*ROLE*	*APPOIN*	*PERCENT*	*MONTHS*	*BASE SALARY*	*Q4 SAL RE*	*FB*	*FB%*	*INS*	*INS COST*	*TOTAL FRING*	*TOTAL COST*
Steven Blair	PI	12	10%	1.20	$250,480	$6,262	$1,390	22.19%	6360	$159	$1,549	$7,811
Gregory Hand	Co-PI	10.5	10%	1.05	$111,248	$2,781	$617	22.19%	6360	$159	$776	$3,557
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$10,000	$2,219	22.19%	6360	$1,590	$3,809	$13,809
James Hebert	Investigator	11	4%	0.39	231,221	$2,023	$449	22.19%	6360	$56	$505	$2,528
James Hardin	Investigator	12	5%	0.60	$108,356	$1,355	$301	22.19%	7414	$93	$394	$1,748
Mei Sui	Investigator	12	10%	1.20	$89,960	$1,749	$388	22.19%	7414	$185	$573	$2,322
Tom Hurley	Investigator	12	10%	1.20	$72,000	$1,800	$399	22.19%	0	$0	$399	$2,199
TOTAL PERSONNEL COSTS:												$33,975
CONSULTANT COSTS:												
Consultants (8 @ $5000)												$40,000
TOTAL CONSULTANT COSTS:												$40,000
EQUIPMENT:												
Freezer												$12,600
TOTAL EQUIPMENT COSTS:												$12,600
SUPPLIES:												
Electronic scales (400 @ $150)												$60,000
Armbands (300 @ $200)												$60,000
Computers (5 @ $1500)												$7,500
Project-specific office/computer supplies												$2,500
Doubly-labeled water												$110,000
Laboratory supplies												$5,360
TOTAL SUPPLIES COSTS:												$245,360
TRAVEL EXPENSES:												
Local travel for recruitment												$2,000
Meeting with consultants												$8,000
TOTAL TRAVEL EXPENSES:												$10,000
OTHER EXPENSES:												
Printing												$20,000
Recruitment costs												$5,000
TOTAL OTHER EXPENSES:												$25,000
TOTAL DIRECT COSTS FOR YEAR 01												$366,935

USC INDIRECT COSTS FOR YEAR 01	$36,693
TOTAL COSTS FOR YEAR 01	$403,628

BUDGET 2011														
PERSONNEL	*ROLE*	*APPOIM*	*PERCENT*	*MONTHS*	*BASE SALAR*	*SALARY ES*	*SAL REQ*	*FB*	*FB%*	*INS*	*INS COST*	*TOTAL FRI*	*FRINGE E*	*TOTAL COST*
Steven Blair	PI	12	6%	0.96	$250,480	$257,994	$20,640	$4,580	22.19%	6360	$509	$5,089	$5,242	$25,881
Gregory Hand	Co-PI	10.5	15%	1.58	$111,248	$114,585	$17,188	$3,814	22.19%	6360	$954	$4,768	$4,911	$22,099
Meghan Baruth	Investigator	12	99%	10.80	$40,000	$41,200	$37,080	$8,228	22.19%	6360	$5,724	$13,952	$14,371	$51,451
James Hebert	Investigator	11	4%	0.39	231,221	$238,158	$8,336	$1,850	22.19%	7414	$259	$2,109	$2,172	$10,508
James Hardin	Investigator	12	5%	0.60	$108,356	$111,607	$5,580	$1,238	22.19%	7414	$371	$1,609	$1,657	$7,238
Mel Sul	Investigator	12	10%	1.20	$69,960	$72,059	$7,206	$1,599	22.19%	7414	$741	$2,340	$2,410	$9,616
Tom Hurley	Investigator	12	15%	1.80	$72,000	$74,160	$11,124	$2,468	22.19%	0	$0	$2,468	$2,542	$13,666
TBN, Project Manager	Project Manage	12	100%	12.00	$60,000	$61,800	$61,800	$13,713	22.19%	7414	$7,414	$21,127	$21,761	$83,561
TBN, Web Site Manager	Web Manager	12	20%	2.40	$45,000	$46,350	$9,270	$2,057	22.19%	7414	$1,483	$3,540	$3,646	$12,916
TBN, Laboratory Tech	Lab Tech	12	100%	12.00	$45,000	$46,350	$46,350	$10,285	22.19%	7414	$7,414	$17,699	$18,230	$64,580
TBN, Laboratory Tech	Lab Tech	12	50%	6.00	$30,000	$30,900	$15,450	$3,428	22.19%	7414	$3,707	$7,135	$7,349	$22,799
TBN, Statistician	Statistician	12	10%	1.20	$80,000	$82,400	$8,240	$1,828	22.19%	7414	$741	$2,569	$2,646	$10,886
TBN, Data Manager	Data Manager	12	50%	6.00	$50,000	$51,500	$25,750	$5,714	22.19%	7414	$3,707	$8,421	$9,704	$35,454
Recruitment/Retention Coordinator	R/R Coordinato	12	100%	12.00	$50,000	$51,500	$51,500	$11,425	22.19%	7414	$7,414	$18,842	$19,407	$70,907
TBN, Graduate Research Assistant	GA	12	100%	12.00	$18,000	$18,540	$18,540	$195	1.05%	0	$0	$195	$201	$18,741
TBN, Graduate Research Assistant	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TBN, Graduate Research Assistant	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TBN, Graduate Research Assistant	GA	12	50%	6.00	$18,000	$18,540	$9,270	$97	1.05%	0	$0	$97	$100	$9,370
TOTAL PERSONNEL COSTS:														$468,412
CONSULTANT COSTS:														
TOTAL CONSULTANT COSTS:														$0
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
Project-specific office/computer supplies														2500
Doubly-labeled water														$55,000
TOTAL SUPPLIES COSTS:														$57,500
TRAVEL EXPENSES:														
Travel to professional meetings														$2,000
Local travel for recruitment														$2,000
TOTAL TRAVEL EXPENSES:														$4,000
OTHER EXPENSES:														
Lab costs (200 @ $45)														$9,000
Printing														$500
Recruitment costs														$10,000

GA tuition													$30,000
Incentives (200 @ $500)													$100,000
24-hour dietary recalls (200 @ $750)													$150,000
Teleconference costs (consultant meetings)													$650
													$300,150
													$0
TOTAL DIRECT COSTS FOR YEAR 02													$850,052
USC INDIRECT COSTS FOR YEAR 02													$85,006
TOTAL COSTS FOR YEAR 02													$935,068

