Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Responsible Officer:	VP – Research & Innovation
Responsible Office:	RI – Research & Innovation
Issuance Date:	9/24/2015
Effective Date:	9/24/2015
Last Review Date:	XX/XX/20XX
Scope:	This Policy applies to all research, regardless of funding source, conducted at any UC Location (campus or Health Center, the Lawrence Berkeley National Laboratory (LBNL), and the Division of Agriculture and Natural Resources (ANR)) 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]

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.

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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.
[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 UC Locations responsible for compliance implementation, including establishing appropriate procedures, documentation and training. ICDURs act as liaisons with the relevant U.S. funding agencies.

Principal Investigators 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 local campus procedures implementing this Policy and any extramural contract and grant terms and conditions supporting their research.

B. Noncompliance

For federally funded research, UC Locations must report to the federal funding agency instances of failure to follow the USG Policy, as well as mitigation measures undertaken to prevent recurrences of similar failures, within 30 calendar days of research institution awareness or research institution receipt of notification of a failure to the federal funding agency.[9]

Noncompliance with this Policy may result in remediation, mandatory training, and/or employment consequences up to and including informal counseling, adverse performance evaluations, and corrective action/discipline.

For academic appointees, formal corrective action/discipline is governed by:

[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.

- The Faculty Code of Conduct (APM-015),
- University Policy on Faculty Conduct and the Administration of Discipline (APM-016),
- Non-Senate Academic Appointees/Corrective Action and Dismissal (APM-150), and
- Other policies and procedures, as applicable.

For policy-covered staff employees, corrective action/discipline is governed by Personnel Policies for Staff Members on

- Corrective Action (PPSM-62),
- Investigatory Leave (PPSM-63),
- Termination and Job Abandonment (PPSM-64) / Termination of Appointment (PPSM-II 64), which applies to Senior Management Group employees, and
- Other policies and procedures, as applicable.

This Policy does not supplant disciplinary processes described in the APM or Academic Senate Bylaws or regulations. For represented employees, formal corrective action/discipline is governed by collective bargaining agreements.

V. PROCEDURES

Each UC Location must ensure that no research with Category 1 or Category 2 agents and toxins will be conducted unless the Principal Investigator has received education and training on Category 1 and Category 2 research. This education and training must enable them to undertake an initial assessment to determine whether the research they wish to undertake potentially falls under Category 1 or Category 2.

UC 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. UC Locations should use the USG Guidance in developing local procedures.

For non-federally funded research, UC 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]

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

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.

VIII. REVISION HISTORY

XXX XX, XXXX: 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.