United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern

July 22, 2015

Working Together Is Essential

Government

INDUSTRY

ACADEMIA

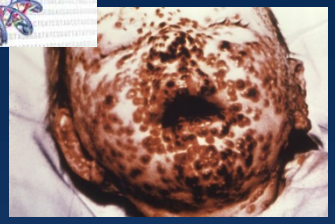
Importance of Life Sciences Research

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

Dual Use Research in the Life Sciences

- 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

2005

2011

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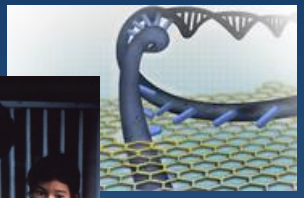



2014

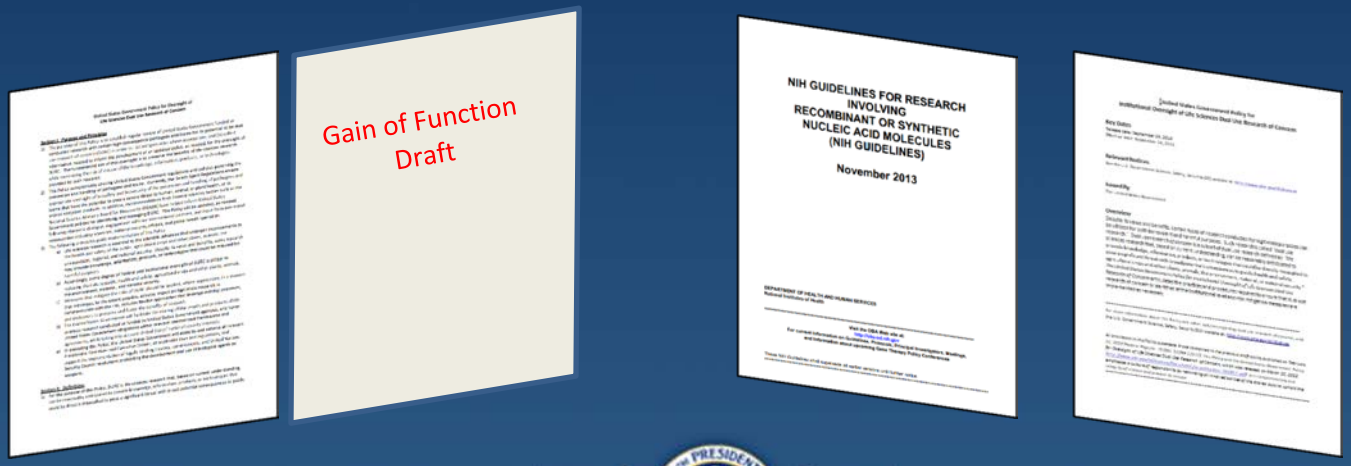


Purpose of DURC Policies

- 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

Dual Use Research of Concern

- *HHS Framework for Highly Pathogenic Avian Influenza Research* (2012)
- *USG Policy for Oversight of Life Sciences Dual Use Research of Concern* (March 29, 2012)
- *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)
- *Burkolderia 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.

Risk Assessment and Risk Mitigation

- Projects determined to meet the definition of DURC must have a risk mitigation plan to apply any necessary and appropriate risk mitigation measures
- Risk Mitigation Strategies may include:
  - Changing the design or conduct of the research or not conducting certain aspects of DURC
  - Applying specific biosecurity and/or biosafety measures
  - Developing a plan for monitoring the research for findings with additional DURC potential
  - Developing plan for responsibly communicating the results of DURC
  - In *rare* instances, when appropriate, restricting communication of experimental details or other specific information

Key Responsibilities of Institutions

- Establish and implement policies and practices for identification and oversight of DURC that include:
  - Establishing and Institutional Review Entity (IRE)
  - Ensuring appropriate review of research with DURC potential
  - Assessing the potential risks and benefits associate with DURC
  - Developing and implementing risk mitigation plans, as necessary
  - Ensuring compliance with the Policy and approved risk mitigation plans
  - Ensuring periodic review and updating of risk mitigation plans
  - Providing education and training on DURC
  - Assisting investigators when questions arise regarding research that may be subject to the Policy

Key Responsibilities of Institutions

- Notify U.S. Government funding agencies of:
  - Research reviewed by the IRE that involves one of the seven experimental effects, including whether the research is determined to be DURC
  - Instances of noncompliance with the Policy
  - Proposed risk mitigation plans for research determined to be DURC
  - Changes in status of DURC or modifications to risk mitigation plans

Key Responsibilities of Investigators

- Identify and refer to the IRE all research involving one or more of the agents or toxins listed in the Policy, along with an assessment of whether the research involves any of the seven listed experimental effects
- Work with the IRE to assess the dual use risks and benefits of the research in question and develop risk mitigation measures
- Conduct DURC in accordance with risk mitigation plan
- Be knowledgeable about and comply with the risk mitigation plan
- Continue to assess research to determine if, at any time, the research becomes subject to the policy

Key Responsibilities of Investigators

- Ensure laboratory personnel conducting research with any of the 15 listed agents have received education and training on DURC
- Communicate DURC in a responsible manner, throughout the research process, not only at the point of publication
- Ensure that communication is in compliance with the risk mitigation plan approved by the appropriate Federal funding agency

Key Responsibilities of the IRE

- Comprise at least 5 members, including persons with knowledge of U.S. Government policies and sufficient range of expertise to assess the dual use potential of research conducted at that institution
- Review research identified by Investigators
  - Verify research involves one or more of the 15 agents, if it meets any of the 7 experimental effects, and determine if it is DURC
- For research determined to be DURC, the IRE:
  - Consider the risks and benefits of conducting the research
  - Works with the appropriate Federal funding agency to develop a risk mitigation plan
  - Review the risk mitigation plan at least annually and modifies the plan, as warranted

Key Responsibilities of the Institutional Contact for Dual Use Research

- Serve as institutional point of contact for questions regarding compliance with and implementation of the requirements for the DURC oversight policies
- Serve as liaison between the institution and the relevant U.S. Government funding agency
- Consult with the relevant U.S. Government funding agency when the institution seeks advice on matters related to DURC

Key Responsibilities of U.S. Government Funding Agencies

- Require policy implementation at all institutions subject to the Policy
- When notified by an institution of research meeting the scope of the Policy:
  - Notify the institution when the U.S. Government funding agency disagrees with any part of the IRE's review outcome
  - For research determined to be DURC, work with the institution to finalize a risk mitigation plan
  - Respond to questions from institutions regarding DURC oversight and compliance with the Policy
- Respond to reports of non-compliance and work with the institution to address such non-compliance

Resources

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

Questions about implementing the Policy: DURC@ostp.gov

Thank you