BUDGET 2012														
PERSONNEL	*ROLE*	*APPOINT*	*PERCENT*	*MONTHS*	*BASE SAL*	*SALARY E*	*SAL REQ*	*FB*	*FBK*	*INS*	*INS COST*	*TOTAL FRING*	*FRINGE eSC*	*TOTAL COST*
Steven Blair	PI	12	8%	0.96	$250,480	$265,734	$21,259	$4,717	22.19%	6360	$509	$5,226	$5,544	$26,803
Gregory Hand	Co-PI	10.8	10%	1.05	$111,248	$118,023	$11,802	$2,619	22.19%	6360	$638	$3,255	$3,453	$15,255
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$42,436	$42,436	$9,417	22.19%	6360	$6,360	$15,777	$16,738	$59,174
James Hebert	Investigator	11	4%	0.41	231,221	$245,302	$9,199	$2,041	22.19%	7414	$278	$2,319	$2,460	$11,659
James Hardin	Investigator	12	5%	0.60	$106,356	$114,955	$5,748	$1,275	22.19%	7414	$371	$1,646	$1,746	$7,494
Mei Sui	Investigator	12	10%	1.20	$69,960	$74,221	$7,422	$1,647	22.19%	7414	$741	$2,388	$2,533	$9,955
Tom Hurley	Investigator	12	10%	1.20	$72,000	$76,385	$7,638	$1,695	22.19%	7414	$741	$2,436	$2,584	$10,222
TBN, Project Manager	Project Manag	12	100%	12.00	$60,000	$63,654	$63,654	$14,125	22.19%	7414	$7,414	$21,539	$22,851	$86,505
TBN, Web Site Manager	Web Manager	12	15%	1.80	$45,000	$47,741	$7,161	$1,589	22.19%	7414	$1,112	$2,701	$2,865	$10,026
TBN, Laboratory Tech	Lab Tech	12	100%	12.00	$45,000	$47,741	$47,741	$10,594	22.19%	7414	$7,414	$18,008	$19,105	$66,846
TBN, Laboratory Tech	Lab Tech	12	50%	6.00	$30,000	$31,827	$15,914	$3,531	22.19%	7414	$3,707	$7,238	$7,679	$23,593
TBN, Statistician	Statistician	12	25%	3.00	$80,000	$84,872	$21,218	$4,708	22.19%	7414	$1,854	$6,562	$6,962	$28,180
TBN, Data Manager	Data Manager	12	50%	6.00	$50,000	$53,045	$26,523	$5,885	22.19%	7414	$3,707	$9,592	$10,176	$36,699
Recruitment/Retention Coordinator	R/R Coordinato	12	40%	4.80	$50,000	$53,045	$21,218	$4,708	22.19%	7414	$2,966	$7,674	$8,141	$29,359
TBN, Graduate Research Assistan	GA	12	100%	12.00	$18,000	$19,096	$19,096	$201	1.05%	0	$0	$201	$213	$19,309
TBN, Graduate Research Assistan	GA	12	100%	12.00	$18,000	$19,096	$19,096	$201	1.05%	0	$0	$201	$213	$19,309
TBN, Graduate Research Assistan	GA	12	50%	6.00	$18,000	$19,096	$9,548	$100	1.05%	0	$0	$100	$106	$9,654
TBN, Graduate Research Assistan	GA	12	50%	6.00	$18,000	$19,096	$9,548	$100	1.05%	0	$0	$100	$106	$9,654
TOTAL PERSONNEL COSTS:														$479,698
CONSULTANT COSTS:														
Consultants (8 @ $5000)														$40,000
TOTAL CONSULTANT COSTS:														$40,000
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
Project-specific office/computer supplies														$2,000
Doubly-labeled water														$55,000
TOTAL SUPPLIES COSTS:														$57,000
TRAVEL EXPENSES:														
Local travel for recruitment														$2,000
Travel to professional meetings														$2,000
TOTAL TRAVEL EXPENSES:														$4,000
OTHER EXPENSES:														
Lab costs (200 @ $45)														$9,000
Printing														$600
Recruitment costs														$5,000

GA tuition	$36,000
Incentives (200 @ $500)	$100,000
24-hour dietary recalls (200 @750)	$150,000
Teleconference costs (consultant meeting)	$650
TOTAL OTHER EXPENSES:	$301,150
Sub-contract Direct Costs	
Sub-contract Indirect Costs	
TOTAL SUB-CONTRACT COSTS	$0
TOTAL DIRECT COSTS FOR YEAR 03	$881,849
USC INDIRECT COSTS FOR YEAR 03	$88,185
TOTAL COSTS FOR YEAR 03	$970,033

Budget 1st - 3rd Quarters 2013

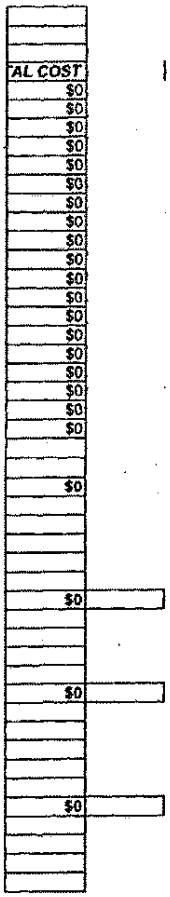
PERSONNEL	ROLE	APPOIN	PERCENT	MONTHS	BASE SAL	SALARY R	SAL REQ	FB	FB%	INS	INS COST	TOTAL FR	FRINGE E	TOTAL COST
Steven Blair	PI	12	10%	1.20	$250,480	$273,706	$20,528	$4,555	22.19%	6360	$477	$5,032	$5,499	$26,027
Gregory Hand	Co-PI	10.5	10%	1.05	$111,248	$121,564	$9,117	$2,023	22.19%	6360	$477	$2,500	$2,732	$11,849
Meghan Baruth	Investigator	12	100%	12.00	$40,000	$43,709	$32,782	$7,274	22.19%	6360	$4,770	$12,044	$13,161	$45,943
James Hebert	Investigator	11	9%	0.94	231,221	$252,661	$16,107	$3,574	22.19%	7414	$473	$4,047	$4,422	$20,529
James Hardin	Investigator	12	10%	1.20	$106,356	$116,404	$8,880	$1,971	22.19%	7414	$556	$2,527	$2,751	$11,641
Mei Sui	Investigator	12	20%	2.40	$69,960	$76,447	$11,457	$2,545	22.19%	7414	$1,112	$3,657	$3,996	$15,463
Tom Hurley .	Investigator	12	20%	2.40	$72,000	$78,676	$11,801	$2,619	22.19%	0	$0	$2,619	$2,862	$14,663
TOTAL PERSONNEL COSTS:														$146,115
CONSULTANT COSTS:														
Consultants (8 @ $5000)														$40,000
TOTAL CONSULTANT COSTS:														$40,000
EQUIPMENT:														
TOTAL EQUIPMENT COSTS:														$0
SUPPLIES:														
TOTAL SUPPLIES COSTS:														$0
TRAVEL EXPENSES:														
Travel to professional meetings														$6,000
TOTAL TRAVEL EXPENSES:														$6,000
OTHER EXPENSES:														
Teleconference costs (consultant meeting)														$650
														$650
														$0
TOTAL DIRECT COSTS FOR YEAR 04														$192,765
USC INDIRECT COSTS FOR YEAR 04														$19,277
TOTAL COSTS FOR YEAR 04														$212,042

