Potential Risks and Benefits of Gain-of-Function Research Symposium Agenda

National Academy of Sciences Building
2101 Constitution Avenue NW
Washington, DC 20036
December 15 - 16, 2014

Monday, December 15

7:30am **Registration**
(coffee and tea will be served)

8:00 **Welcome**
Harvey Fineberg, Moderator
Ralph Cicerone, President, National Academy of Sciences and Chairman, National Research Council
Victor Dzau, President, Institute of Medicine

8:15 **Session 1: Opening Remarks**
Moderator: Harvey Fineberg

Goals of the Symposium: Discussion of Potential Benefits and Risks of Gain of Function (GOF) Research and Identification of Key Principles and Considerations for Risk/Benefit Assessment (10 minutes)
Harvey Fineberg, Chair of Symposium Planning Committee

Summary of Recent European Meetings on GOF Research (5 minutes)
Harvey Fineberg, Chair of Symposium Planning Committee

Current U.S. Government Policy on GOF Research Proposals and Charge to the Academies (15 minutes)
Andrew Hebbeler, Assistant Director for Biological and Chemical Threats, Office of Science and Technology Policy, The White House
Amy Patterson, Associate Director for Biosecurity and Biosecurity Policy, National Institutes of Health (NIH)

Summary of and Response to October 22, 2014 National Science Advisory Board for Biosecurity (NSABB) Meeting (15 minutes)
Samuel Stanley, Chair of the NSABB

Moderated Discussion (15 minutes)
To clarify or expand on key issues that emerge from the presentations

9:15 **Session 2: Overview**
Moderator: Harvey Fineberg

Purpose: To provide a brief introduction to the current scientific and technical

approaches to virology research and the study of pandemic avian influenza, Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome (MERS).

Speaker: Kanta Subbarao, National Institute of Allergy and Infectious Diseases (NIAID)/NIH, influenza (20 minutes)

Virology: What impact does virological research typically have on the viruses being studied? Where does virology cross the line into GOF research as defined by the U.S. government? Explanation of types of GOF research.

What do we know or not know about flu, SARS, and MERS and can GOF research help fill the gaps?

Moderated panel discussion (20 minutes)
To clarify or expand on key issues that emerge from the presentations

Panelists

- Thomas Briese, Columbia University
- Michael Imperiale, University of Michigan

Q&A Discussion (20 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

10:15 **Session 3: What are the Main Points of the Debate on the Potential Risks and Benefits of GOF Research?**
Moderator: Harvey Fineberg

Two Views (15 minutes each)

What are the key issues on benefits that need to be addressed in the assessments the NIH will undertake?
Yoshihiro Kawaoka, University of Wisconsin-Madison

What are the key issues on risks that need to be addressed in the assessments the NIH will undertake?
David Relman, Stanford University

Respondent: Robert Webster, member of Symposium Planning Committee (15 minutes)
To probe and explore the evidence for the statements made by speakers above.

Q&A Discussion (30 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

11:30 **Break**

12:00 **Session 4: Potential Benefits of GOF Research I: Surveillance, Detection and Prediction**
Moderator: Philip Dormitzer, member of Symposium Planning Committee

Focus: Potential for contributions to public health and biosecurity (early detection and identification of dangerous strains) as well as design and operation of disease surveillance or pandemic modeling systems.

Surveillance of emerging zoonotic diseases (10 minutes)
Stacey Schultz-Cherry, St. Jude Children's Research Hospital

Modeling of potential pandemics (10 minutes)
Christophe Fraser, Imperial College, London

Respondent: Colin Russell, University of Cambridge Infectious Diseases

Q&A Discussion (30 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

1:00 **Lunch**
(boxed lunches will be provided)

2:00 **Session 5: Potential Benefits of GOF Research II: Treatment and Response**
Moderator: Baruch Fischhoff, member of Symposium Planning Committee

Focus: Potential for GOF research to accelerate vaccine and antiviral development and potential impact of GOF regulations on vaccine and antiviral development

