UCSB DURC-PEPP Procedures

Summary

These procedures (Procedures) describe the University's plan for ensuring the responsible conduct of research involving Dual Use Research of Concern (DURC), Pathogens with Pandemic Potential (PPP), or Pathogens with Enhanced Pandemic Potential (PEPP).

Definitions

Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.

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 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) is the official designated by UCSB to serve as an internal resource for application of these Procedures as well as the liaison (as necessary) between UCSB and the relevant federal funding agency.

Institutional review entity (IRE) is the committee established at UCSB responsible for oversight of research that may meet the criteria of Category 1 or Category 2.

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.

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.

Scope & Applicability

The purpose of these Procedures is to provide guidelines for identifying, assessing, and managing DURC-PEPP activities conducted at the University. Application of these Procedures is intended to preserve the benefits of this research while preventing misuse, which could pose a significant threat to public health and safety, agricultural crops and other plants, animals, the environment, or national security.

In May 2024, the Federal government issued the "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential." UCSB's Procedures, in conjunction with the associated UC Policy, are intended to comply with the government policy and related federal agency requirements. These Procedures apply to all researchers, faculty, staff, and students involved in University research activities that may be considered DURC-PEPP. This includes any research, regardless of funding source, involving biological agents and toxins classified as Category 1 or Category 2.

Category 1 Research
Category 1 research meets all of the following three criteria:

1. Involves one or more of the biological agents and toxins specified in Section 4.1.1 of the government policy (examples from Appendix C of Implementation Guidance);
2. Is reasonably anticipated to result, or does result, in one of the experimental outcomes specified in Section 4.1.2 of the government policy; and
3. Based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC.

Category 2 Research
Category 2 research meets all of the following three criteria:

1. Involves, or is reasonably anticipated to result in, a PPP as specified in Section 4.2.1 of the government policy;
2. Is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified in Section 4.2.2 of the government policy; 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 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.

Responsibilities

Institutional Contact for Dual Use Research (ICDUR)
The ICDUR is the point of contact for questions regarding compliance with and implementation of these Procedures, as well as the liaison (as necessary) between the institution and the relevant federal funding agency. The ICDUR, or their designee, coordinates education and training on research oversight for individuals conducting life sciences research that may be

within the scope of these Procedures and maintains training records. The ICDUR is responsible for convening the IRE and maintaining records of reviews. The Director of Research Integrity has been designated as the ICDUR.

Principal Investigator (PI)
Principal Investigators engaged in DURC-PEPP research are expected to be knowledgeable about and comply with all applicable institutional and U.S. government policies for the oversight of biological agent and toxin research. PI responsibilities include continually assessing whether their research meets criteria for Category 1 or Category 2, notifying the relevant parties and referring such research to the IRE, and assisting in the development of risk-benefit assessments and mitigation plans, as appropriate, to submit to the federal agency. PIs must also help ensure that any laboratory personnel engaged in DURC-PEPP research receive the appropriate education and training on DURC-PEPP, which may involve notifying the ICDUR about changes in personnel who intend to conduct DURC-PEPP research.

Institutional Review Entity (IRE)
Once a PI makes an initial assessment that research may constitute Category 1 or Category 2, or the IRE is notified of potential DURC-PEPP research by another party, the IRE is responsible for assessing whether research meets the criteria of Category 1 or Category 2 and works with the PI to conduct a risk-benefit assessment and develop the associated risk mitigation plan. The IRE also ensures that the federal funding agency is notified and a risk mitigation plan is reviewed, approved, and implemented prior to the initiation of the proposed Category 1 or Category 2 research.

Biosafety Officer (BSO)
During the course of the Institutional Biosafety Committee's review of Biological Use Authorizations, the BSO is responsible for:

1. Identifying research that involves agents or toxins covered by these procedures,
2. Asking PIs to assess whether the proposed research may fit into Category 1 or Category 2,
3. Notifying the IRE about any research involving these agents or toxins and sharing the PI's assessment, and
4. Reminding PIs who work with these agents or toxins about their responsibility to continually assess whether their research has the potential to meet the criteria for Category 1 or Category 2.

