



## Agenda At-A-Glance

### Day 1

- 8:00 – 9:00 A.M.** **Welcome and Introductory Remarks**
- Purpose of the Workshop
  - Overview of the HPAI H5N1 issue
- 9:00 – 10:50 A.M.** **Panel I: HPAI H5N1 GOF<sup>1</sup> Research and Its Implications for Global Public Health**  
 This session will explore the state of the field of HPAI H5N1 research, including the rationale, experimental aims and designs of studies that increase transmissibility, pathogenicity, and/or host range; the public health context of this research; the current trajectory of the research; and any anticipated benefits associated with the research.
- Moderated discussions with panelists and the audience
- 10:50 – 11:10 A.M.** **Break**
- 11:10 – 1:15 P.M.** **Panel II: Risks and Concerns Associated with HPAI H5N1 GOF Research**  
 This session will explore specific concerns that have been raised over HPAI H5N1 GOF, including biosafety risks, biosecurity risks, dual use/informational risks, and the implications for national and global security.
- Moderated discussions with panelists and the audience
- 1:15 – 2:15 P.M.** **Break**
- 2:15 – 4:10 P.M.** **Panel III: Perspectives on the Proposed Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Highly Pathogenic Avian Influenza H5N1 Gain-of-Function Research**  
 This session will discuss the *Proposed Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Highly Pathogenic Avian Influenza H5N1 Gain-of-Function Research*.
- Moderated discussions with panelists and the audience
- 4:10 – 4:30 P.M.** **Break**
- 4:30 – 6:30 P.M.** **Panel IV: Discussion of HPAI H5N1 Gain-of-Function Research Case Studies**  
 This session will apply the proposed HHS Framework to examples of research that illustrate a range of gain-of-function experiments.

### Day 2

- 9:00 – 9:15 A.M.** **Introductory Remarks**
- 9:15 – 11:30 A.M.** **Panel V: Identifying Conditions, if any, under which HPAI H5N1 GOF Research Should be Conducted**  
 This session will discuss the conditions, if any, under which HPAI H5N1 GOF research should be supported or conducted, identifying specific standards for future research in this area.
- Moderated discussions with panelists and the audience
- 11:30 – 12:25 P.M.** **Break**
- 12:25 – 2:50 P.M.** **Panel VI: Overview and Discussion of Main Points**
- 2:50 – 3:00 P.M.** **Closing Remarks**
- 3:00 P.M.** **Adjourn**

<sup>1</sup> For the purpose of this workshop, “HPAI H5N1 gain-of-function (GOF)” research refers to experiments that increase the transmissibility, pathogenicity, and/or alter the host range of highly pathogenic avian influenza A H5N1 viruses.

# Detailed Agenda

## Day 1

### 8:00 – 9:00 A.M. Introductory Remarks

#### Welcome

- Sally Howard, J.D.  
Chief of Staff  
U.S. Department of Health and Human Services

#### Meeting Co-Moderators:

- Robbert Dijkgraaf, Ph.D.  
Co-chair, InterAcademy Council  
Past President, the Royal Netherlands Academy of Arts and Sciences, the Netherlands  
Director and Leon Levy Professor, Institute for Advanced Study, Princeton, USA
- Harvey Fineberg, M.D., Ph.D.  
President, Institute of Medicine, National Academies  
Professor of Health Policy and Management, Emeritus, Department of Health Policy and Management,  
Harvard University, USA

#### Presenters:

- Anthony S. Fauci, M.D.  
Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA  
[Presentation](#)
- Amy P. Patterson, M.D.  
Associate Director for Science Policy, National Institutes of Health, USA  
[Presentation](#)

The presentations in the opening session will set the stage for the Workshop by briefly highlighting the scientific, public health, biosafety, and biosecurity issues surrounding HPAI H5N1 research that increases transmissibility, pathogenicity, and/or host range; introducing the concept that HHS has developed a draft Framework for guiding funding decisions about proposed HPAI H5N1 GOF research; and noting that the meeting participants will have the opportunity to exercise this Framework through discussion of a series of case studies. The global nature of the research and the benefits and risks associated with it underscore the importance of hearing a broad range of perspectives about the responsible funding and conduct of such research. Discussions over this 2-day workshop will be carefully considered as HHS finalizes its Framework.

