Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

On May 5, 2025, the White House issued an Executive Order ordering the revision or replacement of the 2024 U.S. Government DURC-PEPP Policy by September 2, 2025. The UC DURC-PEPP Policy remains in effect to the extent the funding agency has not rescinded implementation of the 2024 USG DURC-PEPP Policy. Additional guidance can be found at the Research Policy Analysis and Coordination webpage on DURC-PEPP.

Responsible Officer:	VP – Research & Innovation
Responsible Office:	RI – Research & Innovation
Issuance Date:	5/1/2025
Effective Date:	5/1/2025
Scope:	This Policy applies to all research, regardless of funding source, conducted at any Location that may involve Dual Use Research of Concern (DURC) or Pathogens with Enhanced Pandemic Potential (PEPP), which is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be intentionally misused to pose a significant threat, with broad potential consequences, to public health and safety, agriculture, food security, economic security, or national security.

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I. POLICY SUMMARY

This Policy implements the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential ("USG Policy").[1] The USG Policy supersedes earlier United States Government Policy for dual use research of concern and potential pandemic pathogen oversight, i.e., the 2012 Federal DURC Policy,[2] 2014 Institutional DURC Policy,[3] and 2017 P3CO Framework.[4]

II. DEFINITIONS

UC adopts the definitions provided in the USG Policy.[5] For convenience, some definitions are repeated below (with citations).

1. **Category 1 (DURC) Research** (USG Policy § 4.1): Category 1 research meets three criteria:

   (1) it involves one or more of the biological agents and toxins specified as a Category 1 (DURC) Agent;

   (2) it is reasonably anticipated to result, or does result, in one of the experimental outcomes specified as a Category 1 (DURC) Research Experimental Outcome; and

   (3) based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes Category 1 (DURC), i.e., based on current understanding, the research 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

2. **Category 2 (PPP) Research** (USG Policy § 4.2): Category 2 research meets three criteria:

   (1) it involves, or is reasonably anticipated to result in, a PPP;

   (2) it is reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions specified as a Category 2 (PPP) Research Experimental Outcome; 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.

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[1] United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (May 2024).
[2] United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012).
[3] United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014).
[4] Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (2017).
[5] USG Policy § 3, Definitions.

3. **Dual use research** (USG Policy § 3.D): Research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes.
4. **Dual use research of concern** (DURC) (USG Policy § 3.E): 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.
5. **Pathogen with pandemic potential (PPP)** (USG Policy § 3.K): 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.
6. **Pathogen with enhanced pandemic potential (PEPP)** (USG Policy § 3.J): 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.

III. POLICY TEXT

A. Purpose and Scope of Policy

UC adopts the USG Policy for the institutional review and oversight of life sciences research that is within Category 1 and Category 2.[6] Guidance on oversight implementation can be found in the USG Implementation Guidance ("USG Guidance").[7]

This UC Policy is intended to comply with federal requirements for review of Category 1 and Category 2 research to:

- Strengthen the institutional review and oversight by the University of specifically defined life sciences research;
- Identify potential Category 1 and Category 2 research;
- Develop and implement risk mitigation where appropriate;
- Set forth instructions for individuals and committees at UC who are responsible for the implementation of UC's requirements with respect to Category 1 and Category 2 research; and
- Preserve the benefits of dual use life sciences research while minimizing the risk that outputs of such research would be intentionally used for harmful purposes.

[6] The USG Policy categorizes the research previously overseen by the 2012 Federal DURC Policy, the 2014 Institutional DURC Policy, and the 2017 P3CO Framework policies into Category 1 (DURC) and Category 2 (PEPP) research. USG Policy § 4, Category 1 and Category 2 Research that is Subject to this Policy.
[7] Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (May 2024).

B. Category 1 and Category 2 Research Oversight Framework
The oversight framework for Category 1 and Category 2 research is provided in Section 5 of the USG Policy.[8]

C. Non-federally Funded Research
UC is committed to providing appropriate oversight for research that is within Category 1 and Category 2. Therefore, this Policy applies to any such research, regardless of funding source.