PERSONNEL	ROLE	APPOINTM	PERCENT	MONTHS	BASE SAL	SALARY ESC	SAL REQ	FB	FB%	INS	INS COST	TOTAL FRING	FRINGE ES
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
				0.00		$0	$0	$0	22.19%	7414	$0	$0	$0
GA				0.00		$0	$0	$0	1.10%		$0	$0	$0
GA				0.00		$0	$0	$0	1.10%		$0	$0	$0
TOTAL PERSONNEL COSTS:													
CONSULTANT COSTS:													
TOTAL CONSULTANT COSTS:													
EQUIPMENT:													
TOTAL EQUIPMENT COSTS:													
SUPPLIES:													
TOTAL SUPPLIES COSTS:													
TRAVEL EXPENSES:													

TOTAL TRAVEL EXPENSES:												
OTHER EXPENSES:												
TOTAL OTHER EXPENSES:												
Sub-contract Direct Costs												
Sub-contract Indirect Costs												
TOTAL SUB-CONTRACT COSTS												
TOTAL DIRECT COSTS FOR YEAR 05												
DIRECT COSTS - SUB-CONTRACT INDIRECTS												

USC INDIRECT COSTS FOR YEAR 05

TOTAL COSTS FOR YEAR 05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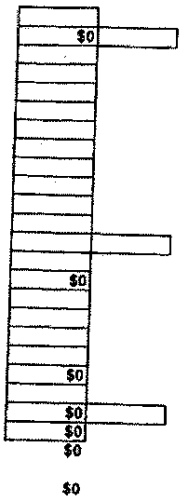
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MODIFICATION AGREEMENT

THIS MODIFICATION AGREEMENT is effective as of June 6, 2013, and is made between **THE COCA-COLA COMPANY** (hereinafter referred to as "**Sponsor**"), and **THE SOUTH CAROLINA RESEARCH FOUNDATION ("SCRF"), THE UNIVERSITY-AFFILIATED RESEARCH FOUNDATION FOR THE UNIVERSITY OF SOUTH CAROLINA ("UNIVERSITY"), DR. GREGORY HAND, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY DIRECTOR"), AND DR. STEVEN BLAIR, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY CO-DIRECTOR")** (UNIVERSITY, STUDY DIRECTOR, STUDY CO-DIRECTOR AND SPONSOR are also referred to herein individual as a "**Party**" and collectively as "**Parties**").

The Parties are parties to a Research Agreement effective as of November 4, 2010 (the "**Agreement**") in connection with an Energy Balance Study. Unless otherwise defined herein, the defined terms used in this Modification Agreement shall have the same meanings as set forth in the Agreement.

The Parties desire to modify the Agreement as follows:

1. Exhibit A (Protocol) is modified by adding the additional provisions attached hereto as Attachment 1.

2. Exhibit B (Budget) is modified by adding the additional information attached hereto as Attachment 2.

3. The Parties desire to modify Exhibit C (Payment Schedule) of the Agreement by deleting the payment schedule for 2013 in its entirety and inserting the following in lieu thereof:

- **2013 Payments:**

  Total payment of $598,568.50

  ½ the total 2013 amount of $299,284.25 paid upon completion of year two start-up and retention of current participants for a second year of measurements (scheduled for late July 2013).

  ½ the total 2013 amount of $299,284.25 paid upon delivery of status report by University to Sponsor at the end of November 2013.

- **2014 Payments:**

  Total payment of $598,568.50

  ½ the total 2014 amount of $299,284.25 paid upon completion of year two measurements (scheduled for July 31, 2014).

½ the total 2014 amount of $299,284.25 paid upon delivery of final results and analyses, delivery of one or more manuscripts suitable for publication and presentations at national meetings (scheduled for November 2014).

This Modification Agreement in no way modifies the remaining terms and conditions of the Agreement, which shall remain in full force and effect.
Any and all attachments referred to in this Modification Agreement are hereby incorporated herein by reference and are made a part hereof as if they were included in the text of this Modification Agreement.

The Parties have executed this Modification Agreement (which may be executed in counterparts and via facsimile or electronically transmitted signature, all of which shall be originals and sufficient to legally bind the parties to this Modification Agreement) effective as of the date first written above.

SOUTH CAROLINA RESEARCH FOUNDATION

By: _____

Print Name: R. Steven Etheredge, Asst. Director
Title: Sponsored Awards Management
Date: 7/3/13

THE COCA-COLA COMPANY

By: _____

Print Name: Rhona S. Applebaum, PhD
Title: Vice President and Chief Scientific & Regulatory Officer
Date: June 28, 2013

STUDY DIRECTOR

By: _____

Print Name: GREGORY A. HAND
Title: PROFESSOR
Date: 7/5/2013

STUDY CO-DIRECTOR

By: _____

Print Name: Steven N. Blair
Title: Professor
Date: July 5, 2013

Attachment 1

See attached

MILESTONES AND PAYMENT SCHEDULE FOR

ENERGY BALANCE: CONTINUATION THROUGH YEAR 2

Payment Schedule

Sponsor will pay University based on completion of the following milestones:

- **2013 Payments:**

  Total payment of: $598,568.50

  ½ the total 2013 amount of $299,284.25 paid upon completion of year two start-up and retention of current participants for a second year of measurements (scheduled for late July 2013).

  ½ the total 2013 amount of $299,284.25 paid upon delivery of status report by University to Sponsor at the end of November 2013.

