From: Neal, Lisa (NIH/NICHD) [E]
Sent: 5 Mar 2014 14:36:56 -0500
To: Bruff, Susan (NIH/OD) [E];Avery, Jessica (NIH/OD) [C];Marner, Juanita (NIH/OD) [E];Hill, Ronna (NIH/OD) [C];Groesch, Mary (NIH/OD) [E]
Cc: Plummer, Mary (NIH/NICHD) [E]
Subject: 2014 NSABB Membership Status and Nomination Slate
Attachments: NSABB Membership Status.pdf

Good afternoon,

Attached is an outline of the current membership status and the nomination candidates for the 2014 nomination slate. Please review the attachment and let me know if there are any changes that need to be done.
I will be discussing with the OFACP Specialist tomorrow as to how we should proceed with the nomination slate reports for submission to the Secretary, DHHS, due to the large amount of candidates, and the need to balance the rotation of the committee membership.

Candidate - Dr. Hammarskjold's justification narrative (b)(5) (b)(5) Please submit the justification by Friday.

I am planning on (b)(6) and would like to get the slate moving before my absence.

Thanks and please let me know if you have any questions.

Lisa

Lisa Neal
Senior Committee Management Specialist
Office of Committee Management
Eunice Kennedy Shriver
National Institute of Child Health
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Bethesda, Maryland 20892
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Fax: 301-480-2115

2014 NSABB Membership Status

Current Members and Term Dates

6/2005-6/2008
Franz
Gordon **
Levy **
Osterholm **
Roth **

6/2005 – 6/2009
Cassdevall **
Imperiale **
Relman **
Lemon
Lumpkin **

6/2008 – 6/2012
Berns
Fitch
Grant
Kanabrocki **
Miller
Stanley

6/2010-6/2014
Endy
Houston
Leach
Parkin
Wolf

Pending Member
Lapham 6/2012-6/2016

Nomination Slate Candidates, Term Dates and Replacements

6/2014 – 6/2018
Cameron – Lemon
Hammarskiold – Vacancy (Cohen)
Kadlec – Vacancy (Murch)
Koehler – Vacancy (Keim)
Layton – Osterholm
LeDuc – Levy
Lee – Roth
Macrina – Lumpkin
McDade - Relman
Morse – Vacancy (Sorensen)
Patterson – Imperiale
Resnick – Gordon
Woodland – Casadevall

Kanabrocki – membership in question: Reappointment (term date 2012-2016) or new appointment (term date 2014-2018)

** Members being replaced

From: Hill, Ronna (NIH/OD) [C]
Sent: 7 Mar 2014 09:45:33 -0500
To: Neal, Lisa (NIH/NICHD) [E];Groesch, Mary (NIH/OD) [E];Bruff, Susan (NIH/OD) [E]
Subject: RE: Membership count for the slate
Attachments: NSABB Member Composition_2014.docx

Hi, Lisa!

You had me going there for a while, and I've attached a copy of the next NSABB Committee composition. The reason you have 26 names as opposed to 25 is because you still have **David Franz** listed as a member – he's coming off the committee.

Ronna

From: Neal, Lisa (NIH/NICHD) [E]
Sent: Friday, March 07, 2014 9:37 AM
To: Groesch, Mary (NIH/OD) [E]; Bruff, Susan (NIH/OD) [E]
Cc: Hill, Ronna (NIH/OD) [C]
Subject: Membership count for the slate
Importance: High

Good morning Mary,

The membership count for the slate is over 25 members. The list below reflects what I currently have as the count of members/nominees. We need to remove one more current member. Please let me know which one is to be removed today.

(b)(5)

1. Stanley –Chair
2. Berns
3. Endy
4. Fitch
5. Franz
6. Grant
7. Houston
8. Leach
9. Miller
10. Parkin
11. Wolf
12. Lapham – pending

Nominees
13. Cameron-Lemon
14. Hammarskjold-vacancy
15. Kadlec-vacancy
16. Kanabrocki -Kanabrocki
17. Koehler-vacancy
18. Layton-Osterholm
19. LeDuc-Levy
20. Lee-Roth
21. Macrina-Lumpkin
22. McDade-Relman
23. Morse-vacancy
24. Patterson-Imperial
25. Resnick-Gordon
26. Woodland-Casadevall

Please let me know if you have any questions.

Lisa

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NSABB Voting Members (2014)

	VOTING MEMBER	EXPERTISE	COMMENTS
	CURRENT MEMBERS		
1	**Samuel Stanley, Jr., MD**	Academia/Chair	
2	**Drew Endy, PhD**	Molec Biol/Genomics	
3	**Clifford Houston, PhD**	Microbiology (bacteriol)	
4	**Jan Leach**	Food Prod./Plant Health	
5	**Rebecca T. Parkin, PhD**	Risk Communication	
6	**Susan M. Wolf, JD**	Bioethics/Law	
7	**Kenneth I. Berns, MD, PhD**	Microbiol (virology)	To be replaced next slate development
8	**J. Patrick Fitch, PhD**	National Security	To be replaced next slate development
9	**Christine Grant, JD**	Industry/Law	To be replaced next slate development
10	**Jeffery F. Miller, PhD**	Molecular Biology	To be replaced next slate development
	IN-COMING MEMBERS		
11	I Gary Resnick, PhD	Biodefense	Replacing Gen. John Gordon
12	Robert P. Kadlec, PhD	Biosecurity	Replacing Randall Murch, PhD
13	James W. LeDuc, PhD	Clinical ID/Diagnosis	Replacing S. Levy, MD/D. Franz, DVM
14	David L. Woodland, PhD	Immunology	Replacing Arturo Casadevall, MD
15	Joseph Kanabrocki, PhD	Lab Biosafety	Replacing Murray Cohen, PhD
16	Theresa M. Koehler, PhD	Microbiology (bacteriol)	Replacing Paul Keim, PhD
17	Craig E. Cameron, PhD	Microbiology (virology)	Replacing Stanley Lemon, MD
18	Jean L. Patterson, PhD	Microbiology (virology)	Replacing Michael Imperiale, PhD
19	Marcelle C. Layton, MD	Molec Biol/Genomics	Replacing Michael Osterholm, PhD **(and)** John R. Lumpkin, MD
20	Gardiner Lapham, RN	Public Perspective	Replacing Susan Ehrlich, JD
21	Marie-Louise Hammarskjöld, MD, PhD	RAC Liason	Replacing Joseph Kanabrocki, PhD
22	Francis L. Macrina, PhD	Responsible Conduct	New Expertise
23	Margie Lee, DVM, PhD	Veterinary Medicine	Replacing James A. Roth, PhD
24	Joseph McDade, PhD	Clinical ID/Diagnosis/IBC	Replacing David Relman, MD
25	Stephen S. Morse, PhD	Pub Health/Epidemiol	Replacing Andrew Sorensen, PhD

From: Neal, Lisa (NIH/NICHD) [E]
Sent: 7 Mar 2014 10:49:35 -0500
To: Hill, Ronna (NIH/OD) [C];Groesch, Mary (NIH/OD) [E];Bruff, Susan (NIH/OD) [E]
Subject: RE: Membership count for the slate

That's not a problem. This slate is complicated and to submit it with members listed on the roster with term dates that go back as 2005 will bring attention to the NSABB. I have been instructed not to list the members going off the committee on the slate reports. As it is, the nominees will be listed as replacing vacancies. The NSABB is required to submit annual slates which would allow members to rotate of the committee in a reasonable time. Because this has not been done, we are not listing the replacements on the slate.

I need to respond back to Dr. Franz as soon as possible. Please concur or advise.

The slate will show 11 current members serving and 1 pending, in addition to the 13 nominees. Once the slate is approve and the nominees are cleared, the committee will have 25 members. At this time and until then, the committee can still function with the 21 current members.

Current:

1.Stanley – Chair
2.Berns
3.Endy
4.Fitch
5. Grant
6. Houston
7. Leach
8. Miller
9. Parkin
10. Wolf
11. Lapham – pending

Nominees:

12. Cameron-Lemon
13. Hammarskjold-vacancy
14. Kadlec-vacancy
15. Kanabrocki -Kanabrocki
16. Koehler-vacancy
17. Layton-Osterholm
18. LeDuc-Levy
19. Lee-Roth
20. Macrina-Lumpkin
21. McDade-Relman
22. Morse-vacancy
23. Patterson-Imperial
24. Resnick-Gordon
25. Woodland-Casadevall

Please let me know if you have any questions.

Lisa

From: Hill, Ronna (NIH/OD) [C]
Sent: Friday, March 07, 2014 10:19 AM
To: Neal, Lisa (NIH/NICHD) [E]; Groesch, Mary (NIH/OD) [E]; Bruff, Susan (NIH/OD) [E]
Subject: RE: Membership count for the slate

Lisa:

If you end Dr. Franz's membership today, there will only be 21 current NSABB members. Dr. LeDuc is the replacement for both Stuart Levy and David Franz.

Ronna

From: Neal, Lisa (NIH/NICHD) [E]
Sent: Friday, March 07, 2014 10:16 AM
To: Hill, Ronna (NIH/OD) [C]; Groesch, Mary (NIH/OD) [E]; Bruff, Susan (NIH/OD) [E]
Subject: RE: Membership count for the slate

Thanks for the info.

Franz is not listed on any of the membership nominations forms with a replacement. With that said, I will end his membership as of today. I cannot put the slate forward with 26 members/nominees listed.

(b)(5)

As of today and until the nominees are in place, the following individuals are serving as voting members with the exception of Dr. Lapham:

1.Stanley – Chair
2.Berns
3.Endy
4.Fitch
5. Grant
6. Houston
7. Leach
8. Miller
9. Parkin
10. Wolf

Members serving until the nominees for the 2014 slate are in place:

11. Gordon
12. Osterholm
13. Levy
14. Roth

15. Casadevall
16. Imperiale
17. Relman
18. Lumpkin
19. Lemon
20. Kanabrocki
21. Lapham – Pending

Please let me know if you have any questions.

Lisa

From: Hill, Ronna (NIH/OD) [C]
Sent: Friday, March 07, 2014 9:46 AM
To: Neal, Lisa (NIH/NICHD) [E]; Groesch, Mary (NIH/OD) [E]; Bruff, Susan (NIH/OD) [E]
Subject: RE: Membership count for the slate

Hi, Lisa!

You had me going there for a while, and I've attached a copy of the next NSABB Committee composition. The reason you have 26 names as opposed to 25 is because you still have **David Franz** listed as a member – he's coming off the committee.

Ronna

From: Neal, Lisa (NIH/NICHD) [E]
Sent: Friday, March 07, 2014 9:37 AM
To: Groesch, Mary (NIH/OD) [E]; Bruff, Susan (NIH/OD) [E]
Cc: Hill, Ronna (NIH/OD) [C]
Subject: Membership count for the slate
Importance: High

Good morning Mary,

The membership count for the slate is over 25 members. The list below reflects what I currently have as the count of members/nominees. We need to remove one more current member. Please let me know which one is to be removed today.

(b)(5)

1. Stanley –Chair

2. Berns
3. Endy
4. Fitch
~~5. Franz~~
6. Grant
7. Houston
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9. Miller
10. Parkin
11. Wolf
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Nominees
13. Cameron-Lemon
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17. Koehler-vacancy
18. Layton-Osterholm
19. LeDuc-Levy
20. Lee-Roth
21. Macrina-Lumpkin
22. McDade-Relman
23. Morse-vacancy
24. Patterson-Imperial
25. Resnick-Gordon
26. Woodland-Casadevall

Please let me know if you have any questions.

Lisa

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Tele: 301-435-6891
Fax: 301-480-2115

From: Neal, Lisa (NIH/NICHD) [E]
Sent: 1 Apr 2014 15:52:37 -0400
To: Bruff, Susan (NIH/OD) [E]
Cc: Groesch, Mary (NIH/OD) [E];Hill, Ronna (NIH/OD) [C];Plummer, Mary (NIH/NICHD) [E]
Subject: NSABB Slate Package Revised Pages
Attachments: 0617_001.pdf

Susan,

I made some minor revisions to several documents that are included in the FedEx package that you should receive tomorrow. Please use the attached revised documents to replace the incorrect documents.

Please let me know if you have any questions.

Lisa

Lisa Neal
Senior Committee Management Specialist
Office of Committee Management
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IDENTIFICATION OF POTENTIAL ADVISORY COUNCIL OR PROGRAM ADVISORY COMMITTEE NOMINEES
NATIONAL INSTITUTES OF HEALTH
2014 NOMINATION SLATE

COMMITTEE NAME AND INSTITUTE/CENTER: **NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY, OFFICE OF THE DIRECTOR**

Date of Vacancies 6/14/2014
Number of Vacancies 14
Scientific Vacancies 14
Public Vacancies

POTENTIAL NOMINEES AND/OR EXPERTISE REQUIRED

VACANCY NUMBER	NAME	DEPT. NOMINEE (YES/NO)	EXPERTISE REQUIRED	AFFILIATION	SCIENTIFIC/PUBLIC VACANCY	GENDER/MINORITY INFORMATION	OS APPROVAL (YES/NO)
1	Cameron, Craig E., Ph.D.		Microbiology (virology)	Department of Biochemistry and Molecular Biology The Pennsylvania State University University Park, PA	Scientific	(b)(6)	
2	Hammarskjöld Marie-Louise, M.D., Ph.D.		Molecular Biology (RAC Liaison)	Myles. H. Center for AIDS and Human Retrovirus Research, Department of Microbiology, University of Virginia Health Sciences Center Charlottesville, VA	Scientific		
3	Kadlec, Robert P., M.D.		Biosecurity	RPK Consulting LLC, Alexandria, VA	Scientific		
4	Kanabrocki, Joseph A., Ph.D.		Lab Biosafety	Department of Microbiology, Biological Sciences Division, The University of Chicago, Chicago, IL	Scientific		
5	Koehler, Theresa M., Ph.D.		Microbiology (bacterial)	Department of Microbiology and Molecular Genetics, University of Texas, Houston Medical School, Houston, TX	Scientific		
6	Layton, Marcelle C., M.D.		Molecular Biology/Genomics	Bureau of Communicable Disease, New York City Department of Health and Mental Hygiene, New York, NY	Scientific		
7	LeDuc, James W., Ph.D.		Clinical ID/Diagnosis	Galveston National Laboratory, University of Texas Medical Branch, Galveston, TX	Scientific		

8	Lee, Margie D., Ph.D.		Veterinary Medicine	Department of Population Health, Center for Food Safety, The University of Georgia, Athens, GA	Scientific	(b)(6)	
9	Macrina, Francis L., Ph.D.		Molecular Pathogenesis of Infectious Diseases	Office of Research, Virginia Commonwealth University, Richmond, VA	Scientific		
10	McDade, Joseph E., Ph.D.		Clinical ID/Diagnosis/IBC	Scientist-in-Residency and Adjunct Faculty Member, School of Mathematical and Natural Sciences, Berry College Mt. Berry, GA	Scientific		
11	Morse, Stephen S., Ph.D.		Public Health/Epidemiology	Mailman School of Public Health, Allan Rosenfield Building, Columbia University, New York, NY	Scientific		
12	Patterson, Jean L., Ph.D.		Microbiology (virology)	Department of Virology and Immunology, Southwest Foundation for Biomedical Research, San Antonio, TX	Scientific		
13	Resnick, I. Gary, Ph.D.		Biodefense	Los Alamos National Laboratory Los Alamos, NM	Scientific		
14	Woodland, David L., Ph.D.		Immunology	Trudeau Institute, Inc. Saranac Lake, NY	Scientific		

OS REPLACEMENT NOMINEES

REPLACEMENT NOMINEE	AFFILIATION	NIH NOMINEE BEING REPLACED	COMMENTS

OS Signature _____ Title _____ Date _____

MEMBERSHIP WAIVERS (if required)

Included is a waiver of Department policy is for James W. LeDuc, PhD, MSPH, who will be serving on the NSABB at the same time with another individual, Clifford W. Houston, PhD, from the same institution and department.

PROFESSIONAL AREA BREAKDOWN

National Science Advisory Board for Biosecurity
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Authorized Positions: 25 Ex Officio Positions: 18

VACANCY (2)

NAME	TERM DATES	EXPERTISE	FED	SCI	PUB	GEOG DIST	MIN	FEM
*Berns	06/15/2008 06/14/2012	Microbiology (viral)		X		FL	(b)(6)	
*Fitch	06/15/2008 06/14/2012	Biodefense, National Security, Industry Perspective		X		MD		
*Grant	06/15/2008 06/14/2012	Law, Public Health, Industry Perspective		X		NJ		
*Miller	06/15/2008 06/14/2012	Microbiology (bacterial)		X		CA		
*Stanley	06/15/2008 06/14/2012	Intestinal Protozoa, Cryptospor DIA, Giardia, Internal Medicine		X		NY		
Endy	06/15/2010 06/14/2014	Bioengineering		X		CA		
Houston	06/15/2010 06/14/2014	Bacteriology, Aeromonas, Gram Negative Toxins, Phagocytes		X		TX		
Leach	06/15/2010 06/14/2014	Plant Pathology, Microbiology, Genetics		X		CO		

'PROFESSIONAL AREA BREAKDOWN

National Science Advisory Board for Biosecurity
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

NAME	TERM DATES	EXPERTISE	FED	SCI	PUB	GEOG DIST	MIN	FEM
Parkin	06/15/2010 06/14/2014	Microbial Pathogen Risk, Risk Communication, Environmental Epidemiology		X		DC		
Wolf	06/15/2010 06/14/2014	Health Law, Bioethics, Law and Medicine, Law and Science		X		MN		
Pending Nominee:								
Lapham	Immediately 06/14/2016	Nursing, International Health Policy, Community Health Nutrition			X	DC		
Proposed Nominees:								
Cameron	06/15/2014 06/14/2018	Microbiology (virology)		X		PA		
Hammarskjold	06/15/2014 06/14/2018	Molecular Biology (RAC Liaison)		X		VA		
Kadlec	06/15/2014 06/14/2018	Biosecurity		X		VA		
Kanabrocki	06/15/2014 06/14/2018	Biosecurity		X		IL		
Koehler	06/15/2014 06/14/2018	Microbiology (bacterial)		X		TX		
Layton	06/15/2014 06/14/2018	Molecular Biology, Genomics		X		NY		
LeDuc	06/15/2014 06/14/2018	Clinical ID/Diagnosis		X		TX		

(b)(6)

PROFESSIONAL AREA BREAKDOWN

National Science Advisory Board for Biosecurity
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH

NAME	TERM DATES	EXPERTISE	FED	SCI	PUB	GEOG DIST	MIN	FEM
Lee	06/15/2014 06/14/2018	Veterinary Medicine		X		GA		
Macrina	06/15/2014 06/14/2018	Molecular Pathogenesis of Infectious Diseases		X		VA		
McDade	06/15/2014 06/14/2018	Clinical ID/Diagnosis/IBC		X		GA		
Morse	06/15/2014 06/14/2018	Public Health/Epidemiology		X		NY		
Patterson	06/15/2014 06/14/2018	Microbiology (virology)		X		TX		
Resnick	06/15/2014 06/14/2018	Biodefense		X		NM		
Woodland	06/15/2014 06/14/2018	Immunology		X		NY		

(b)(6)

Vacancy (1)

Chair: Stanley, Samuel

*Member Administratively Extended

From: Fennington, Kelly (NIH/OD) [E]
Sent: 8 Apr 2014 11:59:38 -0400
To: Groesch, Mary (NIH/OD) [E]
Subject: RE: need bullets for AMy's catch up with Larry

Thanks Mary. I took the last NSABB bullet out because Amy has the slate but she has to sign off.

From: Groesch, Mary (NIH/OD) [E]
Sent: Tuesday, April 08, 2014 11:35 AM
To: Fennington, Kelly (NIH/OD) [E]
Subject: RE: need bullets for AMy's catch up with Larry

iDURC Policy

- The iDURC policy is to be finalized this Friday for on-line publication approximately April 22. We have drafted a note for you to send to the Ferrets in the next week or so updating them on the iDURC policy. Given the timeframe for the policy, this should be good timing.
- (b)(5)

NSABB

- The NSABB charter has been renewed. Last week we received some queries from a *Science* reporter and some NSABB members the reporter had contacted about whether the charter was going to be renewed. The reporter claimed that he had heard a rumor that the charter would not be renewed. Since we don't know how many NSABB members the reported shared that rumor with, we will be sure to tell the members that the charter has been renewed.
- We need to discuss new NSABB topics/activities. Possibilities include providing input on (b)(5)

- NSABB slate is moving, but was still in NIH hands as of late last week. This is the slate that will replace the last of the original NSABB members. Could you check that it is being expedited? If it is far enough along in the Fall, we would like to be able to include the new members on that slate as ad hocs when we convene the NSABB to review DURC training materials.

