Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Policy

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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), Pathogens with Pandemic Proportion (PPP), or Pathogens with Enhanced Pandemic Potential (PEPP), are identified and conducted pursuant to University research missions and applicable federal laws and policies, specifically with the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

Contents:

A. Definitions.

A-1. Life Sciences pertains to living organisms (e.g., microbes, human beings, animals, and plants), viruses, and their products, including all disciplines and methodologies of biology such as: aerobiology, agricultural science, plant science, animal science, biotechnology, 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 misapplied to do harm with no, or only minor, modification 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 the entity 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) is 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.

A-6. Pathogen with pandemic potential (PPP) is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans. Pathogens with pandemic potential are often those with little to no pre-existing immunity in the human population.

A-7. Pathogen with enhanced pandemic potential (PEPP) is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

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 Category 1 research (see section B 2.A) or Category 2 research (see section B 2.B), must, prior to engaging in such research, notify and obtain approval from the IBC, in accordance with University biohazard safety policies. Any research that meets the definition of both Category 1 and Category 2 research is designated as Category 2 research. 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 for Category 1 research or Category 2 research.

A. Category 1 research meets three criteria: (1) it involves one or more of the biological agents and toxins specified in Section B 2.A-1.; (2) it is reasonably anticipated to result, or does result, in one of the experimental outcomes specified in Section B 2.A-2; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC.

A-1 Biological Agents and Toxins within Scope of Category 1 Research:

1. All Select Agents and Toxins listed in 9 CFR 121.3–121.4, 42 CFR 73.3–73.4, and 7 CFR 331.3 and regulated by USDA and/or HHS.

2. All Risk Group 4 pathogens listed in Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) - Classification of Human Etiologic Agents on the Basis of Hazard.
3. A subset of Risk Group 3 pathogens listed in Appendix B of the NIH Guidelines - Classification of Human Etiologic Agents on the Basis of Hazard, this subset consists of all RG3 pathogens except HIV, HTLV, SIV, Mtb (including *mycobacterium bovis*), Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors, vesicular stomatitis virus, *Coccidioides immitis*, *C. posadasii*, *Histoplasma capsulatum*, and *H. capsulatum* var. duboisii.
4. For biological agents affecting humans that have not been assigned a Risk Group in the NIH Guidelines, refer to the current edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) per the BMBL guidance are subject to this policy.

A-2. Category 1 Research Experimental Outcomes. Research within the scope of Category 1 are those experimental outcomes with a biological agent or toxin outlined in Section A-1 that are reasonably anticipated to:

1. Increase transmissibility of a pathogen within or between host species;
2. Increase the virulence of a pathogen or convey virulence to a non-pathogen;
3. Increase the toxicity of a known toxin or produce a novel toxin;
4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin;
5. Alter the host range or tropism of a pathogen or toxin;
6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; or
9. Enhance the susceptibility of a host population to a pathogen or toxin.

B. Category 2 research meets three criteria: (1) it involves, or is reasonably anticipated to result in, a PPP as specified in definition A-6; (2) it is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified in Section B 2.B-1; and (3) based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP (see definition A-7) or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security.

B-2. Research within the scope of Category 2 are those experimental outcomes or actions with a PPP, or any pathogen that will be modified in such a way that is reasonably anticipated to result in a PPP that are reasonably anticipated to:

1. Enhance transmissibility of the pathogen in humans;
2. Enhance the virulence of the pathogen in humans;
3. Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection; or
4. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

In the event that the IBC, acting as the IRE, determines that proposed or ongoing life sciences research meets the definition of DURC or PEPP, 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 or PEPP and to develop risk mitigation measures;
- Understand and comply with all institutional and federal requirements for oversight of DURC or PEPP;
- 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 or PEPP, including but not limited to training on the implementation of the approved risk mitigation plan;
- Conduct DURC or PEPP in accordance with the provisions of a risk mitigation plan approved by the IBC; and
- Communicate the results of DURC and PEPP 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 or PEPP, except in accordance with a risk mitigation plan approved by the IBC and the appropriate federal agency.

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

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 and PEPP. The IBC shall review proposed University research with biohazards, including its potential as DURC or PEPP. All potential DURC or PEPP, as initially identified by the PI, requires a DURC or PEPP review by the IBC. The IBC must verify that at least one category will be met. 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 or PEPP. 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, the ICDUR, or designee shall then notify the appropriate federal funding agency within thirty (30) days of a completed DURC or PEPP 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) being utilized in proposed research;
- A description of why the research is deemed to meet category 1 or 2; and,
- For research that is determined by the IBC to meet the definition of DURC or PEPP:

- The name of the investigator (if different from the PI) responsible for the performance of the research; and
- A description of the IBC's basis for its determination.

Within ninety (90) days of a confirmed DURC or PEPP determination, the IBC shall provide to the appropriate federal agency a draft risk-benefit assessment and risk mitigation plan for review and approval. The plan will be developed jointly by the ICDUR, IBC, PI, and federal agency.

Upon approval of the risk-benefit and 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 or PEPP 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 or PEPP 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.