UCI Environmental Health & Safety

Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Information Sheet

Issued: February 2025

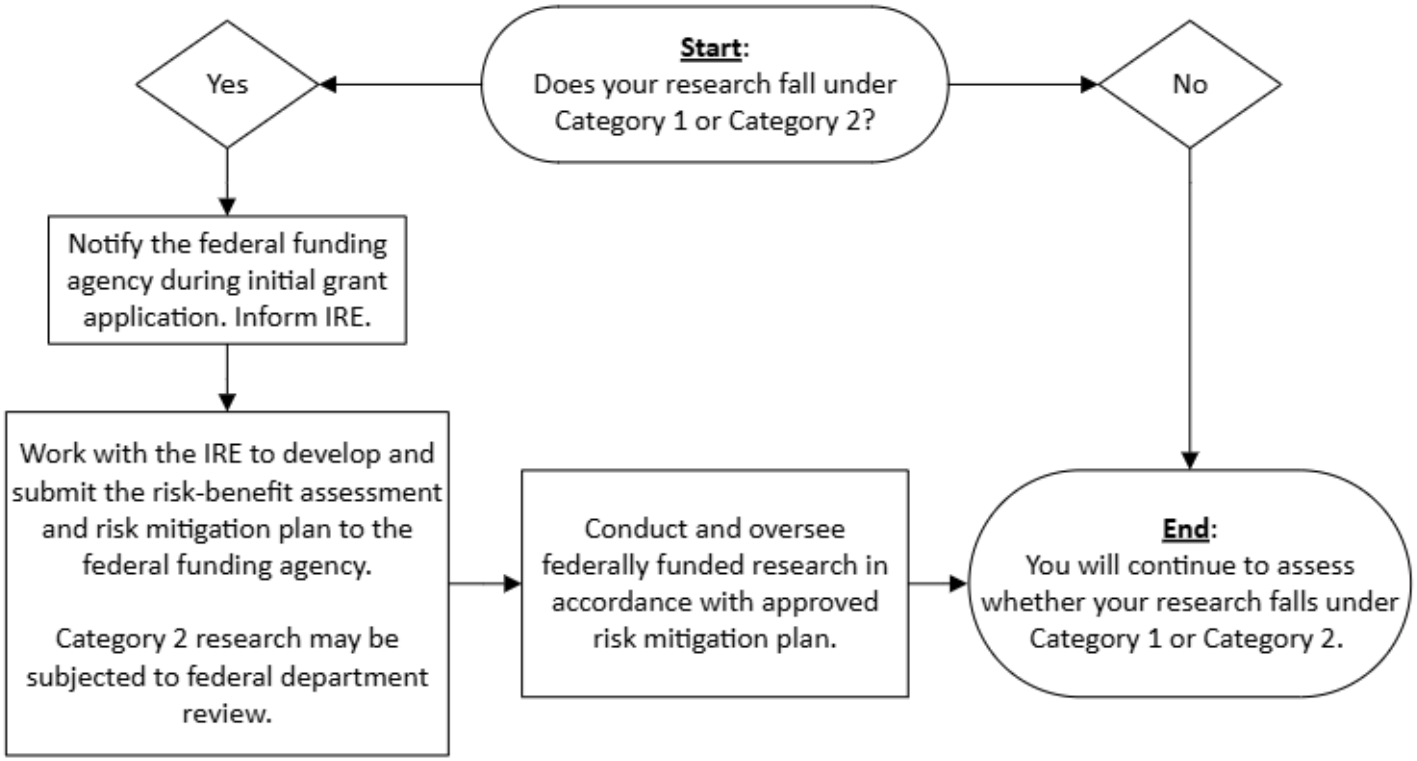
This information sheet is for UCI researchers to determine if their work is subject to the Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Policy (also referred to as the Policy), effective May 6, 2025. Non-compliance may result in federal funding loss and research restrictions. Refer to the full Policy for complete details.

The Policy categories are outlined in the table below:

Category 1	**Category 2**
Does your research use any of the following agents? • **Select agents and toxins**; OR • **Risk Group 4 agents (NIH Guidelines Appendix B-IV)**; OR • **BSL3/BSL4 agents and Risk Group 3 agents (NIH Guidelines Appendix B-III)** Note: A compilation of the preceding bullet points is available in the List of Category 1 Agents.	Does your research use any of the following agents? • **A Pandemic Potential Pathogen (PPP)**, meaning a highly transmissible pathogen capable of causing severe illness; OR • **A Pathogen with Enhanced Pandemic Potential (PEPP)**, which is a PPP modified to increase transmissibility or virulence; OR • **An eradicated or extinct PPP** that poses a public health threat, regardless of whether the experiment enhances the PPP.
AND	AND
Will your research result in one or more of the following outcomes? • Increased transmissibility • Increased virulence • Increased toxin toxicity • Increased stability/dissemination • Altered host range • Decreased diagnostic detectability • Increased resistance to treatments • Disrupted pre-existing immunity • Enhanced host susceptibility	Will your research reasonably anticipate or result in one or more of the following outcomes? • Enhanced transmissibility • Enhanced virulence • Enhanced immune evasion • Reconstitution of an eradicated or extinct pathogen

The UCI Institutional Review Entity (IRE) is charged with oversight of, and education on, life sciences research involving the use of potential DURC agents. Contact them **immediately** if your research falls under either category or for further questions.

To conduct Category 1 or Category 2 research, you will need to follow the review process as described by the Policy's Implementation Guidance (Part D). This process may take several months to complete, so please plan accordingly. Below is a simplified flowchart of the review process, which also extends to non-federally funded research.



Your risk-benefit assessment should answer the following questions:

- Risk Reduction: In what ways can the risks of conducting this research be minimized?
- Dual-Use Potential: Do benefits of this research outweigh risks? How will research findings be responsibly communicated to the public? Are there risks from immediate misuse of this information?
- Benefit Timeline: When will benefits of this research materialize? Is this dependent on other research?
- Benefit/Risk Distribution: Who benefits from this research? Who bears the risks? Are specific populations disproportionately affected?

Your risk mitigation plan will be developed based on your risk-benefit assessment and should include:

- Name and contact details for the PI(s), the UCI Responsible Official (RO), and the ICDUR (Institutional Contact for Dual Use Research)
- Date and details of the PI's initial review and the IRE review, which details the risks identified by IRE and risk mitigation strategies (see table below)
- Identification of whether the research falls under Category 1 or Category 2
- Other materials as requested by the federal government

Existing UCI Risk Mitigation Strategies	Potential Additional Risk Mitigation Strategies
• DURC training and certification • Select agent, NIH, and BMBL compliance • IBC approval • Agent(s) lifecycle management • Occupational health surveillance	• Enhanced biosafety and biosecurity • Medical countermeasure efficacy • Annual DURC and PEPP category review • Communication plan for findings • Other info depending on the agent and work