From: Fennington, Kelly (NIH/OD) [E]
Sent: Tuesday, April 08, 2014 8:46 AM
To: Groesch, Mary (NIH/OD) [E]
Subject: need bullets for AMy's catch up with Larry

Thanks!

From: Groesch, Mary (NIH/OD) [E]
Sent: 14 Jul 2014 00:06:19 +0000
To: 'Arturo Casadevall';'David Franz';'David Relman';'General John Gordon';'James Roth';'John Lumpkin';'Michael Imperiale';'Michael Osterholm';'Paul Keim';'Stanley Lemon';'Stuart Levy'
Cc: Patterson, Amy (NIH/NHLBI) [E];Tabak, Lawrence (NIH/OD) [E];Viggiani, Christopher (NIH/OD) [E];Stanley, Samuel (NIH);'Christopher Logan';'Dannie Smith';'Dawne Buhrow';'Deborah Martin';'Maria Ortiz';'Mary Marrone-Polo';Shipp, Allan (NIH/NHLBI) [E];Fennington, Kelly (NIH/OD) [E]
Subject: NSABB Membership and Next Meeting

Dear Members of the NSABB,

Greetings! I hope that all is well with each of you. My purpose in writing to you—the last of the original NSABB members—is several fold. First, I wanted to tell you that a new slate of NSABB members has been approved as your replacements, and thus your service on the board is ending. Since you have all been so gracious as to extend your service for several years beyond your initial term, this may come as welcome news! But I can assure you, on behalf of the NSABB Chair and the US Government, that you will be missed and that your hard work, dedication, and leadership in the area of dual use research are greatly appreciated. I know that I speak for my colleagues across the government in saying that NSABB advice and recommendations over the years have greatly informed discussions of DURC issues and have contributed substantively to the development of federal DURC oversight policies. Second, I wanted to take a moment to update you on DURC-related policy developments. Third, I welcome you to attend in an *ad hoc* capacity the next meeting of the NSABB, where we will recognize your service on the Board.

As you know, one of the priority activities of the U.S. Government has been the development of policy for the oversight of life sciences dual use research of concern (DURC). In fact, one of the topics we discussed during our last meeting was gain-of-function influenza studies, and what the appropriate focus should be for special review. After consultation with the NSABB and international workshop participants, which also included some NSABB members, HHS finalized in February 2013, the *HHS Framework*for guiding funding decisions about certain types of gain-of-function studies that involve HPAI H5N1 viruses. Proposals for experiments that may generate HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets now receive a multidisciplinary Department-level review that may result in (1) additional risk mitigation measures being required or (2) in HHS not funding certain studies/experiments at all. You may also be aware that a group of influenza researchers stated their intention to perform gain-of-function experiments with LPAI H7N9 strains, which have infected humans in China. In August of last year, we expanded the HHS Framework to include studies that are reasonably anticipated to generate H7N9 viruses with increased transmissibility between mammals by respiratory droplets. Also, CDC has issued additional risk assessment and biosafety level recommendations for working with H7N9 viruses. The aim is to focus special oversight efforts on experiments of concern while allowing routine characterization and other fundamental research to proceed rapidly and safely. The HHS Framework is expected to evolve and as such is periodically revisited in light of scientific and policy developments.

You may recall that the proposed *USG Policy for Institutional Oversight of Life Sciences DURC* was issued for public comment last year. A number of NSABB members contributed very thoughtful comments on the proposed policy, which describes institutional responsibilities for mitigating risks associated with DURC. The institutional DURC policy is intended to complement the DURC Policy issued in March 2012, which focuses on Federal responsibilities for DURC oversight. The USG has carefully considered the

public comments on the proposed policy for the institutional oversight of DURC and will be issuing a final policy in the very near future. We will update the Board when the Institutional Policy is about to be issued, and will provide information for a special briefing of the NSABB on the new policy.

Once the new Institutional policy is released, we anticipate calling on the NSABB to advise on the educational materials and implementation resources that institutions will need to identify DURC, employ risk mitigation measures, and comply with the new policy's requirements. Federal staff have begun developing an array of tools, guidances, and resource materials for these purposes and it would be very helpful to receive NSABB input on them.

We would like to convene the NSABB in the Fall to discuss these issues. We will also recognize your service and introduce the new members to the Board. We also would welcome your attendance at this meeting in a non-voting, *ad hoc* capacity both to contribute to our discussions and to say farewell.

Toward this end, in consultation with the NSABB Chair, we have identified the following dates as potential meeting times. Would you please indicate ASAP your availability for a one day meeting in Bethesda, MD for each of the following dates:

Tuesday, Sept. 30
Wednesday, Oct. 1
Thursday, Oct. 2
Tuesday, Oct. 7
Thursday, Oct. 9
Thursday, Oct. 16
Wednesday, Oct. 22
Thursday, Oct. 23
Tuesday, Oct. 28
Wednesday, Oct. 29

If these dates do not work for the majority of members, we will propose some additional ones in November. Thank you again for your service on the Board.

Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB

Mary E. Groesch, Ph.D.
Senior Advisor for Science Policy
Office of Science Policy
Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785 (direct)
301-496-9838 (OSP)
301-496-9839 (fax)

From: Groesch, Mary (NIH/OD) [E]
Sent: 14 Jul 2014 13:55:35 +0000
To: 'Roth, James A [V MPM]'
Subject: RE: NSABB Membership and Next Meeting

Thanks for the quick reply Jim!

From: Roth, James A [V MPM] [mailto:jaroth@iastate.edu]
Sent: Sunday, July 13, 2014 11:11 PM
To: Groesch, Mary (NIH/OD) [E]
Subject: RE: NSABB Membership and Next Meeting

Hi Mary,
Thanks for the update. Of the dates listed, I could be available on October 2, 23, 28, and 29.
Best regards,
Jim

James A. Roth, DVM, PhD, DACVM
Clarence Hartley Covault Distinguished Professor
Director, Center for Food Security and Public Health
Executive Director, Institute for International Cooperation in Animal Biologics
College of Veterinary Medicine
Iowa State University
Ames, Iowa 50011
Phone: 515-294-8459
Fax: 515-294-8259
email: jaroth@iastate.edu
www.cfsph.iastate.edu

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Sunday, July 13, 2014 7:06 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; Roth, James A [V MPM]; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Viggiani, Christopher (NIH/OD) [E]; Stanley, Samuel (NIH); 'Christopher Logan'; 'Dannie Smith'; Buhrow, Dawne [CFSPH]; 'Deborah Martin'; 'Maria Ortiz'; 'Mary Marrone-Polo'; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]
Subject: NSABB Membership and Next Meeting

Dear Members of the NSABB,

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take a moment to update you on DURC-related policy developments. Third, I welcome you to attend in an *ad hoc* capacity the next meeting of the NSABB, where we will recognize your service on the Board.

As you know, one of the priority activities of the U.S. Government has been the development of policy for the oversight of life sciences dual use research of concern (DURC). In fact, one of the topics we discussed during our last meeting was gain-of-function influenza studies, and what the appropriate focus should be for special review. After consultation with the NSABB and international workshop participants, which also included some NSABB members, HHS finalized in February 2013, the *HHS Framework*for guiding funding decisions about certain types of gain-of-function studies that involve HPAI H5N1 viruses. Proposals for experiments that may generate HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets now receive a multidisciplinary Department-level review that may result in (1) additional risk mitigation measures being required or (2) in HHS not funding certain studies/experiments at all. You may also be aware that a group of influenza researchers stated their intention to perform gain-of-function experiments with LPAI H7N9 strains, which have infected humans in China. In August of last year, we expanded the HHS Framework to include studies that are reasonably anticipated to generate H7N9 viruses with increased transmissibility between mammals by respiratory droplets. Also, CDC has issued additional risk assessment and biosafety level recommendations for working with H7N9 viruses. The aim is to focus special oversight efforts on experiments of concern while allowing routine characterization and other fundamental research to proceed rapidly and safely. The HHS Framework is expected to evolve and as such is periodically revisited in light of scientific and policy developments.

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Thursday, Oct. 2

Tuesday, Oct. 7
Thursday, Oct. 9
Thursday, Oct. 16
Wednesday, Oct. 22
Thursday, Oct. 23
Tuesday, Oct. 28
Wednesday, Oct. 29

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Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB

Mary E. Groesch, Ph.D.
Senior Advisor for Science Policy
Office of Science Policy
Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785 (direct)
301-496-9838 (OSP)
301-496-9839 (fax)

From: Groesch, Mary (NIH/OD) [E]
Sent: 14 Jul 2014 13:55:59 +0000
To: 'Lemon, Stanley M.'
Subject: RE: NSABB Membership and Next Meeting

Thanks for the quick reply, Stan!

From: Lemon, Stanley M. [mailto:smlemon@med.unc.edu]
Sent: Monday, July 14, 2014 6:31 AM
To: Groesch, Mary (NIH/OD) [E]
Subject: Re: NSABB Membership and Next Meeting

Hi Mary,

Congratulations on successfully repopulating the NSABB! My availability for a meeting this fall is as follows. All of the dates currently look OK except for the two highlighted – Oct 23 and 29.

Stan

Tuesday, Sept. 30
Wednesday, Oct. 1
Thursday, Oct. 2
Tuesday, Oct. 7
Thursday, Oct. 9
Thursday, Oct. 16
Wednesday, Oct. 22
Thursday, Oct. 23 - NO
Tuesday, Oct. 28
Wednesday, Oct. 29 - NO

From: <Groesch>, Mary Groesch <GroeschM@OD1TM1.OD.NIH.gov>
Date: Sunday, July 13, 2014 8:06 PM
To: Arturo Casadevall <casadeva@aecom.yu.edu>, 'David Franz' <(b)(6)>, "Relman, David A." <relman@stanford.edu>, 'General John Gordon' <(b)(6)>, 'James Roth' <jaroth@iastate.edu>, 'John Lumpkin' <jlumpki@rwjf.org>, 'Michael Imperiale' <imperial@umich.edu>, Michael Osterholm <mto@umn.edu>, "Keim, Paul" <PKeim@tgen.org>, Stan Lemon <smlemon@med.unc.edu>, 'Stuart Levy' <stuart.levy@tufts.edu>
Cc: "Patterson, Amy (NIH/OD) [E]" <PattersA@OD.NIH.GOV>, "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>, "Viggiani, Christopher (NIH/OD) [E]" <christopher.viggiani@nih.gov>, "Stanley, Samuel (NIH)" <Samuel.Stanley@stonybrook.edu>, 'Christopher Logan' <christopher.logan@tufts.edu>, 'Dannie Smith' <(b)(6)>, 'Dawne Buhrow' <dbuhrow@iastate.edu>, 'Deborah Martin' <deborah.martin@nau.edu>, 'Maria Ortiz' <mtortiz@aecom.yu.edu>, 'Mary Marrone-Polo' <mmarron@rwjf.org>, "Shipp, Allan (NIH/OD) [E]" <ShippA@OD.NIH.GOV>, "Fennington, Kelly (NIH/OD) [E]" <FenningK@OD.NIH.GOV>
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Regards,

Mary Groesch, Ph.D.
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Mary E. Groesch, Ph.D.
Senior Advisor for Science Policy
Office of Science Policy
Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785 (direct)
301-496-9838 (OSP)
301-496-9839 (fax)

From: Marrone-Polo, Mary
Sent: 14 Jul 2014 13:40:39 +0000
To: Groesch, Mary (NIH/NHLBI) [E]
Subject: NSABB Membership and Next Meeting

Availability Reply on behalf of: John R. Lumpkin, MD, MPH:

Tuesday, Sept. 30 – N/A
Wednesday, Oct. 1 – N/A
Thursday, Oct. 2 – Best Date
Tuesday, Oct. 7 – N/A
Thursday, Oct. 9 – N/A
Thursday, Oct. 16 – Might be in Washington, DC, but no guarantee he could attend a NSABB meeting.
Wednesday, Oct. 22 – Good Date
Thursday, Oct. 23 – Might work.
Tuesday, Oct. 28 – N/A
Wednesday, Oct. 29 – N/A

Mary

.....

Mary R. Marrone-Polo
Executive Assistant to John R. Lumpkin, MD, MPH,
Sr. Vice President & Director, Targeted Teams and
Pamela S. Dickson, Associate Vice President, Targeted Teams

Robert Wood Johnson Foundation
PO Box 2316 – M/S #2400k
Route 1 and College Road East
Princeton, NJ 08543-2316
Phone: 609-627-5915 Fax: 609-514-5486
www.rwjf.org

Building a Culture of Health in America

.....

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Sunday, July 13, 2014 8:06 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; Lumpkin, John; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Viggiani, Christopher (NIH/OD) [E]; Stanley, Samuel (NIH); 'Christopher Logan'; 'Dannie Smith'; 'Dawne Buhrow'; 'Deborah Martin'; 'Maria Ortiz'; Marrone-Polo, Mary; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]
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301-496-9838 (OSP)
301-496-9839 (fax)

From: Shipp, Allan (NIH/OD) [E]
Sent: 14 Jul 2014 14:36:08 -0400
To: Patterson, Amy (NIH/OD) [E];Groesch, Mary (NIH/OD) [E];Viggiani, Christopher (NIH/OD) [E]
Subject: Tweet about the NSABB

Jocelyn Kaiser called to say that someone had tweeted about getting "the pink slip" from the NIH regarding his NSABB service. I went poking around and found that it was Michael Imperiale:

https://twitter.com/search?q=nsabb&src=typd

It was also clear that Jocelyn had a copy of Mary's email in hand. She wanted to know why the NSABB was being reconstituted. I clarified on background that the NSABB was not being "reconstituted," but rather it is routine for all FACA committees to rotate off long-serving members, and that she could see from the NSABB charter itself that terms are time-limited. She may be interested in something quotable, so I told her to come to us through OCPL, if she went that route.

From: Groesch, Mary (NIH/OD) [E]
Sent: 14 Jul 2014 18:38:30 +0000
To: 'Deborah Anne Martin'
Subject: RE: NSABB Membership and Next Meeting

Thanks so much, especially for the quick reply!

From: Deborah Anne Martin [mailto:Deborah.Martin@nau.edu]
Sent: Monday, July 14, 2014 1:54 PM
To: Groesch, Mary (NIH/OD) [E]
Cc: Paul S Keim
Subject: RE: NSABB Membership and Next Meeting

Hi Mary,

Below I have listed Dr. Keim's possible availability for this meeting in Maryland.

Tuesday, Sept. 30 - unavailable
Wednesday, Oct. 1 - possible
Thursday, Oct. 2 - possible
Tuesday, Oct. 7 - unavailable
Thursday, Oct. 9 - unavailable
Thursday, Oct. 16 - possible
Wednesday, Oct. 22 - possible
Thursday, Oct. 23 - possible
Tuesday, Oct. 28 - open
Wednesday, Oct. 29 - possible

Please let me know if you have any questions on this.

Debbie

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Sunday, July 13, 2014 5:06 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Viggiani, Christopher (NIH/OD) [E]; Stanley, Samuel (NIH); 'Christopher Logan'; 'Dannie Smith'; 'Dawne Buhrow'; Deborah Anne Martin; 'Maria Ortiz'; 'Mary Marrone-Polo'; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]
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From: Patterson, Amy (NIH/OD) [E]
Sent: 14 Jul 2014 22:09:01 -0400
To: Shipp, Allan (NIH/NHLBI) [E];Groesch, Mary (NIH/NHLBI) [E]
Subject: Fw: ScienceInsider: U.S. biosafety panel to come out of hibernation with new members / 11 original members dismissed

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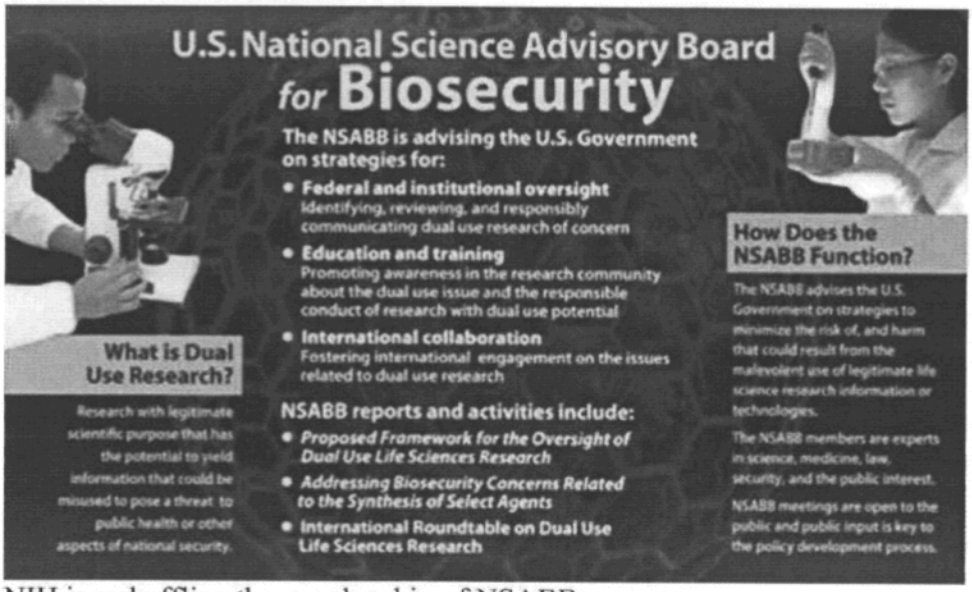
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Monday, July 14, 2014 10:01 PM Eastern Standard Time
To: Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Burklow, John (NIH/OD) [E]
Cc: Patterson, Amy (NIH/OD) [E]
Subject: FW: ScienceInsider: U.S. biosafety panel to come out of hibernation with new members / 11 original members dismissed

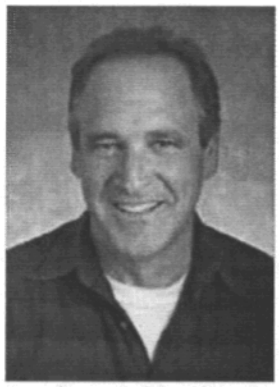
This is unbelievable – apparently the "original members" feel they are entitled to serve on this committee in perpetuity. And, we did respond – but I guess not in time for this "breaking news"...

***Science*Insider**



NIH is reshuffling the membership of NSABB.

U.S. biosafety panel to come out of hibernation with new members



Jon is a staff writer for *Science*.

By

Jon Cohen

14 July 2014 6:45 pm

On the heels of several mishaps involving deadly pathogens, U.S. officials are reconvening an expert advisory panel that hasn't met in nearly 2 years. But the government has also dismissed 11 of the original members of the 23-person panel, called the National Science Advisory Board for Biosecurity (NSABB).

"We had no inkling it was going to happen this way," says Paul Keim, a pathogen genomics researcher at Northern Arizona University in Flagstaff who formerly chaired NSABB and has been on the panel since it was formed in 2005. The 11 members learned they were being dismissed Sunday evening in an e-mail from the board's executive director, Mary Groesch, who works at the U.S. National Institutes of Health (NIH), NSABB's overseer. The e-mail prompted this tweet from NSABB member Michael Imperiale of the University of Michigan, Ann Arbor: "#NIH just gave remaining inaugural NSABB members pink sheets. Bizarre time to eliminate all institutional memory."

The e-mail, which *Science*Insider obtained, cheerily informs Imperiale, Keim, and the other original NSABB members that the board will be reconvening in the fall without them. "I wanted to tell you that a new slate of NSABB members has been approved as your replacements, and thus your service on the board is ending," Groesch wrote. "Since you have all been so gracious as to extend your service for several years beyond your initial term, this may come as welcome news!"

NSABB advises and guides the U.S. government about "dual use" research that involves biological agents that could be used as bioweapons. In 2011, it became embroiled in heated debates about "gain-of-function" experiments with the deadly avian influenza virus H5N1 that made it more transmissible in mammals. Last week, Tom Frieden, director of the U.S. Centers for Disease Control and Prevention, held an unusual press conference to discuss three separate, recent mistakes involving lab safety with smallpox, influenza, and anthrax. He said such breaches "should never happen."

