Policy Date: March 26, 2025

University of Pittsburgh

Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Effective May 6, 2025

OVERVIEW:

In May 2024, the White House Office of Science and Technology Policy (OSTP) issued the "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (USG DURC/PEPP Policy), available at the following link: USG DURC/PEPP Policy Document.

The USG DURC-PEPP Policy applies to proposed or ongoing research on or after May 6, 2025.

APPLICABILITY:

The USG DURC/PEPP Policy establishes enhanced oversight requirements for two distinct categories of research conducted at U.S. government-funded institutions: Category 1 and Category 2.

Category 1 Research

Review is required for life sciences research with specific biological agents and toxins that meet the current definition of Dual Use Research of Concern (DURC).

> DURC: Research that, based on current understanding, can be reasonably anticipated to provide, or does 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 potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security[1].

The updated policy expands oversight of DURC to a wider scope of agents, including all *Select Agents and Toxins*, all Risk Group 4 and most Risk Group 3 agents listed in

[1] USG DURC/PEPP Policy Document: Section 3: Definitions

the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines)*, agents listed in *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* requiring handling at BSL-4 and most agents requiring handling at BSL-3, and biological agents added during future updates to the USG DURC/PEPP Policy Implementation Guidance.

Note that all quantities of toxins fall under the new policy's jurisdiction. Risk Group 3 pathogens that are currently **excluded** from oversight by the policy include:

- Bacteria Agents Including Rickettsia:
  - Mycobacterium bovis
  - Mycobacterium tuberculosis
- Fungal Agents
  - Coccidioides immitis
  - Coccidioides posadasii
  - Histoplasma capsulatum
  - Histoplasma capsulatum var. duboisii
- Viruses and Prions
  - Human immunodeficiency virus (HIV)
  - Human T cell lymphotropic virus (HLTV)
  - Simian immunodeficiency virus (SIV)
  - Clade II Mpox viruses that do not contain nucleic acids coding for Clade I Mpox virus virulence factors
  - Vesicular stomatitis virus

If an investigator is unsure if an agent is covered by the USG DURC-PEPP Policy, they should email durc@pitt.edu for clarification.

Category 2 Research

Covers Pathogens with Enhanced Pandemic Potential (PEPP)—research involving pathogens modified through experimental enhancements to increase transmissibility, virulence, disrupt pre-existing immunity, or generate, use, reconstitute or transfer an eradicated or extinct Pathogen with Pandemic Potential (PPP) where these modifications can be reasonably anticipated to pose a significant threat to public health, the capacity of health systems to function, or national security.

UNIVERSITY OF PITTSBURGH INSTITUTIONAL FRAMEWORK FOR OVERSIGHT OF DURC/PEPP:

The University of Pittsburgh shall comply with the USG DURC/PEPP Policy through the procedures outlined in this policy (PITT DURC/PEPP Policy), and through the Dual Use Research of Concern Committee (DURC Committee). The DURC Committee shall report to the University Institutional Contact for Dual Use Research, who the University's Senior Vice Chancellor for Research shall appoint.

Institutional Review Entity (IRE)

The University of Pittsburgh has established the DURC Committee as the Institutional Review Entity (IRE) as required by the USG DURC/PEPP policy, whose members shall be appointed by the Institutional Contact for Dual Use Research (ICDUR). The DURC Committee plays a key role in identifying, assessing, and mitigating risks associated with DURC/PEPP. It will comprise at least five members with knowledge relevant to DURC/PEPP, biosafety, biosecurity, life sciences research, research ethics, 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.

The DURC Committee will be led by the chair of the Institutional Biosafety Committee and the Institutional Contact for Dual Use Research (ICDUR). The Institutional Biosafety Division of the Office of Research Protections will support the Committee. The ICDUR will serve as the institutional point of contact for implementing and complying with the PITT DURC/PEPP Policy requirements and as the primary liaison between the University and the USG on matters pertaining to DURC/PEPP.

Attendance of a majority of the appointed members of the DURC Committee shall constitute a quorum for 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 it pertains to the University.

Implementation of University DURC/PEPP Policy

To support investigators in fulfilling their responsibilities under the USG DURC/PEPP Policy, a screening question is incorporated into proposal submission of the MyFunding system to determine whether their research may fall within the policy's scope.

If an investigator responds affirmatively, they will receive additional follow-up questions from the Institutional Biosafety Division. These questions will help assess whether a formal evaluation under the PITT DURC/PEPP Policy is required.

If a formal assessment is deemed necessary, the investigator must submit a protocol through the MyIBC system (https://www.myibc.pitt.edu/) for institutional review or, if applicable, modify an existing protocol to provide additional information required for evaluation under the PITT DURC/PEPP Policy.

