



National Measures to Address Dual Use Research in the United States

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BWC Meeting of Experts**

**Susan Coller Monarez, Ph.D.
Office of Science and Technology Policy
White House**

Working Together is Essential

National
Governments



Importance of Life Sciences Research

- Life Sciences Research Supports:
 - Biotechnology and Public Health Advances
 - Improvements in Agriculture
 - Safety and Quality of Food Supply
 - Environmental Quality
 - Strong National Security and Economy

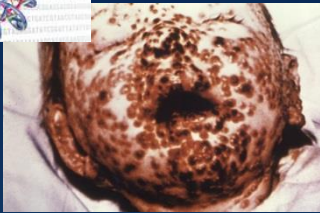
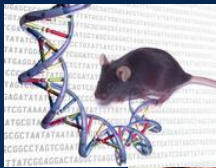


United States Government Definitions

- Dual use research (DUR): research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized both for benevolent and harmful purposes.
- Dual Use Research of Concern (DURC): 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, material, or national security.



Dual Use Research of Concern



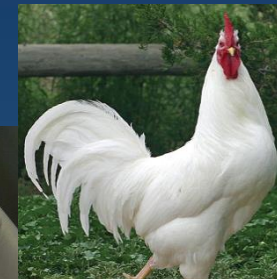
2001

2011

2002

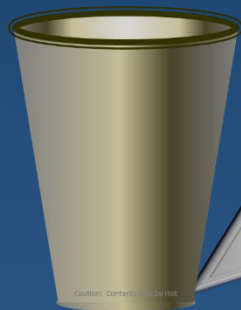
2005

2014



Purpose of DURC Policies

- Aim to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research
- Complement existing regulations and policies governing the safe and secure use of pathogens and toxins



Caution: Contents may be Hot

Wild, Wild West



Dual Use Research of Concern

- *USG Policy for Oversight of Life Sciences Dual Use Research of Concern* (March 29, 2012)
- *HHS Framework for Highly Pathogenic Avian Influenza Research* (February 21, 2013)
- *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (September 24, 2014)
- *USG Gain-of-Function Policy* (under development)



Research Subject to the Policies: 15 Agents



- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (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*
- *Yersinia pestis*



Research Subject to the Policies: 7 Experimental Effects



- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed in the policy



Research Subject to the Policies: Determination



- If the research with any of the 15 agents involves any of the 7 experimental effects, conduct a risk assessment to determine if it meets the definition of DURC:
 - 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, material, or national security.



Re-assessing Gain-of-Function Research

- Recent laboratory incidents prompted a reassessment of the risk/benefit calculus that underpins funding for certain types of gain-of-function studies
- Recent calls from multiple stakeholders for science-based deliberation
 - Cambridge Working Group
 - Scientists for Science
 - European and other efforts
- Highest concern for respiratory pathogens with pandemic potential (MERS, SARS, and influenza)



Gain-of-Function Research Deliberative Process

- On October 17, 2014, the U.S. Government announced the launch of a deliberative process to assess the potential risks and benefits associated with gain-of-function studies.
- During the deliberative process, the U.S. Government instituted a pause on funding for certain kinds of gain-of-function experiments involving influenza, SARS, and MERS viruses.

The screenshot shows the website of the Office of Science and Technology Policy. The main navigation bar includes links for BRIEFING ROOM, ISSUES, THE ADMINISTRATION, PARTICIPATE, and 1600 PENN. Below this, there is a search bar and a breadcrumb trail: Home > The Administration > Office of Science and Technology Policy. The page title is "Office of Science and Technology Policy". The main content area features a blog post titled "Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research" with a "Subscribe" button. The post is dated "Posted by lifed on October 17, 2014 at 03:30 PM EST" and includes social media sharing options for E-Mail, Tweet, and Share. The text of the post begins with "Following recent biosafety incidents at Federal research facilities, the U.S. Government has taken a number of steps to promote and enhance the Nation's biosafety and biosecurity..." and mentions a "deliberative process to assess the potential risks and benefits associated with a subset of life sciences research known as 'gain-of-function' studies." A sidebar on the right contains a "GIVE FEEDBACK ABOUT THIS PAGE" button and a "YOUR FEDERAL TAXPAYER RECEIPT" section with a "Launch the Receipt" button.

The screenshot shows the website of the National Institutes of Health (NIH). The main navigation bar includes links for Health Information, Grants & Funding, News & Events, Research & Training, Institutes at NIH, and About NIH. Below this, there is a search bar and a breadcrumb trail: NIH Home > About NIH > The NIH Director. The page title is "THE NIH DIRECTOR". The main content area features a section titled "Statement on Funding Pause on Certain Types of Gain-of-Function Research" with a date of "October 17, 2014". The text of the statement begins with "The White House Office of Science and Technology Policy announced today that the U.S. government will undertake a deliberative process to assess the risks and benefits of certain gain-of-function (GOF) experiments with influenza, SARS, and MERS viruses..." and mentions a "deliberative process" and a "pause on the funding of any new studies involving these experiments." A sidebar on the right contains a "Related Links" section with links to "OSTP Blog: Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research" and "NSABB Meetings Page".