### 9:00 – 10:50 A.M. [Panel I: HPAI H5N1 GOF Research and Its Implications for Global Health](#)

#### Panelist Presentations:

The panelists will give brief presentations addressing the current state of HPAI H5N1 GOF research, including the experimental aims and designs of studies that increase transmissibility, increase pathogenicity, and/or alter host range; the public health context for this research; the current trajectory of the research; and its anticipated benefits, as well as address the discussion questions.

#### Discussion Questions:

1. What are the different types of HPAI H5N1 GOF experiments conducted to date that have resulted in new strains of HPAI H5N1 viruses with increased transmissibility, pathogenicity, or altered host range, and what were/are purposes of those studies?
2. Has HPAI H5N1 GOF research contributed to public health? If so, how?
  - a. Have the already published HPAI H5N1 GOF research findings been applied to improve biosurveillance? If so, how and how might they be applied in the future?
  - b. Have these findings been important for countermeasure development? If so, how?
3. Are there potential benefits to be gained from future HPAI H5N1 GOF research? If so, what are they?
4. Are there risks associated with not conducting HPAI H5N1 GOF research? If so, what are they?

#### Panel Co-Moderators:

- Kanta Subbarao, M.D., M.P.H.  
Chief, Emerging Respiratory Viruses Section, National Institute of Allergy and Infectious Diseases,  
National Institutes of Health, USA
- Robert Webster, Ph.D.

Member, Department of Infectious Diseases, St. Jude Children's Research Hospital, USA

**Panelists:**

- Tjandra Aditama, M.D.  
Director-General, Disease Control and Environmental Health, Ministry of Health, Indonesia
- Ilaria Capua, D.V.M., Ph.D.  
Director, Research and Development Department, Istituto Zooprofilattico Sperimentale delle Venezie, Italy
- Ron Fouchier, Ph.D.  
Professor, Department of Virology, Erasmus Medical Center, the Netherlands
- Daniel Gerstein, Ph.D.  
Deputy Under Secretary, Science and Technology, Department of Homeland Security, USA
- Thomas Inglesby, M.D.  
Director, Center for Biosecurity, University of Pittsburgh Medical Center, USA
- Le Thi Quynh Mai, M.D., Ph.D.  
Head of Virology Department, National Institute of Hygiene and Epidemiology, Viet Nam
- Adel Mahmoud, M.D., Ph.D.  
Professor, Molecular Biology and Public Policy, Princeton University, USA
- J. S. Malik Peiris, M.D., Ph.D.  
Professor, Centre of Influenza Research and the School of Public Health, The University of Hong Kong, China
- Robin Robinson, Ph.D.  
Director, Biomedical Advanced Research and Development Authority, and Deputy Assistant Secretary for Preparedness and Response, Department of Health and Human Services, USA
- Berhe Tekola, D.V.M., M.V.Sci., Ph.D.  
Director, Animal Production and Health Division, Agriculture and Consumer Protection Department, Food and Agriculture Organization

**Moderated Panel Discussion**

**Moderated Discussion with the Audience**

**10:50 – 11:10 A.M. Break**

**11:10 – 1:15 P.M. [Panel II: Risks and Concerns Associated with HPAI H5N1 GOF Research](#)**

**Panelist Presentations:**

The panelists will identify and discuss the range of concerns that have been raised over HPAI H5N1 GOF research, including biosafety risks, biosecurity risks, dual use and informational risks, and the implications for national and global security in conducting the research.