Panel of Academic, Government, and Industry Representatives (5 minutes each)
Philip Dormitzer, Novartis Vaccines - synthetic influenza vaccine viruses
Ralph Baric, University of North Carolina - vaccines targeting coronaviruses
George Kemble, 3-V Biosciences (formerly Medimmune) - GOF and live attenuated influenza viruses
Jerry Weir, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration - regulatory perspective on viral manipulation for biologics
Mark Denison, Vanderbilt University - GOF research and countermeasures against SARS and MERS

Moderated Discussion (15 minutes)
To clarify or expand on key issues that emerge from the presentations

Q&A Discussion (30 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

3:15 **Session 6: Potential Risks of GOF Research I: Biosafety**
Moderator: Alta Charo, member of Symposium Planning Committee

Focus: Potential for inadvertent releases, laboratory acquired infections, environmental health issues, and risk mitigation for pathogen research in general and as related to GOF research

Panel Discussion (10 minutes each)
Barbara Johnson, Biosafety Biosecurity International
Rob Weyant, Division of Select Agents and Toxins, U.S. Centers for Disease Control and Prevention
Rebecca Moritz, Biosecurity Task Force, University of Wisconsin-Madison
Marc Lipsitch, Harvard University

Q&A Discussion (30 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

4:30 **Session 7: Potential Risks of GOF Research II: Biosecurity**
Moderator: Ronald Atlas, member of Symposium Planning Committee

Focus: Potential for misuse of research for biocrimes or bioterrorism or to develop new biological weapons, as well as the potential for deliberate release or sabotage.

Speakers (10 minutes each)
Carol Linden, Biomedical Advanced Research and Development Authority
Gigi Kwik-Gronvall, University of Pittsburgh Medical Center (UPMC) Center for Health Security
Gregory Koblentz, George Mason University

Q&A Discussion (30 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

5:30 **Adjourn for the day**

Tuesday, December 16

7:45 **Welcome**
(continental breakfast will be provided)

8:00 **Session 8: Models for Risk/Benefit Assessment, Risk Mitigation, and Engaging the Public**
Moderator: Charles Haas, member of the Symposium Planning Committee

What can risk/benefit assessment do and what can it not do? What have we learned from the past about strategies, pitfalls, and limitations of risk and benefit assessments?
(15 minutes)
Baruch Fischhoff, Carnegie Mellon University, member of the Symposium Planning Committee

The Role of Human Factors (15 minutes)
Gavin Huntley-Fenner, Huntley-Fenner Advisors

Ensuring Public Engagement (15 minutes)
Monica Schoch-Spana, UPMC Center for Health Security

What, if any, special considerations about GOF research need to be taken into account in the risk/benefit assessment? (30 minutes)
Ralph Baric, University of North Carolina
Robert Lamb, Northwestern University

- Reversibility / mitigation?
- Special considerations about alternative research methods with less risk?
- Differences among organisms (viruses are not all the same, mice don't sneeze)?
- Exactly what functionality is being gained or lost?
- Are transmissibility, virulence, growth and functionality (necessary for vaccine production) all similar in terms of GOF objectives?)

Q&A Discussion (45 minutes)
There will be ground rules for questions and comments to enable maximum participation from the audience.

10:00 **Session 9: Summary Discussions**
Moderator: Harvey Fineberg

The rapporteurs will report on the main ideas collected from each of the foregoing sessions:

- Risks
- Benefits
- Mitigation and alternative strategies
- Special considerations

11:00 **Break** (heavy snacks will be served, as there will be no lunch break)

11:30 **Session 10: Finding Common Ground**
Moderator: Harvey Fineberg

- What are the major areas of agreement on risks and benefits?
- What are the major areas of disagreement on risks and benefits?
- How should the risks be weighed against the benefits?

- What approaches may be available to diminish risks and achieve benefits simultaneously?
- What are the key principles and issues NIH's risk and benefit assessments need to include?

Moderated Discussion (approximately 2 hours)
There will be ground rules for questions and comments to enable maximum participation from the audience.

1:30 **Session 11: Chairman's Summary of Meeting Highlights**

2:00 **Adjourn**