



INSTITUTIONAL OVERSIGHT FOR DUAL USE RESEARCH OF CONCERN

Overview/Purpose

The Ohio State University is committed to the safe, legal, and ethical use of biologically-derived materials in research. It is recognized that there are certain types of research, conducted for legitimate purposes, which can be utilized for both harmful and beneficial purposes. Such research is called “dual use research”. Dual Use Research of Concern (DURC) is that subset of dual use research that when misapplied could pose significant health and safety threats with broad potential consequences. Under the current regulations, DURC only applies to research conducted involving one of the 15 select agents/toxins that may result in one or more of seven specific categories of experimental outcomes as described below. This document describes the responsibilities and procedures required of the institution and institutional personnel who engage in potential dual use research of concern as identified by the federal government in the *US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*. These responsibilities include ensuring that dual use research of concern is identified and the appropriate risk mitigation measures implemented to comply with the legal and ethical requirements for the responsible conduct of such research.

Definitions

Dual Use Research of Concern (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.”

DURC Agents and Toxins – DURC Select Agents/Toxins are identified by the United States Government in the Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The agents of concern are non-attenuated forms of the agents in the list. All of these agents are also considered a select agent, a biological agent, or toxin that has the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The National Select Agents Registry Program (NSAR) actively oversees the use of select agents and requires registration of facilities including universities, which possess, use or transfer biological agents. The current list of DURC agents are:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (no exempt quantities)
- *Burkholderia 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
- Variola minor virus
- *Yersinia pestis*

Applicable DURC 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.

Institutional Review Entity (IRE) - The university committee created to review whether research that uses one or more of the DURC agents or toxins will produce or is reasonably anticipated to produce one or more of the categories of experiments and outcomes listed in the DURC policy for oversight

Institutional Contact for Dual Use Research (ICDUR) – The person appointed by the Office of Research with the responsibility to ensure the institution adequately reviews research involving a listed agent for potential DURC. ICDUR also serves as the institutional liaison with the appropriate federal agencies.

Risk Mitigation Plan - a formalized, written overview of the DURC-associated risks identified by the IRE for any given research proposal that indicates the specific measures to be employed to reduce the identified risks and how these measures address the identified risks. A risk mitigation plan should address whether existing biosafety and biosecurity measures are adequate, the applicability of existing countermeasures, educational and training measures for research staff, the plan for monitoring the conduct of the research, and the plan for responsible communication of the research findings.

Requirements

I. Institutional Review Entity (IRE)

A. Authority

1. The authority of and the requirements for the Ohio State Institutional Review Entity (IRE) are derived from the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (hereafter referred to as USG Policy).
2. The IRE has responsibility to establish and maintain policies and practices for the review of research for the potential for dual use research of concern and to develop and monitor risk mitigation plans as needed.
3. The IRE ensures that appropriate education and training on DURC are available for individuals conducting life sciences research that involves any of the 15 agents or toxins listed in the USG Policy.

B. IRE Membership and Governance

1. The IRE shall consist of a minimum of five (5) faculty, staff, or community representatives with appropriate expertise consistent with the USG policy and that meets university needs.
2. The IRE shall include persons with sufficient expertise to assess the research conducted at the institution, persons familiar with risk assessment, and risk mitigation considerations including biosafety, biosecurity, and university policies and processes. Ad Hoc members may be added to the IRE as needed to provide specific expertise for any matter under review. Ad hoc members will have voting rights.
3. Any IRE member involved with the planning and/or conduct of, or who has a direct financial interest in the research under review will not participate in the review of the research except to provide information requested by the IRE. All IRE members will be provided access to information in order to conduct the review.
4. The Office of Research will appoint an Institutional Contact for Dual Use Research (ICDUR) who will serve as the institutional point of contact and be responsible for the implementation of the institutional oversight of Dual Use Research of Concern. The ICDUR will be a member of the IRE.
5. The IRE is not required to meet in person to conduct business. Members may participate by telephone or email communication or videoconferencing as needed.
6. Participation by a majority of the appointed IRE members shall constitute a quorum for the purposes of conducting business. A majority vote of a quorum shall be sufficient to approve or disapprove any matter before the IRE.
7. All IRE meetings are closed to the public since the reviews involve select agents.
8. All records of DURC reviews and completed risk mitigation plans will be maintained for the term of the research grant or contract plus three years after completion, but no less than eight years unless a shorter period is required by law or regulation.

