Update on Recent USG Biosecurity and Biosafety Policies

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Overview

- Oversight of dual use research of concern (DURC)
  - USG Policy for Oversight of Life Sciences DURC (March 2012)
  - USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (*September 2014 Policy*)
  - Educational tools and materials
  - Next steps

- USG funding pause on certain Gain-of-Function studies

- National Biosafety Stewardship Month
Aims to preserve the benefits of life sciences research while minimizing the risk of misuse of the information, products, or technologies generated by such research.

Promulgated to establish regular Federal review of US-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be DURC.

Involves:
- Identifying projects (ongoing and new) that may raise significant dual use concerns
- Implementing risk mitigation strategies for these projects.
Addresses roles and responsibilities of USG-funded research institutions and investigators

- Issued for public comment in the spring 2013, and policy revised to reflect comments
- Final policy issued and is available at: http://www.phe.gov/s3/dualuse
- Extensive rollout campaign accomplished; educational campaign underway
- One-year implementation time is being given before full compliance is required
USG Policy for Institutional DURC Oversight: Premise

Institutional oversight of DURC is a critical component of a comprehensive oversight system because institutions are:

- Knowledgeable about the life sciences research conducted in their facilities
- In the best position to provide day-to-day oversight of DURC and to promote and strengthen the responsible conduct and communication of DURC
Entities Subject to the Institutional DURC Oversight Policy

- Federal departments and agencies that fund or conduct life sciences research

- Institutions within the U.S. that:
  - Receive Federal funds to conduct or sponsor life sciences research; and
  - Conduct or sponsor research that is subject to the Policy, regardless of source of funding

- Institutions outside of the U.S. that receive Federal funds to conduct or sponsor research subject to the Policy
Institutions will assess research that:

- Involves one or more of the 15 listed agents or toxins and
- Produces, aims to produce, or is reasonably anticipated to produce one or more of the 7 listed experimental effects

...for its potential to be DURC
Scope of the Policy for Institutional Oversight of DURC

Research involving any of the following 15 listed agents or toxins:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (in any quantity)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*
Scope of the Policy for Institutional Oversight of DURC

Research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects:

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. 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
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin;
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct listed agent or toxin
What is DURC?

If the research with any of the 15 agents and toxins involves any of the 7 experimental effects, does it meet the following definition?

**Dual Use Research of Concern**

Life sciences 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, materiel, or national security.

*(Definition from USG Oversight Policies)*
Overview of Policy

Step 1: Does research involve one or more of the 15 agents and toxins listed in the policy?

Step 2: Does research aim to produce one of the 7 listed experimental effects?

Requires additional Federal and local oversight and risk mitigation strategies to address dual use concerns.

Step 3: Does research meet definition of DURC?
Key Responsibilities of Institutions

1. Establish and implement internal policies and practices for identification and oversight of DURC

2. Establish an institutional oversight process (including the establishment of an Institutional Review Entity) that:
   - Ensures appropriate review of research with DURC potential
   - Assesses the potential risks and benefits associated with DURC
   - Develops and implements risk mitigation plan, as necessary

5. Ensure compliance with the institution’s dual use research policies
Key Responsibilities of Institutions

4. Provide education and training on DURC

6. Consult the Federal funding agency for guidance on assessing risks or developing a risk mitigation plan

7. Promptly inform Federal agencies funding the research of:
   - Research reviewed for DURC potential
   - Research determined to be DURC
   - The risk mitigation plans for research determined to be DURC
   - Instances of noncompliance with the Policy
Key Responsibilities of Principal Investigators

1. Identify whether work involves any of the 15 listed agents and toxins

3. Work with the Institutional Review Entity to assess the risks and benefits of the DURC and to develop risk mitigation plans where appropriate

5. Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC

7. Ensure that lab personnel conducting DURC receive education and training
Responsibilities of Funding Agencies

1. Ensure the implementation of the Policy for all life sciences research funded by the agency

2. For funded and proposed life sciences research that subject to the scope of the policy and meets the definition of DURC:
   - Complete a risk assessment of the DURC
   - Notify an institution of the finding of DURC
   - Review institutional risk mitigation plans
   - Consult with institutions prior to making a final determination about the adequacy of the risk mitigation plan
Responsibilities of Funding Agencies

3. Respond to questions from institutions regarding DURC oversight and provide guidance to institutions regarding compliance

4. Respond to reports of non-compliance with the Policy

7. Serve possibly as the review entity for research institutions in low-resourced environments outside of the U.S. that receive Federal funds.
Responsibilities of the USG

1. Develop training tools and materials for use by the USG agencies and institutions implementing the Policy

3. Provide education and outreach to stakeholders about dual use policies and issues

5. Provide guidance to institutions on DURC and on the communication of DURC

7. Periodically assess the impact of the Policy on life sciences research programs and, as appropriate, update the Federal and institutional dual use research oversight policies
Resources for PIs and Institutions

The Companion Guide: *Tools for the Identification, Assessment, Management, and Responsible Communication of DURC*

- Qs & As on the USG Policies for the Oversight of DURC
- Framework for Risk-Benefit Assessment and Risk Mitigation
- Guidance for the Responsible Communication of Research with DURC Potential
- Resources for outreach and education on dual use research
Educational Tools on DURC