Initial Notification and Institutional Review

Following notification from either a Principal Investigator through a submission in the MyFunding or MyIBC System, or a federal funding agency, the DURC Committee will:

- Review the PI's assessment of whether the proposed or ongoing research falls under Category 1 or Category 2 of the DURC-PEPP Policy.
- Confirm the PI's classification of the research and determine if it meets the definition of Category 1 or Category 2 research.
- Work collaboratively with the PI to conduct a risk-benefit assessment, evaluating the scientific merit and potential risks of the research.
    - Investigators may submit an appeal if they disagree with the DURC Committee's assignment of the research as Category 1 or Category 2, and the committee will deliberate as to whether to accept or reject such appeals.
- Develop a draft risk mitigation plan outlining measures to minimize risks associated with the research's conduct and communication.
- Facilitate, via the ICDUR, communication of risk-benefit assessments, risk mitigation plans, and requests for guidance between the research institution and the funding agency.

If the funding agency initiates the notification process—typically after a merit review when considering funding the proposed research—the Institutional Biosafety

Division, via the ICDUR, will submit the risk-benefit assessment and risk mitigation plan to the funding agency for further review.

If the funding agency approves the risk mitigation plan, either at the proposal stage or after halting ongoing research, the following steps must occur before research can proceed:

- The PI must meet, at a minimum, the requirements of the University Guidelines for Responsibility, Authority, and Resources for Biosafety, Biosafety Guidelines and Biosafety Levels, and Guidelines for Working with Select Agents and Toxins, including obtaining appropriate approvals from the Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), and University Biohazards Committee (BHC) for all activities involving biological agents or toxins as applicable.
- The PI must fully implement the approved risk mitigation plan before resuming or initiating Category 1 or Category 2 research.
- If any modifications to research activities occur, they must be incorporated into the risk mitigation plan and formally approved by the the appropriate institutional review committees (e.g. DURC, IBC, IACUC, and/or BHC) prior to implementation.

Under the USG DURC-PEPP Policy, Principal Investigators must submit annual progress reports for Category 1 (DURC) research and semiannual progress reports for Category 2 (PEPP) research. Additionally, upon request by the federal funding agency, PIs must provide reports for review, evaluation, assessment, and, where necessary, clarification or confirmation regarding their research activities. Before submission to the funding agency, these progress reports must undergo review and approval by the Institutional DURC Committee to ensure compliance with oversight requirements, proper risk assessment, and adherence to the approved risk mitigation plan.

INVESTIGATOR RESPONSIBILITIES:

Required Training

All Principal Investigators, research staff, and trainees involved in DURC-PEPP research must know and follow applicable institutional and U.S. government policies, requirements, and regulations for oversight of biological agent and toxin research.

To facilitate this education all researchers and personnel involved in research with biological agents and toxins specified in the DURC-PEPP policy must complete the *Dual Use Research of Concern (DURC)* training module, which is available on the CITI Program platform: https://www.citi.pitt.edu. Training must be repeated every four years.

Additionally, the University's DURC Committee, which serves as the Institutional Review Entity (IRE) under the U.S. Government DURC-PEPP oversight policy, may determine that supplemental training is necessary to address specific concerns associated with a particular research project.

Research Assessment

Investigators are responsible for evaluating their research in accordance with the DURC/PEPP Policy throughout the entire research lifecycle, beginning with initial planning and proposal development. For Category 1 agents, investigators must continuously evaluate whether their work meets any of the following criteria[2]:

- Increases transmissibility of a pathogen within or between host species.
- Enhances virulence, increasing a pathogen's ability to cause disease or conferring virulence to an otherwise non-pathogenic organism.
- Increases toxicity of a known toxin or results in the production of a novel toxin.
- Enhances stability or dissemination of a pathogen or toxin in the environment, including increasing its resistance to degradation or its ability to disperse (e.g., via aerosolization).
- Modifies host range or tropism of a pathogen or toxin
- Reduces the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
- Increases resistance to prophylactic or therapeutic interventions, including antimicrobials, antivirals, antitoxins, or vaccines, thereby reducing the effectiveness of medical countermeasures.
- Alters a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, whether acquired through vaccination or natural infection.
- Enhances host susceptibility, increasing the likelihood that a population will be affected by a pathogen or toxin.

[2] USG DURC/PEPP Policy Document Section 4.1.2 Category 1 Research Experimental Outcomes; Section 4.2.2 Category 2 Research Experimental Outcomes or Actions

- Generates, uses, reconstitutes, or transfers an eradicated or extinct PPP, or a previously identified PEPP.

If an investigator's self-assessment suggests that their research may qualify as Category 1 (DURC) or Category 2 (PEPP) research under the DURC/PEPP Policy, they must immediately notify the DURC Committee at durc@pitt.edu.

The Institutional Biosafety Division, in their support of the University's DURC Committee, will provide the investigator with guidance on required next steps, which may include:

- Submission of additional research information and completion of a guided risk-benefit assessment either via the MyIBC research registration system or the DURC/PEPP PI Risk assessment form.
- Review of guided risk-benefit assessment by the University DURC Committee.
- If the research is determined to meet the criteria for Category 1 (DURC) or Category 2 (PEPP):
    - Notification of the federal funding agency following federal requirements.
        - If the investigator disagrees with the DurC Committee's determination that research meets the definition of Category 1 or Category 2 they may submit an appeal and the committee will deliberate as to whether to accept or reject such appeals.
    - Development and review of an investigator-specific risk mitigation plan to ensure compliance with biosafety, biosecurity, and regulatory obligations, and submission to funding agency.