**Discussion Questions:**

1. What are the specific risks and concerns associated with HPAI H5N1 GOF research?
  - a. Biosafety risk, i.e., the physical, biological containment; occupational health; and public exposure
  - b. Biosecurity risk, e.g., the intentional misuse of information and/or organisms generated by HPAI H5N1 GOF research
  - c. Other DUR issues, e.g., informational security regarding the experimental details and findings of "sensitive research"
  - d. Undermining international public health or pandemic preparedness agreements (e.g., WHO Pandemic Influenza Preparedness Framework, a.k.a. PIP Framework) or nonproliferation conventions
2. Which components of HPAI H5N1 GOF experiments raise particular concern?
  - a. Increasing transmissibility of HPAI H5N1 viruses that might not occur naturally?
  - b. Increasing pathogenicity of HPAI H5N1 viruses that might not occur naturally?
  - c. Altering host range of HPAI H5N1 viruses that might not occur naturally?
  - d. Combinations of the above?
3. Are there experiments that should not be done, and if so, why not?

**Panel Co-Moderators:**

- Nancy Cox, Ph.D.  
Director, Influenza Division, Office of Infectious Diseases, Centers for Disease Control and Prevention, USA
- Nariyoshi Shinomiya, M.D., Ph.D.  
Professor, National Defense Medical College, Japan

**Panelists:**

- Ilaria Capua, D.V.M., Ph.D.  
Director, Research and Development Department, Istituto Zooprofilattico Sperimentale delle Venezie, Italy
- Seth Carus, Ph.D.  
Deputy Director, Center for Counterproliferation Research, Distinguished Research Professor, National Defense University, USA
- Arturo Casadevall, M.D., Ph.D.  
Professor and Chair, Department of Microbiology and Immunology, Albert Einstein College of Medicine, Yeshiva University, and Member, National Science Advisory Board for Biosecurity, USA
- E. William Colglazier, Ph.D.  
Science and Technology Adviser to the U.S. Secretary of State, USA
- Gerald Epstein, Ph.D.  
Deputy Assistant Secretary for Chemical, Biological, Nuclear, and Radiological Policy, Office of Policy, Department of Homeland Security, USA
- Gary Kobinger, Ph.D.  
Head, Vector Design and Immunotherapy Special Pathogens, National Microbiology Laboratory, Public Health Agency, Canada
- John S. Parker, M.D., Major General (Retired)  
Senior Vice President, SAIC Inc., USA
- Harvey Rubin, M.D., Ph.D.  
Director, University of Pennsylvania Institute for Strategic Threat Analysis and Response, and Associate Dean for Student Affairs, Professor, Division of Infectious Disease, School of Medicine, University of Pennsylvania, USA
- Pretty Multihartina D. Sasono, Ph.D.  
Senior Scientist, National Institute of Health Research and Development, Ministry of Health, Indonesia
- Dawn Wooley, Ph.D., S.M. (N.R.C.M.), R.B.P., C.B.S.P.  
Associate Professor, Department of Neuroscience, Cell Biology and Physiology, Boonshoft School of Medicine, Wright State University, USA

**Moderated Panel Discussion****Moderated Discussion with the Audience**

**1:15 – 2:15 P.M. Break**

**2:15 – 4:10 P.M. [Panel III: Perspectives on the Proposed Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Highly Pathogenic Avian Influenza H5N1 Gain-of-Function Research](#)**

**Special Presentation:**

This presentation will introduce the proposed HHS Framework for guiding funding decisions about HPAI H5N1 GOF research. This panel will then discuss the proposed Framework within the context of their areas of expertise.

- Amy P. Patterson, M.D.  
Associate Director for Science Policy, National Institutes of Health, USA

**Discussion Questions:**

1. What are your perspectives on the proposed HHS Framework?
2. Are there any risks that are not addressed by the Framework, including those identified during the Panel II discussion?