- **2014 Payments:**

  Total payment of: $598,568.50

  ½ the total 2014 amount of $299,284.25 paid upon completion of year two measurements (scheduled for July 31, 2014).

  ½ the total 2014 amount of $299,284.25 paid upon delivery of final results and analyses, delivery of one or more manuscripts suitable for publication and presentations at national meetings (scheduled for November 2014).

Energy Balance: Continuation through Year 2

Steven N. Blair and Gregory A. Hand, Co-Principal Investigators
Department of Exercise Science, Arnold School of Public Health
University of South Carolina

PURPOSE:

The continuation of EB will allow the study team to follow participants for a second 12-month period. This extension will result in 4 more quarterly measurement sessions and provide a more robust dataset that increases the likelihood of uncovering significant interactions among the energy balance components and their potential determinants. It will also dramatically increase the statistical power that could be the critical component to achieve the study's secondary and tertiary aims.

BACKGROUND:

The Energy Balance Study (EB) has achieved the target recruitment of over 400 adults aged 21 to 35 years with a BMI ranging from 20 to 35. This population is at risk for a gradual increase in weight of about 1.5 pounds per year. EB's goal is to follow these individuals to begin to understand the relationships among the three primary components of the energy balance equation (intake, output, and storage), as well as to document determinants of the changes in these relationships. Perhaps EB's greatest strength is the breadth of the potential determinants that are tracked. These fall into the broad categories of physiological, psychological, anthropomorphic, environmental, social, and genetic. With the successful recruitment of EB participants and follow-up measurements that have now progressed into the 12-month period for many subjects, preliminary results are already showing interesting relationships that will be impactful to the field of weight management.

With the support of our expert advisors (Drs. Allison, Hill, Jakicic, Hamilton, Katzmarzyk, Church, Blundell, Welk & Thomas), the continuation of observations through a second year will allow us to approach the following Specific Aims:

SPECIFIC AIMS:

Prefatory Aim 1. To examine the extent to which variation in total energy expenditure and variation in total energy intake contribute to changes in body weight and fat among young adults.

Primary Aim 1. To examine the extent to which changes in body weight and fat are driven by changes in energy expenditure, changes in energy intake, or both.

Secondary Aim 1. To examine the extent to which changes in body weight and fat during specific time intervals are driven by changes in energy expenditure, changes in energy intake, or both.

Secondary Aim 2. To examine the specific components/attributes of energy expenditure and energy intake that drive changes in body weight and fat.

Secondary Aim 3. To determine to what extent demographic characteristics modify the relationship between variance in the changes in energy expenditure and energy intake and variance in the changes in body weight and fat.

Tertiary Aim 1. To study the feasibility of examining the temporal sequence of changes in energy expenditure and changes in energy intake.

SEQUENCE OF MEASUREMENTS FOLLOWING BASELINE:

3M	6M	9M	12M	15M	18M	21M	24M
• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight

INCENTIVES:

In an effort to increase adherence and compliance, participants will receive an incentive upon completion of baseline and quarterly measures. A total of $500 will be given to each subject in Year 2 of the study period, with cash payments varying based on the complexity and length of each visit. The following is the breakdown of the incentive distribution during Year 2:

Visit	15M	18M	21M	24M
Incentive	$75	$150	$75	$200

PUBLICATION PLAN:

Upon completion of the study, a number of manuscripts will be prepared and submitted to top peer-reviewed journals for publication (e.g. Journal of the American Medical Association, New England Journal of Medicine). Study findings will also be presented at national meetings (e.g. American College of Sports Medicine, Experimental Biology,

The Obesity Society, American Nutrition Society) and released to the press/media (e.g. New York Times, Washington Post, USA Today).

Examples of publication titles include:

1. What drives the increase in body weight/fat – energy intake or energy expenditure? Findings from a prospective energy balance study.
2. Changes in energy intake and energy expenditure: What components contribute to these changes?
3. Do demographic factors moderate the relationship between energy intake, energy expenditure and weight/fat gain?
4. Re-thinking the obesity epidemic: Implications for clinicians, public health officials, and policy makers.
5. The importance of energy balance design elements in future obesity research studies.

BUDGET

Budget Summary

Total Direct Costs	$1,088,307
USC Indirect Costs	$ 108,831
TOTAL COSTS	$1,197,137

BUDGET 2014																
PERSONNEL	[redacted]	[redacted]														
Steven Blair	[redacted]	12	5%	[redacted]												
Gregory Hand	[redacted]	12	19%	[redacted]												
James Hebert	[redacted]	11	5%	[redacted]												
Mel Sol	[redacted]	12	19%	[redacted]												
Tim Hurley	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	100%	[redacted]												
[redacted]	[redacted]	12	25%	[redacted]												
[redacted]	[redacted]	12	[redacted]	[redacted]												
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
[redacted]	[redacted]	12	19%	[redacted]												
TOTAL PERSONNEL COSTS:																$400,382
[redacted]																
																$22,500
TOTAL CONSULTANT COSTS:																$22,500
EQUIPMENT:																
Gas Analysis System																$25,024
Excalibur Sport Ergonomic Unit and accessories, plus computer control unit																$25,000
TOTAL EQUIPMENT COSTS:																$50,024
[redacted]																
[redacted]																$1,500
[redacted]																$6,750
[redacted]																$3,000
TOTAL SUPPLIES COSTS:																$11,250
TRAVEL EXPENSES:																
Travel to professional meetings																$7,500
Travel for consultant meetings																$12,500
TOTAL TRAVEL EXPENSES:																$20,000
OTHER EXPENSES:																
Lab costs (400 @ $45)																[redacted]
Publishing Costs																[redacted]
Printing																[redacted]
GA tuition																[redacted]
Incentives (400 @ $500)																[redacted]
24-hour dietary recalls (400 @ $750)																[redacted]
Teleconference costs (consultant meetings)																[redacted]
TOTAL OTHER EXPENSES:																$584,150
																$0
TOTAL DIRECT COSTS FOR YEAR 02																$1,088,307
USC INDIRECT COSTS FOR YEAR 02																$108,831
TOTAL COSTS FOR YEAR 02																$1,197,137

BUDGET JUSTIFICATION

PERSONNEL

The extensive set of measures and multiple follow-up measurement periods throughout the study will require significant time and effort by study personnel. A large study staff will be needed during 2014 to continue follow-up visits with the 400 participants involved for an additional year. During the additional year of follow-up, we will conduct laboratory measures and collect energy intake (24-hour recalls) and energy expenditure (armbands, DLW, basal metabolic rate) data, and considerable effort will be required to maintain contact and insure good adherence to the study protocol.