Assessment & Review Procedures

Overview
The government's Implementation Guidance provides the following overview of the oversight process.

1. The PI is responsible for making an initial assessment of whether their research may be within the scope of Category 1 or 2 research.

2. The PI submits their proposal and includes a notification if the research may be within the scope of Category 1 or 2.
3. If the funding agency is considering funding the proposed research, they will notify UCSB.
4. The IRE reviews the proposed research and determines whether it meets the Category 1 or 2 criteria.
5. If it does, the IRE conducts a risk assessment, drafts a risk mitigation plan, and submits it to the funding agency.
6. The funding agency reviews the plan and determines whether the benefits of the research justify the risks and whether to approve the risk mitigation plan.

PI initial assessment for Category 1 or 2 Research

PIs are required to make an initial self-assessment of whether their proposed research could fall under the DURC-PEPP policy. PIs working with biological agents or toxins covered by the DURC-PEPP policy shall use the DURC-PEPP Self-Assessment tool to determine whether their research may meet the DURC-PEPP criteria.

- During the proposal submission process, PIs must notify the federal funding agency of any potential DURC-PEPP research and then contact the IRE through the ICDUR.
- When identification of potential DURC-PEPP research occurs during the course of experimentation, the PI must halt further work, notify the applicable federal funding agency, and contact the IRE to conduct the required assessments.

Screening for Category 1 or 2 Research

In addition to self assessment by the PI, the institution may identify potential DURC-PEPP research through PI attestations on grant proposal submissions, information submitted to the Institutional Biosafety Committee, incoming and outgoing Material Transfer Agreements and Data Use Agreements, or direct notification by a federal agency. Upon identification of potential DURC-PEPP activities, the responsible University office shall promptly notify the ICDUR, who will communicate with the IRE.

For federally funded research the IRE is not required to review the research for Category 1 or Category 2 designation until after the federal funding agency has determined that the research is eligible for federal funding based on a scientific merit review. For non-federally funded or unfunded research, the IRE review must take place prior to the PI engaging in any research activities that meet the criteria for Category 1 or Category 2.

IRE Review of Category 1 and 2 Research

The IRE is responsible for independently assessing whether research meets the criteria for Category 1 or 2, and when such work is identified, notifying the federal sponsor.

1. The IRE determines whether the research meets the criteria for Category 1 or Category 2. The IRE may form a subcommittee, at the IRE chair's discretion, to make this determination.
2. If the research doesn't meet the criteria, the IRE will notify the PI in writing and inform the PI that they are expected to routinely assess their research for any changes that may

change this status. The IRE may request an annual update, depending on the potential for the PI's research to meet the Category 1 or 2 criteria.

3. If the research meets the criteria for Category 1 or Category 2, the IRE will review the research based on the review process described in the U.S. government implementation guidance. The IRE will also work with the PI on a risk-benefit assessment and risk mitigation plan.
4. The IRE may consult with internal and external experts for advice on identifying and mitigating the risks. In some cases, effective risk mitigation may result in curtailing certain aspects of the research.
5. The ICDUR will follow the reporting requirements described below.

Training

Researchers and staff involved with DURC-PEPP research must receive training and education on the DURC-PEPP policy requirements. CITI training on DURC-PEPP, or substantially similar training, will be required for these individuals. Records of personnel training must be maintained for at least three years after the completion of the funded project. This training is in addition to any Laboratory Safety or Biosafety training required by Environmental Health and Safety. Additional training or retraining may be required, as determined by the IRE, Vice Chancellor for Research, or federal funding agency.

IRE Membership

The IRE shall be composed of the UCSB faculty and staff appointed to the Institutional Biosafety Committee with the addition of *ad hoc* members to meet the U.S. government requirements for breadth of expertise. IRE members are appointed by the Vice Chancellor for Research and the IRE is empowered to ensure that the University of California policy on DURC-PEPP research and these procedures are followed. The IRE may consult with subject matter experts or federal agency representatives on a case-by-case basis to provide scientific or regulatory expertise.

