

The Gain-of-Function Deliberative Process

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Promoting Public Health through Life Sciences Research

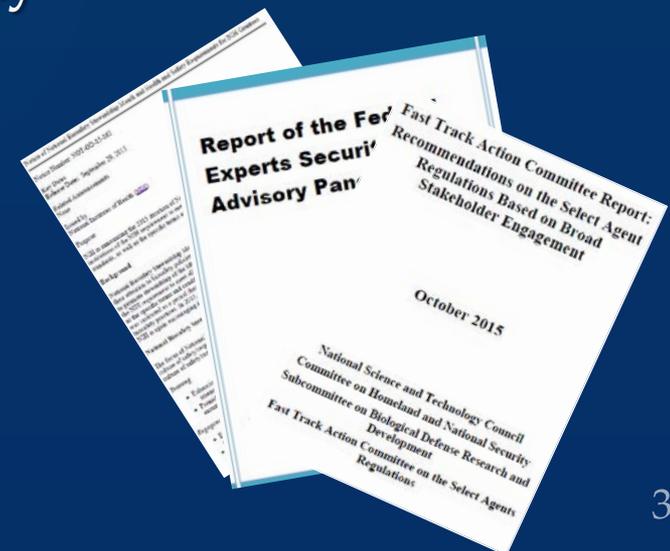
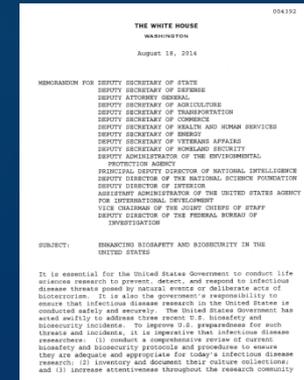
A robust life sciences research endeavor is critical to promoting public health and well-being in light of evolving threats posed by microbial pathogens.

- USG supports a diverse life sciences research portfolio
- Research involving potentially dangerous pathogens have inherent biosafety and biosecurity risks
- Safely realizing the benefits of such research requires effective policies, practices, and oversight

Strengthening Biosafety and Biosecurity in Life Sciences Research

Recent lab incidents have spurred a series of policy activities by the USG aimed at reinforcing commitments to biosafety, biosecurity, and responsible conduct of research among all stakeholders

- Safety stand-down and National Biosafety Stewardship Month
- Federal Experts Security Advisory Panel (FESAP) Report
- Fast-Track Action Committee on Select Agent Regulations (FTAC-SAR) Report



Gain-of-Function (GOF) Research

As part of a renewed focus on biosafety and biosecurity, the risks and benefits associated with gain-of-function (GOF) studies is being carefully re-examined.

- GOF studies are one approach to addressing fundamental scientific questions.
- GOF studies have the potential to:
 - Help define the fundamental nature of host-pathogen interactions
 - Enable assessment of the pandemic potential of emerging infectious agents
 - Inform public health and preparedness efforts
 - Further medical countermeasure development

Concerns about Certain GOF Studies

Certain GOF studies have raised biosafety and biosecurity concerns

- Could engineered pathogens pose a pandemic threat if they were to be accidentally or intentionally released from a laboratory?
- Could the information generated from certain GOF studies be misused to threaten public health or national security?

Policy questions:

- *Under what conditions can these studies be safely conducted?*
- *Should this type of research be conducted at all?*

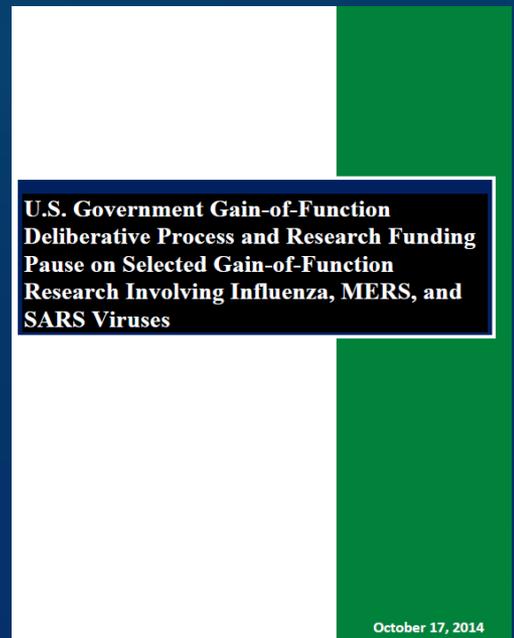
GOF Deliberative Process and Research Funding Pause

