DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

JUN 21 2012

The Honorable F. James Sensenbrenner, Jr.
Vice Chairman, Committee on Science,
Space and Technology
U.S. House of Representatives
Washington, D.C. 20515-4905

Dear Mr. Vice Chairman:

I am writing in response to your April 23 letter in which you express your concerns about the U.S. government's readiness to meet the multiple challenges of H5N1 dual use research of concern (DURC) and about the planning of the National Science Advisory Board for Biosecurity (NSABB)'s March 29-30 meeting.

Your letter references statements by NSABB member Dr. Michael Osterholm, who was critical of the agenda for the March 29-30 NSABB meeting and the quality of the Board's deliberations. As I explain in the following responses to your specific questions, the agenda was crafted with one aim in mind: to enable the Board to hear new, important information, to discuss that information freely and in depth, and to reach sound, defensible judgments about the communication of the research. I believe that aim was achieved.

I offer the following responses to the five specific questions you posed in your letter:

1. Why did NIH request that the NSABB reconsider its previous decision?

NIH did not ask the NSABB to reconsider its November 2011 recommendations concerning the two original H5N1 manuscripts. Those recommendations were based on information available at the time and will always stand as NSABB recommendations. When the manuscripts were revised by their authors (Drs. Ron Fouchier and Yoshi Kawaoka) to reflect additional data, as well as clarifications of pivotal scientific points, the NSABB was asked to review the revised manuscripts at its March 29-30 meeting. Specifically, the Board was charged to consider the additional information and clarifications, along with unpublished epidemiological information presented at the meeting and security information presented in a classified briefing. With this information in mind, NSABB was asked to assess the dual use research implications of the two unpublished, revised manuscripts; analyze and weigh the risks and benefits of communicating the research results; and develop findings and recommendations concerning whether or not the information should be communicated, and if so, to what extent. These elements of the request to the NSABB were clearly laid out in my charge to the Board on the first day of its March meeting.

2. What was done to ensure that the NSABB was briefed by disinterested subject matter experts?

The Board's membership is composed of subject matter experts who are selected on the basis of their ability to offer impartial, objective advice to the U.S. government on highly complex issues such as H5N1 dual use research of concern. It is my opinion that they performed this function and service exceptionally well at the March 29-30 meeting.

Although the agenda for the NSABB's March meeting was developed within a relatively short timeframe, it was, nonetheless, formulated with the aim of ensuring that the members had the requisite resources and time for a systematic, deliberative process. The Board's members include experts in infectious disease, epidemiology, molecular genetics/genomics, and other relevant fields. In addition, we also invited other experts from the field of influenza research, both to inform the discussions and to ensure that the members heard the epidemiologic information that was presented at the World Health Organization (WHO) meeting in mid-February. We heard from attendees at the WHO meeting that the information was highly relevant and would be critical to a comprehensive assessment of the benefits and the risks of communicating the information in the manuscripts.

It is important to note that some of the influenza experts have been intimately involved with developing H5N1 surveillance initiatives in many countries where avian influenza is endemic. They also have trained many of those working on that front. In addition, the laboratories of several of the invited experts provide H5N1 data to the WHO influenza vaccine strain selection meetings that are held two times every year. They are thus exceptionally knowledgeable about issues that were crucial to the Board's deliberations in March.

We also had present *ex officio* members representing the U.S. Department of Agriculture to ensure that issues concerning the implications of the research for animal health could be adequately addressed. In addition, we included the WHO Assistant Director General-Health Security and Environment, Dr. Keiji Fukuda, in the NSABB meeting. Dr. Fukuda is an internationally recognized expert in influenza surveillance and previously served as Director of the WHO Global Influenza Programme.

We worked to develop an agenda that would be responsive to the deliberative needs of the Board and with that aim in mind, circulated a draft version of the agenda first to the Board's Acting Chair, Dr. Paul Keim, and then to the full Board on March 21. We received suggestions from some members of the Board and incorporated these into the final revised agenda. It should be noted that no such suggestions were ever received from Dr. Osterholm.

3. What steps are you taking to investigate the recent allegations of bias?

Although we are confident that we followed a very sound process in organizing the March 29-30 meeting, we have carefully reviewed and analyzed the successive steps in the process of formulating the agenda. My assessment is that the process was absolutely sound and received

ample input from our partners in other federal agencies and direct input from the NSABB Acting Chair. All NSABB members also had an opportunity to propose speakers or comment on the agenda before it was final, as they saw fit. I remain confident that the meeting agenda enabled an unconstrained analysis and discussion of the relevant information by the NSABB. In brief, there is absolutely no basis for these allegations.

4. Which agencies and officials participated in the inter-agency policy process that created the "Policy for Oversight of Life Sciences Dual Use Research of Concern"?

The development of the DURC policy was an interagency effort, involving 15 federal departments and agencies and multiple entities from the Executive Office of the President. Discussions were led by National Security Staff and involved subject matter experts and leadership from the various departments, agencies, and offices. This broad input helped to ensure that the scientific, security, and public health aspects were carefully and comprehensively considered in crafting the DURC oversight policy.

5. What mechanisms does NIH have in place to ensure that agencies comply with the new oversight policy? Is compliance with the policy mandatory?

