

Starrag M. Charr

Steven W. Cheung Chair, Assembly of the Academic Senate Faculty Representative, UC Board of Regents

Academic Senate

Office of the President 1111 Franklin Street Oakland, CA 94607

senate.universityofcalifornia.edu

CALABLICE

CAMPUSES

Berkeley

Davis

Irvine

UCLA

Merced

Riverside

San Diego

San Francisco

Santa Barbara

Santa Cruz

#### MEDICAL CENTERS

Davis Irvine UCLA San Diego San Francisco

NATIONAL LABORATORIES

Lawrence Berkeley Lawrence Livermore Los Alamos April 7, 2025

Theresa Maldonado
Vice President, Research & Innovation

Re: Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC-PEPP)

Dear Vice President Maldonado,

As requested, I distributed for systemwide Academic Senate review the proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC-PEPP). Eight Academic Senate divisions and two systemwide committees (CCGA and UCORP) submitted comments. These were discussed at the Academic Council's April 2, 2025 meeting, and the compiled feedback is attached for your reference.

This policy revises UC's existing Dual Use Research of Concern policy to incorporate updated provisions from the U.S. Government (USG) Office of Science and Technology Policy (OSTP) regarding the oversight of research involving biological agents and toxins. These provisions address potential risks to public health, agriculture, food security, economic stability, and national security.

Overall, the Senate supports the policy's intent to align UC with federal DURC and PEPP oversight policies, recognizing the importance of risk mitigation in research involving biological agents. However, reviewers identified several areas needing clarification and raised concerns about the policy's complexity and administrative burden. Below is a summary of key issues. We encourage you to review the enclosed comments in full.

Vague Policy Language: Several reviewers noted that the policy's use of complex terminology and vague language makes it difficult to determine specific compliance expectations and which researchers or research activities are affected. In addition, reviewers highlighted that the policy does not succinctly define Category 1 (DURC) and Category 2 (PEPP) research. There is also a lack of clarity on how institutional oversight should function in practice, including the specific criteria used to assess whether

research falls under DURC or PEPP classifications. This includes concerns about the roles of review committees, the responsibilities of researchers, and the process for determining compliance. The Senate recommends that the policy include brief definitions of Category 1 and Category 2 research, as well as a direct link to the relevant USG policy outlining these definitions, to improve clarity and accessibility.

Research and Administrative Burden: Reviewers expressed concern that implementing the policy will require additional costs for training and personnel, increasing the administrative burden on faculty researchers, particularly regarding new oversight requirements, which could negatively impact research. There were also questions about whether the policy will require additional institutional resources for compliance and how faculty and campus compliance offices will be supported in implementing the necessary infrastructure.

Institutional and Individual Responsibilities: Reviewers requested greater clarity on the specific responsibilities of Principal Investigators (PIs), institutional review boards, and administrative personnel in ensuring compliance. This includes procedural guidance for how PIs should report research that might fall under DURC or PEPP classifications, along with examples to illustrate how compliance should be maintained in different scenarios. In addition, it is unclear whether the policy considers graduate students or postdoctoral fellows with independent funding as PIs.

**Non-Federally Funded Research**: Some reviewers questioned the policy's flexibility in allowing UC locations to develop distinct oversight frameworks for non-federally funded research, provided they align with federal principles. Concerns were raised about the potential for inconsistent oversight across campuses, leading to compliance gaps or inequitable treatment of researchers based on funding sources. Reviewers suggested establishing clearer systemwide standards to promote consistency.

**Training:** Reviewers emphasized the need for clear education and training programs to ensure faculty and staff understand compliance expectations and can effectively implement the policy.

Thank you for the opportunity to opine. Please do not hesitate to contact me if you have any questions.

Sincerely,

Steven W. Cheung

Chair, Academic Council

Page 3 Encl.

cc: Deputy Provost Lee

Research Policy Analyst Miller Senate Division Executive Directors

Senate Executive Director Lin



March 28, 2025

STEVEN CHEUNG Chair, Academic Senate

Subject: Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Cheung,

On March 17, 2025, the Divisional Council (DIVCO) discussed the proposed *Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*. Discussion was informed by written comments from the committees on Academic Planning and Resource Allocation (CAPRA), Research (COR), and Faculty Welfare (FWEL), which are appended in their entirety. Below, I highlight points from the DIVCO discussion and recommend full review of the CAPRA, COR, and FWEL reports, which go into further detail.

This policy revises the current *UC Dual Use Research of Concern Policy* with new and updated provisions issued by the Office of Science and Technology Policy (OSTP) on May 6, 2024, and effective May 6, 2025. The OSTP issued the *United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) (USG Policy*). "The USG Policy addresses oversight of 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." Compliance with the new policy, which reclassifies pathogens into two categories of toxins and pathogens, requires new practices for applying for grants, executing the grants including continual reporting on potential pathogen threats, and requirements related to publishing such research. The UC policy attempts to bring the prior UC policy into alignment with the updated federal policy. COR notes that with the United States Presidential administration change in January 2025, the website links included in the provided background documents from the UC Office of the President (UCOP) are no longer active. This raised questions about whether there may be changes in how the policy will be

<sup>&</sup>lt;sup>1</sup> https://senate.universityofcalifornia.edu/ files/underreview/durc-pepp-policy-review.pdf

implemented in May 2025. It also raised questions about interactions between administrators at UC campuses overseeing policy compliance and the reporting structures that exist within relevant federal agencies charged with enforcing these policies such as the National Institutes of Health (NIH), Department of Defense (DOD), Department of Energy (DOE), and National Science Foundation (NSF). Given the ongoing changes within federal agencies, a question was raised about the integrity of these interactions if those reporting structures no longer exist. This was noted as a minor concern, given that the structure of some of these federal agencies are in flux.

