

**Oklahoma State University
Institutional Biosafety Committee
Review of Research with Dual Use Potential**

NOTE: This document is based in large measure on the National Institute of Health's *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern*.

I. Purpose

This policy outlines the Oklahoma State University (OSU) institutional review and oversight process for research involving certain high-consequence pathogens and toxins in order to identify dual use research of concern (DURC) and mitigate associated risks.

II. Scope

All research directly involving the biological agents and toxins listed below is subject to additional review and oversight. Principal investigators (PI) are ultimately responsible for ensuring that all research involving these agents is submitted to the Institutional Biosafety Committee (IBC) for review.

III. Definitions

Dual Use Research: Research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

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.

Institutional Contact for Dual Use Research (ICDUR): An individual designated by the institution to serve as an institutional point of contact for questions regarding compliance with the implementation of the requirements for the oversight of DURC as well as the liaison between the institution and relevant federal funding agencies. **At OSU, the Biosafety Officer (BSO) is the ICDUR.**

Institutional Review Entity (IRE): A committee established by the institution to review all research with dual use potential. **At OSU, the IBC will serve as the IRE.**

Life Sciences: Sciences which pertain to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences.

Principal Investigator (PI): An individual who is designated by OSU to direct a project or program and who is responsible for the scientific and technical direction of that project or program.

IV. Research Requiring Review & Oversight

Per the United States Government (USG) Policy for Oversight of Life Sciences Dual Use Research of Concern, research that directly involves non-attenuated¹ forms of one or more of the following agents or toxins and falls into one of the listed experimental categories must be evaluated for DURC potential.

Agents and Toxins

- A. Avian influenza virus (highly pathogenic)
- B. *Bacillus anthracis*
- C. Botulinum neurotoxin²
- 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. Toxin-producing strains of *Clostridium botulinum*
- M. Variola major virus
- N. Variola minor virus
- O. *Yersinia pestis*

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
- 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

¹ The only forms of the listed agents and toxins that are considered to be attenuated can be found in the Select Agent and Toxin Exclusions list under “Attenuated Strains of HHS and USDA Select Agents and Toxins” at <http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html>. If an attenuated form of any of the listed agents is subjected to any manipulation that restores its virulence or toxic activity, the resulting agent or toxin will be subject to oversight.

² At OSU, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin must be reviewed by the IBC and evaluated for DURC potential.

The review and oversight requirements presented in this policy do not apply to research that involves the use of the genes from any of the listed agents, *in silico* experiments (e.g., modeling experiments, bioinformatics, etc.) involving the biology of the listed agents, or research related to the health impact of the listed agents (e.g., modeling the effects of a toxin, developing vaccine delivery methods, etc.).

V. Responsibilities

Principal Investigators (PIs)

- A. Notify the IBC as soon as:
 - 1) The PI's research involves non-attenuated forms of one or more of the listed agents;
 - 2) The PI's research with non-attenuated forms of one or more of the listed agents also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; or
 - 3) The PI concludes that his/her research with non-attenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects may meet the definition of DURC and should be considered or reconsidered by the IBC for its DURC potential.
- B. Work with the IBC to assess the dual use risks and benefits of the DURC and develop risk mitigation measures.
- C. Conduct DURC in accordance with the approved risk mitigation plan.
- D. Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.
- E. Ensure that laboratory personnel conducting life sciences research with one or more of the listed agents have received education and training regarding DURC.
- F. Communicate DURC in a responsible manner.