Original board member Michael Osterholm, director of the Center for Infection Disease Research and Policy at the University of Minnesota, Twin Cities, said he had expected to serve until sometime in 2015. "I don't know why they do or don't do things at the NSABB," Osterholm told *Science*Insider. "I gave up some time ago trying to predict that." The board has 12 other members who apparently are continuing.

Board members are appointed for up to 4-year, overlapping terms that can be extended. NIH had not responded to a query from *Science*Insider as this item went to press.

NSABB last met in November 2012, and Osterholm said his last contact with NIH about the panel was in the spring of 2013. "We got one single e-mail saying NSABB had re-upped its charter," Osterholm says. "That's the only communication we had in 2 years at a time when the issues we've been confronting have been front and center. I don't understand it."

Arturo Casadevall of the Albert Einstein College of Medicine in The Bronx, New York, says he expected to be replaced, but not so abruptly. The real surprise, he says, "is that all the members who have been through the H5N1 debates have been replaced at the same time" and that the news came on a Sunday evening "right after a week of all these headlines." He adds that some of the remaining members "are very experienced."

Keim says the newly reconstituted NSABB has its work cut out for it. "I hope that the U.S. government effectively uses the NSABB to address the shortcomings associated with the three incidents," he says.

With reporting by Jocelyn Kaiser.

Posted in Biology, People & Events

From: Groesch, Mary (NIH/OD) [E]
Sent: 15 Jul 2014 12:05:40 +0000
To: 'Arturo Casadevall'
Subject: RE: NSABB Membership and Next Meeting

Thanks Arturo
M

From: Arturo Casadevall [mailto:arturo.casadevall@einstein.yu.edu]
Sent: Tuesday, July 15, 2014 7:14 AM
To: Groesch, Mary (NIH/OD) [E]
Subject: RE: NSABB Membership and Next Meeting

Dear Mary,
The only dates I can make it are:
Oct 1
Oct 2
Arturo

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Sunday, July 13, 2014 8:06 PM
To: Arturo Casadevall; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Viggiani, Christopher (NIH/OD) [E]; Stanley, Samuel (NIH); 'Christopher Logan'; 'Dannie Smith'; 'Dawne Buhrow'; 'Deborah Martin'; Maria T Ortiz; 'Mary Marrone-Polo'; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]
Subject: NSABB Membership and Next Meeting

Dear Members of the NSABB,

Greetings! I hope that all is well with each of you. My purpose in writing to you—the last of the original NSABB members—is several fold. First, I wanted to tell you that a new slate of NSABB members has been approved as your replacements, and thus your service on the board is ending. Since you have all been so gracious as to extend your service for several years beyond your initial term, this may come as welcome news! But I can assure you, on behalf of the NSABB Chair and the US Government, that you will be missed and that your hard work, dedication, and leadership in the area of dual use research are greatly appreciated. I know that I speak for my colleagues across the government in saying that NSABB advice and recommendations over the years have greatly informed discussions of DURC issues and have contributed substantively to the development of federal DURC oversight policies. Second, I wanted to take a moment to update you on DURC-related policy developments. Third, I welcome you to attend in an *ad hoc* capacity the next meeting of the NSABB, where we will recognize your service on the Board.

As you know, one of the priority activities of the U.S. Government has been the development of policy for the oversight of life sciences dual use research of concern (DURC). In fact, one of the topics we discussed during our last meeting was gain-of-function influenza studies, and what the appropriate focus should be for special review. After consultation with the NSABB and international workshop participants, which also included some NSABB members, HHS finalized in February 2013, the *HHS Framework*for guiding funding decisions about certain types of gain-of-function studies that involve HPAI H5N1 viruses. Proposals for experiments that may generate HPAI H5N1 viruses that are

transmissible among mammals by respiratory droplets now receive a multidisciplinary Department-level review that may result in (1) additional risk mitigation measures being required or (2) in HHS not funding certain studies/experiments at all. You may also be aware that a group of influenza researchers stated their intention to perform gain-of-function experiments with LPAI H7N9 strains, which have infected humans in China. In August of last year, we expanded the HHS Framework to include studies that are reasonably anticipated to generate H7N9 viruses with increased transmissibility between mammals by respiratory droplets. Also, CDC has issued additional risk assessment and biosafety level recommendations for working with H7N9 viruses. The aim is to focus special oversight efforts on experiments of concern while allowing routine characterization and other fundamental research to proceed rapidly and safely. The HHS Framework is expected to evolve and as such is periodically revisited in light of scientific and policy developments.

You may recall that the proposed *USG Policy for Institutional Oversight of Life Sciences DURC* was issued for public comment last year. A number of NSABB members contributed very thoughtful comments on the proposed policy, which describes institutional responsibilities for mitigating risks associated with DURC. The institutional DURC policy is intended to complement the DURC Policy issued in March 2012, which focuses on Federal responsibilities for DURC oversight. The USG has carefully considered the public comments on the proposed policy for the institutional oversight of DURC and will be issuing a final policy in the very near future. We will update the Board when the Institutional Policy is about to be issued, and will provide information for a special briefing of the NSABB on the new policy.

Once the new Institutional policy is released, we anticipate calling on the NSABB to advise on the educational materials and implementation resources that institutions will need to identify DURC, employ risk mitigation measures, and comply with the new policy's requirements. Federal staff have begun developing an array of tools, guidances, and resource materials for these purposes and it would be very helpful to receive NSABB input on them.

We would like to convene the NSABB in the Fall to discuss these issues. We will also recognize your service and introduce the new members to the Board. We also would welcome your attendance at this meeting in a non-voting, *ad hoc* capacity both to contribute to our discussions and to say farewell.

Toward this end, in consultation with the NSABB Chair, we have identified the following dates as potential meeting times. Would you please indicate ASAP your availability for a one day meeting in Bethesda, MD for each of the following dates:

Tuesday, Sept. 30
Wednesday, Oct. 1
Thursday, Oct. 2
Tuesday, Oct. 7
Thursday, Oct. 9
Thursday, Oct. 16
Wednesday, Oct. 22
Thursday, Oct. 23
Tuesday, Oct. 28
Wednesday, Oct. 29

If these dates do not work for the majority of members, we will propose some additional ones in November. Thank you again for your service on the Board.

Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB

Mary E. Groesch, Ph.D.
Senior Advisor for Science Policy
Office of Science Policy
Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785 (direct)
301-496-9838 (OSP)
301-496-9839 (fax)

From: Groesch, Mary (NIH/OD) [E]
Sent: 15 Jul 2014 17:21:34 +0000
To: Fennington, Kelly (NIH/OD) [E]
Subject: FW: AMy's catch up with Larry today!
Attachments: Catch Up Mtg with LT 071514.docx

Can you add this in please? Have to write up a telecon summary ASAP

Have heard back from 4 continuing members, 7 incoming members, 5 departing members. Almost all just provided availability. Two departing members said thanks for update (Roth), and congrats on successfully repopulating the NSABB (Lemon). New members haven't yet gotten the Secretary's invitation letter, but seem pleased to be invited

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From: Fennington, Kelly (NIH/OD) [E]
Sent: Tuesday, July 15, 2014 10:07 AM
To: Groesch, Mary (NIH/OD) [E]
Subject: AMy's catch up with Larry today!

HI Mary,

See attached meeting agenda for Amy's catchup with Larry today. Can you please fill in information for the last item – feedback from NSABB members re letter? And please add anything else you think Amy will want to mention.

Thanks,
Kelly

Kelly Fennington
Senior Health Policy Analyst
Office of Science Policy
Office of the Director

6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
(301) 496-9838
(301) 496-9839 FAX

Catch Up Meeting with Dr. Tabak
Tuesday, July 15, 2014

Meeting Agenda

1. **New Biosecurity and Biosafety Program**
    a. Timing of announcement
    b. Meeting with Larry and small team?
        i. Could we meet in Room 151?
    c. Move date
        i. First week of August?
    d. Storing of exhibit and outreach materials
        i. Any room in the basement?
    e. Equipment (computers, BB's, laptops)
    f. New AO

2. **AMR**
    a. CARB National Action Plan
    b. Executive Order
        i. Interagency Task Force
        ii. FACA Committee
    c. Executive Actions
        i. Current proposals include:
            1. AMR Prize
        ii. Final decisions pending
    d. Workshop
        i. Over 300 people registered (we have registered you)
        ii. Convened call with all session moderators to review format/logistics
            1. Moderators will be convening calls with session participants

3. **DURC**

(b)(5)

    b. NSABB
        i. Letters have been sent out to incoming/outgoing members regarding scheduling next meeting

1. Feedback???

From: Patterson, Amy (NIH/OD) [E]
Sent: 16 Jul 2014 13:38:07 -0400
To: Stanley, Samuel (NIH)
Cc: Shipp, Allan (NIH/OD) [E];Groesch, Mary (NIH/OD) [E]
Subject: Background
Attachments: Experts call for alternatives to 'gain-of-function' flu studies, NSABB FAQS 7 15 14.docx

Dear Sam,
You had asked about fielding questions regarding the NSABB, below are some talking points that we developed to address questions about the routine, partial turnover in membership. Also attached is a set of FAQs with more general background information on the Board just in case it comes in handy.
Amy

Q. Why was there turnover in the NSABB membership?

The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee, and its charter includes a term of membership for its members. It is routine for federal advisory committees to rotate their membership over time so that fresh and diverse perspectives can be brought to bear on the committee's deliberations. Typically, only a portion of the board is rotated off at a time, so that the NSABB has members with "institutional memory," as well as individuals with new perspectives. Under special circumstances, membership terms can be extended, though they cannot be extended indefinitely.

The terms of the individuals who received notification that their service on the NSABB had come to an end were the last among the original members to rotate off of the board. Their terms had already been extended while the government undertook a process of identifying qualified experts to come onto the board to replace them.

Q. Was the timing of the email to NSABB members in any way related to recent events in Federal labs?

There is no relationship between the reconvening of the NSABB and the recently reported events in Federal laboratories. The NSABB's primary charge is to advise the US government on matters related to dual use research of concern (DURC), not biosafety. The board members were contacted at this time because the US government anticipates convening the Board in the fall to advise on matters related to DURC, and it was necessary to coordinate their calendars.

Although the topics of DURC and biosafety are often conflated, they are indeed distinct. "DURC" is a reference to life sciences research that yields knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to national security and public safety. "Biosafety" references the laboratory practices and containment measures to prevent the contamination of laboratory personnel or the environment with hazardous biological agents.

Q. What do you think about gain-of-function influenza research?

There needs to be a dispassionate and balanced scientific debate about the merits and risks of this type of research. The NSABB was consulted previously on the development of an HHS

framework for evaluating the fundability of this type of research, as were the scientific community and public at large. In December 2012, HHS hosted an international meeting to review the risks and benefits of this research, as well as a draft of the framework process, which has since been finalized and implemented.

In the coming months, there will continue to be a broad-based dialogue about this topic.

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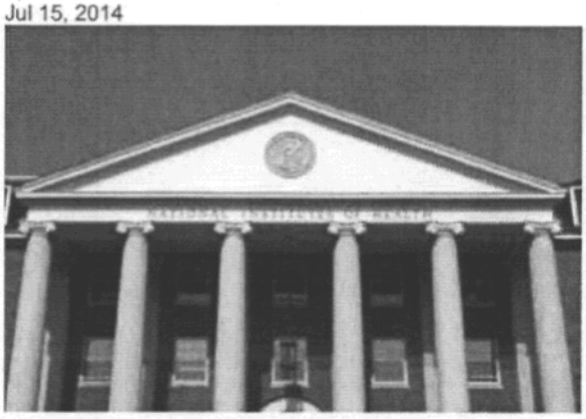
Wholesale roster change coming for US biosecurity board

Filed Under:
Dual-Use Research
;
Biosecurity Issues
Robert Roos | News Editor | CIDRAP News
|
Jul 15, 2014



NIH

The NIH said the move was part of routine membership rotation.

The US National Institutes of Health (NIH) is preparing to reactivate a biosecurity advisory board that has been dormant for close to 2 years, and as part of that process, almost half of the board's voting members learned this week that that they will soon be replaced.

Although the move was not entirely unexpected, some of the 11 exiting members of the board said the timing is strange, as it comes in the wake of recent government lab safety lapses involving *Bacillus anthracis*, H5N1 avian flu virus, and smallpox virus.

The 11 departing members—nearly half of the 23-member voting roster—are the last of the original members of the National Science Advisory Board for Biosecurity (NSABB),

which was established in 2005. The panel advises the government on biosecurity and "dual use research of concern" (DURC), or research that could be used to threaten public health.

Routine membership rotation?

In a statement e-mailed to CIDRAP News today, the NIH said the change in personnel is part of routine membership rotation and noted that the terms of the outgoing members had been extended several times.

The NSABB made frequent headlines in late 2011 and 2012, when it initially opposed publication of the full details of two studies that involved generating H5N1 viruses with airborne transmissibility in ferrets. The board later reversed the recommendation, but the vote on one of the studies was not unanimous.

NSABB Executive Director Mary Groesch, PhD, informed the 11 board members of their impending removal in a Jul 13 e-mail message.

"I wanted to tell you that a new slate of NSABB members has been approved as your replacements, and thus your service on the board is ending," she wrote. "Since you have all been so gracious as to extend your service for several years beyond your initial term, this may come as welcome news!"

She said the NIH plans to convene the board in the fall, when it will be asked for advice on educational materials that will be needed to support a new policy on institutional oversight of life-sciences DURC. The final version of that policy is due to be released soon, she added.

Paul Keim, PhD, of Northern Arizona University, an outgoing NSABB member and former chair, said that normally a few NSABB members should rotate off the board each year, but that wasn't done over the past 2 years.

"We were all surprised [by Groesch's memo], but mainly because of the silence for about 20 months," he told CIDRAP News. He is a microbiologist and Regent's Professor of biology at Northern Arizona and also directs the Pathogen Genomics Division at The Translational Genomics Research Institute.

"I think it's unfortunate that it happens right now in the midst of this crisis [of lab safety missteps], but on the other hand the US government has mothballed the NSABB for essentially 2 years," Keim said. "During that period there should've been a rotation of members off the board. That was the original intent."

"They had a backlog in rotating people off," he said. "It's just too bad they had to rotate so many experienced people off as they're facing this crisis."

He referred to the recent revelations about biosafety lapses involving *B anthracis* and H5N1 virus at Centers for Disease Control and Prevention (CDC) labs and the discovery of 1950s smallpox virus samples in a Food and Drug Administration (FDA) facility.

Keim and other members contacted by CIDRAP News said they're in the dark as to why the NIH has not convened the NSABB since November 2012. "We don't know why we were inactivated," he said.

Questions on board inactivity, timing of notice

In their statement to CIDRAP News today, NIH officials described the changing of the guard as routine but did not explain why the board has been inactive for so long.

"It is routine for federal advisory committees to rotate their membership over time so that fresh and diverse perspectives can be brought to bear on the committee's deliberations," the statement said. "Typically, only a portion of the board is rotated off at a time, so that the NSABB has members with 'institutional memory,' as well as individuals with new perspectives. Under special circumstances, membership terms can be extended, though they cannot be extended indefinitely.

"The terms of the individuals who received notification that their service on the NSABB had come to an end, had been renewed several times. The last time member terms were extended, those extensions were to last until replacement members could be found up until 2015, but not necessarily extending to that date, if less time was required for replacement members to be appointed.

"The decision regarding which members to rotate off the board is predicated on the length of service and the availability of replacement members. The individuals who were notified recently regarding their expiring terms are the last among the original board members to rotate off. This is part of the routine process of membership rotation."

The NIH said the names of the new NSABB members will be released before the board's next meeting. Groesch's memo said plans call for a meeting in September or October.

The current NSABB chair, Samuel L. Stanley Jr, MD, president of Stony Brook University in New York, was not available to comment on the development today. He is not among those rotating off the panel.

Another departing member, Michael Imperale, PhD, of the University of Michigan, said the outgoing members were initially appointed for 4-year terms, but the terms were extended because the NIH hadn't found replacements for them. He is a professor in and associate chair of the Department of Microbiology and Immunology.

Imperiale said he had "no idea" why the NIH picked this particular time to suddenly announce the change in members.

"I guess the related question is, why, after almost 2 years, did the NIH decide it's time to reconvene the board?" he added.

David Relman, MD, of Stanford University, another exiting NSABB member, called the NIH move "quite abrupt" and said he didn't know the reason for the timing, but added that he was not entirely surprised. He is a professor of medicine and of microbiology and immunology at Stanford and also is chief of infectious diseases at Veterans Affairs Palo Alto Health CareSystem.

"What has been far more upsetting has been the degree to which the board has been ignored and in essence, silenced during this past 2 years—2 years of rapidly evolving science, pressing unresolved issues, and great need for work and contributions by a board like this," Relman commented.

He said he has "some suspicion" that the change in members may be related to positions that members have taken in board deliberations, but has "nothing that I can support with objective evidence."

Keim, however, rejected any speculation that members are being dropped from the board for their views: "If they started targeting members for their positions, that would be a major transgression of the government advisory board policies. They did not target us for our views."

See also:

NSABB home page

Roster of current NSABB voting members

Related Jul 15 *Science*Insider story

From: Arturo Casadevall
Sent: 25 Jul 2014 01:14:42 +0000
To: Groesch, Mary (NIH/NHLBI) [E]
Subject: RE: Date for NSABB Meeting: Oct. 22

Dear Mary,
I will try to make it to support the new NSABB. I am at a conference in upstate NY but hopefully will be able to get to DC.
Arturo

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Thursday, July 24, 2014 3:46 PM
To: Arturo Casadevall; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stanley, Samuel (NIH); Viggiani, Christopher (NIH/OD) [E]; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]; 'Christopher Logan'; 'Dannie Smith'; 'Dawne Buhrow'; 'Deborah Martin'; Maria T Ortiz; 'Mary Marrone-Polo'; Groesch, Mary (NIH/OD) [E]; Mosby, Carolyn (NIH/OD) [E]
Subject: Date for NSABB Meeting: Oct. 22

Dear Colleagues,

Thank you for your quick responses about availability for an NSABB meeting in the fall. I wanted to let you know that the NSABB will be convening on **October 22, 2014** in or near Bethesda, Maryland. We welcome you to attend and participate in an ad hoc capacity. We will provide information about the topics to be discussed, background materials, and logistics as it becomes available, but wanted to be sure to get the meeting onto your rapidly filling calendars.

If you hadn't yet indicated availability, and will be able to attend--or if you had indicated a scheduling conflict, but will be able to attend after all--please let me know so that we can work with you on travel arrangements, etc. I hope to see you October.

Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB
Senior Advisor for Science Policy
Program on Biosecurity and Biosafety Policy
Immediate Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785

From: Groesch, Mary (NIH/OD) [E]
Sent: 30 Jul 2014 18:54:27 +0000
To: 'Lemon, Stanley M.'
Subject: RE: Date for NSABB Meeting: Oct. 22

That's wonderful—looking forward to seeing you!
Mary

From: Lemon, Stanley M. [mailto:smlemon@med.unc.edu]
Sent: Thursday, July 24, 2014 10:16 PM
To: Groesch, Mary (NIH/OD) [E]
Subject: Re: Date for NSABB Meeting: Oct. 22

Oct 22 works well for me, Mary. I should be there.