DIVCO raised several concerns with the proposed policy. One concern is the vagueness of the policy language. For example, the policy does not clarify which researchers and/or which research is affected. In addition, the legalistic language may pose challenges for faculty in understanding how to adhere to this new policy. DIVCO is requesting more clarifying and simplistic policy language.

Another concern is that implementing the new policy will likely require additional costs such as for training and personnel (i.e., institutional liaison to govern policy and compliance). It is unclear if an existing campus administrator or if a new position would be required. Related, this policy would require additional faculty training, which raised concerns about how to implement the policy most efficiently. DIVCO suggests that training materials and guidelines be created at the UC systemwide level (i.e., UCOP), instead of at the individual campuses, and that the trainings required by this policy be integrated into a centralized training module.

DIVCO also noted the significant amount of pathogen research conducted internationally and therefore recommends that UC work toward international cooperation and towards setting and enforcing international standards for safety.

Thank you for the opportunity to review and comment.

Sincerely,

Amani Nuru-Jeter

Chair, Berkeley Division of the Academic Senate

**Enclosures** 

cc: Mark Stacey, Vice Chair, Berkeley Division of the Academic Senate
Jocelyn Surla Banaria, Executive Director, Berkeley Division of the Academic Senate
J. Miguel Villas-Boas, Chair, Committee on Academic Planning and Resource Allocation

Abby Dernburg, Chair, Committee on Research

J. Keith Gilless, Co-Chair, Committee on Faculty Welfare

Nancy Wallace, Co-Chair, Committee on Faculty Welfare

Milo Knight, Academic Senate Analyst, Committee on Academic Planning and Resource Allocation

Patrick Allen, Academic Senate Analyst, Committee on Research and Faculty Welfare



March 27, 2025

# PROFESSOR AMANI NURU-JETER Chair, Berkeley Division of the Academic Senate

CAPRA comments on the UC Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

The Committee on Academic Planning and Resource Allocation (CAPRA) considered the proposed UC Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. This UC policy was created in response to the United States Government (USG) Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential issued under the Biden Administration in May 2024. This USG Policy is supposed to go into effect on May 6, 2025, but given the change in Presidential administration and that the links to the USG Policy are not currently active, the status of this USG Policy and its implementation seem more than uncertain. Furthermore, CAPRA would like to have the input of the Chancellors' Advisory Committee for Life Sciences before making a final recommendation. Nevertheless, for now CAPRA has considered the proposal from the point of view of its charge, given the information available.

Given the huge repercussions of the SAR-COVII pandemic, we are all most aware of both the need for research but also the dangers of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Tight regulation is therefore needed, and implementation of the UC presidential Policy is very important to warranty safety. The procedures proposed will require investment, especially in training, as well as personnel involvement for their implementation. Given the seriousness of failure to adhere to the policy, both would seem justified.

Thank you for the opportunity to comment.

Sincerely,

J. Miguel Villas-Boas

I Ville Ban

Chair, Committee on Academic Planning and Resource Allocation



March 25, 2025

CHAIR AMANI NURU-JETER Academic Senate

Re: Proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Nuru-Jeter,

On March 17, 2025, the Committee on Faculty Welfare (FWEL) discussed the proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. After discussion, the Committee would like to offer the following observations and recommendations:

- **Training Requirements**: The policy introduces significant training expectations for Principal Investigators (PIs) working with infectious agents. While the intent is supported, the Committee strongly prefers integrating these requirements into the existing, centralized training systems rather than creating parallel or redundant processes.
- Existing Safety Infrastructure: Following the tragic UCLA chemistry lab incident, the UC system developed robust and centralized lab safety protocols, including mandatory training, protective gear requirements, and chemical inventory procedures. These systems should serve as the foundation for any new DURC or PEPP research requirements.
- **Support for PIs**: The policy outlines obligations for PIs to be knowledgeable about and compliant with U.S. government and institutional policies regarding high-risk biological research. The Committee emphasized that this cannot be an individual burden. Institutional support, particularly from the Sponsored Projects Office (SPO) and the Office of Research, is essential to ensure faculty are adequately informed and supported.
- Scope of Research Oversight: While Category 1 and 2 research classifications are not new, the policy clarifies expectations for compliance—notably for non-federally funded research. The requirements with respect to the necessary BSL rating for laboratories point to the importance of the VCRO maintaining good facilities inventory records and working with departments to make sure that PIs have access to labs with the right BSL rating.
- Changing Funding Landscape: With the potential for decreased NIH involvement or shifts toward philanthropic/private funding, internal compliance

- structures must remain strong. NIH typically ensures rigorous oversight; new funding sources may lack equivalent safeguards.
- Examples from COVID-19: Some labs pivoted to COVID-related projects (e.g., public health testing and wastewater surveillance) during the pandemic without going through formal channels such as SPO. These cases highlight the importance of clear, universal compliance and training processes.