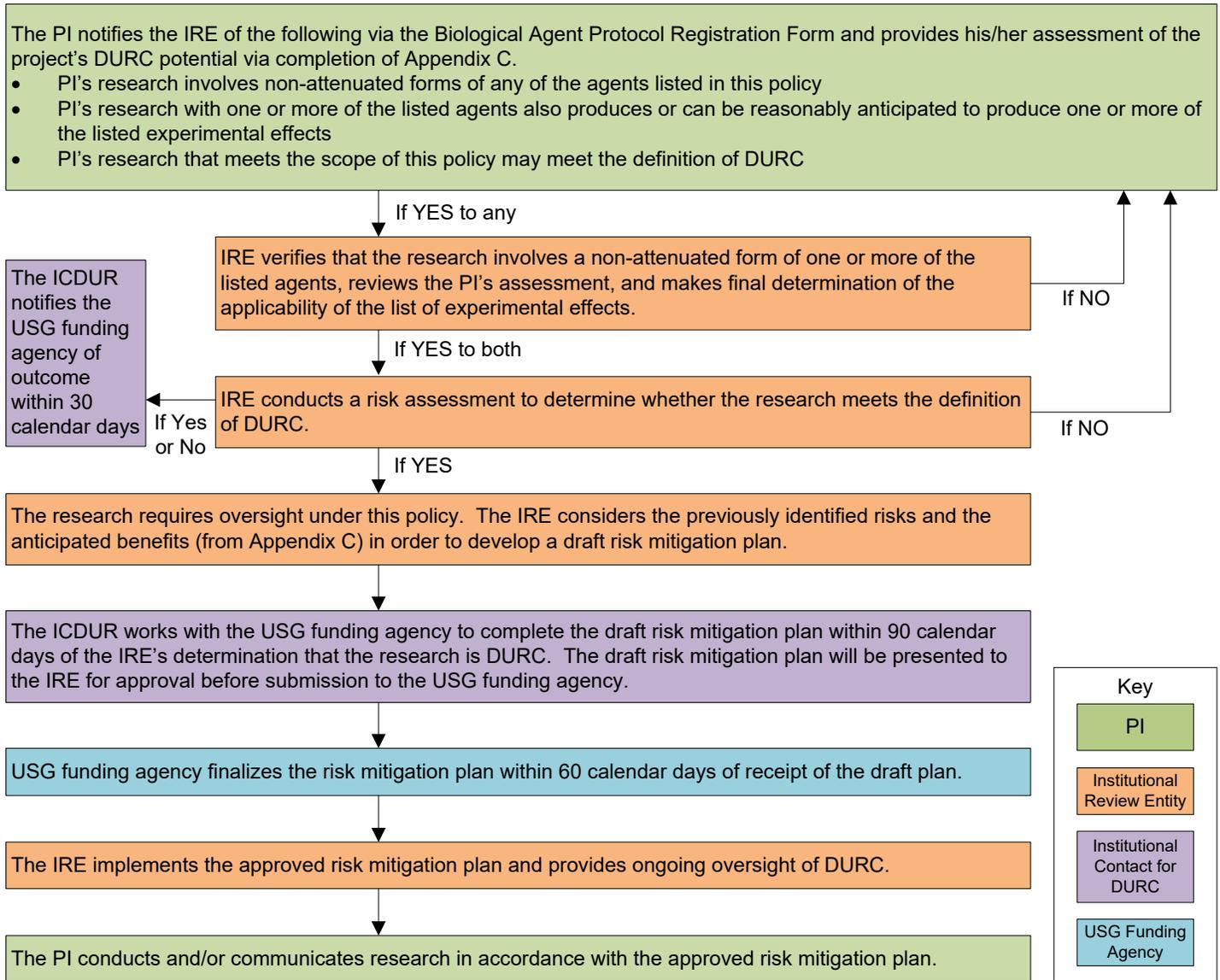
IRE

- A. Establish and implement internal policies and practices that provide for the identification and oversight of DURC.
- B. When research is identified by a PI as utilizing one of the listed agents or toxins, initiate an institutional review and oversight process that includes the following steps, as applicable.
 - 1) Verification that the research identified by the PI utilizes one or more of the listed agents or toxins.
 - 2) Review of the PI's assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the listed experimental effects.
 - 3) If the research has been assessed to meet the scope of the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, determination of whether the research meets the DURC definition.
 - 4) Within 30 calendar days of the institutional review of the research for DURC potential, notification to the funding agency of any research that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects, including whether it meets or does not meet the definition of DURC. Note: For non-USG funded research, notification will be made to the National Institutes of Health.

VI. Review Process

The OSU IRE will use the following process to review research which involves non-attenuated forms of one or more of the above listed agents and toxins for DURC potential.

Process for Review of Life Sciences Research with DURC Potential



This review process will allow the IRE to assess the potential that the information, technology, or products generated by the proposed research could be misused to harm public health, agriculture, or national security. In making this determination, the IRE will consider the following.

- The types of knowledge, information, technology, or products anticipated to be generated through the research.
- How the results or product of the research will be shared or distributed.
- The novelty of the information provided by the research or of the research methods.

- Whether the products of the research are applicable to other pathogenic organisms or agents.
- Whether the research highlights vulnerabilities in existing public health or agricultural infrastructure.
- The expertise and/or resources that would be required to apply the knowledge, information, technology, or product for malevolent purposes.
- Whether the products of the research could be directly misused to pose a threat to public health and safety, agriculture, plants, animals, the environment, materiel, or national security.
- How readily the knowledge, information, technology, or products from the research could be used to threaten public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- The nature of the potential consequences (e.g., harm to the economy, the environment, agriculture, or public health) that could result from misuse of the research results.

If the IRE determines that the research **does not** meet the definition of DURC, the research is not subject to additional institutional DURC oversight. However, if the IRE determines that the research **does** meet the definition of DURC, the PI will be notified and a draft risk mitigation plan will be prepared.

The ICDUR will inform the appropriate USG funding agency of the IRE's assessment of the DURC potential of the project within 30 days of the determination. For research that is not funded by the USG, notification will be made to the National Institutes of Health (NIH) Program on Biosecurity and Biosafety Policy.

VII. Risk Mitigation Plan

If the IRE finds that the proposed research meets the definition of DURC, the committee will work with the PI to develop a draft risk mitigation plan based on an assessment of the risks and benefits associated with the research. The plan will be specifically tailored to the research in question and will outline the strategies that will be used to mitigate all identified risks. Possible risk mitigation measures may include the application of additional biosafety or biosecurity measures, modification of the experimental design or methodology, and/or the application of medical countermeasures. Additionally, the plan may include information regarding the responsible communication of DURC findings.

This draft plan will be submitted to the USG funding agency or NIH within 90 days of the IRE's determination that the research in question is DURC. The USG agency will provide an initial response regarding the draft risk mitigation plan within 30 days and will finalize the plan within 60 days. The project may not be initiated until an approved risk mitigation plan is received from the USG funding agency or NIH.

VIII. Ongoing Review of DURC

The IRE will review all DURC protocols and associated risk mitigation plans on an annual basis. The USG funding agency or NIH will be notified of any modifications or updates to DURC research protocols or risk mitigation plans within 30 days.

IX. Training

All PIs and laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) who will conduct research with one or more of the listed agents or toxins must complete training on DURC at the time that the indicated protocol is submitted for IBC review or when he or she is added to the protocol via modification.

X. References

Oklahoma State University Policy 4-0301, Institutional Biosafety Policy.

Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern. Available from:

<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>

United State Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. Available from: <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

United State Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Available from: <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>