Stan

From: <Groesch>, Mary Groesch <GroeschM@OD1TM1.OD.NIH.gov>
Date: Thursday, July 24, 2014 3:45 PM
To: Arturo Casadevall <casadeva@aecom.yu.edu>, 'David Franz' (b)(6) "Relman, David A." <relman@stanford.edu>, 'General John Gordon' (b)(6) James Roth' <jaroth@iastate.edu>, 'John Lumpkin' <jlumpki@rwjf.org>, 'Michael Imperiale' <imperial@umich.edu>, Michael Osterholm <mto@umn.edu>, "Keim, Paul" <PKeim@tgen.org>, Stan Lemon <smlemon@med.unc.edu>, 'Stuart Levy' <stuart.levy@tufts.edu>
Cc: "Patterson, Amy (NIH/OD) [E]" <PattersA@OD.NIH.GOV>, "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>, "Stanley, Samuel (NIH)" <Samuel.Stanley@stonybrook.edu>, "Viggiani, Christopher (NIH/OD) [E]" <christopher.viggiani@nih.gov>, "Shipp, Allan (NIH/OD) [E]" <ShippA@OD.NIH.GOV>, "Fennington, Kelly (NIH/OD) [E]" <FenningK@OD.NIH.GOV>, 'Christopher Logan' <christopher.logan@tufts.edu>, 'Dannie Smith' (b)(6) 'Dawne Buhrow' <dbuhrow@iastate.edu>, 'Deborah Martin' <deborah.martin@nau.edu>, 'Maria Ortiz' <mtortiz@aecom.yu.edu>, 'Mary Marrone-Polo' <mmarron@rwjf.org>, Mary Groesch <GroeschM@OD1TM1.OD.NIH.gov>, "Mosby, Carolyn (NIH/OD) [E]" <carolyn.mosby@nih.gov>
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Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB
Senior Advisor for Science Policy
Program on Biosecurity and Biosafety Policy
Immediate Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785

From: Roth, James A [V MPM]
Sent: 2 Aug 2014 21:06:02 +0000
To: Groesch, Mary (NIH/NHLBI) [E]
Subject: RE: Date for NSABB Meeting: Oct. 22

Hi Mary,

I won't be able to attend the meeting on October 22nd due to other travel commitments. I greatly appreciated the opportunity to serve on the NSABB! It was a very valuable and worthwhile experience. I am proud of the contributions that NSABB has made and I am confident it will continue to make important contributions. I also appreciated the professional way that the NSABB staff facilitated the meetings.

Best wishes for the future!

Jim

James A. Roth, DVM, PhD, DACVM
Clarence Hartley Covault Distinguished Professor
Director, Center for Food Security and Public Health
Executive Director, Institute for International Cooperation in Animal Biologics
College of Veterinary Medicine
Iowa State University
Ames, Iowa 50011
Phone: 515-294-8459
Fax: 515-294-8259
email: jaroth@iastate.edu
www.cfsph.iastate.edu

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Thursday, July 24, 2014 2:46 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; Roth, James A [V MPM]; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stanley, Samuel (NIH); Viggiani, Christopher (NIH/OD) [E]; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]; 'Christopher Logan'; 'Dannie Smith'; Buhrow, Dawne [CFSPH]; 'Deborah Martin'; 'Maria Ortiz'; 'Mary Marrone-Polo'; Groesch, Mary (NIH/OD) [E]; Mosby, Carolyn (NIH/OD) [E]
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Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB
Senior Advisor for Science Policy
Program on Biosecurity and Biosafety Policy
Immediate Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785

From: Groesch, Mary (NIH/OD) [E]
Sent: 4 Aug 2014 21:09:44 +0000
To: 'Levy, Stuart B.'
Subject: RE: Date for NSABB Meeting: Oct. 22

Thanks so much Stuart, we have many fond memories of working with you as well! I am sorry that you cannot attend the upcoming meeting—should be a very interesting discussion and would as always benefit from your wisdom. Please let us know if your schedule changes.

Warm Regards,
Mary

From: Levy, Stuart B. [mailto:Stuart.Levy@tufts.edu]
Sent: Monday, August 04, 2014 3:14 PM
To: Groesch, Mary (NIH/OD) [E]
Subject: RE: Date for NSABB Meeting: Oct. 22

Mary,
Thank you for the note. Unfortunately, I have a conflict on that day and will be unable to attend.
I have wonderful memories of my time on NSABB and wish the new members my best.
Sincerely yours,
Stuart

From: Groesch, Mary (NIH/OD) [E] [mailto:GroeschM@OD1TM1.OD.NIH.gov]
Sent: Thursday, July 24, 2014 3:46 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; Levy, Stuart B.
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stanley, Samuel (NIH); Viggiani, Christopher (NIH/OD) [E]; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]; Logan, Christopher; 'Dannie Smith'; 'Dawne Buhrow'; 'Deborah Martin'; 'Maria Ortiz'; 'Mary Marrone-Polo'; Groesch, Mary (NIH/OD) [E]; Mosby, Carolyn (NIH/OD) [E]
Subject: Date for NSABB Meeting: Oct. 22

Dear Colleagues,

Thank you for your quick responses about availability for an NSABB meeting in the fall. I wanted to let you know that the NSABB will be convening on **October 22, 2014** in or near Bethesda, Maryland. We welcome you to attend and participate in an ad hoc capacity. We will provide information about the topics to be discussed, background materials, and logistics as it becomes available, but wanted to be sure to get the meeting onto your rapidly filling calendars.

If you hadn't yet indicated availability, and will be able to attend--or if you had indicated a scheduling conflict, but will be able to attend after all--please let me know so that we can work with you on travel arrangements, etc. I hope to see you October.

Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB

Senior Advisor for Science Policy
Program on Biosecurity and Biosafety Policy
Immediate Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785

Groesch, Mary (NIH/OD) [E]

From: Groesch, Mary (NIH/OD) [E]
Sent: Sunday, July 13, 2014 8:06 PM
To: 'Arturo Casadevall'; 'David Franz'; 'David Relman'; 'General John Gordon'; 'James Roth'; 'John Lumpkin'; 'Michael Imperiale'; 'Michael Osterholm'; 'Paul Keim'; 'Stanley Lemon'; 'Stuart Levy'
Cc: Patterson, Amy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Viggiani, Christopher (NIH/OD) [E]; Stanley, Samuel (NIH); 'Christopher Logan'; 'Dannie Smith'; 'Dawne Buhrow'; 'Deborah Martin'; 'Maria Ortiz'; 'Mary Marrone-Polo'; Shipp, Allan (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]
Subject: NSABB Membership and Next Meeting

Dear Members of the NSABB,

Greetings! I hope that all is well with each of you. My purpose in writing to you—the last of the original NSABB members—is several fold. First, I wanted to tell you that a new slate of NSABB members has been approved as your replacements, and thus your service on the board is ending. Since you have all been so gracious as to extend your service for several years beyond your initial term, this may come as welcome news! But I can assure you, on behalf of the NSABB Chair and the US Government, that you will be missed and that your hard work, dedication, and leadership in the area of dual use research are greatly appreciated. I know that I speak for my colleagues across the government in saying that NSABB advice and recommendations over the years have greatly informed discussions of DURC issues and have contributed substantively to the development of federal DURC oversight policies. Second, I wanted to take a moment to update you on DURC-related policy developments. Third, I welcome you to attend in an *ad hoc* capacity the next meeting of the NSABB, where we will recognize your service on the Board.

As you know, one of the priority activities of the U.S. Government has been the development of policy for the oversight of life sciences dual use research of concern (DURC). In fact, one of the topics we discussed during our last meeting was gain-of-function influenza studies, and what the appropriate focus should be for special review. After consultation with the NSABB and international workshop participants, which also included some NSABB members, HHS finalized in February 2013, the *HHS Framework* for guiding funding decisions about certain types of gain-of-function studies that involve HPAI H5N1 viruses. Proposals for experiments that may generate HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets now receive a multidisciplinary Department-level review that may result in (1) additional risk mitigation measures being required or (2) in HHS not funding certain studies/experiments at all. You may also be aware that a group of influenza researchers stated their intention to perform gain-of-function experiments with LPAI H7N9 strains, which have infected humans in China. In August of last year, we expanded the HHS Framework to include studies that are reasonably anticipated to generate H7N9 viruses with increased transmissibility between mammals by respiratory droplets. Also, CDC has issued additional risk assessment and biosafety level recommendations for working with H7N9 viruses. The aim is to focus special oversight efforts on experiments of concern while allowing routine characterization and other fundamental research to proceed rapidly and safely. The HHS Framework is expected to evolve and as such is periodically revisited in light of scientific and policy developments.

You may recall that the proposed *USG Policy for Institutional Oversight of Life Sciences DURC* was issued for public comment last year. A number of NSABB members contributed very thoughtful comments on the proposed policy, which describes institutional responsibilities for mitigating risks associated with DURC. The institutional DURC policy is intended to complement the DURC Policy issued in March 2012, which focuses on Federal responsibilities for DURC oversight. The USG has carefully considered the public comments on the proposed policy for the institutional oversight of DURC and will be issuing a final policy in the very near future. We will update the Board when the Institutional Policy is about to be issued, and will provide information for a special briefing of the NSABB on the new policy.

Once the new Institutional policy is released, we anticipate calling on the NSABB to advise on the educational materials and implementation resources that institutions will need to identify DURC, employ risk mitigation measures, and comply with the new policy's requirements. Federal staff have begun developing an array of tools, guidances, and resource materials for these purposes and it would be very helpful to receive NSABB input on them.

We would like to convene the NSABB in the Fall to discuss these issues. We will also recognize your service and introduce the new members to the Board. We also would welcome your attendance at this meeting in a non-voting, *ad hoc* capacity both to contribute to our discussions and to say farewell.

Toward this end, in consultation with the NSABB Chair, we have identified the following dates as potential meeting times. Would you please indicate ASAP your availability for a one day meeting in Bethesda, MD for each of the following dates:

Tuesday, Sept. 30
Wednesday, Oct. 1
Thursday, Oct. 2
Tuesday, Oct. 7
Thursday, Oct. 9
Thursday, Oct. 16
Wednesday, Oct. 22
Thursday, Oct. 23
Tuesday, Oct. 28
Wednesday, Oct. 29

If these dates do not work for the majority of members, we will propose some additional ones in November. Thank you again for your service on the Board.

Regards,

Mary Groesch, Ph.D.
Executive Director, NSABB

Mary E. Groesch, Ph.D.
Senior Advisor for Science Policy
Office of Science Policy
Office of the Director, NIH
groeschm@od.nih.gov
301-496-0785 (direct)
301-496-9838 (OSP)
301-496-9839 (fax)

National Science Advisory Board for Biosecurity
Past Members

2009 Cohort

- Barry J. Erlick, PhD
- Adel A.F. Mahmoud, MD, PhD
- Harvey Rubin, MD
- Thomas E. Shenk, PhD
- Ret. Admiral William O. Studeman

2012 Cohort

- Murray L. Cohen, PhD, MPH
- Susan A. Ehrlich, JD, LL.M.
- Mark E. Nance, JD
- Anne Vidaver, PhD
- Lynn Enquist, PhD
- Claire M. Fraser, PhD

2014 Cohort

- Arturo A. Casadevall, MD, PhD
- David R. Franz, DVM, Phd
- Gen. John A. Gordon
- Michael J. Imperiale, PhD
- Paul S. Keim, PhD
- Stanley M. Lemon, MD
- Stuart B. Levy, MD
- John R. Lumpkin, MD, MPH
- Michael Osterholm, PhD, MPH
- David A. Relman, MD
- James A. Roth, DVM, PhD, DACVM

National
Science
Advisory
Board for
Biosecurity

NSABB Committee Roster (July 2014)

Chair

Samuel Stanley, Jr., M.D.
President, Stony Brook University
Co-Chair, Brookhaven Science Associates
New York, NY

Other Voting Members

Kenneth I. Berns, M.D., Ph.D.
Distinguished Professor
Dept. of Molecular Genetics & Microbiology
College of Medicine
University of Florida
Gainesville, FL

***Craig E. Cameron, Ph.D.**
Paul Berg Professor of Biochemistry and Molecular Biology
Dept. of Biochemistry & Molecular Biology
The Pennsylvania State University
University Park, PA

Drew Endy, Ph.D.
Assistant Professor
Dept. of Bioengineering
Stanford University,
Stanford, CA

J. Patrick Fitch, Ph.D.
Laboratory Director
National Biodefense Analysis and Countermeasures Center
President, Battelle National Biodefense Institute, LLC
Frederick, MD

Christine M. Grant, J.D.
CEO/Founder
InfecDetect Rapid Diagnostic Tests, LLC
Princeton, NJ

***Marie-Louise Hammarskjöld, M.D., Ph.D.**
Professor of Microbiology, Immunology, and Cancer Biology
Myles H. Thaler Center for AIDS and Human Retrovirus Research
Department of Microbiology
University of Virginia Health Science Center
Charlottesville, VA

Clifford W. Houston, Ph.D.
Professor & Associate V.P. for Educational Outreach
University of Texas Medical Branch
Galveston, TX

***Robert P. Kadlec, M.D.**
Managing Director, RPK Consulting
Alexandria, VA

***Joseph Kanabrocki, Ph.D., C.B.S.P.**
Assistant Dean for Biosafety
Associate Professor of Microbiology
Biological Sciences Division
University of Chicago
Chicago, IL

***Theresa M. Koehler, Ph.D.**
Chair, *ad interim*
Department of Microbiology & Molecular Genetics
Herbert L. and Margaret W. DuPont Professor in Biomedical Science
University of Texas-Houston Medical School
Houston, TX

Gardiner Lapham, R.N., M.P.H.
Member, Board of Directors
Whitman-Walker Clinic
Washington, DC

***Marcelle C. Layton, M.D.**
Assistant Commissioner
Bureau of Communicable Disease
New York City Dept. of Health and Mental Hygiene
New York, NY

Jan E. Leach, Ph.D.
University Distinguished Professor
Bioagricultural Science and Pest Management
Colorado State University
Ft. Collins, CO

***James LeDuc, Ph.D.**
Professor, Microbiology and Immunology
Director, Galveston National Laboratory
Director, Program on Global Health
University of Texas Medical Branch
Galveston, TX

***Margie D. Lee, Ph.D., D.V.M.**
Professor
Dept. of Population Health
Center for Food Safety
Biomedical Health Sciences Institute
The University of Georgia
Athens, GA

***Francis L. Macrina, Ph.D.**
Edward Myers Professor of Dentistry
Vice President for Research
Virginia Commonwealth University
Richmond, VA

***Joseph McDade, Ph.D.**
Scientist-in-Residence and Pre-Med Advisor
Dept. of Biology
School of Mathematical and Natural Sciences
Berry College
Mount Berry, GA

Jeffery F. Miller, Ph.D.
Professor and Chair
Department of Microbiology, Immunology
and Molecular Genetics
David Geffen School of Medicine
University of California – Los Angeles
Los Angeles, CA

***Stephen S. Morse, Ph.D.**
Director, Infectious Disease Epidemiology
Certificate Program
Professor of Epidemiology
Columbia University
Mailman School of Public Health
New York, NY

Rebecca T. Parkin, Ph.D.
Associate Dean for Research and Public Health
Practice
Professor, Depts. Of Environmental and
Occupational Health/Epidemiology & Biostatistics
The George Washington University
Washington, DC

***Jean L. Patterson, Ph.D.**
Chair and Scientist
Department of Virology and Immunology and
SNPRC
Texas Biomedical Research Institute
San Antonio, TX

***I. Gary Resnick, Ph.D.**
Guest Scientist
Los Alamos National Laboratory
Global Security Directorate
Los Alamos, CA

Susan M. Wolf, J.D.
McKnight Presidential Professor, Law, Medicine &
Public Policy
University of Minnesota
Minneapolis, MN

***David L. Woodland, Ph.D.**
Chief Scientific Officer
Keystone Symposia on Molecular and Cellular
Biology
Silverthorne, CO

* Indicates incoming members who will participate in an *ad hoc* (non-voting) capacity until their appointments are final

From: Groesch, Mary (NIH/OD) [E]
Sent: 22 Aug 2014 19:04:48 +0000
To: Fennington, Kelly (NIH/OD) [E]
Subject: FW: NSABB Member Cohorts
Attachments: Important note regarding your NSABB service, Important note regarding your NSABB service, Important note regarding your NSABB service, Important note regarding your NSABB service, NSABB Membership and Next Meeting

Hi Kelly, here are the 2012 letters to Murray Cohen, Claire Fraser, Marc Nance, and Anne Vidaver. Please note that Lynn Enquist also came off in 2012, but had voluntarily left the Board two weeks prior to the notifications being sent out (I have his email exchange with Amy). And Susan Ehrlich was ultimately in this cohort of members replaced at the November 2012 meeting, but did not receive this notification in June because her replacement had fallen through; we ultimately got another replacement for her by the time of the November 2012 meeting.

I have also attached the 2014 letter that went to the remaining 11 original members as a group email. M

2009 Cohort

- Barry J. Erlick, PhD
- Adel A.F. Mahmoud, MD, PhD
- Harvey Rubin, MD
- Thomas E. Shenk, PhD
- Ret. Admiral William O. Studeman

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- Susan A. Ehrlich, JD, LL.M.
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- Anne Vidaver, PhD
- Lynn Enquist, PhD
- Claire M. Fraser, PhD

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- Arturo A. Casadevall, MD, PhD
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- Gen. John A. Gordon
- Michael J. Imperiale, PhD
- Paul S. Keim, PhD
- Stanley M. Lemon, MD
- Stuart B. Levy, MD
- John R. Lumpkin, MD, MPH
- Michael Osterholm, PhD, MPH
- David A. Relman, MD
- James A. Roth, DVM, PhD, DACVM

From: Fennington, Kelly (NIH/OD) [E]
Sent: 25 Aug 2014 13:27:02 -0400
To: Groesch, Mary (NIH/OD) [E]
Subject: FW: note to Slobodin
Attachments: USGPolicies.pdf, NSABB Roster and letters.pdf

Hi Mary,

Amy would like you to please go ahead and transmit the note below along with the attachments to Anne Tatem so she can forward to Mr. Slobodin.

Thanks,
Kelly

Dear Mr. Slobodin,

Thank you again for the opportunity to speak to you last Thursday about the National Science Advisory Board for Biosecurity. Per your request, I am attaching the following documents:

USG Policies

- March 2012 USG policy on federal oversight of DURC
- FRN re public comment on draft USG policy for institutional oversight of DURC
- Draft USG policy for institutional oversight of DURC that was posted for public comment
- HHS Framework for funding decisions on gain-of-function influenza research involving H5N1 virus
- *Science* article about original HHS Framework
- *Science* article about expansion of HHS Framework to include H7N9 influenza virus

NSABB members and requested communications

- 2014 NSABB roster, including incoming members
- Letters to NSABB members notifying them their service was ending (2014 letter and samples of 2009 and 2012 letters)

Please let me know if you have any other questions about the NSABB.

USG Policy for Oversight of Life Sciences DURC
March 2012

United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern

Section I: Purpose and Principles

1) The purpose of this Policy is to establish regular review of United States Government funded or conducted research with certain high-consequence pathogens and toxins for its potential to be dual use research of concern (DURC) in order to: (a) mitigate risks where appropriate; and (b) collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC. The fundamental aim of this oversight is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
2) This Policy complements existing United States Government regulations and policies governing the possession and handling of pathogens and toxins. Currently, the Select Agent Regulations ensure appropriate oversight of biosafety and biosecurity of the possession and handling of pathogens and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products. In addition, recommendations from Federal advisory bodies such as the National Science Advisory Board for Biosecurity (NSABB) have helped inform United States Government policies for identifying and managing DURC. This Policy will be updated, as needed, following domestic dialogue, engagement with our international partners, and input from interested communities including scientists, national security officials, and global health specialists.
3) The following principles guide implementation of this Policy:
    a) Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel, and national security. Despite its value and benefits, some research may provide knowledge, information, products, or technologies that could be misused for harmful purposes.
    b) Accordingly, some degree of Federal and institutional oversight of DURC is critical to reducing the risks to public health and safety, agricultural crops and other plants, animals, the environment, materiel, and national security.
    c) Measures that mitigate the risks of DURC should be applied, where appropriate, in a manner that minimizes, to the extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.
    d) The United States Government will facilitate the sharing of the results and products of life sciences research conducted or funded by United States Government agencies, and honor United States Government obligations within relevant international frameworks and agreements, while taking into account United States' national security interests.
    e) In executing this Policy, the United States Government will abide by and enforce all relevant Presidential Directives and Executive Orders, all applicable laws and regulations, and support the implementation of legally binding treaties, commitments, and United Nations Security Council resolutions prohibiting the development and use of biological agents as weapons.

Section II: Definitions

1) For the purpose of this Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public

health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security[1].

2) "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.
3) Extramural research is that which is funded by a department or agency under a grant, contract, cooperative agreement, or other agreement and not conducted directly by the department or agency.
4) Intramural research is that which is directly conducted by a department or agency.