FWEL endorses the centralization of training for high-risk biological research within the university's existing safety systems. The Committee emphasizes that compliance with applicable policies is a shared responsibility between Principal Investigators (PIs) and the institution, rather than resting solely on individual faculty. Clear institutional guidance and administrative support are essential to ensure that faculty engaging in Dual Use Research of Concern (DURC) or work involving Pathogens with Enhanced Pandemic Potential (PEPP) are adequately informed and supported. Overall, the Committee supports the intent to reinforce safety and compliance while avoiding unnecessary additional burdens on researchers.

We appreciate the opportunity to review these changes.

Regards,

Nancy Wallace, Co-Chair Committee on Faculty Welfare

Tomag 5. Wallace

J. Keith Gilless, Co-Chair Committee on Faculty Welfare

NW/JKG/pga



March 03, 2025

# CHAIR AMANI NURU-JETER Academic Senate

Re: Proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Nuru-Jeter,

On February 13, 2025, the Committee on Research (COR) discussed the proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

The proposed UC Presidential Policy is a revision of previous UC policy in response to a new United States Government (USG) Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. This USG policy was issued under the Biden Administration in May 2024. According to the cover letter issued by UC Vice President for Research & Innovation Theresa Maldonado, which is dated December 2024, this USG Policy will go into effect on May 6, 2025. However, the Presidential administration has turned over since this letter and the Draft UC Presidential Policy was written. We note that the links provided in the letter to the White House communication and the USG Policy in Dr. Maldonado's letter are not currently active. In light of the Trump administration's efforts to roll back many policies of the Biden administration, as well as current efforts by the White House, "DOGE," and Congress to dismantle regulatory and funding structures, the legal status of this USG Policy is highly uncertain. Currently (February 2025) the OSTP and HHS are undergoing major reductions in force, and may not be able to provide guidance or updates. Relevant funding agencies, including NIH, NSF, and DoD, are also being downsized, so it is unclear whether they will have personnel to implement and sustain the compliance structures outlined in the USG Policy. Even if these agencies do not implement or enforce the 2024 policy as previously expected, it will still be useful to update the proposed changes to the UCOP policy, although adjustments in reporting structures and other details may need to be made. Please see the Appendix for an analysis of COR's summaries and interpretation of the policy under review.

The USG and UCOP policy updates are both timely and important. We have all experienced the severe consequences of a global pandemic. It remains unclear whether human intervention contributed to the evolution of COVID-19 or its spread into the human population. However, scenarios in which well-intentioned or nefarious research

could lead to the emergence of new or more dangerous toxins or pathogens are increasingly plausible. Rapid advancements in AI-assisted structural analysis, synthetic biology, and DNA synthesis create fantastic opportunities in many areas, but also raise alarming new risks. Researcher education and accountability will provide some guardrails to mitigate the risks of work involving known or potential pathogens or toxins.

The UCOP policy requires both training and reporting, and also provides guidelines for proper dissemination of research findings. Training materials and effective guidelines will need to be developed by experts in the field and updated regularly. Campuses will also need to hire staff to serve as the Institutional Contact for Dual Use Research (ICDUR), or extend the responsibilities of existing personnel to fill this role. These will require initial and ongoing expenditures.

Finally, we note that the goals of the policy, and the scope of research and researchers who are subject to the regulations should be more clearly communicated. Development of clear messaging, training, checklists, and other tools will be essential to help PIs plan their future research to maximize safety and ensure compliance.

We value the opportunity to provide our perspective on these matters.

Regards,

Abby Dernburg, Chair Committee on Research

AD/pga

Enclosure: USG Policy for Oversight of DURC and PEPP 2024





March 19, 2025

Steven Cheung, Chair Academic Council

Re: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

The Irvine Division Cabinet discussed the proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC-PEPP Policy) at its meeting on March 18, 2025. The Council on Research, Computing, and Libraries (CORCL) also reviewed the proposal. The council's feedback is attached for your review.

The Cabinet draws your attention to multiple links in the draft policy that are already outdated due to changes in the federal government and reiterates CORCL's recommendation that the relevant USG definitions should either be included in the policy text or the policy should link to a UC webpage where these definitions are archived. The policy should also link to a webpage where the USG policy and guidance referenced throughout are available and kept up to date.

The Irvine Division appreciates the opportunity to comment.

Sincerely,

Valerie Jenness, Chair

Academic Senate, Irvine Division

Cc: Jane Stoever, Chair Elect-Secretary

Jisoo Kim, Executive Director Gina Anzivino, Associate Director





March 17, 2025

## VALERIE JENNESS, CHAIR ACADEMIC SENATE, IRVINE DIVISION

# RE: Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

At its February 20, 2025 meeting, the Council on Research, Computing, and Libraries (CORCL) discussed the proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Overall, the Council found the proposed policy to be reasonable. The policy aims to achieve federal compliance for review of Category 1 and Category 2 research through several key measures:

- Strengthening the institutional review and oversight by the University of specifically defined life sciences research
- Identification of potential Category 1 and Category 2 research, development and implementation of risk mitigation where appropriate
- Setting 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
- Preserving the benefits of dual use life sciences research while minimizing the risk that outputs of such research would be intentionally used for harmful purposes

#### CORCL offers the following comments:

- 1. Whether this UC policy exclusively applies to life science research or all research is unclear. Given that the federal policy applies to all federally funded research that utilize Category 1 and Category 2 agents, this should be clarified.
- 2. The Council recognizes the policy's intent to streamline the definitions of Category 1 and Category 2 research for brevity. However, members observed that the current language may be confused with the previous definition of research by NIH. Additional clarification may be helpful for the IRE committee to propose corresponding criteria, especially given that the policy includes a non-permanent link to USG policy, which was already broken while the policy was under review. The relevant USG definitions should either appear in the UC policy or be permanently archived so that a stable link is available.
- 3. In its initial review, the Council observed that the policy does not address training for research teams and recommended that the PI and the research team should be informed and trained if Category I and Category 2 research is conducted. Upon consultation with UCI's Environmental Health & Safety, CORCL was informed that it is the PI's responsibility to determine whether research is considered Dual Use with the support of the IRE. The Council maintains that such clarification should be included in the policy.