The new policy is a U.S. government-wide policy that applies to all departments and agencies that fund or conduct life sciences research with certain high-consequence pathogens and toxins; thus, its scope is much broader than just NIH-funded and -conducted research of this type. The policy stipulates that such departments and agencies are to conduct inventories of the specified research and to report the results of such inventories to the Assistant to the President for Homeland Security and Counterterrorism within 60 days of the March 29, 2012, policy. NIH has completed its inventory and submitted the results as part of the HHS response. Within 90 days of March 29, 2012, these departments and agencies are to submit to the same official: (1) the number of unclassified current and proposed projects of dual use research of concern; (2) the number of current projects identified as dual use research of concern through initial proposals versus progress reports; and (3) a summary of the risks associated with these projects, the mitigation measures already in place to address those risks, along with other measures that have been proposed or implemented, and the number of projects to which each of these measures would be applied. Compliance with the policy is mandatory.

In addition to these five questions answered above, we provide documents prepared by NIH for the March 29-30 NSABB meeting and documents related to NIH's decision to recommend that the NSABB reconvene to review the revised manuscripts, per your request.

I hope that the preceding responses to your questions serve to address your concerns, especially those that have to do with the planning and conduct of the NSABB meeting on March 29-30. Dual use research of concern is complex; however, we have made significant progress in the effort to develop a coordinated policy that will enable us to achieve enhanced biosecurity and continue to stimulate and reap the benefits of life sciences research.

In closing, let me thank you for your attention to these matters of great import to the scientific community and the nation, and let me assure you, too, that the thoughtful stewardship of this research is and always will be a priority for the NIH.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director

Enclosures
Tabs 1–10: Documents Requested by Rep. F. James Sensenbrenner, Jr.,
in Letter (dated April 23, 2012) to NIH Director Francis Collins, M.D., Ph.D.

Documents Requested by Rep. F. James Sensenbrenner, Jr.,
in Letter (dated April 23, 2012)
to NIH Director Francis Collins, M.D., Ph.D.

- **"Documents prepared by NIH for the March 29–30 NSABB meeting"**

  - Tab 1: Federal Register notice of meeting
  - Tab 2: Draft agenda sent to NSABB members prior to meeting
  - Tab 3: Final meeting agenda
  - Tab 4: Slide of Charge to NSABB
  - Tab 5: Confidentiality Agreements for the unpublished manuscripts provided at the NSABB meeting
  - Tab 6: Conflict of Interest and Confidentiality for NSABB Preparatory Session Participants

- **"Documents related to NIH's decision to recommend that the NSABB reconsider its initial recommendations"** (Please note that the USG did not ask the NSABB to reconsider its recommendations; rather, it asked the NSABB to review manuscripts that were revised to reflect additional data and key clarifications.)

  - Tab 7: NIH Statement on H5N1 and the World Health Organization Meeting (Feb. 17, 2012)
  - Tab 8: World Health Organization "Technical consultation on H5N1 research issues"—consensus points)
  - Tab 9: World Health Organization (Public health, influenza experts agree H5N1 research critical, but extend delay)
  - Tab 10: NSABB Acting Chair Overview of Feb 16–17 World Health Organization meeting

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Science Advisory Board for Biosecurity Meeting; Office of Biotechnology Activities, Office of Science Policy, Office of the Director; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting of the National Science Advisory Board for Biosecurity (NSABB).

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice, guidance and leadership regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The NSABB is being convened on March 29–30, 2012, to review two unpublished manuscripts on the transmissibility of highly pathogenic avian influenza H5N1 virus and to provide recommendations about the responsible communication of such information. In addition, representatives from the Intelligence Community will present a classified briefing to the NSABB.

The NSABB meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C. as amended, because premature disclosure of information to be discussed during the meeting would significantly frustrate the agency's ability to determine how the sensitive information in the manuscripts should be responsibly communicated, taking into consideration potential public health and national security concerns. The classified briefing of the NSABB will be closed to the public in accordance with the provisions set forth in section 552b(c)(1), Title 5 U.S.C. as amended, because classified matters sensitive to the interest of national security will be presented.

Name of Committee: National Science Advisory Board for Biosecurity.

Date: March 29–30, 2012.

Time: 4 p.m.–8 p.m. on March 29 and 8:30 a.m.–1:30 p.m. on March 30 (times approximate).

Agenda: NSABB members will review unpublished manuscripts regarding transmissibility of avian influenza H5N1 virus. In addition, representatives from the Intelligence Community will present a classified briefing.

Place: National Institutes of Health, Building 31, Center Drive, 6th Floor, Conference Room 6, Bethesda, Maryland 20892, and a location to be determined for the classified briefing.

Contact Person: Ronna Hill, NSABB Program Assistant, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 496–9838, *hillro@od.nih.gov.*

This meeting is being published less than 15 days prior to the meeting due to timing limitations imposed by administrative matters.

Dated: March 16, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–6949 Filed 3–21–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Published Privacy Impact Assessments on the Web

AGENCY: Privacy Office, DHS.

ACTION: Notice of Publication of Privacy Impact Assessments (PIA).

SUMMARY: The Privacy Office of DHS is making available eleven PIAs on various programs and systems in DHS. These assessments were approved and published on the Privacy Office's Web site between December 1, 2011 and February 29, 2012.

DATES: The PIAs will be available on the DHS Web site until May 21, 2012, after which they may be obtained by contacting the DHS Privacy Office (contact information below).

