

# Gain of Function Research

## Gain of Function Research

Certain gain-of-function studies with the potential to enhance the pathogenicity or transmissibility of potential pandemic pathogens (PPPs) have raised biosafety and biosecurity concerns, including the potential dual use risks associated with the misuse of the information or products resulting from such research.

On October 16, 2014, the White House Office of Science and Technology Policy announced the launch of the U.S. Government (USG) gain-of-function (GOF) deliberative process to re-evaluate the potential risks and benefits associated with certain GOF experiments. During this process the USG paused the release of federal funding for GOF studies anticipated to enhance the pathogenicity or transmissibility among mammals by respiratory droplets of influenza, MERS, or SARS viruses.

The NSABB served as the official federal advisory body on the GOF issue and was tasked with providing recommendations to the USG on a conceptual approach for evaluating proposed GOF research. The NSABB finalized its recommendations on May 24, 2016. The U.S. Government considered the NSABB's findings and recommendations during the development of policy on gain-of-function research. In January 2017, the U.S. Government released policy guidance for the review and oversight of research anticipated to create, transfer, or use enhanced PPPs.

## Department of Health and Human Services P3CO Framework

**Biosafety,  
Biosecurity, and  
Emerging  
Biotechnology**

[› Biosafety and Recombinant DNA Policy](#)

[› Biosecurity Policy](#)

[› Emerging Biotechnology Policy](#)

*Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*

## **U.S. Government Policy on Enhanced PPP Research**

*Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*

## **U.S. Government Gain-of-function Deliberative Process**

[NSABB Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research](#)

[U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses](#)

[FAQs on the U.S. government Gain-of-function Deliberative Process and Research Funding Pause](#)

## **Symposia Summaries and Commissioned Reports**

[1st National Academies Symposium Summary \(December 15-16, 2014\) – Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop](#)

[2nd National Academies Symposium Summary \(March 10-11, 2016\) – Gain-of-Function Research: Summary of the Second Symposium](#)

[Risk and Benefit Analysis of Gain of Function Research – Final Report \(Gryphon Scientific\)](#)

[Gain-of-Function Research: Ethical Analysis \(Professor Michael J. Selgelid\)](#)

## **Additional Material**

[NIH Director's Statement on Funding Pause on Certain Types of Gain-of-Function Research](#)

## [NIH Director's Statement on Lifting of NIH Funding Pause on Gain-of-Function Research](#)

## [NIH Director's Statement on NIH's commitment to transparency on research involving potential pandemic pathogens](#)

## [Supplemental Information on the Risk and Benefit Analysis of Gain-of-Function Research](#)

## [Gain-of-Function Deliberative Process Written Public Comments \(Nov 10, 2014 – June 8, 2016\)](#)

### **External Resources**

#### [S3: Science, Safety, and Security](#)

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