Dr. Steven Blair, Co-PI (5%) has expertise in conducting large-scale prospective studies and randomized trials, and extensive background in physical activity/fitness research in areas related to overweight and obesity. Dr. Blair has used the armband to measure energy expenditure in previous studies.

Dr. Gregory Hand, Co-PI (10%) has expertise in all laboratory measures being conducted in this study, which include body fat measurement (DXA), physiological assessments (i.e. blood draws for lipid and glucose analysis), waist circumference, basal metabolic rate.

Dr. James Hebert, Investigator (2%) has expertise in dietary intake assessment and has used the 24-hour recall in a number of his studies.

Mr. Tom Hurley, Investigator (10%) will oversee conducting the 24-hour recalls at the USC Cancer Prevention and Control Center. He has supervised work in this area for over 125,000 dietary recalls in various studies funded by the National Cancer Institute. He also has expertise in analyzing the dietary data.

Dr. Mei Sui, Investigator (10%) has expertise in data management and coordination, in addition to data analysis. Each investigator will provide guidance in his/her area of expertise during program development and throughout the study period. This set of investigators is among the leaders in the field of energy balance and dietary and physical activity assessment.

A number of individuals, including the Project Manager, Project Coordinator, Retention Coordinator, Data Manager, Lab Manager, Lab Technicians, and Graduate Research Assistants will be hired to conduct the daily operations of the project.

The **Project Manager** will manage the day-to-day aspects of this study and will coordinate laboratory visits and energy intake and expenditure assessments. He/she will meet regularly with the investigators and will supervise the work of the other project staff members.

The **Project Coordinator** will assist the Project Manager in all day-to-day activities. He/She will also be available to participants to answer questions about armbands, 24HR, and other measures (e.g. surveys). They will be responsible for handing out incentive to the participants.

The **Retention Coordinator** will be responsible for executing the retention plan to ensure participants return for follow-up visits. Retaining 400 participants for an additional one-year study period will be crucial for the success of this project.

The **Data Manager**, working with Drs. Sui, Hardin, and Hurley, will be responsible for cleaning, storing, and ensuring the security of the data. Study data will be collected from several measures: survey data (Project Manager), dietary recall data (USC Nutrition Center), and laboratory measures (USC laboratory). The Data Manager will coordinate the data from all of these sources and develop datasets that are clean and properly formatted.

The **Laboratory Manager**, working closely with the Project Manager, will supervise the Laboratory Technicians and Graduate Assistants to perform measurements and train participants on how to use armbands and adhere to study methods. He/She will also be responsible for maintaining all lab supplies and equipment.

The **Laboratory Technicians** will be responsible for collecting all laboratory measures (DXA, blood draws, DLW, fitness, basal metabolic rate, etc). The large sample size and multiple study visits will require multiple technicians to be available.

The **Graduate Research Assistants** will assist the Project Manager, Project Coordinator, Retention Coordinator, Laboratory Manager, and Laboratory Technicians with a wide variety of research and administrative tasks.

CONSULTANTS

A group of world-renowned experts [Drs. David Allison (University of Alabama-Brimingham), James Hill (University of Colorado Health Sciences Center), John Jakicic (University of Pittsburgh), Marc Hamilton (Pennington Biomedical Research Center), Peter Katzmarzyk (Pennington Biomedical Research Center), Timothy Church (Pennington Biomedical Research Center), John Blundell (University of Leeds), Gregory Welk (Iowa State University), and Diana Thomas (Montclair State University)] in the area of energy balance will serve as consultants and advisors to this project. These scientists have provided guidance in the development of the study protocol and will continue to provide their expertise throughout the study. The consultants will meet with study personnel annually, in person or by teleconference, to provide guidance and expertise, problem solve, and help disseminate study findings. Additional discussions with the advisors will be conducted at least quarterly by teleconference and email.

EQUIPMENT

Two Metabolic Measurement System for VO2max Testing will be purchased to measure resting metabolic rates and to measure maximum fitness. To continue testing as we have been to ensure consistency, we require that this system include a canopy for resting metabolic rate. Due to the large volume of participants that we will be testing, we will need to purchase a warranty for the equipment. A 5-year warranty is requested.

SUPPLIES

Previous energy balance studies have relied on self-report measures to assess energy intake and energy expenditure, and many of these approaches are not accurate or precise enough to get a valid assessment of energy balance. A major purpose of this study is to obtain the most accurate and precise measures of body fat, energy intake, and energy expenditure. Therefore, it is important that the best measures available are used in this study.

All participants currently use SenseWearArmbands, which automatically monitor energy expenditure and physical activity, for 10 days on a quarterly basis to measure energy expenditure. The armbands have been shown in a number of validation studies to provide an accurate assessment of energy expenditure. We anticipate that a small number of armbands may need to be replaced.

Computers will be used for data entry, data management, and participant retention activities.

Project-specific office and computer supplies will include shirts that staff will wear during recruitment and data collection activities, data storage supplies, and other project supplies.

TRAVEL

Funds for one in-person meeting of the consultants and several teleconference meetings are included. In addition, travel funds for the Co-PIs and investigators to present the study results at scientific meetings are included.

OTHER COSTS

Laboratory costs include the cost to draw, process and store blood, to conduct fitness assessments, and to test basal metabolic rate. The Clinical Exercise Research Laboratory at USC has a DXA machine, and there will be no equipment costs to obtain DXA data. Technicians to perform these tests are included in the budget.

Printing costs will include retention materials, project letterhead and envelopes, and signage.

Graduate assistant tuition is required by the University when graduate students are included in a research study.

Incentives – As previously mentioned, retaining participants will be very important in this study. In order to encourage ongoing participation in the study, participants will receive a cash incentive after each laboratory and/or energy expenditure and intake assessment period. Incentives will increase as the study progresses. Participants will receive a total of $500 for continuing in the study for an additional year.

Random 24-hour dietary recalls are the gold standard for assessing dietary intake. Three, random 24-hour dietary recalls will be conducted on all participants at baseline and on a quarterly basis (3 recalls x 5 measurement periods = 15 total recalls) by the Diet Assessment Research Unit of the University of South Carolina Cancer Prevention and Control Center. Three assessments per quarter will provide an accurate assessment of each participant's dietary habits. The Center will collect the data,

process it, and analyze it. The Center has provided 24-hour dietary recall services for a number of large scale nutrition studies.