FOR FURTHER INFORMATION CONTACT: Mary Ellen Callahan, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528, or email: *pia@hq.dhs.gov*.

SUPPLEMENTARY INFORMATION: Between December 1, 2011 and February 29, 2012 the Chief Privacy Officer of the DHS approved and published eleven Privacy Impact Assessments (PIAs) on the DHS Privacy Office Web site, *www.dhs.gov/privacy*, under the link for ''Privacy Impact Assessments.'' These PIAs cover eleven separate DHS programs. Below is a short summary of those programs, indicating the DHS component responsible for the system, and the date on which the PIA was approved. Additional information can be found on the web site or by contacting the Privacy Office.

System: DHS/USSS/PIA–007 Forensic Services Division (FSD) Polygraph System.

Component: United States Secret Service (USSS).

Date of approval: December 15, 2011.

The FSD Polygraph Branch of the USSS uses the FSD Polygraph system to track all polygraph examinations that it administers. This database contains information on applicant and criminal polygraph examinations and their results. USSS is conducting this PIA because this system contains PII of individuals who undergo an exam.

System: DHS/FEMA/PIA–019 Firehouse Database (Unclassified and Classified).

Component: Federal Emergency Management Agency (FEMA).

Date of approval: December 15, 2011.

The U.S. DHS FEMA Mount Weather Emergency Operations Center (MWEOC) Emergency Services Division (ESD) owns and operates two Firehouse Databases: (1) Firehouse Database (classified); and (2) Firehouse Database (unclassified). The difference between the two databases is that the classified Firehouse Database contains classified locations on which MWEOC ESD may respond at the MWEOC facility. FEMA uses the unclassified and classified Firehouse Databases to manage the collection, documentation, and reporting of information about emergency incidents, incident investigations, site inventory and inspections, staffing, scheduling, and personnel certifications and training of FEMA paramedics, emergency management technicians, firefighters, and other first responders at MWEOC ESD. FEMA is conducting this PIA because FEMA's unclassified and classified Firehouse Databases collects, uses, maintains, retrieves, and disseminates PII of MWEOC residents, employees and contractors, visitors, as well as members of the immediate local community surrounding MWEOC. This PIA covers both the unclassified and classified Firehouse Databases.

System: DHS/ALL/PIA–028(a) Freedom of Information Act (FOIA) and Privacy Act (PA) Records Program Update.

Component: DHS.

Date of approval: December 16, 2011.

The DHS Privacy Office is publishing an update to the current PIA, DHS/ALL/PIA–028, which outlines the risks presented by the use of PII in the various FOIA and PA processes and systems employed by DHS. This update introduces the use of a FOIA software application used for tracking FOIA requests.

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

NIH Campus
9000 Rockville Pike
Building 31, 6th Floor, Conference Room 6
Bethesda, MD
March 29-30, 2012

DRAFT MEETING AGENDA*

Thursday, March 29

7:00 am	Read manuscripts on-site
9:00 am	Welcome and Overview of the Meeting *Dr. Amy Patterson, Associate Director for Science Policy, National Institutes of Health*
9:10 am	Introductions
9:40 am	Opening Remarks and Charge to the NSABB *Dr. Francis Collins, Director, National Institutes of Health*
9:50 am	Remarks by the Chair, National Science Advisory Board for Biosecurity *Dr. Paul Keim, Cowden Endowed Chair in Microbiology, Northern Arizona University*
9:55 am	Perspectives from recent meetings sponsored by the World Health Organization and the American Society for Microbiology *Invited Guests*
10:20 am	Perspectives from Dutch and Japanese governments regarding safety and security issues *TBD*
10:30 am	Break
10:45 am	Presentation of revised Fouchier manuscript and discussion with NSABB members and influenza experts *Dr. Ron Fouchier, Professor of Virology, Erasmus Medical Centre*
12:45 pm	Lunch

* Yellow-shaded agenda items indicate closed NSABB meeting sessions, unshaded agenda items indicate closed preparatory sessions

1:45 pm	Presentation of revised Kawaoka manuscript and discussion with NSABB members and influenza experts *Dr. Yoshihiro Kawaoka, Professor of Virology, University of Wisconsin-Madison*
3:45 pm	Briefing: New insights into transmission of avian influenza H5N1 and discussion with NSABB members and influenza experts *TBD*
4:15 pm	Break
4:35 pm	Discussion by NSABB members • Queue up questions for Day 2
5:35 pm	NSABB members leave for security briefing
7:00 pm	Security Briefing of NSABB members

Friday, March 30

7:00 am	Welcome *Dr. Amy Patterson*
7:20 am	Discussion with NSABB members, authors, and influenza experts
8:20 am	Discussion by NSABB members
10:00 am	Break
10:15 am	Discussion by NSABB members • Finalize findings and recommendations
12:00 noon	Meeting adjourns

* Yellow-shaded agenda items indicate closed NSABB meeting sessions, unshaded agenda items indicate closed preparatory sessions