Key Voices in the U.S. Gain-of-Function Deliberative Process

National Science Advisory Board for Biosecurity (NSABB)

- Draft a set of recommendations on a conceptual approach to the evaluation of proposed gain of function studies that will be reviewed by the broader life sciences community
- Serve as the official federal advisory body for providing advice on oversight of this area of research to the HHS Secretary

United States National Academies of Science

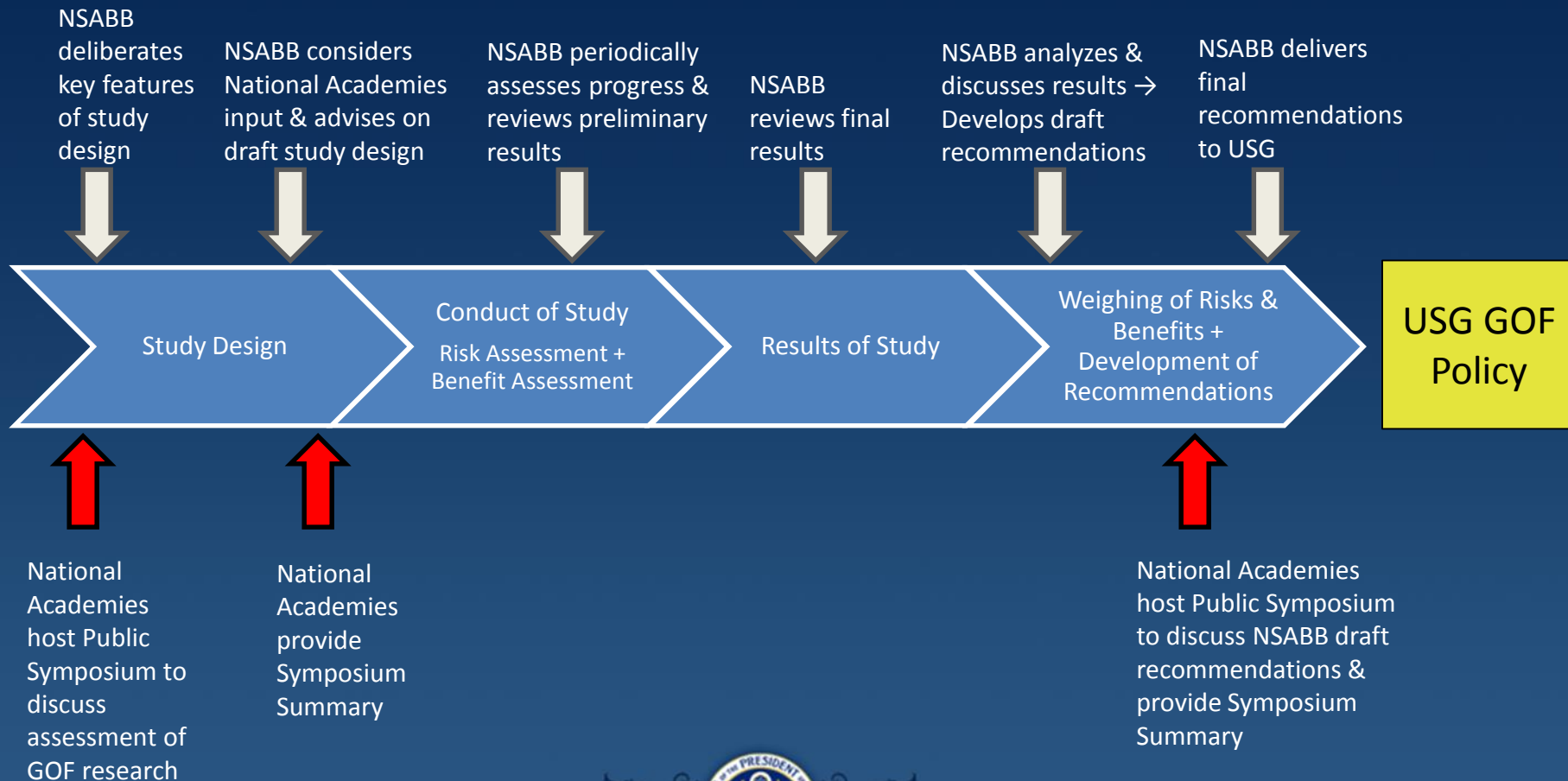
- Convene two public conferences to facilitate broad discussion of the issues associated with gain of function research, to include discussion of the NSABB draft recommendations.
- Provide summary of public discussions and feedback on the forthcoming NSABB draft recommendations



Estimated Timeline

Late 2014 – Early 2015

Mid 2015 – Mid 2016



Resources

Available at: www.phe.gov/s3/dualuse

Questions about implementing the Policy may be sent to DURC@ostp.gov



Thank you