**Panel Co-Moderators:**

- Amy P. Patterson, M.D.  
Associate Director for Science Policy, National Institutes of Health, USA
- Samuel Stanley, M.D.  
President, Stony Brook University, Chair, National Science Advisory Board for Biosecurity, USA

**Panelists:**

- Daniel Altmann, Ph.D.  
Head of Pathogens, Immunology and Population Health, Wellcome Trust, United Kingdom
- Marianne Donker, Ph.D.  
Director of Public Health, Ministry of Health, the Netherlands
- Keith Hamilton, B.V.Sc., M.Sc., MRCVS  
Scientific and Technical Department, World Organisation for Animal Health
- Yoshihiro Kawaoka, D.V.M., Ph.D.  
Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison, USA
- Zarifah Reed, M.D.  
Medical Director, SENTINEXT Therapeutics, Malaysia
- Michael Selgelid, Ph.D., M.A.  
Senior Lecturer and Deputy Director, Centre for Human Bioethics, Monash University, Australia
- David Swayne, D.V.M., Ph.D.  
Southeast Poultry Research Laboratory, Agricultural Research Service, Department of Agriculture, USA

**Moderated Panel Discussion****Moderated Discussion with the Audience**

**4:10 – 4:30 P.M. Break**

**4:30 – 6:30 P.M. Panel IV: [Discussion of HPAI H5N1 Gain-of-Function Research Case Studies](#)**

**Presentations of Case Studies:**

The panelists will be presented with and discuss case studies that illustrate how the HHS Framework, presented in Panel III, would apply to different HPAI H5N1 GOF research projects.

**Discussion Questions:**

1. How well did the proposed Framework function in the analysis of the case studies? Is it a useful tool for guiding funding decisions?
2. Does the Framework appropriately address the range of risks associated with the research?
3. Does the Framework provide for the appropriate review of such research?
4. Are there gaps that should be addressed by the Framework?

**Panel Co-Moderators:**

- Dennis Dixon, Ph.D.  
Chief, Bacteriology and Mycology Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA
- Amy P. Patterson, M.D.  
Associate Director for Science Policy, National Institutes of Health, USA

**Panelists:**

- Tjandra Aditama, M.D.  
Director-General, Disease Control and Environmental Health, Ministry of Health, Indonesia
- Daniel Altmann, Ph.D.  
Head of Pathogens, Immunology and Population Health, Wellcome Trust, United Kingdom
- Nancy Cox, Ph.D.  
Director, Influenza Division, Office of Infectious Diseases, Centers for Disease Control and Prevention, USA
- Thomas Inglesby, M.D.  
Director, Center for Biosecurity, University of Pittsburgh Medical Center, USA
- Joseph Kanabrocki, Ph.D.  
Assistant Dean, Biosafety, and Associate Professor of Microbiology, University of Chicago, USA

- Yoshihiro Kawaoka, D.V.M., Ph.D.  
Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison, USA
- J. S. Malik Peiris, M.D., Ph.D.  
Professor, Centre of Influenza Research and the School of Public Health, The University of Hong Kong, China
- Adel Mahmoud, M.D., Ph.D.  
Professor, Molecular Biology and Public Policy, Princeton University, USA
- Robin Robinson, Ph.D.  
Director, Biomedical Advanced Research and Development Authority, Deputy Assistant Secretary for Preparedness and Response, Department of Health and Human Services, USA

#### **Moderated Panel Discussion**

#### **Moderated Discussion with the Audience**

## Day 2

### **9:00 – 9:15 A.M. Introductory Remarks**

- Robbert Dijkgraaf, Ph.D.  
Co-Chair, InterAcademy Council  
Past President, the Royal Netherlands Academy of Arts and Sciences, the Netherlands  
Director and Leon Levy Professor, Institute for Advanced Study, Princeton, USA
- Harvey Fineberg, M.D., Ph.D.  
President, Institute of Medicine, National Academies  
Professor of Health Policy and Management, Emeritus, Department of Health Policy and Management, Harvard University, USA

### **9:15 – 11:30 A.M. [Panel V: Identifying Conditions, if any, under which HPAI H5N1 GOF Research Should be Conducted](#)**

#### **Panelist Presentations:**

The panelists will address biosafety and biosecurity requirements applicable to HPAI H5N1 GOF research and discuss the conditions, if any, under which HPAI H5N1 GOF research could be supported and conducted, identifying specific standards that should be in place for future research in this area.