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

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March 29-30, 2012

MEETING AGENDA*

Thursday, March 29

7:00 am	Read manuscripts on-site
9:00 am	Welcome and Overview of the Meeting *Dr. Amy Patterson, Associate Director for Science Policy, National Institutes of Health*
9:10 am	Introductions
9:40 am	Opening Remarks and Charge to the NSABB *Dr. Francis Collins, Director, National Institutes of Health*
9:50 am	Perspectives from recent meetings sponsored by the World Health Organization and the American Society for Microbiology o *Dr. Philip Campbell, Editor-in-Chief, Nature, Nature Publishing Group* o *Dr. Nancy Cox, Director, Influenza Division, Centers for Disease Control and Prevention* o *Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, NIH* o *Dr. Keiji Fukuda, Assistant Director-General, Health Security and Environment, World Health Organization* o *Dr. Barbara Jasny, Deputy Editor for Commentary, Science/AAAS* o *Dr. Paul Keim, Acting Chair, NSABB*
10:15 am	Perspectives from The Netherlands and Japanese governments *Peter Bootsma, Counselor for Health, Welfare and Sports; and Nathalie Jaarsma, Deputy Head of the Political Department Embassy of the Kingdom of the Netherlands* *Takashi Inutsuka, Chief of Science Section, Science Counselor; and Kristi B. Jamrisko, Special Assistant, Science Section Embassy of Japan*

* Yellow-shaded agenda items indicate closed NSABB meeting sessions, unshaded agenda items indicate closed preparatory sessions

10:25 am	Remarks by the Chair, National Science Advisory Board for Biosecurity *Dr. Paul Keim, Cowden Endowed Chair in Microbiology, Northern Arizona University*
10:30 am	Conflict of Interest Statement *Dr. Amy Patterson*
10:35 am	Presentation of revised Fouchier manuscript *Dr. Ron Fouchier, Professor of Virology, Erasmus Medical Centre*
11:10 am	Discussion with NSABB members, authors, and influenza experts
12:25 pm	Lunch
1:25 pm	Presentation of revised Kawaoka manuscript *Dr. Yoshihiro Kawaoka, Professor of Virology, U. Wisconsin-Madison*
2:00 pm	Discussion with NSABB members, authors, and influenza experts
3:15 pm	Presentation: The potential for aerosol transmissible A/H5N1 viruses to evolve in nature *Dr. Derek Smith, Professor of Infectious Disease Informatics, U. Cambridge*
3:55 pm	Break
4:10 pm	Discussion by NSABB members o Queue up questions for Day 2
5:35 pm	NSABB members leave for security briefing
7:00 pm	Security Briefing of NSABB members

Friday, March 30

7:00 am	Welcome *Dr. Amy Patterson*
7:05 am	Discussion with NSABB members, authors, and influenza experts
8:20 am	Discussion by NSABB members o Finalize findings and recommendations
12:00 noon	Meeting adjourns

* Yellow-shaded agenda items indicate closed NSABB meeting sessions, unshaded agenda items indicate closed preparatory sessions

Charge to the NSABB

- **Taking into account the additional information in the revised manuscripts, epidemiological information presented during the meeting, and the security information that will be presented in the classified briefing:**
  - **Assess the dual use research implications of two unpublished, revised manuscripts on the transmissibility of avian influenza A/H5N1 virus;**
  - **Consider the risks and benefits of communicating the research results; and**
  - **Develop findings and recommendations regarding whether or not the information should be communicated, and if so, to what extent.**

CONFIDENTIALITY AGREEMENT

During the National Science Advisory Board for Biosecurity (NSABB) meeting and associated preparatory session held on March 29-30, 2012, on the National Institutes of Health campus in Bethesda, Maryland, revised versions of two unpublished manuscripts on the transmissibility of avian influenza H5N1 virus will be discussed ("Aerosol transmission of avian influenza A/H5N1 virus" and "Haemagglutinin mutations that confer human-type receptor recognition and support respiratory droplet transmission of H5N1 influenza A virus in ferrets"). Materials made available to meeting and preparatory session participants as well as the discussions that take place during the meeting and preparatory session are strictly confidential and may not be disclosed to or discussed with anyone who has not been officially designated to participate in the meeting. The papers and related information presented during the NSABB meeting and associated preparatory session will be made available to participants consistent with the terms and conditions of export control licenses issued by the governments of the United States and the Netherlands. The United States is obligated to ensure that participants do not make unauthorized disclosures of any of the sensitive information in the manuscripts provided to them at this meeting. The United States may invoke all available means, including civil or criminal penalties, to meets its obligations.

In order to receive numbered copies of this confidential material or participate in the meeting, you must verify in writing that you agree to the conditions outlined below:

1. Any discussion related to the manuscripts or information presented during NSABB proceedings, including associated preparatory session, must be strictly limited to the meeting room;
2. Any information related to the research findings under consideration that is provided during the meeting or preparatory session and is not in the public domain may not be disclosed or discussed with any individuals who are not NSABB meeting or preparatory session participants, except with the permission of NIH. NIH may grant permission for disclosure only to USG officials with a need to know the information to review the NSABB recommendations;
3. All inquiries concerning any aspect of the review of these manuscripts will be referred to NSABB staff;
4. Participants may not create any video or audio recordings of the meeting;
5. If a participant receives manuscripts, he or she will receive numbered copies of the manuscripts, for which he or she will be responsible;
6. Participants may not photocopy or create a photographic or video recording of the manuscripts;
7. Participants may not remove any manuscripts from the meeting room; in the event that a participant with responsibility for manuscripts leaves the room during the meeting, he or she will leave the manuscripts on the table by his or her seat;
8. Participants may not further distribute the manuscripts or any documents related to the manuscripts;
9. At the end of each day, participants must return all numbered copies of the manuscripts that they were assigned;
10. At the end of each day, participants must leave any notes that they have taken during the course of the meeting or preparatory session in the meeting room; and
11. Upon completion of the NSABB discussions regarding these manuscripts, all copies of the confidential material and related notes will be destroyed.