#### 4. The policy states:

"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." (IV. Compliance/Responsibilities, B. Noncompliance; Page 3)

Members suggested the following revision for clarity:

"For federally funded research, UC Locations must report any instances of non-compliance with USG Policy to the federal funding agency. This report, along with details of the mitigation measures implemented to prevent recurrence of similar issues, 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."

On behalf of the Council,

James Weatherall, Chair

c: Jisoo Kim, Executive Director Gina Anzivino, Assistant Director Michelle Chen, CORCL Analyst





March 20, 2025

Steven Cheung Chair, UC Academic Senate

Re: (Systemwide Senate Review) Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Cheung,

The divisional Executive Board (EB) reviewed the Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and divisional council feedback at its meeting on March 20, 2025. Members voted in favor of a motion to share the attached council feedback with the Office of the President for consideration. (One student representative voted in favor.)

Thank you for the opportunity to advise on this matter.

Sincerely,

Kathleen Bawn

Chair

**UCLA Academic Senate** 

Encl.

Cc: April de Stefano, Executive Director, UCLA Academic Senate

Andrea Kasko, Immediate Past Chair, UCLA Academic Senate Megan McEvoy, Vice Chair/Chair Elect, UCLA Academic Senate Adriana Rosalez, Administrative Analyst, UCLA Academic Senate



March 14, 2025

Kathleen Bawn, Chair Academic Senate

Re: (Systemwide Senate Review) Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Bawn,

At its meetings on February 5 and March 5, 2025, the Council on Research (COR) reviewed and discussed the Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Members offered the following comments.

COR understands that NIH intends to implement the DURC/PEPP Policy effective May 6, 2025 (<a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-061.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-061.html</a>). The merger of what were previously two distinct policies over DURC and PEPP will require administrative changes to comply, and the expansion of pathogens/activities that this policy will cover will no doubt lead to greater administrative costs and time from the PIs that are impacted. Nonetheless, ultimately this will be a requirement of any NIH funded work, which will need to be adopted at UCLA.

The only specific recommendation of COR is that the policy should add back the definitions of "A. Dual Use Research" and "B. Dual Use Research of Concern" (page 2 of 12 on the original document) for clarity.

If you have any questions for us, please do not hesitate to contact me at <u>dlettenm@geog.ucla.edu</u> or via the Council's analyst, Elizabeth Feller, at <u>efeller@senate.ucla.edu</u>.

Sincerely,

Dennis Lettenmaier, Chair Council on Research

cc: Megan McEvoy, Vice Chair/Chair-Elect, Academic Senate
Andrea Kasko, Immediate Past Chair, Academic Senate
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Associate Director, Academic Senate
Members of the Council on Research



March 12, 2025

To: Kathleen Bawn, Chair, Academic Senate

Academic Senate

From: Kriss Ravetto-Biagioli, Chair, Charges Committee

cc: Megan McEvoy, Vice Chair/Chair-Elect, Academic Senate

Andrea Kasko, Immediate Past Chair, Academic Senate April de Stefano, Executive Director, Academic Senate

Marian M. Olivas, Principal Policy Analyst, Academic Senate

Members of the Charges Committee

Re: Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic

**Potential** 

The Charges Committee had an opportunity to discuss this policy at their January 2025 meeting. During that meeting, members noted that the link to the relevant White House communication on dual use research no longer worked. The Committee has since revisited the issue. Although there is still no information on the White House pages, the Committee was able to find postings of the May 2024 oversight policy posted on other government pages.

Members remain concerned that there is still no guidance link on the White House page for a policy that is supposed to go into effect in a couple of months. The proposed policy seems reasonable. Faculty who have federal grants will presumably have more guidance as part of the grant process. The policy promises that "UC is committed to providing appropriate oversight for (non-federally funded) research." Given that faculty could be subject to disciplinary action for failing to comply, it would be helpful if, along with the policy, UCOP is clear about what support they will give divisions for "appropriate oversight."



3125 Murphy Hall 410 Charles E. Young Drive East Los Angeles, California 90095

February 24, 2025

To: Kathleen Bawn, Chair, UCLA Academic Senate

From: Deepak Rajagopal, Chair, Graduate Council

Re: Systemwide Senate Review: Proposed Presidential Policy – Dual Use Research of Concern and

**Pathogens with Enhanced Pandemic Potential** 

At its meeting on February 14, 2025, the Graduate Council reviewed and discussed the proposed *Presidential Policy – Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* and offered the following for the Executive Board's consideration.

Members noted that the policy has implications for most life sciences departments and programs. One member noted that the list of agents and toxins under the USG policy has expanded. If the mandate is to have everything federally regulated, it may be difficult to comply if the list constantly changes. In addition to the potential impact on faculty research, graduate student doctoral research may also be affected.

Some members also expressed concern about tying research to federal funding, given the uncertainty of NIH funding, and queried about the possibility of separating research from federal funding.