Teleconferences will be scheduled periodically for advisors to consult with investigators. The university charges a fee for hosting a dedicated line for participants to call in.

Publication costs for abstracts and manuscripts are requested.

MODIFICATION AGREEMENT NO. 2

THIS MODIFICATION AGREEMENT NO. 2 is effective as of November 19, 2013, and is made between **THE COCA-COLA COMPANY** (hereinafter referred to as "**Sponsor**"), and **THE SOUTH CAROLINA RESEARCH FOUNDATION ("SCRF"), THE UNIVERSITY-AFFILIATED RESEARCH FOUNDATION FOR THE UNIVERSITY OF SOUTH CAROLINA ("UNIVERSITY"), DR. GREGORY HAND, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY DIRECTOR"), AND DR. STEVEN BLAIR, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY CO-DIRECTOR")** (UNIVERSITY, STUDY DIRECTOR, STUDY CO-DIRECTOR AND SPONSOR are also referred to herein individual as a "**Party**" and collectively as "**Parties**").

The Parties are parties to a Research Agreement effective as of November 4, 2010 (the "**Agreement**") in connection with an Energy Balance Study, and a Modification Agreement thereto effective June 6, 2013 (the "**Modification Agreement**"). Unless otherwise defined herein, the defined terms used in this Modification Agreement No. 2 shall have the same meanings as set forth in the Agreement and the Modification Agreement, as applicable.

The Parties desire to modify Exhibit C (Payment Schedule) of the Modification Agreement by deleting the payment schedule in its entirety and inserting the following in lieu thereof:

Sponsor will pay University based on completion of the following milestones:

- **2013 Payments:**

  Total payment of $997,614.50

  3/10 the total 2013 amount ($299,284.25) paid upon completion of year two start-up and retention of current participants for a second year of measurements (scheduled for late July 2013).

  2/10 the total 2013 amount ($199,522.25) paid upon delivery of one or more manuscripts suitable for publication and presentations at national meetings.

  1/4 the total 2013 amount ($249,404.00) paid upon delivery of status report by University to Sponsor at the end of November 2013.

  1/4 the total 2013 amount ($249,404.00) paid upon 25% of participants completing year two measurements (scheduled for December 2013).

- **2014 Payments:**

  Total 2014 payment: $199,522.50

  1/2 the total 2014 amount ($99,761.25) paid upon completion of year two measurements (scheduled for July 2014).

1/2 the total 2014 amount ($99,761.25) paid upon delivery of final results and analyses (scheduled for November 2014).

This Modification Agreement No. 2 in no way modifies the remaining terms and conditions of the Agreement or Modification Agreement, both of which shall remain in full force and effect.

Any and all attachments referred to in this Modification Agreement No. 2 are hereby incorporated herein by reference and are made a part hereof as if they were included in the text of this Modification Agreement No. 2.

The Parties have executed this Modification Agreement No. 2 (which may be executed in counterparts and via facsimile or electronically transmitted signature, all of which shall be originals and sufficient to legally bind the parties to this Modification Agreement No. 2) effective as of the date first written above.

SOUTH CAROLINA RESEARCH FOUNDATION

By: _____

Print Name: R. Steven Etheredge, Asst. Director
Title: Policy and Compliance
Date: 12/17/13

THE COCA-COLA COMPANY

By: _____

Print Name: WARWARA WATCHUNG
Title: VP SRA
Date: NOV 19 2013

STUDY DIRECTOR

By: _____

Print Name: Greg Hand
Title: Professor
Date: 12/12/2013

STUDY CO-DIRECTOR

By: _____

Print Name: Steven Blair
Title: Professor
Date: 12/9/2013

MODIFICATION AGREEMENT NO. 3

THIS MODIFICATION AGREEMENT NO. 3 is effective as of May __, 2014, and is made between **THE COCA-COLA COMPANY** (hereinafter referred to as "**Sponsor**"), and **THE SOUTH CAROLINA RESEARCH FOUNDATION ("SCRF"), THE UNIVERSITY-AFFILIATED RESEARCH FOUNDATION FOR THE UNIVERSITY OF SOUTH CAROLINA ("UNIVERSITY"), DR. GREGORY HAND, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY DIRECTOR"), AND DR. STEVEN BLAIR, PROFESSOR, ARNOLD SCHOOL OF PUBLIC HEALTH ("STUDY CO-DIRECTOR")** (UNIVERSITY, STUDY DIRECTOR, STUDY CO-DIRECTOR AND SPONSOR are also referred to herein individual as a "**Party**" and collectively as "**Parties**").

The Parties are parties to a Research Agreement effective as of November 4, 2010, in connection with an Energy Balance Study, including all modifications thereto (collectively, the "**Agreement**"). Unless otherwise defined herein, the defined terms used in this Modification Agreement No. 3 shall have the same meanings as set forth in the Agreement.

The Parties desire to modify the Agreement as follows:

1. Section 6.1 of the Agreement is modified so that the new expiration date is December 31, 2015, unless sooner terminated in accordance with Article 6.2 of the Agreement or otherwise agreed to by the parties in writing.

2. Exhibit A (Protocol) and Exhibit B (Budget) are modified by adding the additional provisions attached hereto as Attachment 1, which are applicable to the extended period of this Modification Agreement No. 3.

3. Exhibit C (Payment Schedule) is modified by deleting the payment schedule in its entirety for purposes of this Modification Agreement No. 3 and inserting the following in lieu thereof:

   Sponsor will pay University based on completion of the following milestones:

   - **2014 Payment:**

     Total payment of $319,836

     100% of the total 2014 amount of $319,836 paid within thirty (30) days of execution of this Modification Agreement No. 3, as compensation for the following services for Year 3: start-up, retention of current participants for a third year of measurement, and delivery of status report by University to Sponsor. Anticipated completion date is November 1, 2014.

   - **2015 Payment:**

     Total payment of $319,836

     100% of the total 2015 amount of $319,836 payable June 1, 2015, as compensation for the following services: completion of Year 3 measurements, delivery of final results and analyses, delivery of one or more manuscripts suitable for publication, and presentations at national meetings. Anticipated completion date is November 1, 2015.

This Modification Agreement No. 3 in no way modifies the remaining terms and conditions of the Agreement, which shall remain in full force and effect.

Any and all attachments referred to in this Modification Agreement No. 3 are hereby incorporated herein by reference and are made a part hereof as if they were included in the text of this Modification Agreement No. 3.