II. IRE Review and Approval Process

- A. The Principal Investigator (PI) must make initial notification of the use of one or more of the 15 listed select agents/toxins in the electronic application for review by the Institutional Biosafety Committee (IBC) (i.e., e-protocol form).
- B. Office of Responsible Research Practices (ORRP) staff will notify the ICDUR of the potential use of a select agent/toxin and will provide a copy of the IBC submission.
- C. The ICDUR will notify the IRE of the proposed use of a select agent/toxin of concern and arrange for a meeting to review the proposed research. The PI must also provide a determination as to whether the specific use of the agent/toxin could be considered to fall into one or more of the seven categories of regulated activities outlined above and in the USG Policy.

- D. The IRE will review the information provided and determine if the research involves or produces one or more of the seven regulated activities or outcomes identified in the USG Policy. The IRE may request additional information from the PI at any time to aid in the review process, including review of the anticipated benefits of the research.
1. If the IRE determines that the use of the select agent/toxin in the proposed (or ongoing) research does not meet any of the regulated activities or outcomes, then the IRE will notify the IBC that the research is approved and can proceed pending IBC approval. The IBC will notify the PI of IRE and IBC approval. The PI is required to notify the IRE immediately of any changes in the research or any unexpected results that might implicate one of the seven categories of regulated activities.
 2. If the IRE determines that the use of the select agent/toxin in the proposed (or on-going) research involves or produces one or more of the seven regulated activities or outcomes identified in the USG Policy then the IRE will need to determine if the proposed (or on-going) research meets the federal definition of Dual Use Research of Concern (DURC).
 - a. If the IRE determines that the research does not meet the federal definition of DURC then:
 - i. The institution (ICDUR) will notify the NIH or appropriate USG funding agency within 30 days.
 - ii. The IRE will notify the IBC of their findings and research may begin once final approval from the IBC has been obtained.
 - iii. The PI is required to notify the IRE immediately of any changes in the research or any unexpected results that might implicate one of the seven categories of regulated activities.
 - b. If the IRE determines that the research does meet the federal definition of DURC then:
 - i. The institution (ICDUR) will notify the NIH or USG funding agency within 30 days that the research has been determined to be DURC.
 - ii. The IRE will notify the PI and the IBC of their findings and will work with the PI to develop and submit to the NIH or USG funding agency a Risk Mitigation Plan for review and approval. The draft Risk Mitigation Plan is to be submitted to the funding agency within 90 days of the IRE's determination.
 - iii. No work can be conducted until the Risk Mitigation Plan has received approval from the NIH or USG funding agency and final approval obtained from IBC.
 - iv. The PI is required to notify the IRE immediately of any changes in the research or any unexpected results that might implicate one of the seven categories of regulated activities.
 - v. The institution (ICDUR) will notify the NIH or USG funding agency within 30 days of any changes in the status of the research (including research that is no longer DURC).
 - c. The IRE will review all active risk mitigation plans annually and modify the plans as needed.

- E. The IBC will not give final approval for any research subject to this policy to proceed until approval is received from the IRE.

III. Corrective Measures

- A. Failure of researchers to follow the requirements of this policy may result in university disciplinary action under applicable faculty, staff or student policies. Disciplinary actions may include a loss or limitation of an investigator's privilege to use biologically-derived hazardous materials in research at the university.

Applicable Regulations/Guidelines

1. [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)
2. [A Companion Guide to the USG Policy](#)

Additional Information/Guidance

1. Science, Safety and Security Program website (<http://www.phe.gov/s3/dualuse>)

History of Revisions

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