Membership should minimally include:

- Chair of the Institutional Biosafety Committee (IBC) & IRE
- Two or more faculty IBC members in scientific fields
- Biosafety Officer
- Export Control Officer
- ICDUR

If the IRE chair appoints a subcommittee to expedite the screening of potential DURC-PEPP research, the subcommittee will meet as needed to determine whether research meets the criteria for Category 1 or 2. The subcommittee will refer Category 1 or Category 2 research to the full IRE for review. In the event the subcommittee does not come to a unanimous decision, the research will be referred to the full IRE.

Reporting
Within 30 calendar days of the institutional review, the ICDUR notifies the federal funding agency of any research identified as potentially DURC-PEPP, including whether it meets or does not meet the definition of Category 1 or Category 2 research.

Within 90 calendar days from the time that the research institution determines the research to be Category 1 or Category 2 research, provides a copy of the risk mitigation plan to the federal funding agency for review.

For non-federally funded research, the ICDUR will notify the NIH-designated agency.

Risk Mitigation Plan
The U.S. government Implementation Guidance provides detailed instructions for assessing risk and developing a risk mitigation plan. The IRE and PI will work together to develop a risk mitigation plan. Within 90 days of the IRE's determination that the research meets the criteria of Category 1 or Category 2, the ICDUR shall provide a draft risk mitigation plan to the appropriate federal agency. Federal agencies are expected to complete their review within 90 days of receiving the institution's risk-benefit assessments and draft risk mitigation plan. Approved and implemented risk mitigation plans must be reviewed at least annually and modified as necessary.

Monitoring
PIs must promptly report any noncompliance with this policy to the ICDUR. The IRE shall review all reports of noncompliance and recommend a corrective action plan, or modification of an existing Risk Mitigation Plan.

The ICDUR shall report instances of noncompliance with this policy, as well as any mitigation measures taken, within 30 days to the federal funding agency, or the NIH-designated agency for non-federally funded research.

PIs must continually monitor for any changes to the status of their research or for risks that were not addressed in the IRE's review process and risk mitigation plan development. The PI must promptly notify the ICDUR of any such changes.

Appeals
PIs have 10 days to appeal an institutional decision that their research meets the criteria for Category 1 or Category 2 research. Appeals must be submitted in writing to the ICDUR and explain the reason for the appeal and evidence that supports the appeal. The IRE will review the appeal and may consult with external experts, including the relevant federal funding agency. The ICDUR will notify the PI of the IRE's decision.

Research at Multiple Sites
When potential Category 1 or Category 2 research is being carried out at multiple research institutions through a subaward, the primary institution is responsible for ensuring compliance

with the U.S. government policy. These responsibilities include notifying the federal funding agency of research determined to be Category 1 or Category 2, providing copies of each institution's risk mitigation plan, or a single plan with relevant components. If Category 1 or Category 2 research will only take place at the subrecipient institution, UCSB may rely on their IRE's review. However, the primary institution will be responsible for the items listed in the preceding sentence.

Transfers of Data and Materials

Any transfer of materials or non-public information associated with Category 1 or Category 2 research must be assessed and receive institutional approval. Depending on the details, federal agency or other government approval may be necessary. Agents and toxins described in this policy are controlled under the Export Administration Regulations. These regulations control the export of materials and controlled technology/software to foreign destinations or the transfer of controlled technology to non-U.S. persons within the United States. PIs shall notify and work with the ICDUR and Export Control Officer prior to transferring materials to another institution or transferring controlled technology to a non-U.S. person.

UCSB's office of Technology and Industry Alliances routinely contacts the Biosafety Officer about any Material Transfer Agreement and Data Use Agreement requests involving biological materials. If the Biosafety Officer identifies a request that may involve Category 1 or Category 2 research, they shall consult with the ICDUR and Export Control Officer prior to approving the agreement.

Contact Information

ICDUR - Barry Rowan, rowan@research.ucsb.edu
BSO - Jamie Bishop, bishop@ucsb.edu
General inquiries - researchintegrity@research.ucsb.edu

Resources and links	
U.S. Government Policy	https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf
U.S. Government Implementation Guidance	https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf
UC Policy	https://policy.ucop.edu/doc/2500637/DURC-PEPP
NIH NOT-OD-25-061	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-061.html