Dual Use Research of Concern

Policy Requirements for Institutions

Effective September 24, 2015

DURC

- “Dual Use Research of Concern (DURC) is 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.”
- http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf

Background

- March, 2012: *USG Policy for Oversight of Life Sciences Dual Use Research of Concern*
- Established process of regular Federal review of USG-funded or conducted research
- Requires Federal agencies that fund or sponsor life sciences research to:
  - Identify DURC
  - Evaluate this research for possible risks, benefits
  - Ensure risks are appropriately managed and benefits realized

Background

- September, 2014: *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*
  - Details of Institutional responsibilities
  - Effective date: **September 24, 2015**

Who has to establish policies and procedures?

Institutions which receive Federal funds for life sciences research

Goals of Policies

- Culture of responsibility
- Engage life sciences research community & Federal departments/agencies funding such research
- Shared commitment to address risk from research which might be used for harm
  - Knowledge
  - Information
  - Products
  - Technologies

Intent of Policies

- Mitigate risks where appropriate
- Collect information needed to inform the development of an updated policy for oversight of DURC
- Preserve the benefits of life sciences research
- Minimize risk of misuse

Research Subject to the Policies:

- Does research involve one of 15 agents/toxins listed in the Policy?

a) Avian influenza virus (highly pathogenic)
b) *Bacillus anthracis*
c) Botulinum neurotoxin (any quantity)
d) *Burkholderia mallei*
e) *Burkholderia pseudomallei*
f) Ebola virus
g) Foot-and-mouth disease virus
h) *Francisella tularensis*
i) Marburg virus
j) Reconstructed 1918 Influenza virus
k) Rinderpest virus
l) *Clostridium botulinum* (Toxin-producing strains)
m) *Variola major* virus
n) *Variola minor* virus
o) *Yersinia pestis*

Research Subject to the Policies:

- Does research aim to produce one of the seven listed experimental effects?

a) Enhances the harmful consequences of the agent or toxin

b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification

c) 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

Research Subject to the Policies:

- Does research aim to produce one of the seven listed experimental effects?

d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin

e) Alters the host range or tropism of the agent or toxin

f) Enhances the susceptibility of a host population to the agent or toxin

g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Research Subject to the Policies:

- Does research meet the definition of DURC?

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.

Non-compliance may result in:

- Suspension of USG funding
- Limitation of USG funding
- Termination of USG funding
- Loss of future USG funding for non-compliant project
- Loss of future USG funding for other life sciences research at Institution
- Other potential penalties

Process for Institutional Review for DURC

- PI identifies research as possible DURC
- PI notifies Institution
- Institution- verifies and reviews for DURC
- Institution- conducts risk assessment and benefit analysis
- Institution- notifies USG funding agency
- Institution- develops risk mitigation plan, submits to funding agency
- Institution- implements plan
- PI conducts research, communicates findings in compliance with plan

Institutional oversight involves:

- Principal Investigators (PIs)
  - Need training on DURC
- Institutional Review Entity (IRE)
  - Mandate to new committee, which draws upon expertise of the Institutional Biosafety Committee (IBC)
- Institutional Contact for Dual Use Research (ICDUR)
  - Dr. Traystman, Vice Chancellor for Research
- Institutional commitment
  - Research Administration, Compliance
- United States Government (USG)
  - Primarily the funding agencies

DURC 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 an IRE
  - Ensuring appropriate review of research with DURC potential
  - Assessing the potential risks and benefits associated with DURC
  - Developing and implementing risk mitigation plans, as necessary

Key Responsibilities of Institutions

- 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 USG 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 modification 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 the risk mitigation plan
- Be knowledgeable about and comply with all institutional and Federal policies and requirements for oversight of DURC
- Continue to assess research to determine if, at any time, the research becomes subject to the policy

Key Responsibilities of Investigators

- Ensure that laboratory personnel (e.g. graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) 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 IRE

- Be composed of at least 5 members, including persons with knowledge of US government policies and sufficient range of expertise to assess the dual use potential of research conducted at that institution
- Review of research identified by PIs:
  - 1. Verification that the research involves one or more of the 15 listed agents
  - 2. Review of the PI's assessment and final determination of whether the research meets any of the seven experimental effects
  - 3. When appropriate, make a determination of whether the research meets the definition of DURC

Key Responsibilities of Institutional Review Entity (IRE)

- For research determined to be DURC, the IRE:
  - Considers the risks and benefits of conducting the research
  - Works with the appropriate Federal funding agency to develop a risk mitigation plan
  - Reviews the risk mitigation plan at least annually and modifies the plan, as warranted

Key Responsibilities of ICDUR: Vice Chancellor for 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 USG funding agency
- Consult with the relevant USG funding agency when the institution seeks advice on matters related to DURC

Key Responsibilities of US 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 USG 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

Key Responsibilities of the US Government

- Provide guidance to institutions regarding review, management, and responsible communication of DURC
- http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern
- Develop training tools and materials for use by the USG agencies and institutions implementing the Policy
- http://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf
- http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-of-concern/dialogue
- Provide education and outreach to stakeholders about dual use policies and issues
- http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- Assess periodically the impact of the Policy on life sciences research programs and, as appropriate, update the Federal and institutional dual use research oversight policies

Proposed UCD Process for Institutional DURC Oversight