I, _____, have read the confidentiality statement, fully understand the confidential nature of the information being discussed during the NSABB meeting, and agree to the conditions laid out above. I understand that I am taking temporary possession of manuscripts listed below, and **violating the terms of this agreement puts me at risk of civil and criminal penalties**.

Signature: _____ Date: _____
(Participant's Name)

Reviewed by: _____ Date: _____
(Federal Official)

NAME:
MANUSCRIPTS: Kawaoka Orginal
Kawaoka Revised
Fouchier Original
Fourchier Revised

ACKNOWLEDGMENT OF NOTIFICATION OF EXPORT LICENSE TERMS

I hereby acknowledge that I have read and understand the export license terms issued by the Dutch government concerning the manuscript, "Aerosol transmission of avian influenza A/H5N1 virus," authored by Ronald Fouchier, and the information in that manuscript.

Signature: _____ Date: _____

(Participant's Name)

Reviewed by: _____ Date: _____

(Federal Official)

I hereby acknowledge that I have read and understand the export license terms issued by the United States government concerning the manuscript, "Haemagglutinin mutations that confer human-type receptor recognition and support respiratory droplet transmission of H5N1 influenza A virus in ferrets," authored by Yoshii Kawaoka, and the information in the manuscript.

Signature: _____ Date: _____

(Participant's Name)

Reviewed by: _____ Date: _____

(Federal Official)

CONFIDENTIALITY AGREEMENT

During the National Science Advisory Board for Biosecurity (NSABB) meeting and associated preparatory session held on March 29-30, 2012, on the National Institutes of Health campus in Bethesda, Maryland, an unpublished manuscripts on the transmissibility of avian influenza H5N1 virus will be discussed ("The potential for aerosol transmissible avian A/H5N1 influenza viruses to evolve in nature"). Materials made available to meeting and preparatory session participants as well as the discussions that take place during the meeting and preparatory session are strictly confidential and may not be disclosed to or discussed with anyone who has not been officially designated to participate in the meeting. The paper and related information presented during the NSABB meeting and associated preparatory session will be made available to participants consistent with the terms and conditions of export control licenses issued by the government of the Netherlands. The United States is obligated to ensure that participants do not make unauthorized disclosures of any of the sensitive information in the manuscript provided to them at this meeting. The United States may invoke all available means, including civil or criminal penalties, to meets its obligations.

In order to receive a numbered copy of this confidential material or participate in the meeting, you must verify in writing that you agree to the conditions outlined below:

1. Any discussion related to the manuscript or information presented during NSABB proceedings, including associated preparatory session, must be strictly limited to the meeting room;
2. Any information related to the research findings under consideration that is provided during the meeting or preparatory session and is not in the public domain may not be disclosed or discussed with any individuals who are not NSABB meeting or preparatory session participants, except with the permission of NIH. NIH may grant permission for disclosure only to USG officials with a need to know the information to review the NSABB recommendations;
3. All inquiries concerning any aspect of the review of this manuscript will be referred to NSABB staff;
4. Participants may not create any video or audio recordings of the meeting;
5. If a participant receives a manuscript, he or she will receive a numbered copy of the manuscript, for which he or she will be responsible;
6. Participants may not photocopy or create a photographic or video recording of the manuscript;
7. Participants may not remove the manuscript from the meeting room; in the event that a participant with responsibility for the manuscript leaves the room during the meeting, he or she will leave the manuscript on the table by his or her seat;
8. Participants may not further distribute the manuscript or any documents related to the manuscript;
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10. At the end of each day, participants must leave any notes that they have taken during the course of the meeting or preparatory session in the meeting room; and
11. Upon completion of the NSABB discussions regarding this manuscript, all copies of the confidential material and related notes will be destroyed.

I, _____, have read the confidentiality statement, fully understand the confidential nature of the information being discussed during the NSABB meeting, and agree to the conditions laid out above. I understand that I am taking temporary possession of the manuscript listed below, and **violating the terms of this agreement puts me at risk of civil and criminal penalties**.

Signature: _____ Date: _____

(Participant's Name)

Reviewed by: _____ Date: _____

(Federal Official)

NAME:

MANUSCRIPTS:

ACKNOWLEDGMENT OF NOTIFICATION OF EXPORT LICENSE TERMS

I hereby acknowledge that I have read and understand the export license terms issued by the Dutch government concerning the manuscript, "The potential for aerosol transmissible avian A/H5N1 influenza viruses to evolve in nature," authored by Colin A. Russell et al., and the information in that manuscript.

Signature: _____ Date: _____

(Participant's Name)

Reviewed by: _____ Date: _____

(Federal Official)

CONFLICT OF INTEREST AND CONFIDENTIALITY INFORMATION FOR NSABB PREPARATORY SESSION PARTICIPANTS

Conflict of Interest

It is essential that the business of the National Science Advisory Board for Biosecurity (NSABB or Board) not be compromised by conflict of interest. For this purpose, the term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization. A conflict of interest exists when a participant has a financial interest that may bias the participant's opinion regarding the charge of the Board or an item on the agenda of an NSABB preparatory session. Session participants are most familiar with their own situation, and it is their personal responsibility to bring to the attention of the Board and its Federal official any conflict of interest that may pertain to the agenda items. The Federal official and the Board will respond to the concern by taking the conflict into account either before the preparatory session, by recusing the participant with the conflict from all discussion or by disqualifying the participant from a recommendation or vote on the issues to be discussed.

