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University of Pittsburgh Institutional Policy for Dual Use Research of Concern (DURC)

Overview

The University of Pittsburgh shall comply with the US Government's (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse) through the procedures outlined in this policy, and through the work of the Dual Use Research of Concern Committee (the "DURC Committee"). The DURC Committee shall report to the University Institutional Contact for Dual Use Research, who shall be appointed by the Chancellor of the University.

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 consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security."

Life sciences research that meets the scope of DURC is subject to oversight by the University of Pittsburgh and the US Government. The purpose of this oversight is to preserve the benefits of life sciences research while minimizing the risk that the knowledge, information, products, or technologies generated by DURC could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security. Oversight includes the identification of life sciences research that raises dual use concerns, as well as the implementation of measures to mitigate the risk that DURC is used in a manner that results in harm.

DURC currently applies to research at an institution that involves one or more of the 15 select agents and toxins listed below and that may result in one or more of the seven specific categories of experimental outcomes listed below.

Agents and Toxins

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (no exempt quantities)
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*

Categories of Experiments

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 or agricultural justification
3. 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
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 susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Organizational Framework for Identifying and Mitigating Risks from DURC

Institutional Review Entity (IRE)

The University of Pittsburgh has established the DURC Committee, whose members shall be appointed by the Institutional Contact for Dual Use Research (ICDUR). The ICDUR will serve as the institutional point of contact for implementation of and compliance with the requirements of the USG policy on DURC. The ICDUR will serve as the primary liaison between the University and the USG on matters pertaining to DURC.

The DURC Committee shall meet at least annually and comprise at least five members and include individuals with knowledge relevant to DURC, biosafety, biosecurity, life sciences, and/or institutional policies and procedures. *Ad hoc* committee members with relevant expertise will be recruited as necessary where specific expertise is needed to review a proposed protocol.

Attendance of a majority of the appointed members of the DURC Committee shall constitute a quorum for purposes of conducting protocol review, policy changes, or any other business of the DURC Committee. A majority vote of a quorum shall be sufficient to approve or disapprove any matter before the DURC Committee. *Ad hoc* members shall not be counted towards a quorum, but shall be counted in any vote regarding a protocol.

The DURC Committee will work with the ICDUR to comply with the USG Policy on DURC as they pertain to the University. The DURC Committee has the authority to:

I. Review potential DURC activities to determine if the definition of DURC is met.
II. Through the ICDUR, notify the relevant funding agency within 30 days of the identification of potential DURC.
III. Work with the Principal Investigator (PI) of the potential DURC to develop a risk mitigation plan for the DURC activities.
IV. Through the ICDUR, submit to the funding agency a risk mitigation plan for approval within 90 days of the identification of DURC.

V. Following funding agency approval, review the DURC activities and risk mitigation plan at least annually until the project ceases or changes direction such that it is no longer considered to be DURC.

VI. Accept appeals from the PI of a designation of a particular research proposal as meeting the definition of DURC and deliberate as to whether to accept or reject such appeals.

Principal Investigator Responsibilities

It shall be the responsibility of all principal investigators intending to work with any of the select agents or toxins identified in the USG DURC policy to interrogate the list of categories of research outcomes that may lead to a determination of DURC. This identification of potential risk shall occur at the time of select agent registration. It is incumbent upon the PI wishing to work with the identified select agents and toxins to justify why the research activity does not constitute DURC.

Each PI working with any agents on the list set forth above shall answer a set of screening questions as part of the Institutional Biosafety Committee submission of any protocol for work involving such agents. A positive answer by the PI to any of the screening questions, or a notification from a funding agency that a funded proposal involves DURC, shall be promptly forwarded to the DURC Committee. The DURC Committee will conduct its own review to determine whether the research constitutes DURC. If the DURC Committee determines, based on a majority vote of a quorum of its members, that a particular research project constitutes DURC, they will work with the PI to develop a DURC risk mitigation plan to be sent to the USG funding agency for approval.

Institutional Administrative Support

Administrative support for the DURC IRE shall reside in the University of Pittsburgh Research Conduct and Compliance Office (RCCO). A representative of the RCCO shall take and maintain records of DURC IRE meeting minutes. The RCCO shall maintain records of DURC IRE reviews, risk mitigation plans, and any appeals of decisions for the term of the research grant or contract and for at least three additional years.