#### **Discussion Questions:**

1. What are the common principles among biosafety and biosecurity requirements around the world?
  - a. Are any changes needed in extant biosafety requirements, biosecurity requirements, DURC policies, or in roles for international organizations if HPAI H5N1 GOF research is to continue?
  - b. Are there other models for oversight of research utilizing highly pathogenic agents that would be applicable or useful?
2. Do the designs of some HPAI H5N1 GOF experiments conducted to date raise fewer concerns than other HPAI H5N1 experimental designs? If so, why? How might some of these designs, if used more broadly in the future, obviate concerns while advancing public health? Are the strategies proposed in this panel applicable beyond HPAI H5N1 GOF research?

#### **Panel Co-Moderators:**

- Kirsten Jacobsen, Ph.D.  
Manager, Biosafety Risk Assessment, Pathogen Regulation Directorate, Public Health Agency, Canada
- Zarifah Reed, M.D.  
Medical Director, SENTINEXT Therapeutics, Malaysia

#### **Panelists:**

- Celia Alpuche-Aranda, M.D., Ph.D.  
Director, Institute of Epidemiological Diagnosis and Reference, National Public Health Institute, Mexico
- David Harper, C.B.E.  
Special Advisor, Office of the Assistant Director-General, Health Security and Environment, World Health Organization
- Joseph Kanabrocki, Ph.D.  
Assistant Dean, Biosafety, and Associate Professor of Microbiology, University of Chicago, USA

- Gary Kobinger, Ph.D.  
Head, Vector Design and Immunotherapy Special Pathogens, National Microbiology Laboratory, Public Health Agency, Canada
- Gene Matthews, J.D.  
Senior Fellow, North Carolina Institute for Public Health, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, USA
- Anna Lönnroth Sjöden, Ph.D.  
Deputy Head of Unit, Infectious Disease and Public Health, DG Research and Innovation, European Commission
- Robbin Weyant, Ph.D.  
Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, USA
- Kevin J. Wolf, J.D.  
Assistant Secretary of Commerce for Export Administration, Bureau of Industry and Security, Department of Commerce, USA

### **Moderated Panel Discussion**

### **Moderated Discussion with the Audience**

**11:30 – 12:25 P.M. Break**

**12:25 – 2:50 P.M. Panel VI: Overview and Discussion of Main Points**

A co-moderator from each panel will identify the main points from their respective sessions. These points will be discussed by the panel participants and the audience and will be useful for HHS, other governments and research funders to approach decisions about pursuing HPAI H5N1 gain-of-function research. These discussions will be an important contribution to the ongoing global dialog on this issue.

### **Meeting Co-Moderators:**

- Robbert Dijkgraaf, Ph.D.  
Co-chair, InterAcademy Council  
Past President, the Royal Netherlands Academy of Arts and Sciences, the Netherlands  
Director and Leon Levy Professor, Institute for Advanced Study, Princeton, USA
- Harvey Fineberg, M.D., Ph.D.  
President, Institute of Medicine, National Academies  
Professor of Health Policy and Management, Emeritus, Department of Health Policy and Management, Harvard University, USA

### **Panelists:**

- Nancy Cox, Ph.D.  
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Professor, National Defense Medical College, Japan
- Samuel Stanley, M.D.  
President, Stony Brook University, Chair, National Science Advisory Board for Biosecurity, USA

- Kanta Subbarao, M.D., M.P.H.  
Chief, Emerging Respiratory Viruses Section, National Institute of Allergy and Infectious Diseases,  
National Institutes of Health, USA
- Robert Webster, Ph.D.  
Department of Infectious Disease, St. Jude Children's Research Hospital, USA

**2:50 – 3:00 P.M. Closing Remarks**

**3:00 P.M. Meeting Adjournment**