The Parties have executed this Modification Agreement No. 3 (which may be executed in counterparts and via facsimile or electronically transmitted signature, all of which shall be originals and sufficient to legally bind the parties to this Modification Agreement No. 3) effective as of the date first written above.

SOUTH CAROLINA RESEARCH FOUNDATION

By: _____

Print Name: R. Steven Etheredge
Title: Asst. Director, SAM
Date: June 18, 2014

THE COCA-COLA COMPANY

By: _____

Print Name: _____
Title: _____
Date: _____

STUDY DIRECTOR

By: _____

Print Name: Gregory Hand
Title: Professor
Date: June 18, 2014

STUDY CO-DIRECTOR

By: _____

Print Name: Steven N. Blair
Title: Professor
Date: June 18, 2014

ATTACHMENT 1

See attached

April 25, 2014

Energy Balance: Continuation through Year 3

Steven N. Blair and Gregory A. Hand, Co-Principal Investigators
Department of Exercise Science, Arnold School of Public Health
University of South Carolina

PURPOSE:

The continuation of Energy Balance will allow the study team to follow participants for a third 12-month period. This extension will result in 2 more measurement sessions at 30 and 36 months and provide a more robust dataset that increases the likelihood of uncovering significant interactions among the energy balance components and their potential determinants. It will also dramatically increase the statistical power that could be the critical component to achieve the study's secondary and tertiary aims.

BACKGROUND:

The Energy Balance Study (EB) achieved the year one target recruitment of over 400 adults aged 21 to 35 years with a BMI ranging from 20 to 35. This population is at risk for a gradual increase in weight of about 1.5 pounds per year. EB's goal is to continue to follow the individuals retained from year 2 to further understand the relationships among the three primary components of the energy balance equation (intake, output, and storage), as well as to document determinants of the changes in these relationships. Perhaps EB's greatest strength is the breadth of the potential determinants that are tracked. These fall into the broad categories of physiological, psychological, anthropomorphic, environmental, social, and genetic. With the successful recruitment of EB participants and follow-up measurements that have now progressed into the 24-month period for many subjects, results are already showing interesting relationships that will be impactful to the field of weight management.

SPECIFIC AIMS:

Prefatory Aim 1. To examine the extent to which variation in total energy expenditure and variation in total energy intake contribute to changes in body weight and fat among young adults.

Primary Aim 1. To examine the extent to which changes in body weight and fat are driven by changes in energy expenditure, changes in energy intake, or both.

Secondary Aim 1. To examine the extent to which changes in body weight and fat during specific time intervals are driven by changes in energy expenditure, changes in energy intake, or both.

Secondary Aim 2. To examine the specific components/attributes of energy expenditure and energy intake that drive changes in body weight and fat.

Secondary Aim 3. To determine to what extent demographic characteristics modify the relationship between variance in the changes in energy expenditure and energy intake and variance in the changes in body weight and fat.

Tertiary Aim 1. To study the feasibility of examining the temporal sequence of changes in energy expenditure and changes in energy intake.

SEQUENCE OF MEASUREMENTS FOLLOWING BASELINE:

3M	6M	9M	12M	15M	18M	21M	24M	30M	36M
• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • ActivPal • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight	• Armband 10 days • 3 random 24-hr dietary recalls • Weight

INCENTIVES:

In an effort to increase adherence and compliance, participants will receive an incentive upon completion of measures. A total of $400 will be given to each subject in Year 3 of the study. The following is the breakdown of the incentive distribution during Year 3:

Visit	30M	36M
Incentive	$200	$200

PUBLICATION PLAN:

Numerous publications have been submitted and / or have been approved. Upon completion of the study, additional manuscripts will be prepared and submitted to top peer-reviewed journals for publication (e.g. Journal of the American Medical Association, New England Journal of Medicine). Study findings have been and will continue to be presented at national meetings (e.g. American College of Sports Medicine, Experimental Biology,

The Obesity Society, American Nutrition Society) and released to the press/media (e.g. New York Times, Washington Post, USA Today).

Examples of publication titles include:

1. What drives the increase in body weight/fat – energy intake or energy expenditure? Findings from a prospective energy balance study.
2. Changes in energy intake and energy expenditure: What components contribute to these changes?
3. Do demographic factors moderate the relationship between energy intake, energy expenditure and weight/fat gain?
4. Re-thinking the obesity epidemic: Implications for clinicians, public health officials, and policy makers.
5. The importance of energy balance design elements in future obesity research studies.

April 25, 2014

BUDGET

Budget Summary

Total Direct Costs	$581,520
USC Indirect Costs	$ 58,152
TOTAL COSTS	$639,672

Energy Balance 2015												
PERSONNEL	*ROLE*	*APPOIN*	*PERCENT*	*MONTHS*	*BASE SALAR*	*SAL REQ*	*FB*	*FB%*	*INS*	*INS COST*	*TOTAL FRI*	*OTAL COST*
Steven Blair	PI	12	5%	0.60	$250,480	$12,524.00	$2,982	23.81%	7564	$378	$3,360	$15,884
Gregory Hand	Co-PI	10.5	12%	1.26	$155,000	$18,600.00	$4,429	23.81%	7564	$908	$5,337	$23,937
James Hebert	Investigator	11	2%	0.22	$231,221	$4,624.42	$1,101	23.81%	7564	$151	$1,252	$5,876
Tom Hurley	Investigator	12	10%	1.20	$72,000	$7,200.00	$1,714	23.81%	0	$0	$1,714	$8,914
Sarah Schumacher	Project Manage	12	100%	12.00	$57,000	$57,000.00	$13,572	23.81%	7564	$7,564	$21,136	$78,136
Madison DeMello	Lab Manager	12	100%	12.00	$30,000	$30,000.00	$7,143	23.81%	7564	$7,564	$14,707	$44,707
TBN, Data Manager (Samira)	Data Manager	12	10%	6.00	$50,000	$5,000.00	$1,191	23.81%	7564	$756	$1,947	$6,947
Retention Coordinator	Coordinator	12	100%	12.00	$45,000	$45,000.00	$10,715	23.81%	7564	$7,564	$18,279	$63,279
Laboratory Technicians (2)	Lab Tech	24	200%	48.00	$29,471	$58,942.00	$14,034	23.81%	7564	$15,128	$29,162	$88,104
TBN, Graduate Research Assistant	GA	12	100%	12.00	$18,000	$18,000.00	$99	0.55%	0	$0	$99	$18,099
TBN, Graduate Research Assistant	GA	12	100%	12.00	$18,000	$18,000.00	$99	0.55%	0	$0	$99	$18,099
TBN, Graduate Research Assistant	GA	12	100%	12.00	$18,000	$18,000.00	$99	0.55%	0	$0	$99	$18,099
TOTAL PERSONNEL COSTS:												**$390,081**
CONSULTANT COSTS:												
TOTAL CONSULTANT COSTS:												**$0**
EQUIPMENT:												
TOTAL EQUIPMENT COSTS:												**$0**
SUPPLIES:												
Project-specific office/computer supplies												$1,500
Armbands (50 @ $200)												$10,000
TOTAL SUPPLIES COSTS:												**$11,500**
TRAVEL EXPENSES:												
Travel to professional meetings												$15,000
TOTAL TRAVEL EXPENSES:												**$15,000**
OTHER EXPENSES:												
Lab costs (150 @ $45)												$6,750
Publishing Costs												$15,000
Printing												$8,500
GA tuition												$29,689
Incentives (150 @ $400)												$60,000
24-hour dietary recalls (150 at $300)												$45,000
TOTAL OTHER EXPENSES:												**$164,939**
TOTAL DIRECT COSTS FOR YEAR 03												**$581,520**
USC INDIRECT COSTS FOR YEAR 03												**$58,152**
TOTAL COSTS FOR YEAR 03												**$639,672**