We appreciate the opportunity to express our views on this matter. If you have any questions, please contact us via Graduate Council Analyst, Emily Le, at <u>ele@senate.ucla.edu</u>.



February 18, 2025

Kathleen Bawn, Chair Academic Senate

Re: (Systemwide Senate Review) Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Bawn,

At its meeting on February 10, 2025, the Council on Planning and Budget (CPB) reviewed and discussed the proposed presidential policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Members offered the following comments.

Though members are aware of the limitations such policies may place on various research endeavors, they understand this is a regulatory mandate and that the policy must be followed as it is a requirement from the federal government. Members did however raise a concern over the costs of compliance and the potential for difference in the reimbursements for compliance between federally funded and non-federally funded research across the UCs.

If you have any questions for us, please do not hesitate to contact me at <a href="mailto:smith@anthro.ucla.edu">smith@anthro.ucla.edu</a> or via the Council's analyst, Elizabeth Feller, at <a href="mailto:efeller@senate.ucla.edu">efeller@senate.ucla.edu</a>.

Best regards,

Monica Smith, Chair

Council on Planning and Budget

cc: Megan McEvoy, Vice Chair/Chair-Elect, Academic Senate
Andrea Kasko, Immediate Past Chair, Academic Senate
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Associate Director, Academic Senate
Members of the Council on Planning and Budget

#### UNIVERSITY OF CALIFORNIA

RERECLEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA · SANTA CRUZ

#### OFFICE OF THE ACADEMIC SENATE

Kevin Mitchell, Chair of the Academic Senate senatechair@ucmerced.edu

UNIVERSITY OF CALIFORNIA, MERCED 5200 North Lake Road Merced, California 95343

February 24, 2025

To: Steven Cheung, Chair, Academic Council

From: Kevin Mitchell, Chair, UCM Divisional Council (DivCo)

Re: Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

The proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential was distributed to the Merced Division Senate Committees and School Executive Committees. The following committees offered comments for consideration. Their comments are appended to this memo and summarized below.

- Committee on Research (CoR)
- Committee on Rules and Elections (CRE)

**CoR** supports the policy and notes that the UCOP policy on Dual Use Research of Concern (DURC) has been revised and renamed the "Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" (PEPPs or PPPs). The updated policy streamlines guidelines by aligning with the U.S. Government Policy on DURC and PEPPs. UC Merced researchers must follow these federal guidelines and consult the campus DURC committee as needed. The Committee on Research (COR) supports the revised policy.

**CRE** finds the policy to be more concise by directly referencing federal guidelines. It requires the Vice Chancellor for Research (VCR) to establish a local Institutional Review Entity (IRE) and appoint an Institutional Contact for Dual Use Research. CRE recommends the UC Merced Committee on Committees (CoC) appoint Senate representatives to the IRE, given CoC's prior involvement in similar processes. While the policy focuses on life sciences, CRE highlights the growing relevance of generative AI and emerging technologies in developing biological agents and suggests including experts in these fields on oversight committees.

Additionally, CRE notes that "Category 1 and 2" research is not clearly defined in the document, requiring users to consult external links. A brief summary of these categories and their significance would improve clarity.

DivCo endorses the policy and supports the committees' various points and suggestions.

We thank you for the opportunity to review this policy.

Cc: DivCo Members

School Executive Committee Chairs

UCM Senate Office

Monica Lin, Executive Director, Systemwide Senate Office Michael LaBriola, Assistant Director, Systemwide Senate Office

# UNIVERSITY OF CALIFORNIA, MERCED

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

ACADEMIC SENATE, MERCED DIVISION COMMITTEE ON RESEARCH (COR) TAO YE, CHAIR tye2@ucmerced.edu UNIVERSITY OF CALIFORNIA, MERCED 5200 NORTH LAKE ROAD MERCED, CA 95343

#### January 27, 2025

To: Kevin Mitchell, Senate Chair

From: Tao Ye, Chair, Committee on Research (CoR)

**Re:** Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic

Potential

CoR reviewed the Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. We offer the below comments.

The UCOP Policy on research involving Dual Use Research of Concern (DURC) agents has been revised and renamed to the "Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential". This policy now includes both DURC agents and Pathogens with Enhanced Pandemic Potential (PEPPs or PPPs).

The UC policy has been streamlined and now has University of California researchers refer to the US Government Policy (USG) policy "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential". University of California researchers will follow the government guidelines as needed.

UC Merced has a DURC committee <a href="https://rci.ucmerced.edu/durc/durc-process">https://rci.ucmerced.edu/durc/durc-process</a>. Research that falls under the policy needs to follow the USG guidelines and work with the committee as needed.

COR supports the revised and renamed policy outlined by UCOP. We appreciate the opportunity to opine.

cc: Senate Office

# UNIVERSITY OF CALIFORNIA, MERCED

BERKELEY · DAVIS · IRVINE · LOS ANGELES · MERCED · RIVERSIDE · SAN DIEGO · SAN FRANCISCO



SANTA BARBARA · SANTA CRUZ

ACADEMIC SENATE, MERCED DIVISION COMMITTEE ON RULES AND ELECTIONS (CRE)

UNIVERSITY OF CALIFORNIA, MERCED

January 27, 2025

To: Kevin Mitchell, Chair, Divisional Council

From: Committee on Rules and Elections (CRE)

**Re:** Presidential Policy on Dual Use Research of Concern and Pathogens with

**Enhanced Pandemic Potential** 

The Committee on Rules and Elections (CRE) has reviewed the Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and offer the following comments.

