NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

January 7 & 8, 2016

National Institutes of Health
9000 Rockville Pike
Bldg. 31, C Wing, 6th Floor, Conf. Rm. 6
Bethesda, Maryland

MEETING AGENDA

Thursday, January 7, 2016. Informing NSABB Deliberations: Considering Risks, Benefits, Ethics, and Policy

8:30 am – 8:50 am **Welcome and Introductions**

Opening Remarks
Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

Introduction of NSABB Voting and Ex Officio Members
Christopher J. Viggiani, Ph.D., Executive Director, NSABB, National Institutes of Health

Review of Conflict of Interest Rules
Christopher J. Viggiani, Ph.D.

Approval of NSABB Meeting Minutes
Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

8:50 am – 9:00 am **The Gain-of-Function Deliberative Process**

Carrie Wolinetz, Ph.D., Associate Director for Science Policy, National Institutes of Health

9:00 am – 9:30 am **NSABB Working Group: An Overview of Progress, Preliminary Findings, and the NSABB's Draft Working Paper**
Joseph Kanabrocki, Ph.D., C.B.S.P., Co-chair, NSABB Working Group

NSABB Discussion

9:30 am – 10:30 am **Session I: Results of the Risk & Benefit Assessments of Gain-of-Function Studies**

Co-Moderators:

- James W. LeDuc, Ph.D., NSABB member
- Gary Resnick, Ph.D., NSABB member

Presenter: Rocco Casagrande, Ph.D., Principal Investigator, Managing Director, Gryphon Scientific

10:30 am – 10:45 pm **Break**

10:45 am – 12:30 pm **Session I, Continued**

Panelists

- Thomas Inglesby, M.D., UPMC Center for Health Security
- Stephen Eubank, Ph.D., Virginia Tech
- Ron Fouchier, Ph.D., Erasmus Medical Center
- Daniel Jernigan, M.D., M.P.H., Centers for Disease Control and Prevention
- Kanta Subbarao, M.B., B.S., M.P.H., National Institutes of Health
- David Relman, M.D., Stanford University

Questions to Address

- What are the strengths and limitations of the risk and benefit assessments?
- Which gain-of-function (GOF) studies are of greatest concern, if any? Which are of less concern?
- Are the assumptions, approaches, and findings about risks and benefits associated with GOF studies comprehensive and sound?
- Are there specific risks or benefits that are over- or understated in the risk and benefit assessments?

Open Q & A Session
NSABB Discussion

12:30 pm – 1:30 pm **Lunch Break**

1:30 pm – 3:15 pm **Session II: Examination of Ethical Issues Associated with Gain-of-Function Studies and Discussion of Potential Decision Frameworks**

Co-Moderators:

- Susan Wolf, J.D., NSABB member
- Francis L. Macrina, Ph.D., NSABB member

Presenter: Michael Selgelid, Ph.D.

Panelists

- R. Alta Charo, J.D., University of Wisconsin Law School
- Jonathan Moreno, Ph.D., University of Pennsylvania
- David Fidler, J.D., M.Phil., Indiana University, Bloomington
- John Kadvany, Ph.D., Independent consultant on decision science

Questions to Address

- What ethical values should NSABB consider in moving beyond the risk and benefit assessments in order to formulate policy recommendations on GOF studies involving pathogens with pandemic potential?
- What ethical or other decision-making frameworks should be brought to bear when considering whether to fund and conduct certain GOF studies?

- How can ethical decisions be made in light of the inherent uncertainty associated with potential risks and benefits?
- Is there GOF research that should not be funded or conducted? If so, what are the features of such studies and what considerations should guide the identification of GOF studies that might meet such designation?

Open Q & A Session
NSABB Discussion

3:15 pm – 3:30 pm **Break**

3:30 pm – 5:00 pm **Session III: Analysis of the Current Policy Landscape and Potential Policy Options for Gain-of-Function Studies**

Co-Moderators:
- Joseph McDade, Ph.D., NSABB member
- Marie-Louise Hammarskjöld, M.D., Ph.D., NSABB member

Panelists:
- Gigi Kwik Gronvall, Ph.D., UPMC Center for Health Security
- Michael Imperiale, Ph.D., University of Michigan Medical School
- Barbara Jasny, Ph.D., Science Magazine
- Regine Aalders, M.Sc., Embassy of the Kingdom of the Netherlands

Questions to Address
- What are the major drivers of risks associated with GOF studies of concern? Are there any deficiencies with current policies in managing those risks?
- If risks are not currently adequately managed, what policy options or oversight might be available to help manage the risks? What should that oversight entail? Should that oversight occur at the federal or institutional level, or both?
- What challenges are associated with managing risks at the stage where research results are being communicated or published? What would journal editors find most helpful upstream to manage risks prior to publication?
- How can oversight measures be developed and employed in ways that would allow the benefits associated with GOF studies of concern to be realized?

Open Q & A Session
NSABB Discussion

5:00 pm – 5:30 pm **Public Comment Period**

Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

5:30 pm – 5:35 pm **Day 1 Closing Remarks and Adjourn**

Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

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MEETING AGENDA

Friday, January 8, 2016. A potential path forward for gain-of-function studies

8:30 am – 8:45 am **Opening Remarks**

Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

8:45 am – 10:30 am **Session IV: Discussion of NSABB Preliminary Findings and Draft Recommendations**

Co-Moderators:

- Ken Berns, M.D., Ph.D., Co-chair, NSABB Working Group
- Joseph Kanabrocki, Ph.D., C.B.S.P., Co-chair, NSABB Working Group

Panelists

- Marc Lipsitch, D. Phil., Harvard School of Public Health
- Jill Taylor, Ph.D., Wadsworth Center, NYS Department of Public Health
- Mark Denison, M.D., Vanderbilt University
- Yoshihiro Kawaoka, D.V.M., Ph.D., University of Wisconsin, Madison
- Philip Potter, Ph.D., St. Judes Children's Research Hospital
- Beth Willis, Co-founder, Frederick Citizens for Bio-lab Safety

Questions to Address

After considering the risks and benefits, as well as ethical and policy considerations:

- Are there GOF studies that may be conducted but should require an additional level of review or oversight? If so, what should that oversight entail? Should that oversight occur at the federal or institutional level, or both?
- How well does the NSABB's draft working paper identify the GOF studies of greatest concern?
- Are there GOF studies that should not be conducted? If so, which studies and why?
- How well would the NSABB's draft principles and criteria permit the review GOF studies that have raised concerns and inform decisions about whether

to fund such studies?

- Are there specific risk mitigation measures that should be required in order for certain GOF studies to be safely conducted?

Open Q & A Session
NSABB Discussion

10:30 am – 10:45 am **Break**

10:45 am – 11:15 am **Public Comment Period**

Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University

11:15 am – 11:30 pm **Discussion of Upcoming Meeting Hosted by the National Academies**

Speaker: Jo Husbands, Ph.D., Scholar/Senior Project Director, National Academies of Science

11:30 pm – 12:00 pm **Brief Break Before Working Lunch**

12:00 pm – 1:20 pm **Working Lunch—NSABB Discussion**

- In light of the discussion from the meeting, are there new considerations or modifications to NSABB's preliminary findings or draft working paper to discuss?
- What analysis or next steps should the NSABB working group persue?

1:20 pm – 1:30 pm **Closing Remarks and Adjourn**

Samuel L. Stanley, M.D., NSABB Chair, President, Stony Brook University