Section III: Scope

Under this Policy, review will focus on research that involves one or more of the agents or toxins listed in Section (III.1) below, which pose the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section (III.2) below:

1) Agents and toxins[2]:
   a) Avian influenza virus (highly pathogenic)
   b) *Bacillus anthracis*
   c) Botulinum neurotoxin
   d) *Burkholderia mallei*
   e) *Burkholderia pseudomallei*
   f) Ebola virus
   g) Foot-and-mouth disease virus
   h) *Francisella tularensis*
   i) Marburg virus
   j) Reconstructed 1918 Influenza virus
   k) Rinderpest virus
   l) Toxin-producing strains of *Clostridium botulinum*
   m) Variola major virus
   n) Variola minor virus
   o) *Yersinia pestis*
2) Categories of experiments:
   a) Enhances the harmful consequences of the agent or toxin;
   b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
   c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
   d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
   e) Alters the host range or tropism of the agent or toxin;

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[1] This definition of DURC is derived from the NSABB definition, but is modified for purposes of this Policy.

[2] These agents and toxins are regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, and 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

f) Enhances the susceptibility of a host population to the agent or toxin; or
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.

Section IV: Department and Agency Responsibilities

1) Federal departments and agencies that conduct or fund life sciences research should implement the following actions:
   a) Conduct a review to identify all current or proposed, unclassified intramural or extramural, life sciences research projects that fall within the scope of Section III. This review will include, at a minimum, initial proposals and any progress reports.
   b) Determine which, if any, of the projects identified in Section (IV.1.a) meet the definition of DURC in Section (II.1) of this document.
   c) Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.
   d) Based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures. In addition:
      i) For DURC that is proposed and not yet funded, departments and agencies will assess whether to incorporate risk mitigation measures in the grant, contract, or agreement.
      ii) For currently funded DURC, funding departments and agencies will consider modifying the grant, contract, or agreement to incorporate risk mitigation measures. If such modifications are not possible or desirable, departments and agencies will seek voluntary implementation of mitigation measures by the institution.
   e) A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:
      i) Modifying the design or conduct of the research.
      ii) Applying specific or enhanced biosecurity or biosafety measures.
      iii) Evaluating existing evidence of medical countermeasures (MCM) efficacy, or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications.
      iv) Referring the institution to available DURC educational tools such as: http://oba.od.nih.gov/biosecurity/biosecurity.html
      v) Regularly reviewing, at the institutional level, emerging research findings for additional DURC.
      vi) Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed.
      vii) Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.
      viii) Reviewing annual progress reports from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention and applying potential mitigation measures as described above, as necessary.
      ix) If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:
         (a) Request voluntary redaction of the research publications or communications [3];
         (b) Classify the research:
            (i) In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within

[3] Actions taken to restrict the publication of technology may have implications under export control laws and regulations (e.g., 15 CFR parts 730-774 and 22 CFR parts 120-130).

the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.

(ii) Departments and agencies may consider whether to refer classified research to another department or agency for funding.

(c) Not provide or terminate research funding.

2) Federal departments and agencies are requested to report the following to the Assistant to the President for Homeland Security and Counterterrorism:
   a) Within 60 days of issuance of this Policy, the following results of the review conducted in response to Section (IV.1.a):
      i) Aggregate number of current and proposed unclassified, intramural, and extramural research projects identified that include work with one or more of the agents and toxins in Section (III.1).
      ii) Aggregate number of current and proposed unclassified, intramural, and extramural research projects that include work with one or more of the agents and toxins in Section (III.1) and produces, aims to produce, or are reasonably anticipated to produce one or more of the effects listed in Section (III.2).
   b) Within 90 days of issuance of this Policy, the following results of the review conducted in response to Sections (IV.1. b. c. and d):
      i) Number of unclassified current and proposed DURC projects.[4]
      ii) Number of current projects identified as DURC through initial proposals versus progress reports.[5]
      iii) Summary of risks, mitigation measures already in place that address those risks, any additional mitigation measures that have been proposed or implemented, and number of projects to which each mitigation measure would be applied.
3) Following completion of the reporting requirements in Section (IV.2), Federal departments and agencies are requested to submit periodic reports on items in Section (IV.2.a. and b) biannually.
4) Federal departments and agencies should implement Section IV in accordance with their relevant and applicable authorities, regulations, and statutes.
5) For additional guidance on how to conduct the risk assessment identified in Section (IV. 1.c), departments and agencies may refer to the "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," which identifies useful assessment tools and is available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html .

Section V: Consultation

As necessary and appropriate, the United States Government will continue to consult with the NSABB (in compliance with provisions of the Federal Advisory Committee Act) or convene the Countering Biological Threats Interagency Policy Committee for guidance on matters relating to the review and conduct of DURC and the mitigation of DURC risks.

[4,5] Report the number of projects by agent and/or toxin plus the category of experiment.

Federal Register notice soliciting public comment on draft USG policy for institutional oversight of DURC
February 2013

their amended systems of records in the **Federal Register** when there is a revision, change, or addition. The Postal Service™ has reviewed this system of records and has determined that this General Privacy Act System of Records should be revised to modify Categories of Records in the System, Purpose(s), and Retention and Disposal.

I. Background

The U.S. Postal Service has a Web site called keepingposted.org available for retired USPS employees who want to stay connected with postal news, events and people. This site also provides links to other retirement resources and services.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The Postal Service wants to contact postal retirees to make them aware they can find on the Keeping Posted Web site up-to-date news and information about the organization, messages to retirees from the Postmaster General, as well as continuing federal retiree benefit information.

III. Description of Changes to Systems of Records

The Postal Service is modifying one system of records listed below. Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the proposed modifications has been sent to Congress and to the Office of Management and Budget for their evaluation. The Postal Service does not expect this amended notice to have any adverse effect on individual privacy rights. The affected system is as follows:

USPS 100.000

SYSTEM NAME:

General Personnel Records

Accordingly, for the reasons stated, the Postal Service proposes changes in the existing system of records as follows:

USPS 100.000

SYSTEM NAME:

General Personnel Records

CATEGORIES OF RECORDS IN THE SYSTEM

* * * * *

[CHANGE TO READ]

1. *Employee, former employee, and family member information:* Name(s), Social Security Number(s), Employee Identification Number, date(s) of birth, place(s) of birth, marital status, postal assignment information, work contact information, home address(es) and phone number(s), finance number(s), duty location, and pay location.

* * * * *

[ADD NEW TEXT]

9. *Email Addresses:* personal email address(es) for retired employees are retained in a separate database and file from other current and former employee information.

PURPOSE(S):

* * * * *

[ADD NEW TEXT]

6. To provide federal benefit information to retired employees.

* * * * *

RETENTION AND DISPOSAL:

* * * * *

[ADD NEW TEXT]

7. Records to provide federal benefit information to retired employees are retained 10 years. The record may be purged at the request of the retired employee.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–04053 Filed 2–21–13; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Return Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* February 22, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on February 15, 2013, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Return Service Contract 3 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2013–39, CP2013–51.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2013–04055 Filed 2–21–13; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Sunshine Act Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on March 6, 2013, 10:00 a.m. at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois, 60611. The agenda for this meeting follows:

Portion open to the public:

(1) Executive Committee Reports.

The person to contact for more information is Martha P. Rico, Secretary to the Board, Phone No. 312–751–4920.

Dated: February 15, 2013.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2013–04184 Filed 2–20–13; 11:15 am]

BILLING CODE 7905–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice; request for comment.

SUMMARY: The United States Government (USG) invites comments on the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The proposed Policy establishes institutional review and oversight requirements for certain categories of life sciences research at institutions that accept Federal funding for such research. These requirements are intended to address risks of dual use research not addressed under existing Federal regulations or guidelines. Requirement for compliance with this Policy, once finalized, will be incorporated by Federal funding agencies in accordance with their relevant statutory authorities, into the terms and conditions of awards with funded institutions that conduct research falling into the categories identified in the Policy. The public input provided through this Notice will inform future deliberations and issuance of a final Policy.

DATES: *Release date:* February 22, 2013. *Response date:* April 23, 2013.

ADDRESSES: Comments may be submitted electronically to: *durcpolicy@ostp.gov.* Comments may also be mailed to: Dr. Franca R. Jones, Assistant Director—Chemical and Biological Countermeasures, Office of

Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, DC 20504. See **SUPPLEMENTARY INFORMATION** for specific information about submitting comments.

The proposed Policy is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Web site: *http://www.phe.gov/s3/dualuse/Pages/default.aspx.*

FOR FURTHER INFORMATION CONTACT: Dr. Franca R. Jones, Assistant Director—Chemical and Biological Countermeasures, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, Washington, DC 20504, *durcpolicy@ostp.gov.*

SUPPLEMENTARY INFORMATION:

Background

The United States Government (USG) invites comments on the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The proposed Policy establishes institutional review and oversight requirements for certain categories of life sciences research at institutions that accept Federal funding for such research. These requirements are intended to address risks of dual use research not addressed under existing Federal regulations or guidelines. Requirement for compliance with this Policy, once finalized, will be incorporated by Federal funding agencies in accordance with their relevant statutory authorities, into the terms and conditions of awards with funded institutions (see Applicability, Section 6.1) that conduct research falling into the categories identified in the Policy (see Scope, Section 6.2). The public input provided through this Notice will inform future deliberations and issuance of a final Policy.

Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel,[1] and national security. Life sciences research has and will continue to yield benefits, but no life sciences research comes without risk. Indeed, certain types of research that are conducted for legitimate purposes may also be utilized for harmful purposes. Such research is called "dual use research." Dual use research of concern (DURC) is a smaller subset of dual use research defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and synergistic statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability.[2] Some risks relate directly to the characteristics of DURC—the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all these domains to ensure that risks are appropriately managed and benefits realized. This proposed Policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

Given these dual use risks, the USG issued, on March 29, 2012, its Policy for Oversight of Life Sciences Dual Use Research of Concern (March 29 Policy). The March 29 Policy formalized a process of regular federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement mitigation measures, where applicable. The goal of the March 29 Policy is to preserve the benefits of life sciences research while minimizing the risk that the knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm.

Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research. The proposed Policy herein, United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, addresses the institutional oversight of DURC, and will operate in tandem with the March 29 Policy that requires Federal agencies to implement similar measures for oversight of DURC. Oversight includes policies, practices, and procedures that are put in place to ensure DURC is identified and risk mitigation measures are implemented, where appropriate. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. This proposed Policy delineates the procedures for the oversight of DURC and responsibilities of Principal Investigators, research institutions, and the USG. This proposed Policy, in addition to the March 29 Policy, emphasizes a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.[3] The components outlined in the March 29 Policy and in this Policy, once finalized, will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.

Because institutional oversight of DURC will be a new undertaking for many institutions, the USG is currently limiting the requirements in this proposed Policy, as well as the March 29 Policy, to research that meets the scope in Section 6.2, which focuses on a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the Policy; will evaluate the impact of DURC oversight on the life sciences research enterprise; will assess the benefits and risks of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and will update the Policy, as warranted. Research institutions are

[1] Materiel includes food, water, equipment, supplies, or material of any kind.

[2] e.g. Select Agents and Toxins Program (42 CFR part 73, 9 CFR part 121, and 7 CFR part 331); National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (*http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf*); Biosafety in Microbiological and Biomedical Laboratories 5th Edition (*http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf*).

[3] The March 29 Policy and this proposed Policy are complemented by other extant laws and treaties (e.g. 18 U.S.C. 175 and the Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

encouraged to be mindful that research outside of the categories articulated in this proposed Policy may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their oversight to other types of life sciences research as they deem appropriate.

Finally, and importantly, research that meets the definition of DURC often increases our understanding of the biology of pathogens and makes critical contributions to the development of new treatments and diagnostics, improvements in public health surveillance, and the enhancement of emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this proposed Policy supersedes the Department of Health and Human Services and the United States Department of Agriculture Select Agents and Toxins Program's (SAP) statutory authority or SAP regulations as published in 42 CFR part 73, 9 CFR part 121, and 7 CFR part 331.

Specific Questions

Public comments are sought on the entirety of the proposed United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. In addition, we are seeking input on the following specific questions:

1. For institutions conducting research that involves one or more of the 15 listed agents, please describe the feasibility and anticipated burden (administrative, resources, etc.), if any, to implement the requirements of this proposed Policy. What effect, if any, do you anticipate the proposed Policy would have on your ability to support or engage in research on any of the listed pathogens or toxins?

2. Are there alternatives to the administrative requirements of this proposed Policy that could be more easily implemented by Federally-funded research institutions and that would meet the intent of this proposed Policy or the March 29 Policy? If so, please specify.

3. How could DURC oversight be usefully integrated with other existing institutional oversight processes in order to reduce duplication and any resulting excess administrative burdens on institutions?

4. For institutions who have registered an Institutional Biosafety Committee (IBC) with the NIH Office of Biotechnology Activities in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, is it feasible for the IBC to conduct the DURC institutional review process? What are the benefits or limitations of using IBCs in this role?

5. Should research that has undergone institutional DURC review but has been determined not to be DURC be monitored for emerging DURC issues? If so, how often should such review take place?

6. Is it feasible for a single individual, the Institutional Contact for Dual Use Research (ICDUR), to be the point of contact for all dual use research-related questions to and from the funding agency? If not, who else could help fill this role?

7. The proposed Policy calls for principal investigators (PIs) to refer any research involving one or more of the 15 listed agents to an institutional dual use research review entity (Section 7.1.A). The institutional review entity will then determine whether the research can be reasonably anticipated to produce any of the seven effects, and if so, if that research meets the definition of DURC. Is it preferable to instead require PIs to determine both whether their research involves one or more of the listed agents and also whether their research can be reasonably anticipated to produce any of the listed effects? In this scenario, the institutional dual use research review entity would then only determine whether the research meets the definition of DURC. (Note: In either scenario, the institutional dual use research review entity would also then assess the risks and benefits of the research and develop a risk management plan.)

8. Is additional guidance or explanation needed for interpreting the seven effects/categories of experiments listed in Section 6.2.2?

9. The USG is developing a document that contains the following analytic tools and guidance to assist in implementation of the Policy, once finalized:

a. Understanding and identification of DURC
b. Assessment of risks and benefits associated with DURC
c. Developing a risk mitigation plan for DURC
d. Responsibly communicating DURC
e. Training and education on DURC

Are there any additional tools or guidance documents that would be useful in implementing and complying with this Policy, once finalized?

10. We are interested in views on the optimum relationship between the March 29 Policy and this proposed Policy. Are there any conflicts or challenges posed by implementing both policies? Should research institutions review projects for DURC issues prior to proposals being submitted to a funding agency for review? (If not, funding agencies implementing the March 29 Policy will not have the benefit of input from institutional dual use review when reviewing research proposals for DURC.) If so, should the PI and/or institution designate on the grant application that such a review has taken place and indicate its findings?

11. This proposed Policy is intended to apply to projects that directly use non-attenuated forms of the 15 agents or toxins listed in Section 6.2.1 and/or use botulinum toxin at any quantity. Should the scope also include (please provide information to support your answer):

a. The use of any of the listed 15 agents or toxins in attenuated forms;

b. The use of the genes from any of the listed 15 agents or toxins (all genes? Only certain types of genetic information? If the latter, how could this be specified?);

c. *In silico* experiments (e.g. modeling experiments, bioinformatics approaches) involving the biology of the listed 15 agents or toxins;

d. Research related to the public, animal, and agricultural health impact of any of the 15 listed agents or toxins (e.g. modeling the effects of a toxin, developing new methods to deliver a vaccine, developing surveillance mechanisms for a listed agent)?

12. Is the scope of the proposed Policy appropriate? If not, why not? Should the scope be expanded to all select agents, microbes, or all life sciences? If so, why? What factors should be considered in determining the final scope of oversight? What criteria might be used to determine what research should/should not be subject to oversight? If the Policy, once finalized, were expanded to cover other types of life sciences research (i.e. beyond the 15 listed agents), what effect, if any, would it have on your ability to conduct that research?

13. The USG recognizes that there may be some institutions that choose to expand their oversight beyond the 15 agents listed in Section 6.2.1 and/or beyond the seven categories listed in Section 6.2.2 or currently have a DURC oversight process in place that is beyond the scope of this proposed Policy. For

those institutions, what additional agents or toxins, other categories of experiments, and/or other domains within the life sciences were considered for potential oversight? What impact has the expanded oversight had on the conduct and administration of the institution's life sciences research?

14. The USG recognizes that there will be situations where a PI is conducting potential DURC at multiple institutions. Should each institution have oversight of these projects and if DURC is being conducted at their institution, develop and implement risk mitigation plans? Or should the PI's primary institution have this responsibility? (Refer to "Note" following Section 7.2.K)

15. The proposed Policy requires institutions that would be subject to the proposed Policy by virtue of Federal funding, to apply the proposed Policy to non-Federally funded research. Under the proposal, institutions would submit information about DURC reviews and risk mitigation plans on non-Federally funded projects to the National Institutes of Health (which may in turn refer the results and plans to the appropriate Federal agency based upon the nature of the research). Applying the DURC policy to Federally and non-Federally funded research promotes more meaningful oversight of DURC at the institutional level and fosters uniform approaches to the responsible conduct and communication of all research that may raise DURC concerns at an institution. Is this approach feasible? If not, what is the best mechanism for structuring oversight for non-Federally funded research?

16. The proposed Policy requires institutions to maintain records of DURC reviews, risk mitigation plans, and personnel training for three years. However, grant cycles are often longer than three years and DURC communications may arise even after funding has ended. This could result in situations where important records (e.g., the risk mitigation plan) are not available at the institution for certain DURC projects. Should the record-keeping requirements for this proposed Policy be longer to allow access to records over (and beyond) the lifetime of a DURC project? What is an appropriate amount of time that institutions should be required to retain such records?

Availability of the Proposed Policy

The proposed Policy is available on the U.S. Department of Health and Human Services Science Safety Security (S3) Web site: *http://www.phe.gov/s3/dualuse/Pages/default.aspx.*

Comment Submission

Comments may be submitted electronically to: *durcpolicy@ostp.gov.* Comments may also be mailed to: Dr. Franca R. Jones, Assistant Director—Chemical and Biological Countermeasures, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Avenue Washington, DC 20504. In your response, please provide the following information:

Date
Name/Email/Phone Number
Affiliation/Organization
City, State

General Comments

Comments to Specific Questions (1–16) Listed in Supplementary Information as Follows:
Comment to Question 1
Comment to Question 2
Comment to Question 3
Comment to Question 4
Comment to Question 5
Comment to Question 6
Comment to Question 7
Comment to Question 8
Comment to Question 9
Comment to Question 10
Comment to Question 11
Comment to Question 12
Comment to Question 13
Comment to Question 14
Comment to Question 15
Comment to Question 16

You will receive an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback on any suggestions. No basis for claims against the U.S. Government shall arise as a result of a response to this request for comment or from the Government's use of such information.

Ted Wackler,
Deputy Chief of Staff.

[FR Doc. 2013–04127 Filed 2–21–13; 8:45 am]
BILLING CODE 3270–F3–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–30383; 812–14105]

UBS AG, et al.; Notice of Application and Temporary Order

February 15, 2013.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Temporary order and notice of application for a permanent order under section 9(c) of the Investment Company Act of 1940 ("Act").

Summary of Application: Applicants have received a temporary order exempting them from section 9(a) of the Act, with respect to a guilty plea entered on December 19, 2012, by UBS Securities Japan Co., Ltd. (the "Settling Firm") in the U.S. District Court for the District of Connecticut ("District Court") in connection with a plea agreement between the Settling Firm and the U.S. Department of Justice ("DOJ"), until the Commission takes final action on an application for a permanent order. Applicants have requested a permanent order.

Applicants: UBS AG; UBS IB Co-Investment 2001 GP Limited ("ESC GP"); UBS Financial Services Inc. ("UBSFS"); UBS Alternative and Quantitative Investments LLC ("UBS Alternative"); UBS Willow Management, L.L.C. ("UBS Willow"), UBS Eucalyptus Management, L.L.C. ("UBS Eucalyptus") and UBS Juniper Management, L.L.C. ("UBS Juniper") (UBS Willow, UBS Eucalyptus, and UBS Juniper are referred to collectively as "UBS Alternative Managers"); UBS Global Asset Management (Americas) Inc. ("UBS Global AM Americas"); UBS Global Asset Management (US) Inc. ("UBS Global AM US"); and the Settling Firm (each an "Applicant" and collectively, the "Applicants").[1]

Filing Date: The application was filed on December 19, 2012, and amended on January 31, 2013.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on March 12, 2013, and should be accompanied by proof of service on Applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: UBS AG, ESC–GP, and the Settling Firm, c/o UBS Investment Bank, 677 Washington Boulevard, Stamford, CT 06901; UBSFS, 1200 Harbor

[1] Applicants request that any relief granted pursuant to the application also apply to any existing or future company of which the Settling Firm is or may become an affiliated person within the meaning of section 2(a)(3) of the Act (together with the Applicants, the "Covered Persons").

