



**Biosafety Considerations for Research with
Highly Pathogenic Avian Influenza Virus H5N1
that is Transmissible between Mammals
by Respiratory Droplets**



**National Institutes of Health (NIH)
Recombinant DNA Advisory Committee**

**January 24, 2013
Building 31, Conference Room 10
NIH
Bethesda, MD**

Agenda

8:30 AM

Welcome and Opening Remarks

Amy P. Patterson, M.D. Office of Science Policy, NIH, Bethesda MD

Yuman Fong, M.D., Chair, NIH Recombinant DNA Advisory Committee
Memorial Sloan Kettering Cancer Center, N.Y., NY

Jacqueline Corrigan-Curay, J.D., M.D., Office of Biotechnology Activities, NIH

Session I: Overview of H5N1 Influenza Virus

8:40 AM

H5N1 Influenza Virus: An Overview

Sylvie Briand, M.D., World Health Organization, Geneva, Switzerland
(*Teleconference*) – [Slide Presentation](#)

Joseph Malik Peiris, M.D., Ph.D., The University of Hong Kong,
People's Republic of China (*Teleconference*)-- – [Slide Presentation](#)

9:10 AM

Antivirals for Influenza H5N1 Infections

Frederick Hayden, M.D., University of Virginia, Charlottesville, VA
(*Teleconference*) -- – [Slide Presentation](#)

9:25 AM

H5N1 Pre-Pandemic Influenza Vaccine Stockpile

Armen Donabedian, Ph.D., Biomedical Advanced Research and Development
Authority, U.S. Department of Health & Human Services, Washington, DC
– [Slide Presentation](#)

9:45 AM

**Implications of Biosafety Recommendations on Derivation of Influenza
Vaccine Reference Virus and Vaccine Manufacture**

Carolyn Wilson, Ph.D., Food and Drug Administration, Bethesda MD
– [Slide Presentation](#)

9:55 AM

**Research HPAI H5N1 Viruses Transmissible between Mammals by
Respiratory Droplets**

Daniel Perez, Ph.D., University of Maryland, College Park, MD
– [Slide Presentation](#)

10:10 AM **Resurrection of the 1918 H1N1 Influenza: What did we learn?**
Terrence Tumpey, Ph.D., Centers for Disease Control and Protection,
Atlanta, GA -- -- [Slide Presentation](#)

10:30 AM **QUESTIONS**

10:40 AM **BREAK**

Session II: Current Biosafety Guidance for Influenza Virus Research

10:55 AM **USDA Select Agent Regulation of HPAI H5N1 Research**
Freeda Isaac, D.V.M., Animal and Plant Health Inspection Service,
U.S. Department of Agriculture, Riverdale, MD -- [Slide Presentation](#)

11:10 AM **Proposed Biosafety Containment, Practices, Training, and Occupational Health Guidance for Research with Mammalian-transmissible H5N1 in the NIH Guidelines: Working Group Recommendations**
Jacqueline Corrigan-Curay, J.D., M.D., NIH, Bethesda, MD
-- [Slide Presentation](#)

Session III: Containment, Practices and Occupational Health

11:45 AM **RAC Discussion**

Moderator: Yuman Fong, M.D.

Panelists:

Joseph Kanabrocki, Ph.D., University of Chicago, Chicago, IL (*Teleconference*)

Nicoletta Previsani, Ph.D., World Health Organization, Geneva, Switzerland
(*Teleconference*)

Stephen Redd, M.D., Centers for Disease Control and Prevention, Atlanta, GA

David Swayne, Ph.D. Southeast Poultry Research Laboratory, Agricultural
Research Service, U.S. Department of Agriculture, Athens, GA (*Teleconference*)

Dawn Wooley, Ph.D., Wright State University, Dayton, OH

Discussion

1. Is BL3 enhanced appropriate for this type of work?
2. What is the best mechanism to address research with a mammalian transmissible strain of HPAI H5N1 for which there is resistance to one or more antivirals?

12:45 PM	Working Lunch
1:30 PM	Discussion
2:00 PM	Public Comment
2:15 PM	RAC Vote on Recommendations

Session IV: Risk Assessment for Future Research with Highly Pathogenic and Mammalian-Transmissible Influenza Viruses

2:30 PM Panel Discussion

Moderators: Saswati Chatterjee, Ph.D., City of Hope National Medical Center, Duarte, CA
 Marie-Louise, Hammarskjöld, M.D., Ph.D., University of Virginia, Charlottesville, VA

Panelists:

Robert Webster, Ph.D., St. Jude Children’s Research Hospital, Memphis, TN

Andrew Pekosz, Ph.D., Johns Hopkins University, Baltimore, MD

Terrence Tumpey, Ph.D., Centers for Disease Control and Prevention

Daniel Perez, Ph.D., University of Maryland, College Park, MD

Discussion

1. What should be the criteria for determining which novel viruses require modified containment or risk management?
 - a. Is the ferret model the best model for establishing whether a HPAI H5N1 virus is transmissible between mammals? Are there any other models that can be used?
 - b. Should a virus with certain mutations in the HA gene that render it able to bind human sialic acid receptors be treated as mammalian-transmissible until proven otherwise?

2. Are there types of experiments with HPAI H5N1 that are not intended to generate mammalian-transmissible strains but because of the experimental design the risk of generating a mammalian transmissible strain is sufficiently high to warrant enhanced containment practices and occupational health measures as soon as HPAI H5N1 viruses are generated but before testing is done on transmissibility or pathogenicity?
 - a. For example, should research that involves serial passaging of HPAI H5N1 in mammals which are susceptible to human influenza strains, e.g. ferrets, guinea pigs, be a type of experiment that should be conducted in enhanced containment?

3. Should enhanced containment measures (e.g. BL3 enhanced) be considered when performing research to increase transmissibility, pathogenicity and/or host range of influenza viruses which have pandemic potential due to low pre-existing immunity in community?
 - a. What criteria can be used to identify those experiments that warrant enhanced containment without unnecessarily raising containment on all research with novel influenza viruses?

4:00 PM RAC Vote on Recommendations

4:15 PM PUBLIC COMMENT

4:45 PM ADJOURN