Deliberative Process

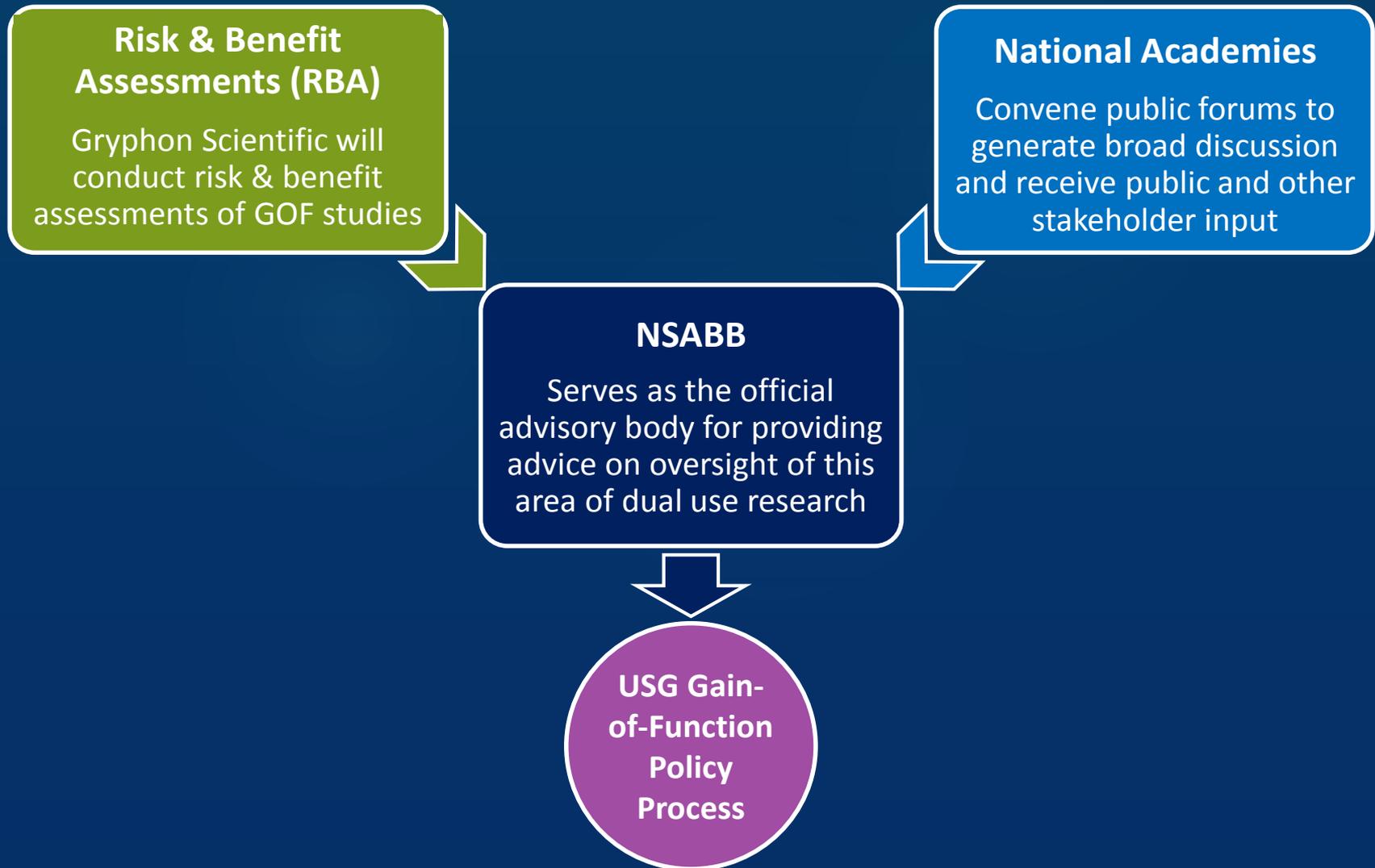
The USG announced a process to re-evaluate the potential risks and benefits associated with GOF research involving pathogens with pandemic potential.

Research Funding Pause

Deliberative process is accompanied by a pause in funding for projects that may be reasonably anticipated to generate influenza, MERS, or SARS viruses with enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.



GOF Deliberative Process



The Charge to the NSABB

Task 1

Advise on the design, development, and conduct of risk-benefit assessment of GOF studies

❑ Deliverable 1

Framework for the design and conduct of risk and benefit assessments of GOF studies

Task 2

Provide formal recommendations to the USG on the conceptual approach to the evaluation of proposed GOF studies

❑ Deliverable 2

Recommendations to the USG informed by the results of the risk and benefit assessments and other input

Key Milestones

- October 2014: NSABB was issued its charge
- November: NSABB issued a statement recommending more guidance for the community about the GOF funding pause; USG issued FAQs and worked closely with relevant researchers
- December: National Academies hosted two-day meeting; broad discussions of risks, benefits, risk-benefit assessments, risk mitigation, public engagement
- May 2015: NSABB approved its framework for guiding the RBA
- September: NSABB convened to discuss its progress
- January 2016: Discussion of the RBA, the ethics analysis, and the NSABB's preliminary findings and draft recommendations

Next Steps

- March 2016: National Academies will host a second meeting on GOF research to discuss the results of the RBA, the NSABB's draft recommendations, and related issues
- Spring 2016: NSABB to finalize its findings and recommendations to the USG

➤ USG to consider NSABB's recommendations on a conceptual approach to the evaluation of proposed GOF studies and develop policy