Draft USG Policy for Institutional Oversight of Life Sciences DURC
Posted for public comment Feb. 2013

United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Contents

Section 1. Introduction

Life sciences research is essential to the scientific advances that underpin improvements in the health and safety of the public, agricultural crops and other plants, animals, the environment, materiel[1], and national security. Despite its value and benefits, however, certain types of research conducted for legitimate purposes can be utilized for benevolent or harmful purposes. Such research is called "dual use research." Dual use research *of concern* (DURC) is a subset of dual use research defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and synergistic statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability.[2] Some risks relate directly to the characteristics of DURC – the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all these domains, to ensure that risks are appropriately managed and benefits realized. This Policy addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research. A comprehensive oversight system must include both Federal and institutional oversight processes. The goal of oversight is to preserve the benefits of life sciences research while minimizing the risk that knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm. On March 29, 2012, the U.S. Government (USG) issued its "Policy for Oversight of Life Sciences Dual Use Research of Concern" (*March 29 Policy*). That policy formalized a process of regular Federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins to identify DURC and implement mitigation measures, where applicable.

The Policy herein, "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," addresses institutional oversight of DURC. Oversight includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures

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[1] Materiel includes food, water, equipment, supplies, or material of any kind.

[2] e.g. Select Agents and Toxins Program (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.pdf); Biosafety in Microbiological and Biomedical Laboratories 5th Edition (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)

are implemented, where applicable. Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC. This Policy, in addition to the *March 29 Policy*, emphasizes a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.[3] The components outlined in the *March 29 Policy* and in this Policy will be updated, as needed, following domestic dialogue, international engagement, and input from interested communities including scientists, national security officials, and global health specialists.

Because institutional oversight of DURC will be a new undertaking for many institutions, the USG is currently limiting the requirements in this Policy, as well as the *March 29 Policy*, to research that meets the scope in Section 6.2, which focuses on a well-defined subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the Policy; will evaluate the impact of DURC oversight on the life sciences research enterprise; will assess the benefits and risks of expanding the scope of the Policy to encompass additional agents and toxins and/or categories of experiments; and will update the Policy, as warranted. Research institutions are encouraged to be mindful that research outside of the categories articulated in this Policy may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their oversight to other types of life sciences research as they deem appropriate.

It is important to note that research that meets the definition of DURC often increases our understanding of the biology of pathogens and makes critical contributions to the development of new diagnostic, prevention, and treatment measures, improvements in public, animal, and plant health surveillance, and the enhancement of emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this Policy supersedes the Department of Health and Human Services and the United States Department of Agriculture Select Agents and Toxins Program's (SAP) statutory authority or SAP regulations as published in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

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[3] The *March 29 Policy* and this Policy are complemented by other extant laws and treaties (e.g. United States Code Title 18 Section 175 part a, 175 part b, and 175b and Biological and Toxin Weapons Convention) that prohibit the development, production, acquisition, or stockpiling of biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and that prohibit the use of biological agents and toxins as weapons.

Section 2. Purpose

The purpose of this Policy is to strengthen regular institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential DURC and mitigate risks where appropriate. This Policy delineates the roles and responsibilities of Federal funding agencies, research institutions, and life scientists, and establishes requirements and performance standards for review of research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC, where applicable. In so doing, the Policy seeks to preserve the benefits of DURC while minimizing the risk that the knowledge, information, products, or technologies generated from such research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Section 3. Guiding Principles for Oversight of Life Sciences Dual Use Research

The following principles serve as a guide for oversight of life sciences dual use research generally:

A. Life sciences research makes possible advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong national security and economy.

B. Life sciences research has the potential to produce beneficial knowledge, information, technology, or products that can also be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, or the environment. Therefore, it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.

C. Life sciences research is by nature dynamic and can produce unanticipated results, and therefore must be evaluated on an ongoing basis for dual use potential.

D. Oversight of DURC must recognize both the need for security and the need for research progress; as such, the degree of oversight should be consistent with the possible consequences of misuse.

E. Effective oversight helps maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of DURC and is acting responsibly to protect public welfare and security.

F. Federal agencies that fund DURC, the recipients of those public funds, and individuals who conduct this research share the oversight responsibility.

G. It is essential to have a consistent approach to the oversight of DURC.

H. Any oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.

I. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research.

J. Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior.

K. No policy or set of guidelines can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key considerations in the responsible evaluation of research for dual use potential. It is incumbent on those engaged in life sciences research to adhere to the intent of this Policy as well as to the performance standards described herein.

Section 4. Definitions

For the purpose of this Policy the following terms are defined:

A. "Dual use research" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

B. "Dual use research of concern," or "DURC," is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

C. "Institution" is any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity involved in funding, conducting, or sponsoring research.

D. "Institutional Contact for Dual Use Research," or "ICDUR," is designated by the institution to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant Federal funding agency.

E. "Institutional review entity" is established by the institution to execute the requirements in Section 7.2.B.i-7.2.B.v below and has the attributes described in Section 7.2.E below.

F. "Life sciences" pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic biology, environmental science, public health, modeling,

engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

G. "National Science Advisory Board for Biosecurity" (NSABB) is a Federal advisory committee established to advise the USG on dual use research issues.

Section 5. Policy Statement

It is the policy of the USG that:

A. Life sciences research that meets the scope specified in Section 6.2 of this Policy is subject to Federal as well as institutional oversight. The purpose of this oversight is to preserve the benefits of such research while minimizing the risk that the knowledge, information, products, or technologies generated by DURC could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security; and

B. Oversight includes the identification of life sciences research that raises dual use concerns as well as the implementation of measures to mitigate the risk that DURC is used in a manner that results in harm. Measures that mitigate the risks of DURC should be applied in a manner that minimizes, to the maximum extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.

Section 6. Applicability of this Policy and Scope of Oversight of DURC

6.1. Applicability

This Policy and its oversight requirements apply to:

A. Federal departments and agencies that fund or conduct life sciences research.

B. Institutions within the United States that receive Federal funds to conduct or sponsor life sciences research, and conduct or sponsor research that is within the scope identified in Section 6.2, regardless of source of funding.

C. Institutions outside of the United States that receive Federal funds to conduct or sponsor research that is within the scope identified in Section 6.2.

Non-compliance with this Policy may result in suspension, limitation, or termination of Federal funding, or loss of future Federal funding opportunities for the non-compliant Federally-funded research project and of Federal funds for other life sciences research at the institution. While each Federal funding agency is responsible, in accordance with their

relevant statutory authorities, for determining how best to ensure compliance with the oversight requirements set forth in this Policy for research it funds, the USG, to the maximum degree possible, will develop and promulgate consistent processes for this purpose.

Institutions that do not receive any Federal funds for life sciences research, but that nevertheless conduct life sciences research that has the potential to generate knowledge, information, products, or technologies that could be used in a manner that results in harm, are strongly encouraged to implement similar oversight procedures consistent with the culture of shared responsibility underpinning this Policy.

6.2. Scope of Oversight Required Under this Policy

Consistent with the *March 29 Policy*, under this Policy, life sciences research that uses one or more of the agents or toxins listed in Section 6.2.1, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 will be evaluated for DURC potential.

6.2.1. Agents and toxins[4]

a) Avian influenza virus (highly pathogenic)
b) *Bacillus anthracis*
c) Botulinum neurotoxin[5]
d) *Burkholderia mallei*
e) *Burkholderia pseudomallei*
f) Ebola virus
g) Foot-and-mouth disease virus
h) *Francisella tularensis*
i) Marburg virus
j) Reconstructed 1918 Influenza virus
k) Rinderpest virus
l) Toxin-producing strains of *Clostridium botulinum*
m) Variola major virus
n) Variola minor virus
o) *Yersinia pestis*

6.2.2. Categories of experiments

a) Enhances the harmful consequences of the agent or toxin
b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification

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[4] These agents and toxins are regulated by the Select Agent Program under Federal law (7 C.F.R. part 331, 9 C.F.R. part 121, 42 C.F.R. part 73), and have the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products.

[5] For the purposes of this Policy, there are no exempt quantities of toxin. Research involving any quantity of Botulinum neurotoxin should be evaluated for DURC potential.

c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e) Alters the host range or tropism of the agent or toxin
f) Enhances the susceptibility of a host population to the agent or toxin
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in 6.2.1, above.

Section 7. Organizational Framework for Oversight of DURC

This Section describes the organizational framework for the oversight of DURC and articulates the roles and responsibilities of PIs, institutions, Federal funding agencies, and the USG under this Policy. Generally, components of the oversight system for DURC include:

A. Identification, by the PI, of life sciences research that falls within the scope of Section 6.2.1 (described in Section 7.1 below);

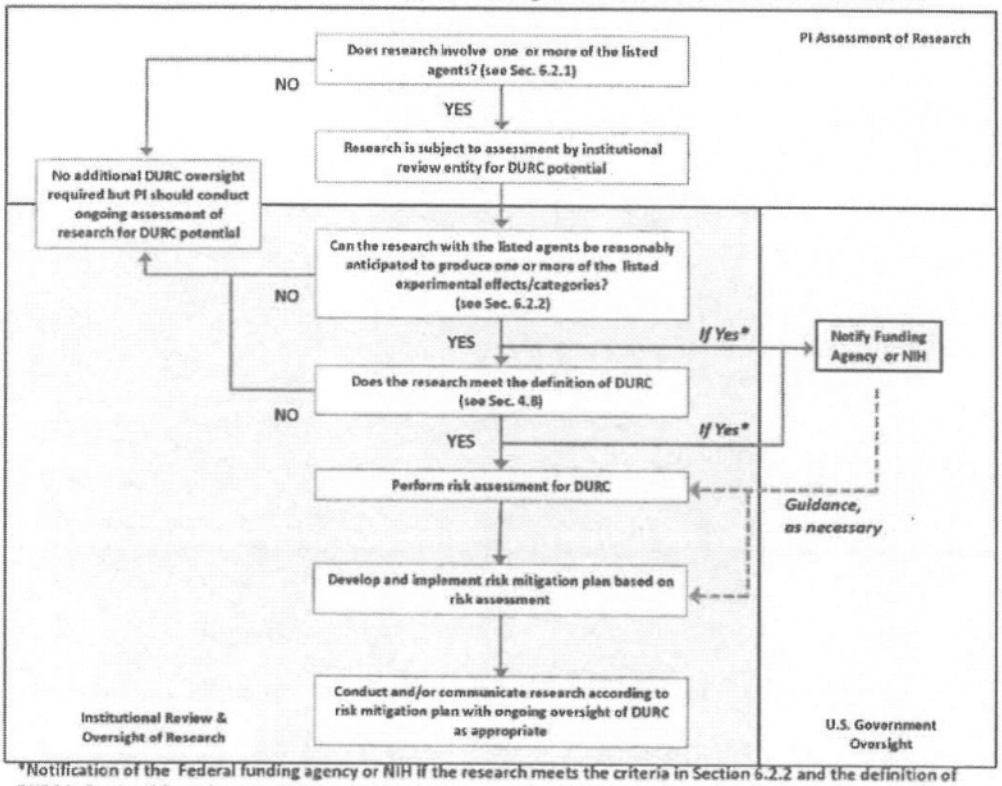
B. An institutional review process for assessing whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2, and if so, determining whether the research meets the definition of DURC in Section 4.B. This includes assessing the benefits and risks associated with its conduct and communication, developing a plan for mitigating identified risks, and ensuring that research is conducted in accordance with the risk mitigation plan (described in Section 7.2 below);

C. Notification of the results of this review process and provision of the risk mitigation plan by the institution to the Federal funding agency or for non-Federally funded research, to the National Institutes of Health (NIH) (which will receive for administrative purposes on behalf of all of the institution's Federal funders) and annual assurance of compliance with the Policy described in Section 7.2 below; and

D. Oversight by Federal funding agencies and the USG as articulated in the *March 29 Policy* with additional responsibilities with respect to this Policy described in Section 7.3 and 7.4 below.

Figure 1 provides an overview of the institutional oversight process.

Steps in the Institutional Review and Oversight of Dual Use Life Sciences Research



*Notification of the Federal funding agency or NIH if the research meets the criteria in Section 6.2.2 and the definition of DURC in Section 4.B can be concurrent.

7.1. Responsibilities of Principal Investigators of Research that is Subject to Institutional DURC Oversight

In accordance with this Policy, PIs are to:

A. Identify his or her research involving one or more of the agents or toxins listed in Section 6.2.1 and refer that research to an appropriate institutional review entity to be reviewed for its DURC potential. If a PI determines that his or her research does not utilize any of the agents or toxins listed in Section 6.2.1, no further action by the PI is needed in terms of DURC oversight (Figure 1).

B. Work with the institutional review entity to develop risk mitigation measures where appropriate.

C. Conduct DURC in accordance with the provisions in the risk mitigation plan.

D. Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC.

E. Ensure that laboratory personnel conducting life sciences research that falls within the scope of this Policy (i.e., those under the supervision of laboratory leadership,

including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) have received education and training on DURC.

F. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not simply at the point of publication. When researchers are planning to communicate DURC, it is their duty to ensure that it is done in a responsible manner, and in compliance with any risk mitigation plan stipulated by the institutional review entity.

7.2. Responsibilities of Research Institutions that Conduct Research that is Subject to Institutional DURC Oversight

In accordance with this Policy, research institutions are to:

A. Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC.

B. When research is identified by a PI as utilizing one of the agents or toxins listed in Section 6.2.1, initiate an institutional oversight process that includes (Figure 1):
   i. Verification that research utilizes one or more of the agents or toxins listed in Section 6.2.1;
   ii. Determination of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2;
   iii. Determination of whether the research meets the DURC definition (Section 4.B) and is therefore DURC. If the institutional review determines that the research in question does not fall within the scope of Section 6.2.2 or does not meet the definition of DURC, the research can continue without additional DURC oversight;
   iv. Assessment of the dual use risks and the benefits of the research;
   v. Development of a risk mitigation plan for DURC, as necessary;
   vi. Implementation of the risk mitigation plan. After a risk mitigation plan is developed, the research must be conducted in accordance with that plan and must be periodically reviewed by the institution to determine if additional modifications to the risk mitigation plan are appropriate. For research that has been proposed but not yet initiated, the DURC component of the project should not be initiated until a risk mitigation plan is implemented;
   vii. Within 30 calendar days of the institutional review of the research for DURC potential, notification of the Federal funding agency of any research that falls within the scope of 6.2, including whether it meets or does not meet the definition of DURC. For non-Federally funded research, notification may be made to NIH (who may in turn notify the appropriate Federal funding agency, based upon the nature of the research); and

viii. Within 90 calendar days from the time that the institution determined the research to be DURC, provision of a copy of the risk mitigation plan to the funding agency for review – or for non-Federally funded research, provision of the plan to NIH for review (or referral to the appropriate funding agency).

C. Ensure that internal policies establish a mechanism for the PI to refer a project to the institutional review entity if, at any time, his or her work with one or more of the agents or toxins listed in Section 6.2.1 also produces or can be reasonably anticipated to produce one or more of the 7 effects listed in Section 6.2.2, or may meet the definition of DURC.

D. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of Section 6.2 and/or meets the definition of DURC. If questions arise regarding compliance, implementation of this Policy, or the *March 29 Policy*, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the Federal funding agencies, or for non-Federally funded research, between the institution and NIH (or the appropriate Federal funding agency to which NIH refers the institution).

E. Establish an institutional review entity to execute the requirements in Section 7.2.B.i-7.2.B.v above. A range of mechanisms for fulfilling the role of an institutional review entity are acceptable as long as the review entity is appropriately constituted and authorized by the institution to conduct the dual use review. Options include: (1) a committee established for dual use review; (2) an extant committee (such as an Institutional Biosafety Committee[IBC]) whose constitution meets or could meet, with the addition of ad hoc members, the requirements outlined below; or (3) an externally administered committee (e.g., an IBC or review entity at a neighboring or regional institution or a commercial entity).

   Regardless of the mechanism selected to fulfill the institutional responsibility of reviewing research that falls within the scope of Section 6.2.1, the review entity must:

   i. Be sufficiently empowered by the institution to ensure compliance with the institution's dual use research policies.
   ii. Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility.
   iii. Have knowledge of dual use issues, concerns, and related institutional and Federal policies and understand risk assessment and risk management considerations. The review entity should be aware that a variety of risk mitigation measures are available and that designating research as DURC does

not necessarily mean that the research should not be conducted or communicated.

iv. Make its procedures for reviewing life sciences research for dual use potential accessible to the public. The posted policies of the institution should include an overview of the institution's procedures or review process, but should not include details of particular cases or the minutes of the DURC review entity's proceedings.

v. On a case by case basis, recuse any member of an institutional review entity who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity.

vi. Engage in an ongoing dialogue with the PI of the research in question when developing appropriate risk mitigation plans.

vii. Maintain records of institutional DURC reviews and completed risk mitigation plans for three years.

F. Provide education and training on DURC for individuals conducting life sciences research that falls within the scope of this Policy. Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research.

G. Maintain records of personnel training on dual use research for three years.

H. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days to the Federal funding agency or, for non-Federally funded research, to NIH (which will receive for administrative purposes on behalf of all of the institution's Federal funders).

I. As necessary, assist the PIs of life sciences research when questions arise about whether their research may require further review or oversight.

J. Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the institutional review entity to meet the definition of DURC.

K. On an annual basis, provide a formal assurance to the Federal funding agencies that the institution is in compliance with all aspects of this Policy.

Note: The USG recognizes that there will be situations where a PI is conducting potential DURC at multiple institutions. It is under the purview of each institution to review these projects and if DURC is being conducted at their institution, develop and implement risk mitigation plans as appropriate.

7.3. Responsibilities of Federal Departments and Agencies that Fund Research that is Subject to DURC Oversight

The oversight process and the roles and responsibilities of the Federal departments and agencies that fund life sciences research are delineated in the complementary *March 29 Policy*. In accordance with this Policy aimed at institutions, Federal departments and agencies that fund DURC are to:

A. Require all institutions they fund that meet the applicability criteria in Section 6.1 to implement this Policy. One mechanism for implementing the Policy is through a term and condition of award.

B. Respond to questions from institutions regarding the oversight of DURC and provide guidance to institutions regarding compliance with this Policy.

C. For department- or agency-funded and proposed life sciences research that meets the criteria listed in Section 6.2.1, assess the applicability of the criteria listed in Section 6.2.2, and for such research that also meets the definition of DURC, complete a risk assessment prior to the funding decision and when progress reports are submitted by PIs. Federal departments and agencies will review projects on an ongoing basis for DURC and are to:
   i. For research that meets the criteria in Section 6.2.1, notify an institution when the department or agency assesses that the research meets the criteria listed in Section 6.2.2 and meets the definition of DURC;
   ii. Notify an institution when the department or agency does not agree with an institution's assessment of the applicability of the criteria listed in Section 6.2.2 or with an institution's determination of the DURC status of such research;
   iii. Review institutional risk mitigation plans and notify an institution of any concerns or disagreements with a risk mitigation plan; and
   iv. Prior to reaching its final determination, the funding agency will consult with institutions to address any disagreements identified in accordance with sections 7.3.D.i, ii, and iii above.

D. Respond to reports of non-compliance with this Policy and work with institutions to address such non-compliance.

E. For research institutions in low-resource environments outside of the United States that receive USG funds, the funding department or agency may elect to serve as the implementing institutional review entity if appropriate.

7.4. Responsibilities of the USG

In accordance with this Policy, the USG is to:

A. Develop training tools and materials for use by the USG agencies and by institutions implementing this Policy.

B. Provide education and outreach to affected stakeholders about dual use policies and issues.

C. Provide guidance to institutions on the distribution of DURC research products and on the communication of DURC.

D. Convene advisory bodies such as NSABB, as necessary, to develop recommendations on particularly complex cases of DURC.

E. Periodically assess the impact of this Policy on life sciences research programs and institutions, and update the Federal and institutional dual use research oversight policies as appropriate. This should be informed by national and international dialogue with interested communities, including scientists, research administrators, security experts, and public health officials.

