Northeastern University

Oversight of Practices and Procedures for Potential Dual Use Research of Concern

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, material, or national security.

On September 24, 2014, the USG released the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable.

This government policy outlines the criteria for what qualifies as Dual Use Research of Concern (DURC), listing specific agents and toxins and descriptions of types of experiments, when combined define the parameters for research considered as DURC and subject to oversight under the policy. This policy is effective as of September 24, 2015.

At Northeastern University it is the Principal Investigator's responsibility to identify research that involves any of the agents on the IODURC list and to notify the Northeastern University Institutional Biosafety Committee (IBC) so a review can be done.

Research involving any nonattenuated agents or toxins on the following list must be reviewed for DURC:

- Botulinum neurotoxin (any quantity)
- Avian influenza virus (highly pathogenic)
- *Bacillus antrhacis*
- *Burkholderia pseudomallei*
- *Burkholderia mallei*
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Reconstructed 1918 influenza virus
- Rinderpest virus
- Toxin-producing strains of *Clostridium botulinum*
- *Yersinia pestis*
- Ebola virus
- Marburg virus
- Variola major virus
- Variola minor virus

If any of these agents is anticipated to create any of the experimental effects listed below, it can be DURC:

- Enhance the harmful consequences of the agent or toxin
- Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
- Confers to the agent or toxin resistance to clinically 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 above

Principal Investigator Responsibilities

As soon as the Principal Investigator's research involves one or more the agents listed above, he or she must notify the Institutional Biosafety Committee in writing. The notification must include an assessment of whether any research involving these agents or toxins produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed above.

Additionally, the Principal Investigator must:

- Work with the Institutional Review Entity (IRE) to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures.
- Conduct DURC in accordance with the provisions in the risk mitigation plan.
- Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.
- Ensure that all laboratory personnel (including postdoctoral fellows, graduate students, undergraduate students, technicians, staff, visiting scientists, volunteers, etc.) conducting life sciences research with one or more of the agents listed above have received education and training on DURC.
- Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan.

Procedures

A subcommittee of the IBC consisting of bio-research faculty and senior administration staff including the Biosafety Program Manager will act as the IRE. When the IBC receives written notification from a Principal Investigator, the Biosafety Program Manager will convene a separate meeting for the IRE to initiate the review process. The review process will begin with verification that the research identified utilizes one or more agents or toxins on the DURC list and the IRE will review the Principal Investigator's assessment. The IRE will execute all requirements of the DURC policy, including the development, implementation and annual review of a risk mitigation plan.

Contact

1. **Northeastern University Institutional Biosafety Committee**

Regulations

1. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Resources

1. Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Frequently Asked Questions
2. Training Slides for DURC
3. A Companion Guide to the Policies for Oversight of DURC
4. NIH DURC Policy
5. DURC Case Studies