The proposed Dual Use Research of Concern (DURC) Policy revises the current UC DURC and aligns with recent updates to US government policy on the same topic, which were updated and will go into effect in May 2025 (see Section VI. Related Information/Resources on page 5 of the Policy). In particular, the document is notably condensed by directly referencing and incorporating the US government policy.

According to the document, "The Vice Chancellor for Research (VCR) must establish a local Institutional Review Entity (IRE) in compliance with this Policy and designate an individual to serve as the Institutional Contact for Dual Use Research." At UC Merced, the Institutional Biosafety Committee (IBC) serves as the Institutional Review Entity to ensure compliance with the Policy and oversee periodic assessment. The UC Merced IBC Handbook states that the Office of Research and Economic Development appoints both the chairperson and members for the IBC IRE. CRE recommends that the Committee on Committees be charged with appointing Senate members to this committee, if they are serving as Senate representatives, and notes that it has been involved in this process in the past.

CRE believes it is unclear why the Policy specifically defines DURC and PEPP within the context of "life sciences", as the basic premise/risks could be extended to computer/technology system pathogens that could also generate a pandemic of sorts. Also, "Category 1 and 2" research are not succinctly defined within the document, which requires following the hyperlink to the USG document for their definition. Hence, the documents could benefit from a brief description of Category 1 and 2 research and how their distinctions are relevant to the scope and intended use of the Policy.

We thank you for the opportunity to review and comment.

CC: CRE Members

Senate Office

### UNIVERSITY OF CALIFORNIA, RIVERSIDE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED● RIVERSIDE • SAN DIEGO • SAN FRANCISCO



CHAIR, ACADEMIC SENATE RIVERSIDE DIVISION UNIVERSITY OFFICE BUILDING, RM 225 Kenneth Barish PROFESSOR OF PHYSICS AND ASTRONOMY RIVERSIDE, CA 92521-0217 TEL: (951) 827-5023 EMAIL: kenneth.barish@ucr.edu

March 19, 2025

Steven Cheung, Chair, Academic Council 1111 Franklin Street, 12th Floor Oakland, CA 94607-5200

RE: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Steven,

On March 10, 2025 the Riverside Academic Senate Executive Council discussed the *Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* along with comments received from divisional committees.

As you'll find from the attached memos, overall, reviewers, including the Executive Council found the policy acceptable and had no substantive objections or concerns.

Sincerely yours,

Kenneth Barish

Professor of Physics and Astronomy and Chair of the Riverside Division

CC: Monica Lin, Executive Director of the Academic Senate Cherysa Cortez, Executive Director of UCR Academic Senate Office



#### 2/19/25

**To:** Kenneth Barish, Division Chair of the UCR Division of the Academic Senate and Cherysa Cortez, Executive Director of the UCR Academic Senate

From: Katherine Meltzoff, Ph.D., Faculty Chair of the School of Education Executive Committee

**Subject:** Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

The SOE Executive Committee reviewed the Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Comments/feedback were solicited at our executive committee meeting and via email.

We do not have any feedback or concerns.

Thank you for the opportunity to provide feedback.

Sincerely,

Katherine Meltzoff
Faculty Executive Committee Chair
School of Education
University of California, Riverside



February 3, 2025

TO: Ken Barish, PhD, Chair, Academic Senate, UCR Division

FROM: Marcus Kaul, Ph.D., Chair, Faculty Executive Committee, UCR School of Medicine

SUBJECT: Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and

**Pathogens with Enhanced Pandemic Potential** 

Dear Ken,

The Committee reviewed the Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

The FEC agrees with the policy and had no additional comments.

Yours sincerely,

Marcus Kaul, Ph.D.

Chair, Faculty Executive Committee School of Medicine

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



OFFICE OF THE ACADEMIC SENATE

9500 GILMAN DRIVE LA JOLLA, CALIFORNIA 92093-0002 TELEPHONE: (858) 534-3640 FAX: (858) 534-4528

March 20, 2025

Professor Steven Cheung Chair, Academic Senate University of California VIA EMAIL

Re: Divisional Review of Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Cheung,

The proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential was distributed to San Diego Divisional Senate standing committees and discussed at the March 17, 2025 Divisional Senate Council meeting. Senate Council endorsed the proposal and had no further comments.

The response from the Divisional Committee on Research is attached.

Sincerely,

Olivia A. Graeve

Olivia Source

Chair

San Diego Divisional Academic Senate

Attachment

cc: Rebecca Jo Plant, Vice Chair, San Diego Divisional Academic Senate Lori Hullings, Executive Director, San Diego Divisional Academic Senate Monica Lin, Executive Director, UC Systemwide Academic Senate February 19, 2025

# OLIVIA GRAEVE, Chair Academic Senate, San Diego Division

SUBJECT: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

The Committee on Research (COR) discussed the Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and had no objections. The Committee endorsed the proposed policy.