Section 8. Resources for Institutional Oversight of DURC

It is the expectation of the USG that PIs and institutions will be able to identify, assess, and appropriately manage DURC. To assist in these processes, the following resources are available for optional use:

A. Guidance Documents for DURC Oversight. The USG has developed a compendium of tools to assist investigators and research institutions in the implementation of DURC oversight outlined in this Policy and the *March 29 Policy*. These tools will aid in the understanding and identification of DURC, the risk assessment and development of risk mitigation plans and risk management processes, the responsible communication of DURC, and training and education on DURC.

B. Consultation with the Federal Funding Agency. Institutions may consult with the Federal department or agency that is funding the research in question for advice on matters related to DURC. Such consultations should involve the ICDUR. The funding agency program officers can provide guidance on DURC issues. Questions regarding non-Federally funded research can be directed to the NIH or to the Federal funding agency to which NIH refers the institution based on the nature of the research in question. Consultation with the funding agency is not mandatory or intended as a substitute for institutional dual use review or the reporting requirement (see Section 7.2.B above). Such consultations may be appropriate when:

   i. The institutional review entity requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
   ii. The institutional review entity considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;

iii. The PI does not agree with the finding of the institutional review entity and so the institution would like to request outside advice;
iv. The research in question represents a particularly complex case or appears to fall outside the current definition of DURC, but still seems to present significant concerns; or
v. Guidance is required to ensure a clear understanding of how the Federal government interprets the definition of DURC and related terms.

A Framework for Guiding US Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets

March 2013

A Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets

Executive Summary

In 2011, two studies funded by the National Institutes of Health (NIH), which examined the mammalian transmissibility of highly pathogenic avian influenza (HPAI) H5N1 viruses, raised concerns regarding the potential for a global pandemic due to accidental or intentional release of an engineered virus or misuse of the research information. To address these concerns, the U.S. Department of Health and Human Services (HHS), a major funder of influenza research, has developed this Framework for guiding HHS funding decisions on individual proposals involving HPAI H5N1 research with specific attributes. The Framework aims to ensure a robust review of research proposals—prior to making a funding decision—that considers the scientific and public health benefits of the proposal; the biosafety and biosecurity risks associated with the proposal; and the risk mitigation measures that are required.

The HHS Framework requires additional review for research proposals that are anticipated to generate HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets. Such proposals will undergo additional funding agency review as well as Department-level review in order to determine its acceptability for funding by HHS. Following reviews for both scientific merit and dual use research of concern (DURC),[1] the HHS funding agency will determine if the proposal is reasonably anticipated to generate an HPAI H5N1 virus[2] that is transmissible among mammals by respiratory droplets.[3] If so, the funding agency will determine whether the proposed research is in accord with the following criteria:

1) The virus anticipated to be generated could be produced through a natural evolutionary process;
2) The research addresses a scientific question with high significance to public health;
3) There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach;
4) Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed;
5) Biosecurity risks can be sufficiently mitigated and managed;
6) The research information is anticipated to be broadly shared in order to realize its potential benefits to global health; and
7) The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

If a proposal meets these criteria and is being contemplated for funding, the agency will submit the proposal for Department-level review. The Department-level review will provide multidisciplinary expertise—including public health, scientific, security, intelligence, countermeasures, and preparedness and response—to evaluate these proposals. The Department-level review will also identify any additional risk mitigation measures that are required, and determine whether a given proposal is acceptable for HHS funding. For proposals that are deemed acceptable for HHS funding, the funding agency within HHS will make the final funding decision. Proposals that have been determined to be unacceptable for HHS funding through Department-level review are not eligible for funding agency support. Figure 1 outlines the review process described by the Framework.

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[1] The *U.S. Government Policy for Oversight of Life Science Dual Use Research of Concern* (March 29, 2012) defines dual use research of concern as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security."

[2] HPAI H5N1 viruses are defined here as influenza viruses that express the virulent form of the hemagglutinin (HA) gene from highly pathogenic H5N1 virus.

[3] Proposals aimed at characterizing naturally occurring strains are exempt from this Framework.

I. Purpose

To address concerns raised by studies that alter the mammalian transmissibility of highly pathogenic avian influenza (HPAI) H5N1 viruses, the U.S. Department of Health and Human Services (HHS) has developed a Framework for guiding HHS funding decisions on individual proposals involving HPAI H5N1 research with specific attributes. The Framework described here is intended to ensure a robust review of research proposals—prior to making a funding decision—that considers the scientific and public health benefits of the proposal; the biosafety and biosecurity risks associated with the proposal; and the risk mitigation measures that are required.

II. Issue and Task at Hand

In 1997, the HPAI H5N1 virus appeared in Hong Kong, and since 2006, descendants of this virus have posed a smoldering threat in many regions of the world. Humans are infected primarily by contact with infected birds, but naturally occurring HPAI H5N1 viruses do not appear well-adapted for transmission among mammals. Approximately 600 laboratory-confirmed human cases have been reported since 2003, with a fatality rate of nearly 60%, and hundreds of millions of birds have died as a result of infection or culling to prevent further outbreaks among domestic flocks.[4]

Today, the public health community remains vigilant as HPAI H5N1 influenza viruses continue to evolve and potentially gain the ability to spread efficiently in humans. One of the goals of HPAI H5N1 research is to identify the genetic changes that correlate with transmission or enhanced virulence of these viruses in mammals. For the purposes of this paper, studies that enhance these biological properties are referred to as "gain-of-function" research.[5] Information gained from these studies is intended to contribute to pandemic preparedness efforts. Such research may also enable the development and evaluation of countermeasures, such as vaccines, antivirals, and diagnostics for HPAI H5N1 strains that have the potential to spread among humans. The question that ensues is whether HPAI H5N1 gain-of-function research is needed to achieve these aims, and if so, under what conditions such studies should be conducted.

In 2011, two studies funded by the National Institutes of Health (NIH), which examined the mammalian transmissibility of HPAI H5N1 viruses, raised concerns regarding the potential for a global pandemic due to accidental or intentional release of an engineered virus or misuse of the research information.[6,7] Others argued that the risk of <u>not</u> conducting HPAI H5N1 gain-of-function studies would compromise the ability of the scientific and public health communities to prepare for and respond to potential influenza pandemics—both naturally-occurring and those stemming from intentional misuse.
In light of the difficult and important questions raised by the debate over whether and how to conduct and communicate gain-of-function studies, the influenza research community initiated a voluntary moratorium in January 2012 on research with HPAI H5N1 viruses that could generate new viruses with increased transmissibility in mammals, or any research with H5N1 or H5 hemagglutinin (HA) reassortant viruses already shown to be transmissible in ferrets.[8,9] The international scientific community and policy

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[4] http://www.cdc.gov/flu/avianflu/h5n1-virus.htm
[5] "Gain-of-function" is typically defined more broadly as a mutation that confers a new or enhanced activity to a protein. For the purposes of this paper, "gain-of-function" studies refer specifically to those that increase the transmissibility, increase the pathogenicity, or alter the host range of HPAI H5N1 viruses.
[6] Herfst S, *et al.* Science. 336(6088):1534-1541 (22 June 2012).
[7] Imai M, *et al.* Nature 486: 420–428 (21 June 2012).
[8] Fouchier RA, *et al.* Nature. 481:443 (26 January 2012).

makers called for a discussion of the future direction of this research that includes experts in the life sciences, public health, biosecurity, biosafety, law, and science policy.[10,11]

III. A Path Forward

Framework for guiding HHS funding decisions

HHS is a major funder of influenza research, and as such will need to determine which, if any, HPAI H5N1 gain-of-function research projects are acceptable for HHS funding. This Framework will be used by HHS and its funding agencies to guide funding decisions on individual proposals involving certain HPAI H5N1 gain-of-function research. Figure 1 provides a comprehensive outline of this process. The Framework is intended to ensure a robust review by HHS—prior to making a funding decision—that considers the scientific and public health benefits of the proposal; the risks associated with biosafety, biosecurity, and dual use; and the appropriate risk mitigation measures that are required.

As part of developing this funding Framework for HPAI H5N1 gain-of-function research, HHS solicited the perspectives of the various stakeholders at an international consultative workshop held at NIH in Bethesda, Maryland on December 17-18, 2012. An international group of influenza and non-influenza scientists, as well as experts in biosafety, biosecurity, public health, and representatives from other governments and international organizations were present at this public workshop and provided input on the proposed Framework. The workshop included a full and open discussion by the participants and audience members of the draft Framework document and of representative case studies. During these discussions, it became evident that a subset of research generated enough concern to warrant special consideration prior to its funding—namely, research that is anticipated to generate HPAI H5N1 viruses that are transmissible by respiratory droplets among mammals.

When considering whether to fund certain HPAI H5N1 gain-of-function proposals, it is important that HHS analyze the potential risks and benefits associated with each proposal on a case-by-case basis. Risk assessments will include careful consideration of the scope and magnitude of the potential risks and benefits associated with the research proposal, evaluation of whether the risks outweigh the benefits, and strategies for mitigating potential risks. Such assessments will consider the risks associated with the intrinsic nature of the virus used in the proposal (i.e., the transmissibility, pathogenicity, and host range of the starting viral strain) as well as the risks associated with any experimental manipulations outlined in the proposal (i.e., the likelihood that the virus will become more transmissible or more virulent in mammals). Risk assessments will also consider the ease with which the research could be misused and the possible timeframe for such misuse.

Risk assessments will also occur during other reviews, such as review by the Institutional Biosafety Committee and funding agency review for dual use research of concern (DURC).[12] Such assessments will

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[9] Fouchier RA, *et.al.* Science. Vol. 335, no. 6067. (26 January 2012)

[10] Technical consultation on H5N1 research issues – consensus points. World Health Organization, Geneva, 16-17 February 2012. http://www.who.int/influenza/human_animal_interface/consensus_points/en/index.html

[11] Fauci AS. 2012. Research on highly pathogenic H5N1 influenza virus: the way forward. mBio 3(5):e00359-12. doi:10.1128/mBio.00359-12 http://mbio.asm.org/content/3/5/e00359-12.full

[12] The *U.S. Government Policy for Oversight of Life Science Dual Use Research of Concern* (March 29, 2012) defines dual use research of concern as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security."

factor into the risk-benefit assessments performed specifically for HPAI H5N1 gain-of-function research proposals. Risk-benefit assessments will occur during the funding agency's review of the proposal to determine whether it meets the funding criteria (see Box 2) and the Department-level review (see Box 3).

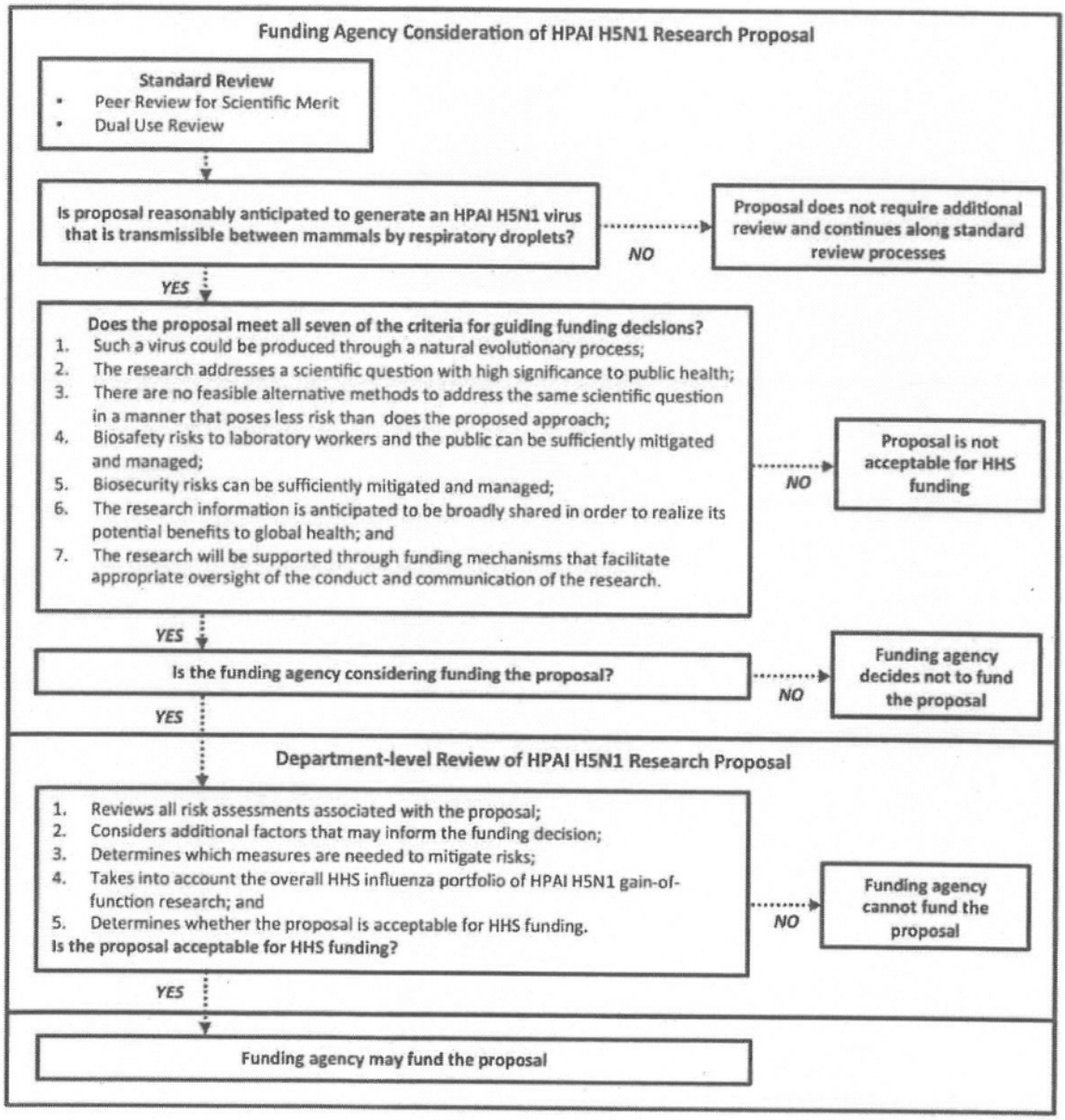

Figure 1. Overview of HHS Review of HPAI H5N1 Gain-of-Function Research Proposals

Applicability of the Framework

The HHS Framework requires higher-level review for funding applications that include or are reasonably anticipated to generate HPAI H5N1 viruses with gain-of-function attributes that enable respiratory droplet transmission of the virus among mammals (Box 1).[13]

> **Box 1. Applicability of the Framework.**
>
> HHS will apply this review Framework to proposals that are reasonably anticipated to confer gain-of-function attributes that enable influenza viruses expressing the virulent form of the hemagglutinin (HA) gene from highly pathogenic H5N1 to be transmissible among mammals by respiratory droplets.
>
> The scope of the Framework does not include routine characterization studies of naturally occurring H5N1 viruses.

"Characterization studies" of naturally occurring H5N1 viruses, including studies that examine the virus's potential for transmissibility among mammals by respiratory droplets, are intentionally exempted from the Framework. Characterization studies include sequencing and testing of antigenicity, antiviral drug susceptibility, and pathogenicity. "Naturally occurring" is intended to refer to mutations that arise in nature or through a natural process, and were not engineered by researchers or obtained by serial passaging of viruses. Characterization studies do not intend, nor are they reasonably anticipated to generate, novel viruses with gain-of-function attributes. In addition, the characterization of naturally occurring viruses does not introduce the risks associated with generating or engineering new H5N1 viruses.

To ensure that this Framework can be applied throughout the course of the research, HHS will include a term and condition of award for all HPAI H5N1 projects that requires researchers to report to HHS any unanticipated results that involve the generation of a virus that is transmissible among mammals by respiratory droplets. Of note, this Framework does not supersede any existing policies, regulations, rules, or guidelines.

Criteria for guiding HHS funding decisions about HPAI H5N1 gain-of-function research proposals

As part of the funding decision, and after scientific merit and DURC reviews, HHS funding agencies will determine whether HPAI H5N1 gain-of-function research proposals meet the criteria listed in Box 2. Proposals that do not accord with all of these criteria are not acceptable for HHS funding.

> **Box 2. Criteria for guiding HHS funding decisions for research proposals with the potential to produce HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets.**
>
> Gain-of-function research proposals that are anticipated to produce HPAI H5N1 strains that are transmissible among mammals by respiratory droplets are acceptable for HHS funding only if:
>
> 1. Such a virus could be produced through a natural evolutionary process;
> 2. The research addresses a scientific question with high significance to public health;
> 3. There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach;
> 4. Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed;
> 5. Biosecurity risks can be sufficiently mitigated and managed;
> 6. The research information is anticipated to be broadly shared in order to realize its potential benefits to global health; and
> 7. The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

[13] This Framework will apply to extramural as well as intramural research.

HHS funding agencies will apply the above criteria when considering a funding proposal for a gain-of-function research project and will continue to consider the principles inherent in these criteria throughout the lifespan of the research to inform the planning of its conduct and oversight. Researchers and institutions should be mindful of these criteria when submitting research proposals and when conducting research that may be covered under this Framework. Researchers and institutions should continue to apply these criteria throughout the lifespan of any HPAI H5N1 research project that receives HHS funding when determining how to conduct the research and whether to continue conducting certain studies.

The funding agency will make an initial determination of whether the proposed risk mitigation strategies identified by the biosafety and biosecurity reviews are adequate, and it will incorporate any additional measures into the terms and conditions of award, as necessary. Risk mitigation measures may include, but are not limited to, those described in the *U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern*.

Review by the HHS funding agency of a gain-of-function research proposal with the potential for generating an HPAI H5N1 virus that is transmissible among mammals by respiratory droplets may result in one of two outcomes. The HHS funding agency may:

- Not fund the research proposal; or
- Refer the research proposal for Department-level review.

HPAI H5N1 gain-of-function research proposals that warrant Department-level HHS review

If a research proposal that has the potential to produce HPAI H5N1 strains that are transmissible among mammals by respiratory droplets has satisfactorily undergone peer review and DURC review, is in accord with all of the criteria in Box 2, and is being considered for funding by the HHS funding agency, then additional Department-level HHS review is required to determine if the proposal is acceptable for HHS funding (Box 3). For NIH awards, Department-level review will occur before NIH council review.

Box 3. Department-level review of research proposals with the potential to produce HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets.

HPAI H5N1 gain-of-function research proposals that meet the criteria in Box 2, and that the HHS funding agency is considering funding, require Department-level review.

The purpose of the Department-level HHS review is to:

- Review the funding agency's risk assessments;
- Provide additional and multidisciplinary expertise to consider whether additional factors may alter assessment of whether the research can be funded;
- Carefully consider proposals that are reasonably anticipated to:
  - Increase pathogenicity in mammals;
  - Disrupt the induction of a host's innate immunity;
  - Interfere with the effectiveness of an available vaccine;
  - Confer to the agent resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent; or
  - Facilitate the virus' ability to evade detection methodologies.
- Determine which measures are needed to mitigate risks;
- Take into account the overall HHS influenza portfolio of HPAI H5N1 gain-of-function research; and
- Determine whether the proposal is acceptable for HHS funding.

The purpose of the Department-level review is to provide balanced, multidisciplinary expertise and perspectives to the consideration of proposals that involve HPAI H5N1 gain-of-function studies. This will include expertise in countermeasure development and availability, national security, law, public health preparedness and response, biodefense, select agent regulations, and science and public health policy, as well as funding agency perspectives and other areas. A core review group will draw on relevant expertise within HHS, as well as *ad hoc* consultants from other departments and agencies as necessary. In some cases, HHS may wish to seek additional expertise from within HHS and/or from additional departments or agencies. Moreover, there may be cases in which additional consultation with outside *ad hoc* experts or consultation with Federal advisory bodies (such as the National Science Advisory Board for Biosecurity, the NIH Recombinant DNA Advisory Committee, and the National Biodefense Science Board) is desirable.

The Department-level review will consider proposals in the context of the entire HHS research portfolio of HPAI H5N1 research. For instance, HHS can determine whether the proposal meets a critical, unmet research need that requires HHS investment, or whether the risks associated with the project in question are not justified, given the other, perhaps similar, research being supported by HHS and/or other Federal agencies. The Department-level review will also help to address real or perceived conflicts of interest with respect to the funding agency.

