# Session IV
# Discussion of NSABB Preliminary Findings and Draft Recommendations

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# GOF Studies of Concern – Draft Recommendations

The WG has formulated draft recommendations regarding GOF studies of concern for consideration:

1. Research proposals involving GOF studies of concern entail the greatest risks and should be reviewed carefully for biosafety and biosecurity implications, as well as potential benefits, prior to determining whether they are acceptable for funding. If funded, such projects should be subject to ongoing oversight at the Federal and institutional levels.

2. In general, oversight mechanisms for GOF studies of concern should be incorporated into existing policy frameworks. The risks associated with some GOF studies of concern can be identified and adequately managed by existing policy frameworks if those policies are implemented properly. However, the level of oversight provided by existing frameworks varies by pathogen. For some pathogens, existing oversight frameworks are robust and additional oversight mechanisms should generally not be required. For other pathogens, existing oversight frameworks are less robust and may require supplementation. All relevant policies should be implemented appropriately and enhanced when necessary to effectively manage risks.

# GOF Studies of Concern – Draft Recommendations

Draft recommendations continued

3. The risk-benefit profile for GOF studies of concern may change over time and should be re-evaluated periodically to ensure that the risks associated with such research is adequately managed and the benefits are being realized.

4. The U.S. government should continue efforts to strengthen biosafety and biosecurity, which will foster a culture of responsibility that will support not only the safe conduct of GOF studies of concern but of all research involving pathogens.

# Proposed Conceptual Approach for Funding Potential GOF Studies of Concern

**1. Identify proposals anticipated to involve GOF studies of concern, as described by the following attributes:**

i. The pathogen generated is highly transmissible in a relevant mammalian model

ii. The pathogen generated is significantly virulent in a relevant mammalian model, and

iii. The pathogen generated is likely resistant to control measures or more capable of being spread among human populations than currently circulating strains of the pathogen.

**2. Review proposal to determine whether they meet the following criteria:**

i. The research proposal has been evaluated by a peer-review process and determined to be scientifically meritorious and has been assessed to be likely to exert a sustained, powerful influence on the research field(s) involved.

ii. An assessment of the overall potential risks and benefits associated with the project determines that the potential risks compared to the potential benefits are justified.

iii. There are no feasible, equally efficacious alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach.

iv. The investigator and institution proposing the research have the demonstrated capacity to carry it out safely and securely.

v. The research information is anticipated to be broadly and legally shared in order to realize its potential benefits to global health.

vi. The research will be supported through funding mechanisms that include appropriate oversight of: a) all aspects of the research including its conduct, b) the sharing of data and materials, and c) the communication of the research.

vii. The proposed research is ethically justifiable.

**Proposals not meeting these criteria should not be funded.**

**3. Fund, do not fund, or fund with required additional risk mitigation measures or stipulations.**

**4. Conduct the research in accordance with applicable oversight policies and employ any additional risk mitigation strategies that were identified at the time of funding or that are deemed necessary during the course of the research.**

i. Research should be reviewed regularly at the institutional level

ii. Research should be reviewed regularly by the Federal funding agency

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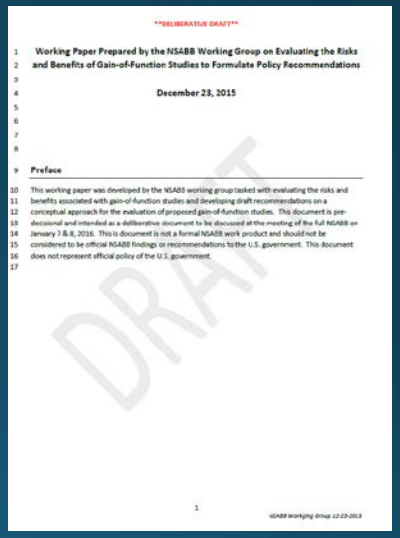
<u>Discussion Panelists:</u>

- 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, Frederick Citizens for Bio-lab Safety



**DELIBERATIVE DRAFT**

**Working Paper Prepared by the NSABB Working Group on Evaluating the Risks and Benefits of Gain-of-Function Studies to Formulate Policy Recommendations**

**December 23, 2015**

**Preface**

This working paper was developed by the NSABB working group tasked with evaluating the risks and benefits associated with gain-of-function studies and developing draft recommendations on a conceptual approach for the evaluation of proposed gain-of-function studies. This document is pre-decisional and intended as a deliberative document to be discussed at the meeting of the full NSABB on January 7 & 8, 2016. This is document is not a formal NSABB work product and should not be considered to be official NSABB findings or recommendations to the U.S. government. This document does not represent official policy of the U.S. government.

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nSABB Working Group 12-23-2015

**Submit questions:** nsabb@od.nih.gov

# NSABB Preliminary Findings and Draft Recommendations

Questions for Discussion

- 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 review of GOF studies of concern 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?