Sincerely yours,

Julie Burelle, Chair Committee on Research

cc: J. Coomer L. Hullings R. Plant



Academic Senate Rita Raley, Chair Shasta Delp, Executive Director

1233 Girvetz Hall Santa Barbara, CA 93106-3050 http://www.senate.ucsb.edu

March 24, 2025

To: Steven Cheung, Chair

Academic Senate

From: Rita Raley, Divisional Chair

Academic Senate

Re: Systemwide Review of Proposed Presidential Policy on Dual Use Research of Concern

and Pathogens with Enhanced Pandemic Potential

The Santa Barbara Division distributed the Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential to the Council on Faculty Welfare, Academic Freedom, and Awards (CFW), the Council on Planning and Budget (CPB), the Graduate Council (GC), the Committee on Research Policy and Procedures (CRPP), and the Faculty Executive Committees (FECs) for the College of Letters and Science (L&S), the College of Engineering (COE), the College of Creative Studies (CCS), the Gevirtz Graduate School of Education (EDUC), and the Bren School of Environmental Science and Management (BREN). CPB and the L&S, CCS, EDUC, and BREN FECs elected not to opine.

The response to the proposed policy was somewhat mixed. While the alignment of University of California policy with federal policy was generally seen as positive, concern was expressed about both the policy's complexity and the burden of compliance on faculty and staff. Given the proliferation of compliance mandates and their periodic updates, employees are experiencing change fatigue and the implications of policy implementation on workload are not inconsequential. CRPP points out that this has a deleterious effect on researchers, whose time is increasingly pivoted toward compliance-related tasks and away from their research.

We thank you for the opportunity to comment.

February 28, 2025

To: Rita Raley, Divisional Chair

Academic Senate

Laurie Freeman

From: Laurie Freeman, Chair

Council on Faculty Welfare, Academic Freedom and Awards

Re: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with

**Enhanced Pandemic Potential** 

At its meeting of January 8, 2025, the Council on Faculty Welfare, Academic Freedom and Awards (CFW) discussed the proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. The Council agreed that, where appropriate, it may be necessary for the University of California to align its own policies with federal policies. Having a single policy that researchers have to comply with might simplify administrative burdens.

CC: Shasta Delp, Executive Director, Academic Senate

February 19, 2025

To: Rita Raley, Divisional Chair

Academic Senate

From: Stephanie Malia Hom, Chair

Committee on Research Policy and Procedures

Re: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with

Sepla: Hu

**Enhanced Pandemic Potential** 

At its meeting of January 24, 2025, the Committee on Research Policy and Procedures (CRPP) discussed the proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. While CRPP agreed that it is helpful for University of California policy to align with federal policy, there were concerns about the complexity and burden of compliance on faculty and staff, as well as constantly shifting norms of policy. Faculty and staff have change fatigue, and these are more standards of compliance that need to be learned. These administrative burdens have a deleterious effect on researchers, who have to spend an increased amount of time on these tasks.

CC: Shasta Delp, Executive Director, Academic Senate

January 10, 2025

TO: Rita Raley

Divisional Chair, Academic Senate

FROM: Carl Meinhart,

College of Engineering, Faculty Executive Committee

—884262A07C384CC...

RE: Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with

**Enhanced Pandemic Potential** 

The College of Engineering FEC met on Wednesday, January 8<sup>th</sup> and reviewed the Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

Committee member Mukherjee explained current policies as they are implemented at UCSB. Committee member Dey confirmed Mukherjee's analysis. The proposal aligns policy with federal policy and mandates campuses to design oversight policies for non-federal grants. Mukherjee and Dey noted that there is no DURC and PEPP research at UCSB at this time. UCSB does not currently have the infrastructure to implement this policy should faculty wish to undertake DURC or PEPP research. Mukherjee and Dey strongly recommend that UCSB begin the processes of building infrastructure to be able to meet the policy before there becomes an urgent need. They feel the policy is excellent as written and support its approval.





Office of the Academic Senate
Wayne & Gladys Valley Center for Vision
490 Illinois Street, 5th Floor
San Francisco, CA 94158
Campus Box 0764
academic.senate@ucsf.edu
https://senate.ucsf.edu

Steve Hetts, MD, Chair Errol Lobo, MD, PhD, Vice Chair Elizabeth Rogers, MD, Secretary Kathy Yang, PharmD, MPH, Parliamentarian March 24, 2025

Steven Cheung
Chair, Academic Council
Systemwide Academic Senate
University of California Office of the President
1111 Franklin St., 12th Floor
Oakland, CA 94607-5200

Re: Proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Cheung:

The San Francisco Division of the Academic Senate is pleased to comment on the Proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. This Presidential Policy will adopt the USG Policy for institutional oversight of DURC and PEPP research, require UC Locations to review all research regardless of funding source, outline compliance responsibilities for Principal Investigators and institutional contacts, and provide high-level procedural requirements for adherence to the USG Policy. One committee commented on this review, the Committee on Research (COR).

COR acknowledges the policy revision necessary for compliance with the updated United States Government Policy and supports updating the UC policy to align with federal regulations. With that said, COR recommends including brief definitions of Category 1 and Category 2 research in the policy as well as linking the governmental policy that outlines these definitions. This addition would help researchers quickly determine if their research falls under these categories, as the governmental policy is dense. Despite UC policy requiring Principal Investigators to have sufficient training to assess their research, having the definitions directly in the policy would be beneficial, which was the case in the previous policy version. The previous policy version included a brief definition of Dual Use Research of Concern (DURC), now known as Category 1. Including these definitions would also help safeguard against potential issues with accessing federal policy information, as evidenced by a broken link in the current policy draft reviewed by COR.

Thank you for the opportunity to opine on this review. If you have any questions, please let me know.