In addition, the Federal official may make determinations regarding conflicts of interest and require that a participant not be involved in the discussion of an item that presents a potential conflict of interest.

The overriding objective of the conflict of interest inquiry in each case is to identify whether there are interests - primarily financial in nature - that conflict with the committee service of the individual because they could impair the individual's objectivity or could create an unfair competitive advantage for any person or organization. The fundamental question in each case is does the individual, or others with whom the individual has substantial common financial interests, have identifiable interests that could be directly affected by the outcome of the project activities of the Board in whose preparatory session the individual has been invited to participate.

The following guidance will assist in determining whether a conflict of interest exists.

BASES FOR CONFLICTS OF INTEREST

- When a preparatory session participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept is involved in the deliberations;

- When a preparatory session participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept competes with a product or product concept being discussed;

- When a preparatory session participant or a member of that individual's immediate family is seeking employment in an organization or serves as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on the agenda…(for example, when a participant or spouse is negotiating for employment with a company whose product is being considered or participant or spouse works for a company that has a competing product from the product being

considered);

- When a preparatory session participant or a member of that individual's immediate family holds financial, equity, or proprietary interest in, or receives research support from, an organization whose product or product concept would substantially benefit from research emphasis in a defined area (for example, when a participant holds stock in a company that is one of a very few companies conducting a certain type of vaccine research and the research area being discussed is that type).

Confidentiality

Closed sessions and confidential documents - Materials made available to preparatory session participants as well as the discussions that take place during closed sessions are strictly confidential and may not be disclosed to or discussed with anyone who has not been officially designated to participate in the preparatory session. Participants will be asked to return or destroy all confidential materials at the conclusion of the Board's business. Preparatory session participants must certify on the Conflict of Interest and Confidentiality Certification form that they will maintain the confidentiality of the materials and discussions and not disclose this information to any other individual, except as authorized by the NIH.

Open sessions and public documents - Discussions and documentation distributed during an open session are not considered confidential. Discussions involve information that is a matter of public record or general in nature. Documentation provided to preparatory session participants in an open session may be freely distributed, copied or made available to the public.

Adapted from:
OFACP
Revised 06/14/2005

********Sign and return form to Jessica Avery********
Fax (301-496-9839) or Email (averyjl@mail.nih.gov)

Conflict of Interest and Confidentiality Certification for NSABB Preparatory Session Participants

Preparatory Session Name: National Science Advisory Board for Biosecurity

Date(s) of Preparatory Session: March 29-30, 2012

Name of Participant: _____

Check only one:

I have read the attached Conflict of Interest and Confidentiality Information for NSABB Preparatory Session Participants and have examined the group's charge and the session agenda. I have also read the below statements, and **I hereby certify that I do not have a potential or actual conflict of interest in relation to any agenda item.**

I have read the attached Conflict of Interest and Confidentiality Information for NSABB Preparatory Session Participants and have examined the group's charge and the session agenda. I have also read the below statements, and **I hereby certify that I have a potential or actual conflict of interest with an item on the agenda**. I will disclose the conflict to the working group and the Federal official managing the group prior to any discussion of that item so it can be reflected in the minutes along with the group's determination of how to handle the conflict.

Statements:

The central purpose of the project for which this disclosure form is being prepared is not a critical review and evaluation of my work or that of my employer.

I do not have an existing professional obligation that effectively requires me to publicly defend a previously established position on an issue that is relevant to the functions to be performed in this Board activity.

To the best of my knowledge, my participation in this Board activity will not enable me to obtain access to a competitor's or potential competitor's confidential proprietary information.

As a current, or former, U.S. Government employee (either civilian or military), there are no federal conflict of interest restrictions that may be applicable to my service in connection with this Board activity.

As a current U.S. Government employee, I am not currently employed by a federal agency that is sponsoring this project; OR, as a non-U.S. Government employee, I am not employed by any other sponsor (e.g., a private foundation) of this project.

I am not interested in seeking an award under the program for which the Board is developing the request for proposals, work statement, and/or specifications B and, I am not employed in any capacity by, or have a financial interest in or other economic relationship with, any person or organization that to the best of my knowledge is interested in seeking an award under this program

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is involved in the deliberations of this Board.

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept is competing with a product or product concept being discussed by this Board.

Neither I nor any member of my immediate family is seeking employment in an organization or serve as an officer, director, trustee, partner, or employee of an organization whose product or product concept competes with, is involved in the deliberations of, or would benefit from research in an area that is on this Board's agenda.

Neither I nor any member of my immediate family hold financial, equity, or proprietary interest in, or receive research support from, an organization whose product or product concept being discussed by this Board would substantially benefit from research emphasis in a defined area.

I fully understand the confidential nature of the discussions held during closed sessions of the NSABB and agree: (1) to destroy or return all materials related to the preparatory sessions; (2) not to disclose or discuss the materials associated with the preparatory sessions or my evaluations with any other individual except as authorized by the NIH; and (3) to refer all inquiries concerning the preparatory session to the Federal official managing the Board.