IV. COMPLIANCE/RESPONSIBILITIES

A. RESPONSIBILITIES

Campus Vice Chancellors for Research (or equivalent administrator at LBNL and ANR) are responsible for ensuring compliance with this Policy, unless the Chancellor designates the responsibility to another institutional officer. The VCR must establish the local Institutional Review Entity (IRE) in compliance with this Policy and designate an individual to serve as the Institutional Contact for Dual Use Research.

Institutional Contacts for Dual Use Research (ICDURs) are the designated officials at the Locations responsible for compliance implementation, including establishing appropriate procedures, documentation and training. ICDURs act as liaisons with the relevant U.S. funding agencies.

Institutional Review Entity (IRE) is the committee established at the Location to execute the oversight responsibilities in this Policy, including confirming whether proposed or ongoing research is Category 1 or Category 2 Research, conducting risk-benefit assessments, and developing risk mitigation plans.

Principal Investigators (PIs) of research projects must:

1. Be knowledgeable about, comply with, and follow all applicable institutional and U.S. government policies, requirements, and regulations for oversight of use, movement, and modifications of biological agents and toxins that may fall under Category 1 or Category 2 research.
2. Assess the research at the proposal stage, and continuously throughout the research progress, to reasonably anticipate if it will fall within the scope of Category 1 or Category 2 research.
3. Comply with any Location specific procedures implementing this Policy and any extramural contract and grant terms and conditions supporting the research.

B. NON-COMPLIANCE

For federally funded research, Locations must report any instances of non-compliance with the USG Policy to the federal funding agency. This report, along with details of the mitigation measures implemented to prevent recurrence, must be submitted within 30 calendar days of the research institution becoming aware of the failure or receiving notification of the failure from the federal funding agency.[9]

Non-compliance with this Policy may result in remediation, mandatory training, and/or

[8] USG Policy § 5, Oversight Framework for Category 1 and Category 2 Research that is Subject to this Policy.
[9] USG Policy § 5.2.K, Responsibilities of Research Institutions.

employment consequences up to and including informal counseling, adverse performance evaluations, and corrective action/discipline, in accordance with applicable UC and campus policies.

V. PROCEDURES

Each Location must provide education and training to individuals conducting Category 1 or Category 2 research before they participate in the research. The PI must also receive education and training to be able to determine whether their research is reasonably anticipated to be within the scope of Category 1 or Category 2 research at the proposal stage, and continuously throughout the research lifecycle.

Locations must develop procedures to implement this Policy, including the establishment of an IRE committee for the identification and oversight of Category 1 and Category 2 research. Locations must use the USG Guidance in developing local procedures.

For non-federally funded research, Locations may develop a different oversight framework provided it is consistent with the principles in Section 2.3 of the USG Policy.[10]

The oversight for both federally funded and non-federally funded research must include a process managed by an IRE to:

- Identify Category 1 and Category 2 research;
- Conduct risk-benefit assessments before proceeding with Category 1 and Category 2 research; and
- Implement a risk mitigation plan for Category 1 and Category 2 research, consistent with the principles described in the USG Policy and USG Guidance.[11]

VI. RELATED INFORMATION/RESOURCES

- United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (2024).
- Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (2024).
- Other research-related University policies that may overlap with this Policy:
  - Export Control Policy
  - Use of Animals in Research and Teaching
  - Protection of Human Subjects in Research
- Administration for Strategic Preparedness & Response FAQS (2024).

VII. FREQUENTLY ASKED QUESTIONS

Not applicable.

[10] USG Policy § 2.3, Guiding Principles.
[11] USG Policy § 5.4, Non-Federally Funded Research.

VIII. REVISION HISTORY

May 1, 2025: Revised to conform with updated USG Policy and USG Guidance issued May 6, 2024.

September 1, 2017: The following technical revisions made to the policy:

- Misleading language from bullets 2 and 3 under the ICDUR responsibilities were removed and replaced with new language more closely aligned with what is required by DHS and actual practice at UC campuses.
- Removed paragraph 1 under IRE Review Process and replaced with new language to more clearly define the IRE's responsibility in compliance with DHS policy.
- Policy contact information was also updated.

This Policy was also remediated to meet Web Content Accessibility Guidelines (WCAG) 2.0.

September 24, 2015: Issued as a new policy.