Sincerely,

Steven Hetts, MD, 2023-25 Chair

**UCSF Academic Senate** 

Enclosures (1)

Cc: Kartika Palar, Chair, Committee on Research (COR)





# Communication from the Academic Senate Committee on Research Kartika Palar, PhD, Chair

March 17, 2025

TO: Steven Hetts, Chair of the UCSF Division of the Academic Senate

FROM: Kartika Palar, Chair, UCSF Committee on Research

CC: Todd Giedt, Executive Director of the UCSF Academic Senate Office

RE: Systemwide Review of Proposed Presidential Policy on Dual Use Research of

Concern and Pathogens with Enhanced Pandemic Potential

#### Dear Chair Hetts:

The Committee on Research (COR) writes to comment on the Systemwide Review of the Proposed Presidential Policy on Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. As an advocate for researchers at UCSF, COR appreciates the opportunity to provide feedback on this policy.

COR understands that the policy has been revised to implement the changes to the United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP), which will go into effect on May 6, 2025, and which supersedes previous federal policies. COR supports updating the UC policy to ensure that federally funded research remains compliant with the law and, as such, is supportive of the content of the policy.

To make the policy more useful for researchers, COR recommends that the UC policy include brief definitions of Category 1 and Category 2 research in addition to linking to the governmental policy that provides these definitions. Although the UC policy stipulates that Principal Investigators must receive sufficient education and training to undertake an initial assessment to determine whether the research they wish to undertake potentially falls under Category 1 or Category 2, including the definitions in the policy will make it easier for researchers to quickly ascertain whether their research falls into one of these categories, as the governmental policy is fairly dense. Indeed, the previous version of the systemwide policy included a brief definition of Dual Use Research of Concern (DURC), which is now Category 1. Including this information directly in the policy may also provide a safeguard against unexpected changes in the availability of federal policy information (e.g., the link provided in the policy draft that COR reviewed is broken as of March 17, 2025, although an archived version remains).

Thank you for the opportunity to comment on this important issue. If you have any questions on the Academic Senate Committee on Research's comments, please contact me or Academic Senate Analyst Liz Greenwood (liz.greenwood@ucsf.edu).



\_

**Academic Senate** 

Office of the President 1111 Franklin Street Oakland, CA 94607

senate.universityofcalifornia.edu

**CAMPUSES** 

Berkeley Davis Irvine UCLA Merced

Riverside San Diego San Francisco Santa Barbara Santa Cruz

#### MEDICAL CENTERS

Davis Irvine UCLA San Diego San Francisco

NATIONAL LABORATORIES

Lawrence Berkeley Lawrence Livermore Los Alamos UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)

Susanne B. Nicholas

Email: sunicholas@mednet.ucla.edu

March 24, 2025

STEVEN CHEUNG
CHAIR, ACADEMIC COUNCIL

RE: Proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

Dear Chair Cheung,

UCORP members discussed the proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential with consultants and staff from the Research Policy Analysis and Coordination (RPAC) unit within UCOP's Research & Innovation at its meetings in November and in March. UCORP members appreciate UC's efforts to efficiently update policies to align with federal rules and regulations. The committee has two primary concerns about the policy:

- Cost of implementation and administrative burden. Although
  implementation of the policy will be specific to each UC location,
  UCORP members suggested that basic training materials and reporting
  structures could be provided at an aggregate level, perhaps even in
  conjunction with higher education associations.
- Effectiveness. Strengthening guardrails around pathogen-related research within the UC system is important, but true safety will only occur if other institutions nationally and around the world adopt and implement similar policies.

Overall, the policy and procedures seem well thought-out, with input provided from subject and legal experts throughout the drafting process and a UC-wide workgroup that will guide its implementation.

Thank you for providing the opportunity to comment on the revisions.

Sincerely,

Susanne B. Nicholas Chair, UCORP



\_\_\_

**Academic Senate** 

Office of the President 1111 Franklin Street Oakland, CA 94607 COORDINATING COMMITTEE ON GRADUATE AFFAIRS

James Bisley, Chair

jbisley@mednet.ucla.edu

senate.universityofcalifornia.edu

January 13, 2025

CAMPUSES
Berkeley
Davis
Irvine
UCLA
Merced
Riverside
San Diego
San Francisco
Santa Barbara

Dear Chair Cheung,

At its January 8 meeting, CCGA discussed the proposed Presidential Policy on the Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Members had questions and concerns which are outlined below.

Firstly, while there is a mention of the Berkeley National Laboratory, there is no mention of the Livermore or Los Alamos National Laboratories. The committee is not sure if that is by design or an oversight.

Secondly, the term Principal Investigator (PI) is not defined and within the USG Policy is defined as "the senior/key person seeking or receiving federal research and development funding (i.e., extramural funding)". It is not clear whether this includes graduate students or post-doctoral fellows who bring in their own funding and, if it does, what their responsibilities would be. If it does not, we suggest this be stated explicitly in the UC policy.

Thirdly, with regard to the processes for code of conduct investigations, this policy may result in a bypassing of Senate processes and an encroachment/enforcement of federal processes in their place. This is very concerning.

CCGA appreciates the opportunity to provide feedback on this proposed policy. Please let me know if you have any questions or require additional information.

#### MEDICAL CENTERS

Santa Cruz

Davis Irvine UCLA San Diego San Francisco

NATIONAL LABORATORIES
Lawrence Berkeley
Lawrence Livermore
Los Alamos

Page 2

Sincerely,

James Bisley Chair, CCGA

cc: Academic Senate Vice Chair Palazoglu Academic Senate Executive Director Lin Academic Senate Assistant Director LaBriola CCGA Members