April 25, 2014

BUDGET JUSTIFICATION

Energy Balance Study

Personnel

The extensive set of measures and multiple follow-up measurement periods throughout the study will require significant time and effort by study personnel. A large study staff will be needed during 2015 to continue follow-up visits with the 150 participants involved for an additional year. During the additional year of follow-up, we will conduct laboratory measures and collect energy intake (24-hour recalls) and energy expenditure (armbands, basal metabolic rate) data, and considerable effort will be required to maintain contact and insure good adherence to the study protocol.

Dr. Steven Blair, PI (5%) has expertise in conducting large-scale prospective studies and randomized trials, and extensive background in physical activity/fitness research in areas related to overweight and obesity. Dr. Blair has used the armband to measure energy expenditure in previous studies.

Dr. Greg Hand, co-PI (12%) has expertise in all laboratory measures being conducted in this study, which include body fat measurement (DXA), physiological assessments (i.e. blood draws for lipid and glucose analysis), waist circumference and basal metabolic rate.

Dr. James Hebert, Investigator (2%) has expertise in dietary intake assessment and has used the 24-hour recall in a number of his studies.

Dr. Tom Hurley, Investigator (10%) will oversee conducting the 24-hour recalls at the USC Cancer Prevention and Control Center. He has supervised work in this area for over 125,000 dietary recalls in various studies funded by the National Cancer Institute. He also has expertise in analyzing the dietary data.

A number of individuals, including the Project Manager, Retention Coordinator, Data Manager, Lab Manager, Lab Technicians and Graduate Research Assistants will be hired to conduct the daily operations of the project.

The **Project Manager** will manage the day-to-day aspects of this study and will coordinate laboratory visits and energy intake and expenditure assessments. He/she will meet regularly with the investigators and will supervise the work of the other project staff members.

Retaining participants for an additional one-year study period will be crucial for the success of this project. The **Retention Coordinator** will be responsible for executing the retention plan to ensure participants return for follow-up visits.

The **Data Manager**, working with Dr. Hurley, will be responsible for cleaning, storing

and ensuring the security of the data. Study data will be collected from several measures: survey data (Project Manager), dietary recall data (USC Nutrition Center) and laboratory measures (USC laboratory). The Data Manager will coordinate the data from all of these sources and develop datasets that are clean and properly formatted.

The **Laboratory Manager**, working closely with the Project Manager, will supervise the Laboratory Technicians and Graduate Assistants to perform measurements and train participants on how to use armbands and adhere to study methods. He / She will also be responsible for maintaining all lab supplies and equipment.

The **Laboratory Technicians** will be responsible for collecting all laboratory measures (DXA, blood draws, DLW, fitness, basal metabolic rate, etc). The large sample size and multiple study visits will require multiple technicians to be available.

The **Graduate Research Assistants** will assist the Project Manager, Project Coordinator, Retention Coordinator, Laboratory Manager and Laboratory Technicians with a wide variety of research and administrative tasks.

Supplies

Previous energy balance studies have relied on self-report measures to assess energy intake and energy expenditure, and many of these approaches are not accurate or precise enough to get a valid assessment of energy balance. A major purpose of this study is to obtain the most accurate and precise measures of body fat, energy intake, and energy expenditure. Therefore, it is important that the best measures available are used in this study.

All participants currently use SenseWearArmbands, which automatically monitor energy expenditure and physical activity, for 10 days on a quarterly basis to measure energy expenditure. The armbands have been shown in a number of validation studies to provide an accurate assessment of energy expenditure. We anticipate that several armbands may need to be replaced.

Project-specific office and computer supplies will include shirts that staff will wear during recruitment and data collection activities, data storage supplies and other project supplies.

Travel

In addition, travel funds for the PI and investigators to present the study results at scientific meetings are included.

Other Costs

Laboratory costs include the cost to draw, process and store blood, to conduct fitness assessments, and to test basal metabolic rate. The Clinical Exercise Research Laboratory at USC has a DXA machine, and there will be no equipment costs to obtain DXA data. Technicians to perform these tests are included in the budget.

Printing costs will include retention materials, project letterhead and envelopes, and signage.

Graduate assistant tuition is required by the University when graduate students are included in a research study.

Incentives – As previously mentioned, retaining participants will be very important in this study. In order to encourage ongoing participation in the study, participants will receive a cash incentive after each laboratory and/or energy expenditure and intake assessment period. Participants will receive a total of $400 for continuing in the study for an additional year.

Random 24-hour dietary recalls are the gold standard for assessing dietary intake. Three, random 24-hour dietary recalls will be conducted on all participants at baseline and on a quarterly basis (3 recalls x 2 measurement periods = 6 total recalls) by the Diet Assessment Research Unit of the University of South Carolina Cancer Prevention and Control Center. Three assessments per quarter will provide an accurate assessment of each participant's dietary habits. The Center will collect the data, process it, and analyze it. The Center has provided 24-hour dietary recall services for a number of large scale nutrition studies.

Publication costs for abstracts and manuscripts are requested.