Educational DVD

On-line Video

Brochure for PIs

Awareness-raising poster

Training Slides

www.phe.gov/s3/dualuse

Case studies
Future Education and Outreach on Policy for Institutional DURC Oversight

- Webinar for Institutional Contacts for Dual Use Research (ICDURs) and others
- Stakeholder Meeting
- Presentations at key society and association meetings
  - Institutional
  - Scientific
Additional Information

Information about dual use research in the life sciences as well as specific details on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern can be found at:

www.phe.gov/s3/dualuse

Policy implementation Questions can be sent to:

DURC@OSTP.GOV
Funding pause for certain gain-of-function research experiments
Gain-of-Function Studies

- Some researchers have used a “gain-of-function” (GOF) approach to better understand the genetic determinants of pathogenicity, transmissibility, and host range in certain pathogens
  - For example, researchers engineered HPAI H5N1 viruses that were transmissible between ferrets by respiratory droplets

- Gain-of-function (and loss-of-function) studies are routinely performed in life sciences research

- Gain-of-function in the context of pathogen research: Scientific research that generates pathogens with an enhanced ability cause disease
  - Enhanced pathogenicity
  - Enhanced transmissibility (by respiratory droplets)
GOF Studies Have Raised Concerns

- **Dual Use**: Do the studies generate information that could be utilized to create a potentially human-transmissible form of a pathogen that, in the wrong hands, could be intentionally released to threaten public health and security?

- **Biosafety**: Could the engineered pathogens accidentally infect a lab worker or be released into the environment?

Should such research findings be communicated? If so, how can they be responsibly communicated?

Under what conditions can these studies be safely conducted?

Should this type of research be conducted at all?
Guiding HHS Funding Decisions for HPAI H5N1 Gain-of-Function Research: A Framework

- Requires additional in-depth and multi-disciplinary review and approval, prior to being funded, for a subset of proposals for research of greatest concern:
  - Research that is reasonably anticipated to generate HPAI H5N1 viruses that are transmissible in mammals via the respiratory route
  - Has been expanded to include review of similar proposals involving H7N9 virus
USG to Deliberate GOF Studies

- In light of biosafety incidents occurring at U.S. Federal laboratories in the summer of 2014, the U.S. government is re-assessing the risk/benefit calculus underpinning funding decisions for a certain subset of gain-of-function research involving agents that pose a significant risk to public health.

- The U.S. government will undertake a robust and broad deliberative process with the aim of adopting new Federal GOF research policy.
Funding Pause for Certain GOF Studies

- During the deliberative process, the U.S. government will pause new USG funding for certain gain-of-function research on influenza, MERS or SARS viruses.
- The funding pause applies to studies involving these viruses that may be reasonably anticipated to enhance the pathogenicity or transmissibility of these pathogens in mammals via the respiratory route.
- The funding pause does not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses unless these tests reasonably are anticipated to increase transmissibility or pathogenicity.
The deliberative process will:

- Explicitly evaluate the potential risks and benefits of GOF research with potential pandemic pathogens
- Be time-limited and involve two distinct, but collaborating, entities (NSABB and NAS)
- Enable robust engagement with the life sciences community
- Will conclude when the US government has adopted a Federal policy regarding whether and under what circumstances gain-of-function studies should be funded
National Biosafety Stewardship Month
National Biosafety Stewardship Month

- During September 2014, NIH and other HHS agencies instituted National Biosafety Stewardship Month
  - Promote stewardship of the life sciences and biosafety awareness across Federal entities
  - Reinforce attention to safe practices in biomedical laboratories
National Biosafety Stewardship Month

- Promoting a culture of Safety by:
  - Highlighting the importance of the requirements and activities that are already part and parcel of a robust biosafety program
  - Creating an opportunity to further optimize biosafety oversight and strengthen the institutional safety culture
Role of NIH Grantee Institutions

- Conduct comprehensive reviews of current biosafety and biosecurity protocols and procedures to ensure they are adequate for today’s research;
- Identify and rectify any gaps in the institutional biosafety and biosecurity oversight programs;
- Maximize the positive effect of lessons learned from recent laboratory incidents;
- Strengthen communications to all those involved in the conduct and oversight of life sciences research to increase attentiveness throughout the community to ensure safety; and
- Promote partnerships with the investigator community to achieve shared biosafety goals.
Role of NIH Grantee Institutions

- Reinforce biosafety training
  - Investigators
  - Laboratory staff
  - Members of IBCs

- Reexamine training materials and practices update materials as appropriate

- Examine the frequency of training

- Conduct training when the interval between training or other considerations warrant it
Looking Forward

- The intramural community at NIH and the grantee institutions that the NIH funds must ensure that we have rigorous and effective biosafety programs
- Whether individuals are involved in the oversight or the conduct of biological research, we must all work together to protect the health, safety, and well-being of our laboratory workers, the public and the environment
- Sustaining attention to biosafety stewardship
  - Make biosafety stewardship month an annual event
  - Discussions with the ABSA
  - Input from stakeholders such as COGR
Contact PBBP

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