Signature: _____ Date: _____
(Participant's Name)

Reviewed by: _____ Date: _____
(Federal Official)

********Sign and return form to Jessica Avery********
Fax (301-496-9839) or Email (averyjl@mail.nih.gov)

TAB 7

NIH Statement on H5N1 and the World Health Organization Meeting

February 17, 2012

Today, an international group of public health and influenza experts convened by the World Health Organization (WHO) concluded a two-day meeting examining issues regarding two unpublished manuscripts that describe National Institutes of Health (NIH)-funded research on the transmissibility of H5N1 influenza. We continue to stand by the December 2011 recommendations of the National Science Advisory Board for Biosecurity (NSABB) but we intend to consider carefully the information discussed during the WHO-hosted meeting. We remain committed to the advancement of scientific inquiry to improve public health while balancing national security concerns.

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

More Information

Public health, influenza experts agree H5N1 research critical, but extend delay

NIH Statement on H5N1, January 20, 2012

TAB 8

World Health Organization

Influenza

Technical consultation on H5N1 research issues - consensus points

WHO Headquarters, Geneva
16-17 February 2012

Two recent research studies examining some factors affecting transmissibility of influenza A(H5N1) viruses prompted WHO to convene a technical consultation on 16–17 February 2012. The participants at this meeting reached consensus on the following points.

- Recent work discussed at this meeting underscores that influenza A (H5N1) viruses remain an important risk for causing a future pandemic. Therefore, research on these viruses, including on transmissibility and pathogenicity, remains critical to close important gaps in knowledge in order to reduce the danger posed; such research should continue. The PIP Framework, which was adopted by all WHO Member States in 2011 now provides a global framework for the sharing of influenza viruses with human pandemic potential and the sharing of benefits arising from such sharing. Implementation of this Framework is integral to global pandemic preparedness and response. Future research projects should involve countries from which source material were obtained.
- The two studies that were conducted to better understand the transmissibility of H5N1 influenza viruses have shown that these viruses have the potential to become more transmissible among mammals. In light of the continuing evolution of H5N1 viruses, the results of these studies provide an important contribution to public health surveillance of H5N1 viruses and to a better understanding of the properties of these viruses.
- At the same time, these studies have raised important and valid concerns about whether they increase risks to the safety of humans. Concerns which have been raised include the potential misuse of the results or methods as well as potential breaches in biosafety and biosecurity related to pathogens. These concerns highlight how important it is that researchers are aware of such issues, exercise judgement about the conduct of their research, dissemination of the results, and for institutional bodies reviewing such studies to identify and address potential concerns about "dual use". Such safeguards already exist, but continued emphasis should be placed on assuring and reinforcing safety and security.
- The laboratory-modified H5N1 viruses are currently stored in well-established research facilities with high security and high safety (BSL3+). There have been no safety breaches related to the storage of the laboratory-modified H5N1 viruses at these facilities. At the same time, the biosafety and biosecurity conditions under which further research is conducted on the laboratory-modified H5N1 viruses should be fully addressed by relevant authorities. This is a matter of urgency

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Related links

Report on technical consultation on H5N1 research issues
pdf, 49kb
16-17 February 2012

Information about the event

Public health, influenza experts agree H5N1 research critical, but extend delay
News release

PIP Framework

and should be achieved as quickly as possible. In the interim, the laboratory-modified H5N1 viruses should remain in their present locations. In addition, the current moratorium on research to enhance the transmissibility of H5N1 influenza viruses and the further research on the laboratory-modified viruses should continue until the conditions have been determined. Other research on H5N1 viruses should not stop.

- There is a preference, from a public health perspective, for full disclosure of the information in these papers. However, there are significant social concerns surrounding this research. Two critical issues that must be addressed before publication of the papers are: (1) a focused communications plan to increase public awareness and understanding of the significance of these studies and the rationale for their publication, and (2) a review of the essential biosafety and biosecurity aspects of the newly developed knowledge.
- Participants discussed the concept of publication of redacted manuscripts with a mechanism for providing the restricted information to legitimate recipients. The group recognized the difficulty of rapidly creating and regulating such a mechanism in light of the complexity of international and national legislation. A consensus was reached that the redaction option is not viable to deal with the two papers under discussion in view of the urgency of the above mentioned public health needs. The participants noted there may be a need for such a mechanism in the future.
- Apart from consideration of these two manuscripts, participants acknowledged the existence of broader issues requiring more detailed exploration and advised that these be considered in subsequent consultations involving other stakeholders.

TAB 9

World Health Organization

Media centre

Public health, influenza experts agree H5N1 research critical, but extend delay

WHO to convene additional meeting to discuss next steps

News release

17 FEBRUARY 2012 | GENEVA - A small group of global public health and influenza experts at a WHO-convened meeting reached consensus on two urgent issues related to the newly created H5N1 influenza viruses: extending the temporary moratorium on research with new laboratory-modified H5N1 viruses and recognition that research on naturally-occurring H5N1 influenza virus must continue in order to protect public health.

“Given the high death rate associated with this virus -- 60% of all humans who have been infected have died -- all participants at the meeting emphasized the high level of concern with this flu virus in the scientific community and the need to understand it better with additional research," says Dr Keiji Fukuda, Assistant Director-General of Health Security and Environment for the World Health Organization. “The results of this new research have made it clear that H5N1 viruses have the potential to transmit more easily between people underscoring the critical importance for continued surveillance and research with this virus.”