Within 14 working days of receipt of a proposal with supporting information from a funding agency, the Office of the Assistant Secretary for Preparedness and Response, with assistance from the HHS Office of General Counsel, will convene the core review group and, as necessary, any *ad hoc* consultants. Funding agency staff will describe the proposal, its importance, its relevance to the field and to the agency's portfolio, and the results of applying the Framework. The core review group and *ad hoc* consultants will discuss the proposal and consider the implications for national security, public health, international agreements, and any other issues and relevant information. Summary observations and recommendations from the Department-level review will be sent to the Assistant Secretary for Preparedness and Response to determine whether a given proposal is acceptable for HHS funding. The decision will be transmitted to the funding agency within HHS to make the final funding decision. Proposals that have been determined to be unacceptable for HHS funding after Department-level review are not eligible for funding agency support. Of note, if the research project generates results that are both unanticipated and concerning during the course of the research, the funding agency will apply the Framework and work with the research institution to determine the appropriate path forward.

If a proposal is determined to be unacceptable for HHS funding, applicants will be provided with a brief justification explaining why a proposal was determined to be unacceptable. If the investigators so choose, they may address concerns and resubmit their proposal during a future grant cycle.

IV. Next Steps

Investigators who submit proposals that fall within the scope of the Framework are encouraged to be mindful of the Criteria listed in Box 2 and to develop their proposals accordingly. The Framework will be reevaluated periodically and modified as necessary to reflect scientific advances and changes in the regulatory landscape.

Science article about HHS Framework
March 2013

RESEARCH FUNDING

A Framework for Decisions About Research with HPAI H5N1 Viruses

The U.S. Department of Health and Human Services unveils a Framework for funding decisions about highly pathogenic avian influenza H5N1 research.

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Since it appeared in Hong Kong in 1997, the highly pathogenic avian influenza (HPAI) H5N1 virus has presented a persistent threat to public health and agriculture. Worldwide, hundreds of millions of birds have died as a result of infections or culling to prevent further spread of outbreaks among domestic flocks (*1*). HPAI H5N1 has caused severe respiratory illness and death in a relatively small number of humans—primarily those who have worked in direct contact with infected poultry (*2*). Of the ~600 laboratory-confirmed human cases from 2003 to the present, nearly 60% were fatal. At present, the virus does not appear well-adapted for sustained transmission among mammals by respiratory droplets. However, if the viruses occurring in nature were to become readily transmissible among mammals, they could pose the risk of a pandemic.

Research aimed at understanding the host adaptability and transmission of HPAI H5N1 virus is a public health imperative. Internationally, scientists are seeking insights that will enable more effective surveillance capabilities, vaccines, and therapies, as well as a foundation for innovative public health solutions in the future.

In 2011, two studies funded by the National Institutes of Health (NIH), which examined mammalian transmissibility of HPAI H5N1, generated controversy (*3*, *4*). Using a "gain-of-function" approach, researchers engineered HPAI H5N1 viruses to render them transmissible by respiratory droplets among ferrets, an animal commonly used to model human influenza infection. These studies provided critical information to scientists and public health officials by demonstrating that HPAI H5N1 viruses can mutate to enable them to spread efficiently among certain mammals and, therefore, perhaps among humans. However, the generation of these strains raised safety and security concerns centered on whether the engineered strains could be released accidentally or used nefariously to threaten public health or national security. They triggered a global discussion regarding the benefits and risks of funding, conducting, and publishing these types of gain-of-function studies.

As a result, members of the influenza research community initiated a voluntary moratorium on gain-of-function studies involving HPAI H5N1 mammalian transmissibility (*5*, *6*). This pause allowed for intense discussions of the risks and benefits associated with the research and provided governments and other funding organizations an opportunity to develop appropriate oversight policies. The moratorium was initially intended to last 60 days but was extended for 1 year. Recently, the signatories have announced an end to the moratorium for scientists with appropriate facilities and national oversight (*7*). They urged scientists to continue the research pause if they are working in countries that had not yet finalized the appropriate conditions for conducting HPAI H5N1 transmission research.

The U.S. Department of Health and Human Services (HHS) has grappled with the challenge of how best and, indeed, whether to support certain types of HPAI H5N1 gain-of-function research (*8*). Toward this end, HHS has developed a Framework (www.phe.gov/S3/dualuse) for guiding funding decisions on individual proposals involving HPAI H5N1 research with specific attributes. The Framework aims to ensure a robust review of research proposals—before making a funding decision—that considers the scientific and public health benefits of the proposal, the biosafety and biosecurity risks associated with the proposal, and the appropriate risk mitigation measures required for such research. In November 2012, a draft version of this Framework was presented to the National Science Advisory Board for Biosecurity (NSABB) for its consideration and subsequently posted for public comment.

HHS also sought international and multidisciplinary perspectives at a workshop held in Maryland on 17 and 18 December 2012 (*9*). Participants discussed the risks and benefits of HPAI H5N1 gain-of-function research, the biosafety conditions that should be in place for conducting such research, and the importance of international cooperation in preventing future pandemics. Some expressed concerns that the information generated by this research could enable others to replicate the studies under less-than-ideal biosafety conditions or for malevolent purposes. Although it was generally noted that gain-of-function studies will provide important scientific insights, there was debate over how readily and directly this information can be applied to vaccine development or surveillance efforts, at least in the near term.

Commenters noted that while gain-of-function experiments that enhance virulence or alter host range of HPAI H5N1 are concerning, it is conferring the ability to efficiently spread among mammals by respiratory droplets that raises the most concern and warrants special consideration prior to funding. This and other input was instrumental in finalizing the HHS Framework. In developing the Framework, HHS has considered several key questions: Is this subset of gain-of-function experiments necessary to address the public health threat

CRITERIA FOR GUIDING HHS FUNDING DECISIONS FOR CERTAIN H5N1 GAIN-OF-FUNCTION RESEARCH PROPOSALS

- Such a virus could be produced through a natural evolutionary process.
- The research addresses a scientific question with high significance to public health.
- There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach.
- Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed.
- Biosecurity risks can be sufficiently mitigated and managed.
- The research information is anticipated to be broadly shared in order to realize its potential benefits to global health.
- The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

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posed by HPAI H5N1 viruses? Would discontinuing this type of research introduce new risks by compromising our ability to prepare for and respond to influenza outbreaks? Should such research be supported by HHS and its funding agencies? If so, under what biosafety conditions should this research be conducted? In considering these questions, a number of important principles have emerged.

First, open communication of research methodologies and results is a hallmark of the life sciences and of the research that HHS and its agencies support. Widespread dissemination of research results allows rapid and sustained scientific progress and facilitates full realization of the associated public health benefits. As hypotheses and conclusions are validated or repudiated, our knowledge base is expanded, laying the foundation for new therapeutics and other applications. Therefore, HHS will only fund research that is reasonably anticipated, at the proposal stage, to generate information that can be broadly shared and openly communicated.

Second, HPAI H5N1 research involving transmission among mammals by respiratory droplets must address a scientific question with high significance to public health. HHS is a strong supporter of fundamental research, which may add to our understanding of basic biological processes and often contributes to new innovations and technologies. However, because HPAI H5N1 gain-of-function research of this type may involve a higher level of risk than other areas of study, it is important that the fundamental questions to be addressed by the research not only have high scientific merit but can be reasonably anticipated to generate information that will ultimately advance public health. Before committing to a gain-of-function approach that brings with it certain risks, researchers should explore alternative methods for addressing the same scientific question in a manner with the fewest attendant risks.

Third, the biosafety and biosecurity risks associated with a research project must be manageable. With its principal mission to protect and promote public health, HHS must, out of necessity, support some scientific research that involves a certain level of inherent risk but that is nevertheless essential for our health and well-being. Furthermore, HHS should only support proposals through funding mechanisms that allow implementation of additional risk mitigation measures as appropriate.

Like all proposals submitted to HHS funding agencies, HPAI H5N1 gain-of-function proposals are subjected to peer review to assess scientific merit. In addition, this research falls within the scope of the *U.S. Government Policy for the Oversight of Life Sciences Dual Use Research of Concern* and thus undergoes an initial and periodic review for dual use potential (*10*). The new HHS Framework requires additional funding agency and department-level review for research proposals that are anticipated to generate HPAI H5N1 viruses transmissible among mammals by respiratory droplets.

The Framework lists seven criteria (see the table), all of which must be met for such research proposals to be acceptable for HHS funding. The funding agency will assess whether proposed research meets these criteria and, if so, will submit the proposal for additional HHS-level review. The department-level review will bring to bear multidisciplinary expertise—including public health, scientific, security, intelligence, and countermeasures—in assessing the risks and benefits of the proposal and will also consider the proposal within the context of the broader HHS influenza research portfolio. Other federal departments and agencies; external advisory bodies—such as the NSABB, the NIH Recombinant DNA Advisory Committee (RAC), and the National Biodefense Science Board; and nongovernmental experts—may be consulted. The department-level review will determine the appropriate risk mitigation measures and whether a given proposal is acceptable for HHS funding. Research proposals that do not meet the seven criteria or involve risks that cannot be adequately mitigated will not receive HHS funding. Characterization studies of naturally occurring H5N1 viruses are not subject to this review Framework.

HPAI H5N1 research, in common with other life-sciences research, is subject to guidelines, policies, laws, and international agreements that govern biosafety, physical security, personnel reliability, informational risks, and nonproliferation (*11*). Such oversight is aimed at managing risks throughout the course of the research. Risks associated with infectious disease research cannot be eliminated entirely. However, they can be managed, and as the risk-benefit landscape changes, our policy response must also change as necessary. In this regard, the Centers for Disease Control and Prevention has sought public comment regarding whether certain HPAI H5N1 viruses should be regulated as an HHS Select Agent, as well as whether any special precautionary measures (i.e., biosafety containment and practices) are necessary (*12*).

The NIH RAC has also recently recommended additional enhancements to biosafety level 3 containment and practices for work with HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets (*13*). The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*14*) have been amended to include these measures.

Science is unpredictable, and not all research results can be anticipated. The HHS Framework aims to ensure consideration, at the outset, of gain-of-function research proposals that may generate HPAI H5N1 viruses that are transmissible among mammals by respiratory droplets and to make the most-informed decisions possible about whether and how to support and conduct this research. The HHS Framework will be evaluated over time and adapted to ensure that critical research needs are being met and that risks are managed appropriately. HHS will continue to engage in the collective global effort to identify the best path forward so that important research addressing this critical public health concern can continue in the most responsible manner possible.

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Science article about expansion of the HHS Framework
August 2013

LETTERS

edited by Jennifer Sills

Develop, Then Intensify

WE APPLAUD THE RECENT EFFORT BY T. GARNETT *ET AL.* ("SUSTAINABLE intensification in agriculture: Premises and policies," Policy Forum, 5 July, p. 33) to place the concept of sustainable intensification into a decision-making context. The authors emphasize that sustainable intensification must be part of a multipronged and context-dependent strategy for food security, which also includes efforts to curb consumption, improve governance, and reduce waste.

However, we question the framing of sustainable intensification as one of several issues to be tackled in parallel. Such parallel framing rests on a fundamental misunderstanding. Food insecurity is most frequently caused by poverty and political and structural problems (*1*, *2*). If a lack of production is not the primary cause of food insecurity, then an increase in production cannot be the primary solution (*3*). Only if issues such as equity, access, and distribution are addressed can increases in production improve food security. Addressing these issues offers other important benefits. For example, improved gender equality and education have been related to reduced population growth, as well as increased food production and food security (*4*, *5*).

Progress. Sustainable development programs in the Democratic Republic of Congo have led to the formation of community farming groups, which now grow enough food for their families and for sales to local markets.

Sustainable development must be the overarching framework, which incorporates food security and also provides criteria for judging whether intensification of agricultural systems is sustainable or not. Sustainable intensification cannot be a meaningful goal without regard for who intensifies, where, and who benefits from the changes. Whereas higher yields are needed in some areas (such as parts of sub-Saharan Africa), the mechanisms by which the hungry are going to benefit from intensification in other locations (such as Eastern Europe) are far less certain.

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Extra Oversight for H7N9 Experiments

THE U.S. DEPARTMENT OF HEALTH AND Human Services (HHS) announces a new review process for certain gain-of-function (GOF) experiments with the avian influenza A (H7N9) virus, some of which were proposed last week by influenza scientists (*1*). Specifically, before being undertaken using funds from the HHS, proposed studies that are reasonably anticipated to generate H7N9 viruses with increased transmissibility between mammals by respiratory droplets will undergo an additional level of review by the HHS.

The HHS review will consider the acceptability of these experiments in light of potential scientific and public-health benefits as well as biosafety and biosecurity risks, and will identify any additional risk-mitigation measures needed. The review will be carried out by a standing, multidisciplinary panel of federal experts with backgrounds in public health, medicine, security, science policy, global health, risk assessment, U.S. law, and ethics. This approach, similar to that for certain H5N1 influenza virus experiments (*2*, *3*), allows the HHS to focus special oversight efforts on experiments of concern while allowing routine characterization and other fundamental research to proceed rapidly, thereby enabling a robust public-health response.

GOF studies can provide important insights into how the A (H7N9) virus adapts to mammalian hosts, causes disease, and spreads to other hosts, but they may also pose biosafety and biosecurity risks. To ensure that research involving H7N9 virus is conducted safely and securely, the U.S. Centers for Disease Control and Prevention recently reexamined the requisite biosafety conditions for conducting experiments involving H7N9 and, in June 2013, issued interim risk assessment and biosafety level recommendations (*4*).

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The Systematic Place of Morals in Markets

IN THEIR RESEARCH ARTICLE "MORALS AND markets" (10 May, p. 707), A. Falk and N. Szech gave participants a choice between saving the life of a mouse and receiving money. The value of the mouse's life was higher when participants sold it directly to the experimenter than when they bargained over the price with other participants.

For the particular comparison they draw between selling a mouse's life directly and bargaining for it, the findings mark a substantial advance in experimental economics and experimental moral philosophy. We do not believe, however, that the general claim that "markets erode moral values" (p. 710) can be justified by this observation. The real-world examples of "immoral markets" chosen by the authors—slave trade and the sale of indulgences—are extreme cases. It is easy to find counterexamples in which markets lead to moral improvements. For example, as Falk and Szech acknowledge, replacing potentially arbitrarily acting private or state authorities with markets can benefit all affected parties (*1*, *2*) and is a direct moral improvement. More important, free markets can sometimes even create incentives for their participants to morally improve, such as by yielding lower returns to vendors who discriminate against certain groups of customers (*3*, *4*).

The moral consequences of real markets, we think, are mostly determined by the regulatory framework in which those markets are embedded (*5*, *6*). Falk and Szech's conclusions reach too far in that they claim to discuss "the market" without taking into account that different markets, while using the same mechanism of supply and demand, are subject to quite distinct rules.

Finally, Falk and Szech's design, ingenious as it is, is unable to answer the crucial question: Which institutional alternative to markets would cause less moral erosion? Therefore, their critique of the market mechanism does not lead to any constructive policy recommendation.

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Response

IN OUR RESEARCH ARTICLE, WE RAN A SERIES of controlled laboratory experiments and report a causal effect of market institutions on moral transgression. Our findings contribute to the literature on the malleability of morality in general and the effects of institutions on moral transgression in particular.

As we argue in our Research Article, we do not aim at questioning market economies per se. Markets often improve social welfare for market participants in efficiently allocating goods (*1*). Competition in markets may also pressure firms to reduce discrimination against certain groups of workers or customers (*2*). Our research interest, however, was not to study effects of markets on active market participants but on third parties—i.e., those who are not directly involved in market trading, and who potentially suffer from trade. Our study shows that market interaction reduces how people value harm and damage done to third parties.

To study how markets affect moral outcomes, we implemented bilateral and multilateral markets, using the double auction institution. This is a well-established and widely used market set-up in economics, which displays the positive properties of allocation mentioned above (*3*). We deliberately abstained from imposing additional regulatory details, to allow for more general conclusions. As is standard in economics, these markets are real, with real participants and real incentives. Thus, we are convinced that the chosen market institution is well suited for the research questions at hand.

We agree that our findings raise the pressing question of how to design policies that mitigate the problem of moral erosion in markets. This, however, requires a thorough understanding of the relevant underlying mechanisms, as we discuss in our Research Article. First, markets generate information about selling and buying behavior and thus provide systematic social information about prevailing norms. Second, because trading involves at least two parties, market interactions allow traders to share guilt associated with immoral outcomes. Third, in markets with many buyers and sellers, the notion of being pivotal is diffused: Traders may apply a "replacement logic" (*4*), telling themselves that if they do not trade, some other trader may. These mechanisms potentially play a crucial role not only in markets but also in many nonmarket contexts. For example, in group decision-making, sharing of guilt and diffusion of pivotality may contribute to moral transgression. In recent work, we used the same mouse paradigm and found causal evidence that the diffusion of pivotality in groups erodes moral behavior compared with individual decision-making (*5*).

We hope that our study laid ground for thinking about moral consequences of market interaction and that it will stimulate research on relevant mechanisms.

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CORRECTIONS AND CLARIFICATIONS

News Focus: "Insistence on gathering real data confirms low radiation exposures" by D. Normile (10 May, p. 678). The article and the caption for the image on p. 679 incorrectly describe the location of solar-powered radiation monitors and radiation monitors that plug into wall sockets as being Minamisoma. These programs are actually in Soma City. The HTML and PDF versions online have been corrected.

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***David L. Woodland, Ph.D.**
Chief Scientific Officer
Keystone Symposia on Molecular and Cellular Biology
Silverthorne, CO

* Indicates incoming members who will participate in an *ad hoc* (non-voting) capacity until their appointments are final

Patterson, Amy (NIH/OD) [E]

From: Harvey Rubin <rubinh@upenn.edu>
Sent: Monday, November 30, 2009 9:43 AM
To: Patterson, Amy (NIH/OD) [E]
Subject: RE: Service on NSABB

Dear Amy
Thanks for making the NSABB work so well—it is a major accomplishment and is in great measure a function of your devotion to the cause. I enjoyed every minute. Please do not hesitate to call if you think I may help in any way.
Harvey

From: Patterson, Amy (NIH/OD) [E] [mailto:PattersA@OD.NIH.GOV]
Sent: Wednesday, November 11, 2009 6:41 PM
To: 'rubinh@mail.med.upenn.edu'
Subject: Service on NSABB

Dear Harvey,

We have very much appreciated your willingness to continue serving on the NSABB until your replacement was on board. As you may know, we have been working for some time to bring on the first group of new NSABB members, and have just learned that the last bit of red tape has been completed. One of the new individuals is your replacement, so this is to let you know that your term of service on the NSABB has officially ended.

Since 2005, you have provided an invaluable service to the government and the public through your participation on the NSABB. Your contributions have informed the development of recommendations on a range of timely and pressing concerns regarding biosecurity and dual use research that are now informing the development of federal policy. Your insights and the wealth of experience you brought to this dialogue have been tremendously appreciated by the NIH and all of the other participating federal agencies.

Although your official obligations to the NSABB are over, we nonetheless wanted to extend an invitation to you to attend the upcoming NSABB meeting on December 3, as we are planning to publicly acknowledge your service and that of the other members who are rotating off at this point. You would also be able to hear about the latest report of the NSABB (on synthetic biology) which will be presented at the meeting. Please let me know if you would be available and interested in attending the meeting; we will be pleased to cover your travel and lodging costs.

NSABB program assistant Ronna Hill will be contacting you about your participation in the meeting. In the meantime, please accept our deepest appreciation for all that you have contributed to this very important effort.

Sincerely,

Amy

Amy P. Patterson, M.D.
Executive Director
National Science Advisory Board for Biosecurity

Groesch, Mary (NIH/OD) [E]

From: Groesch, Mary (NIH/OD) [E]
Sent: Thursday, June 28, 2012 5:07 PM
To: cmfraser@som.umaryland.edu
Cc: bali@som.umaryland.edu
Subject: Important note regarding your NSABB service

Dear Claire,

I hope all is well with you!

Hopefully this is not news to you, but I wanted to be sure that you are aware that you will be rotating off of the NSABB after the next NSABB full board meeting in the Fall. As you know, we asked you to stay on the Board (and on and on!) while a number of key reports were being completed and until we could bring on a replacement for you. We greatly appreciate your willingness to extend your service. We have now completed all of the administrative steps necessary for bringing on a replacement for you and for several other of the original members who also kindly continued to serve well beyond the call of duty.

I will be sending out a note to NSABB members shortly announcing the new members and those rotating off, and wanted to be sure that this did not catch you by surprise. We are looking forward to seeing you at the Fall NSABB meeting!

Warm Regards,
Mary

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