# Addressing the Charge to NSABB

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#### **GOF Deliberative Process**

Risk and Benefit Assessment Studies

**NSABB** 

National Academies

USG Gainof-Function Policy

#### **Estimated Timeline**

National

Public

discuss

Academies host

Symposium to

assessment of GOF research

**National** 

provide

**Academies** 

**Symposium** 

Summary

#### Oct-Nov 2014 August 2015 **NSABB** Nov 2014-Jan 2015 **Early 2015** June 2015 **NSABB** delivers deliberates **NSABB** considers NSABB analyzes & **NSABB** periodically June 2015 final key features **National Academies** assesses progress & discusses results → **NSABB** recommendations of study input & advises on reviews preliminary reviews final Develops draft design draft study design results to USG results recommendations Weighing of Risks & **Conduct of Study** Benefits + Study Design Results of Study Risk Assessment + Development of **Benefit Assessment** Recommendations **Dec 2014 July 2015** Jan 2015

**National Academies** 

host Public Symposium

to discuss NSABB draft

recommendations &

provide Symposium

Summary

### **Charge to NSABB**

- NSABB is to:
  - Advise on the design, development, and conduct of risk and benefit assessment studies
  - NSABB is to provide recommendations to the USG on a conceptual approach to the evaluation of proposed GOF studies
- In developing its recommendations to the USG, the NSABB will consider:
  - The results of the risk and benefits assessments
  - Spectrum of potential risks and benefits associated with such studies
  - Any alternative methods that may be employed to yield similar scientific insights or benefits, while reducing potential risks.
  - Discussions hosted by the National Academies, and
  - Any additional consultations with relevant subject matter experts, as needed, to ensure that appropriate expertise is brought to bear on the issues.

## Advising on the Risk and Benefit Assessments

In advising on the design and conduct of the risk and benefits assessments, NSABB will:

- Advise on the assumptions to be included in the risk assessment, including those related to:
  - Characteristics of the pathogens with pandemic potential in question
  - Proposed experiments to be assessed
  - Biosafety practices and containment features to be utilized for the studies, and
  - Inventories of the pathogens
- Evaluate the methodologies, scope, and scenarios to be used in the risk assessment
- Consider the adequacy of the scenarios in the risk assessment and propose additional scenarios to address other concerns or factors, as appropriate
- Consider the discussions and input generated during a National Academies forum

## Advising on the Risk and Benefit Assessments

In advising on the design and conduct of the risk and benefits assessments, NSABB will:

- Advise on the assessment of the benefits, including the types of benefits that should be examined and methods for examining them
- Provide advice at key milestones in the conduct of the risk and benefit assessment studies

#### **NSABB Deliverables**

- 1. Advice on the design, development, and conduct of risk and benefit assessments.
- 2. Formal recommendations on the conceptual approach to the evaluation of proposed GOF studies.