Charge to the National Science Advisory Board for Biosecurity (NSABB)

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NSABB Meeting
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NSABB Charge

Phase 1 – Balancing Security and Public Transparency

- Provide recommendations to OSTP and HHS on balancing considerations regarding security and public transparency when sharing information about research involving enhanced potential pandemic pathogens
  - In developing these recommendations, consider the process adopted by HHS for the review and oversight of proposed research involving enhanced potential pandemic pathogens

NSABB Charge

Phase 2A - DURC Policy Review and Evaluation

- For OSTP and NSC, evaluate and analyze the U.S. Government federal and institutional policies for the oversight of dual use research of concern (DURC) to:
  - Evaluate effectiveness in achieving their intent
  - Evaluate impact on research institutions and U.S. Government's ability to support research
  - Identify implementation challenges
  - Evaluate effectiveness with regard to publication, public communication, and dissemination of dual-use research methodologies and results

NSABB Charge

Phase 2A - DURC policy review and evaluation

- The NSABB should also:
  - Reevaluate the DURC definition, considering advances in life sciences research and convergence with other scientific disciplines and sectors
  - Evaluate the effectiveness of the DURC pathogen list and experimentation type construct to determine:
    - If the approach sufficiently addresses future potential threats, including across the spectrum of life sciences
    - If the approach is conducive to research risk-mitigation, and
    - Whether alternative approaches warrant consideration

DURC DEFINITION:

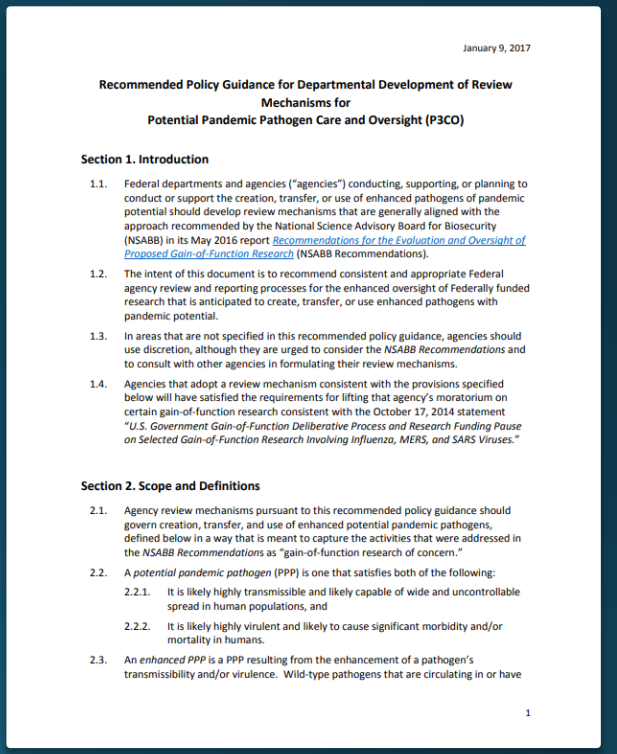
Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any quantity)
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

NSABB Charge

Phase 2B - P3CO policy review and evaluation

- With regard to the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)*, the NSABB should:
  - Evaluate Section 8 "Future Commitments" and provide recommendations on possible *P3CO Policy Guidance* incorporation into policy frameworks associated with any recommended revisions of the DURC policies



January 9, 2017

Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)

Section 1. Introduction

1.1. Federal departments and agencies ("agencies") conducting, supporting, or planning to conduct or support the creation, transfer, or use of enhanced pathogens of pandemic potential should develop review mechanisms that are generally aligned with the approach recommended by the National Science Advisory Board for Biosecurity (NSABB) in its May 2016 report *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research* (NSABB Recommendations).

1.2. The intent of this document is to recommend consistent and appropriate Federal agency review and reporting processes for the enhanced oversight of Federally funded research that is anticipated to create, transfer, or use enhanced pathogens with pandemic potential.

1.3. In areas that are not specified in this recommended policy guidance, agencies should use discretion, although they are urged to consider the *NSABB Recommendations* and to consult with other agencies in formulating their review mechanisms.

1.4. Agencies that adopt a review mechanism consistent with the provisions specified below will have satisfied the requirements for lifting that agency's moratorium on certain gain-of-function research consistent with the October 17, 2014 statement "*U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses.*"

Section 2. Scope and Definitions

2.1. Agency review mechanisms pursuant to this recommended policy guidance should govern creation, transfer, and use of enhanced potential pandemic pathogens, defined below in a way that is meant to capture the activities that were addressed in the *NSABB Recommendations* as "gain-of-function research of concern."

2.2. A *potential pandemic pathogen* (PPP) is one that satisfies both of the following:

2.2.1. It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations, and

2.2.2. It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

2.3. An *enhanced PPP* is a PPP resulting from the enhancement of a pathogen's transmissibility and/or virulence. Wild-type pathogens that are circulating in or have

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NSABB Charge

Throughout Phase 2

- In its deliberations, the NSABB should consider the need for flexible and adaptive governance approaches that:
  - Keep pace with scientific advances and the evolving understanding of risks and benefits;
  - Can coalesce and integrate existing governance, guidance, or policy; and
  - Can be applied to mitigate risk not only from research of concern but other biosecurity and biosafety considerations

Anticipated Timeline

- **Feb 2020:** NSABB forms working group and develops workplan to address Phase 1
- **Late Spring/Early Summer 2020:** NSABB develops recommendations on balance of security and public transparency (Phase 1 completion)
- **Late Spring/Early Summer 2020:** NSABB forms working group(s) and begins review and evaluation of DURC and P3CO policies (Phase 2 launch)
- **Spring 2021:** NSABB delivers recommendations regarding DURC and P3CO policies (Phase 2 completion)