UCLA Interim Policy 995: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

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I. PURPOSE & SCOPE

The United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (USG Policy) sets forth requirements for oversight of certain types of federally funded life sciences research with biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. The University of California Office of the President has issued a DURC and PEPP Policy for system-wide application of the USG Policy. This Policy incorporates and implements the UC and USG policies and outlines the responsibilities of those individuals and committees at UCLA who are accountable for executing the requirements of those Policies.

Although the USG Policy applies to federal departments and agencies that fund or sponsor specific research with biological agents or toxins, this Policy applies the same evaluation and oversight requirements to all research, regardless of funding mechanism, conducted at UCLA or under the campus auspices.

II. DEFINITIONS

For the purposes of this Policy:

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 an individual designated by the UCLA Vice Chancellor for Research and Creative Activities as the point of contact for questions regarding compliance with and implementation of the USG Policy. The ICDUR also serves as the liaison (as necessary) between UCLA and the relevant federal funding agency.

Institutional Review Entity (IRE) is the committee responsible for oversight of research with specific agents and toxins as defined by the USG Policy.

Life Sciences is the study or use of living organisms, viruses, or their products, including all disciplines, methodologies, and applications of biology (including biotechnology, genomics, proteomics, bioinformatics, and pharmaceutical and biomedical research and techniques).

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.

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. Examples include H5N1 influenza viruses, SARS-CoV and SARS-CoV-2, and MERS.

Principal Investigator (PI) is an employee of UCLA (normally with an academic appointment), who is or becomes eligible under UCLA Policy 900, to submit a proposal for extramural support for a research, training, or public service project, who personally participates in the project to a significant degree, and who has primary responsibility for the scientific, technical, and administrative conduct, and reporting of the project, including financial matters. A Principal Investigator who is the head of a training or public service project may be known as a Project Director or Project Administrator.

Risk Mitigation Plan (RMP) is developed by the IRE, in partnership with the PI, and describes measures to be instituted for the conduct and communication of Category 1 and Category 2 research (as outlined below). The RMP will include details of the risks identified by the IRE in its review of the research, and an explanation of the risk mitigation strategy or strategies that are being implemented to address those risks.

III. POLICY STATEMENT

The USG Policy identifies two Categories of research that must be proactively assessed by the PI when described as part of a federal grant application:

- Category 1 Research - Research within the scope of Category 1 corresponds to "dual use research of concern." Refer to the IRE website (https://rsawa.research.ucla.edu/ire/category-1-and-2-research/#category1) for a full description of biological agents and toxins, and experimental outcomes related to Category 1.
- Category 2 Research - Research within the scope of Category 2 corresponds to "pathogens with enhanced pandemic potential" research. Refer to the IRE website for details about the biological agents and experimental outcomes related to Category 2.

Proposed and ongoing research that may fall within the scope of Category 1 or Category 2 must be evaluated by the PI during preparation of a federal funding proposal and an initial determination provided in the grant application as required by the funding agency. At the time of proposal submission, UCLA will certify institutional compliance with the research oversight framework described in the USG Policy.

A federal funding agency that is considering funding a grant involving research that may fall within the scope of Category 1 or Category 2 will notify UCLA upon completion of a merit review, prompting the Institutional Review Entity (IRE) to evaluate the PI's initial assessment and confirm whether research is within the scope of Category 1 or Category 2.

If research is determined to fall within the scope of Category 1 or Category 2:

- The IRE will perform a risk-benefit assessment and develop a draft risk mitigation plan (RMP), describing conduct and communication of the research.
- Documentation of the IRE risk-benefit assessment and draft RMP will be provided to the federal funding agency for evaluation and further risk-benefit analysis. Agency approval of the RMP must be obtained prior to initiating Category 1 or Category 2 research.
- PIs must provide progress reports to the federal funding agency on a schedule consistent with the category of research and the agency's reporting requirements.

If the IRE determines that the proposed research does not fall within the scope of Category 1 or Category 2:

- The IRE will report this determination to the federal funding agency.
- The PI will continuously monitor the research during the course of the award and report any changes that warrant reassessment to the IRE.

UCLA has established the IRE as an independent committee and has appointed an Institutional Contact for Dual Use Research (ICDUR) within the Office of Research Policy & Compliance.

IV. RESPONSIBILITIES

A. Principal Investigator (PI)

In accordance with the USG Policy, prior to initiating research and continuously throughout the research lifecycle, the PI is required to:

- Identify whether the research is reasonably anticipated to be within the scope of Category 1 or Category 2;
- Upon identification of Category 1 or Category 2 research, notify the federal funding agency and IRE;
- Work with the IRE to assess the risks and benefits of the proposed research and develop a draft RMP;
- Conduct Category 1 and Category 2 research in accordance with the provisions of the approved RMP;
- Provide progress reports on a schedule corresponding to the category of research and agency requirements;
- Be knowledgeable about, and comply with, all institutional, UC, and USG policies and requirements for Category 1 and Category 2 research;
- Ensure that laboratory personnel conducting research within the scope of this Policy have received education and training as required by the IRE and any RMPs; and
- Communicate Category 1 and Category 2 research responsibly and in compliance with the approved RMP.

B. Institutional Review Entity (IRE)

Research subject to this Policy will be referred to the IRE via a PI self-report (e.g., during proposal preparation or IBC submission) and after notification from a federal funding agency. If research is determined to fall within the scope of Category 1 or Category 2, the ICDUR and IRE will:

- Notify the PI that the proposed work meets the criteria for Category 1 or Category 2;
- Conduct a risk-benefit assessment on the proposed research;
- Develop a draft RMP in collaboration with the PI for the research;
- Provide education and training for individuals conducting Category 1 and Category 2 research, as needed;
- Review all active RMPs at least annually (shorter cycles may be imposed, especially for Category 2 research) and modify as needed; and
- Maintain records of IRE reviews and completed RMPs for the term of the research grant or contract plus three years after its completion.

V. COMPLIANCE

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 in accordance with UC and UCLA policies and any relevant collective bargaining agreements.

Section 5.6 of the USG Policy describes consequences of PI and institutional failure to follow the research oversight framework described in the Policy. In cases of deliberate non-compliance, grant funding agencies may choose to take additional action. For deliberate non-compliance associated with Federal Select Agents, criminal and financial penalties may apply.

VI. REFERENCES

1. United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Release date: May 6, 2024;
2. USG Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);
3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). Amended April 5, 2024;
4. University of California Policy: Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential;
5. UCLA Policy 900, Principal Investigator Eligibility.

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Vice Chancellor for Research and Creative Activities

Questions concerning this policy or procedure should be referred to the Responsible Department listed at the top of this document.