WHO convened the meeting as a first step to facilitate the discussion of differing opinions that have arisen in recent months after two research groups, one in the Netherlands and the other based in the United States, have created versions of the H5N1 influenza virus which are more transmissible in mammals than the H5N1 virus that occurs naturally.

The experts at the meeting included lead researchers of the two studies, scientific journals interested in publishing the research, funders of the research, countries who provided the viruses, bioethicists and directors from several WHO collaborating-center laboratories specializing in influenza.

Consensus to delay publications

The group also came to a consensus that delayed publication of the entire manuscripts would have more public health benefit than urgently partially publishing.

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Related links

More on influenza at the Human-Animal Interface (HAI)

List of participants
Technical consultation on H5N1 research issues

Technical consultation on H5N1 research issues - consensus points

Virtual press briefing
Audio file and transcript from the briefing

Report on technical consultation on H5N1 research issues
pdf, 49kb

“There is a preference from a public health perspective for full disclosure of the information in these two studies. However there are significant public concern surrounding this research that should first be addressed,” says Fukuda.

Two critical issues are to increase public awareness and understanding of this research through communications and the review of biosafety and biosecurity aspects raised by the new laboratory-modified H5N1 influenza virus. WHO will continue discussion with relevant experts to move this forward.

Broad issues raised, but not limited to, these research studies will be discussed at future meetings convened by WHO soon with participation by a broader range of experts and interested parties relevant to these issues.

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Subject: Geneva WHO H5N1 meeting

Dear NSABB members,

There has been considerable misreporting and misunderstanding about the WHO H5N1 meeting in Geneva. I'll try to clarify what this meeting was, who was there and what it all means.

This was primarily a group of collaborating influenza scientists (see URL below) involved in the WHO pandemic influenza plan. There were a few others including the senior authors of the papers, editors from Science and Nature magazines, a USG representative (Dr. Fauci) and myself. This was a global mixture of scientists, but really only represented a very a narrow subset of all flu scientists. They represented even a smaller subsection of global science and society, which partially explains their reaction to the NSABB recommendations. No doubt that this is an important group, but it was narrowly based.

The meeting itself operated under a confidentiality agreement and participants were provided with both the redacted and non-redacted papers. We were given a short period of time to read them and then the investigators (Fouchier and Kawaoka) presented the work. I presented the NSABB procedures, recommendations and their rationale. Then, there was a very structured and controlled discussion

followed by a search for consensus. (Note – a consensus is just a majority and there were no actual votes taken at this meeting.)

There was a clear consensus from the group that the current research moratorium (on increasing mammalian transmissibility of the H5N1 virus) should be extended and that the papers should not be published during this period. Note, that WHO and this group have no power to enforce this moratorium as it is a voluntary situation imposed by researchers on themselves. Individual researchers can comply or not, as they wish. The two primary research groups stated that they are going to comply for now. Both groups are undergoing additional biosecurity and biosafety reviews of their facilities and work. While these are ongoing, they will not be working on this research nor publishing. Again, this is mostly a voluntary situation though there are governmental and institutional forces in play here as well.

Likewise, there was no "WHO decision" on publishing or not publishing. WHO has no authority concerning these papers and publishing or not is really at the discretion of the authors and journals. There was an announcement that this WHO hosted meeting reached a consensus that the redacted papers should not be published and that they favored publishing the full papers. This is true, though it was not unanimous as originally reported – I was certainly against it as was the USG's representative (Dr. Fauci). There were no votes taken during the meeting, but I think it is fair to say that a majority of the participants saw no value in publishing the redacted papers. In my opinion, there were two main reasons for this:

1) These are influenza experts and they already knew or anticipated everything in the redacted papers. Hence, the redacted papers were of no value to them. Likewise, I think that they did not appreciate the value of these papers to broader scientific and societal segments. The detailed full papers were of great interest to them because they contained specific results that they thought they could use in their programs.

2) There was considerable additional data presented that was not in the original NSABB-reviewed manuscripts. Some of this data was unpublished and outside the scope of the original papers; some of it was data relevant to the original papers but generated after they were written. These additional data are covered by the WHO confidentiality agreement signed by all participants. The confidentiality agreement precludes any discussion of specifics, but I would judge that these additional data had a significant impact on the conclusions and consensus reached. You'll have to trust me, for now, that some of these new data are very important to the issues.

What next? The WHO meeting participants clearly saw that these particular papers were harbingers for future DURC issues concerning H5N1 and other pathogens, as well. The meeting participants recognized that NSABB was the foremost and, really, only authoritative body concerning DURC – in the entire world. While there was disagreement with our specific recommendations, there was also a lot of respect for our work and how we have carried it out. For Science and Nature, we are still the authoritative body. The WHO meeting cannot be the final "statement" on this issue and we need additional discussion of these specific papers and on these types of experiments. A number of us are looking for mechanisms for this and a number of forums are being sought.

Paul Keim

Participant List:
http://www.who.int/influenza/human_animal_interface/list_participants/en/index.html

WHO statement:
http://www.who.int/influenza/human_animal_interface/consensus_points/en/index.html
WHO press release:
http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/index.html

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