

Dual Use Research of Concern
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Preamble: *This policy, and the related policies and procedures described herein, is intended to ensure that any life sciences research undertaken at Washington State University that may entail Dual Use Research of Concern (DURC) is identified and conducted pursuant to University research missions and applicable federal laws and policies, specifically with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.*

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A. Definitions.

A-1. Life Sciences pertains 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. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

A-2. Dual Use Research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

A-3. 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.

A-4. Institutional Review Entity (IRE) is a committee established and empowered to execute the federal requirements for DURC identification, reporting, and oversight. The Institutional Biosafety Committee (IBC) is designated as the University IRE and, when functioning as the IRE, its membership shall be constituted in a manner that complies with federal DURC policy.

A-5. Institutional Contact for Dual Use Research (ICDUR) means the individual designated to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant

federal funding agency. The Vice President of Research is designated as the University ICDUR.

B. Policy.

B-1. Introduction. The University, in pursuit of life sciences research, may on occasion undertake research that qualifies as Dual Use Research of Concern (DURC). Life sciences research that qualifies as DURC is beneficial to increase public and scientific understanding of the biology of pathogens and has numerous other benefits. Identifying particular life sciences research that qualifies as DURC preserves the benefits of this research while minimizing the risk of misuse of the knowledge, information, product, or technologies provided by such research. Federal policy requires the University to identify research which may qualify as DURC, to implement measures to mitigate the risk that DURC is used in a manner that results in harm, and to report any research thought to qualify as DURC to the National Institutes of Health (NIH) or other federal funding agency. A designation of research as DURC does not necessarily mean that the research should not be conducted or communicated. This policy is to ensure University compliance with federal policies regarding DURC.

B-2. Policy. A principal investigator (PI) who intends to conduct life sciences research using one or more of the 15 agents or toxins listed in Section B-2.A (DURC Agents and Toxins) must, prior to engaging in such research, notify and obtain approval from the IBC, in accordance with University biohazard safety policies. Notification by the PI shall include a preliminary assessment of whether the proposed research aims to produce, or is reasonably anticipated to produce, one or more of the effects listed in Section B-2.B (Categories of Experiment).

In the event that the IBC, acting as the IRE, determines that proposed or ongoing life sciences research meets the definition of DURC, the PI shall:

- work with the IBC, in its role as the IRE, and the appropriate federal agency, to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures;
- understand and comply with all institutional and federal requirements for oversight of DURC;
- work with the IBC to ensure that all laboratory personnel (*i.e.* those under the supervision of the laboratory leadership) have received education and training on DURC, including but not limited to training on the implementation of the approved risk mitigation plan;
- conduct DURC in accordance with the provisions of a risk mitigation plan approved by the IBC; and
- communicate the results of DURC in a manner that complies with the approved risk mitigation plan.

No PI may conduct life sciences research that the IBC has determined to be DURC, except in accordance with a risk mitigation plan approved by the IBC and the appropriate federal agency.

A. Nonattenuated forms of the following DURC agents and toxins:



1. Avian influenza virus (highly pathogenic)
 2. *Bacillus anthracis*
 3. Botulinum neurotoxin (in any quantity)
 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*
- B. DURC Categories of Experiment:
1. Enhances the harmful consequences of the agent or toxin
 2. Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
 3. 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
 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 the susceptibility of a host population to the agent or toxin
 7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

C. Scope of Authority and Responsibility for Review, Approval, Reporting, and Monitoring of DURC

C-1. IBC. The IBC shall serve as the University IRE and shall have primary responsibility for ensuring compliance with this policy and federal requirements for DURC. The IBC shall review proposed University research with biohazards, including its potential as DURC. All potential DURC, as initially identified by the PI, requires a DURC review by the IBC. The IBC must verify that at least one DURC agent or toxin will be used in a way that may produce at least one of the categories of experiment. If verified, the IBC shall perform a full risk assessment of the proposed research and make a final determination whether research meets the definition of DURC. The IBC will notify the PI and the Institutional Contact for Dual Use Research (ICDUR), in writing, of the results of a DURC review.

The IBC, through the ICDUR, shall then notify the appropriate federal funding agency within thirty (30) days of a completed DURC review. In the case of research not

funded by a federal agency, such notice and any approval or subsequent notification shall be provided to the NIH. Initial notification by the IBC shall include:

- the grant or contract number related to the research (if the research is funded by the U.S. Government);
- the name(s) of PI(s);
- the name(s) of the agent(s) listed in B-2.A being utilized in proposed research;
- a description of why the research is deemed to produce one or more of the experimental effects listed in B-2.B; and,
- for research that is determined by the IBC to meet the definition of DURC:
 - the name of the investigator (if different from the PI) responsible for the performance of the DURC; and
 - a description of the IBC's basis for its determination.

Within ninety (90) days of a confirmed DURC determination, the IBC shall provide to the appropriate federal agency a draft risk mitigation plan for review and approval. The plan will be developed jointly by the ICDUR, IBC, PI, and federal agency and should include consideration of the anticipated benefits as well as risk of the research.

Upon approval of the risk mitigation plan by the federal agency, the IBC shall approve the plan on behalf of the University and provide notice of the approved plan to the PI. The IBC shall ensure institutional implementation and ongoing compliance with the approved risk mitigation plan.

The IBC shall review, at least annually, all active risk mitigation plans.

The University PI shall be responsible for timely notification to the IBC of any changes to the research. The IBC shall notify the appropriate federal agency of any change in the status of a DURC project at the University within thirty (30) calendar days. Changes to an approved risk mitigation plan must be approved by the federal agency prior to approval by the IBC and implementation at the University.

C-2. The Vice President of Research, who serves as the ICDUR, shall have ultimate institutional responsibility for ensuring that all regulatory and programmatic requirements for the conduct of DURC at the University are met.

D. Contact Information. For further information regarding implementation of this policy, contact the Office of Research Assurances, the Institutional Biosafety Committee, or visit the IBC website.
