

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

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NATIONAL LABORATORIES Lawrence Berkeley Lawrence Livermore Los Alamos June 2, 2025

Kevin Confetti Associate Vice President & Chief Risk Officer

Re: Systemwide Senate Review of Proposed New Presidential Policy on High-Containment Research

Dear Associate Vice President Confetti,

As requested, I distributed for systemwide Academic Senate review the proposed new Presidential Policy on High-Containment Research. Nine Academic Senate divisions and two systemwide Senate committees (CCGA and UCORP) submitted comments. These were discussed at the Academic Council's May 28, 2025 meeting, and the compiled feedback is attached for your reference.

Overall, Senate reviewers expressed support for the policy's intent to strengthen biosafety, biosecurity, and regulatory compliance across UC's High-Containment Laboratories (HCLs). There was general agreement that the policy offers a clear framework for managing high-risk biological materials safely and responsibly.

However, several reviewers highlighted concerns about potential administrative and financial burdens, particularly for smaller campuses and those with limited or no HCL activity. They noted that the creation of new roles—such as the High-Containment Laboratory Director (HCLD) and the High-Containment Laboratory Oversight Group (HCLOG)—could duplicate existing biosafety structures. Reviewers emphasized the need for adequate staffing, training, and funding, and recommended that compliance costs, if permissible, be included in research grant budgets rather than borne by campuses. Some also suggested providing compensation or support for faculty and staff serving in oversight roles.

Questions were also raised about the policy's scope—specifically whether it applies to all UC locations or only those with relevant operations. Several reviewers recommended flexibility in implementation or allowing existing biosafety or compliance committees to fulfill oversight responsibilities where appropriate. UCORP expressed concerns about oversight authority in cases where HCLs are owned by outside entities but operated by UC personnel. The San Francisco Senate Division flagged questions about the policy's applicability to affiliate institutions and recommended that it undergo campus-level regulatory review before implementation.

Additional recommendations include adding an organizational chart to clarify roles and reporting lines; developing guidance on classifying highcontainment research and managing shared lab spaces; and establishing an appeals process for classification decisions. CCGA suggested explicitly including students and trainees in relevant policy sections, and the Irvine Senate Division recommended designating alternates for key oversight roles to ensure continuity of high-containment laboratory oversight.

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

Sincerely,

Jan me

Steven W. Cheung Chair, Academic Council

Encl.

cc: Academic Council Executive Director Smith Senate Division Executive Directors Senate Executive Director Lin

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320 STEPHENS HALL UNIVERSITY OF CALIFORNIA

May 16, 2025

STEVEN CHEUNG Chair, Academic Senate

Subject: Systemwide Review of Proposed New Presidential Policy on High-Containment Research

Dear Chair Cheung,

On May 12, 2025, the Divisional Council (DIVCO) discussed the new *Presidential Policy on High-Containment Research*, informed by written comments from the committees on Academic Planning and Resource Allocation (CAPRA) and Research (COR). This cover letter summarizes the committee comments.

This new proposed policy establishes minimum standards for the safe and effective management of high-containment facilities and research activities across the UC system. It outlines responsibilities for various oversight bodies at both campus and systemwide levels, including the requirement for each campus to appoint a High-Containment Laboratory Director (HCLD) and form a High-Containment Laboratory Oversight Group (HCLOG). These groups are tasked with developing and maintaining High-Containment Laboratory (HCL) Programs, ensuring regulatory compliance, and supporting research aligned with UC's mission. The UC systemwide High-Containment Laboratory Oversight Committee (UC HCLOC) coordinates oversight across all locations and prepares regular reports for the UC President. The new policy also requires a campus High-Containment Laboratory Plan that must include the management and operational safety plan for each high-containment facility.

The policy also defines compliance responsibilities, such as with the Biosafety Officer, Animal Care and Use Committee, and Institutional Review Entity. The HCLD oversees aspects of High-Containment Lab operations, while the HCLOG, chaired by a faculty member, must include representatives from key administrative and safety units. Together, they are responsible for risk assessments, biosafety, training, medical surveillance, and emergency management. Each campus submits an annual report to UC HCLOC, which compiles a triennial systemwide review.

DIVCO committee comments expressed a few concerns that include the potential increases in research costs, administrative burdens, and additional bureaucratic layers, especially for campuses like UC Berkeley with limited HCL activity. However, it was unclear whether the proposed policy would, in fact, contribute to these impacts. The policy creates new administrative roles beyond existing safety committees, potentially increasing workload and complexity. CAPRA stresses that the cost of these safety requirements should be incorporated into the direct costs of research grants funding high-containment work to avoid straining campus resources.

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 Dernberg, Chair, Committee on Research Patrick Allen, Senate Analyst, Committee on Research Milo Knight, Senate Analyst, Committee on Academic Planning and Resource Allocation



UNIVERSITY OF CALIFORNIA

May 1, 2025

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

Re: CAPRA comments on the proposed new Presidential Policy on High-Containment Research

The Committee on Academic Planning and Resource Allocation (CAPRA) discussed the proposed new Presidential Policy on High-Containment Research at its meeting on April 30, 2025. This memo addresses issues of academic and physical planning, budget, and resource allocation that emerged through the review process and our discussion, consistent with the charge of CAPRA.

The High-Containment Research Policy sets the minimum standards for the design, construction, operation, maintenance, training, and oversight necessary for the effective management of High-Containment Laboratories. The use of such laboratories is essential to UC's teaching, research, and healthcare mission that aims to facilitate an understanding of pathogens and the diseases they cause. This Policy requires that all High-Containment Research adheres to all relevant regulations and guidelines and provides guidance on how to work safely and protect public health and the environment. Given both the value of High-Containment Research and the seriousness of failures to have proper safety enforces, the participation of faculty and technical personnel as defined in the policy are essential.

The policy defines a number of groups and individuals involved in operation and oversight, both at the campus level and over the whole UC system (which includes LBNL, Agriculture and Natural Resources (ANR), and the Natural Reserve System (NRS)) and establishes their responsibilities.

According to the policy, each campus must have a High-Containment Laboratory Director (HCLD) and a High-Containment Laboratory Oversight Group (HCLOG). Chancellors or equivalent are responsible for forming a HCLOG and designating a HCLD, as well as for establishing a HCL Program and for the overall local implementation of this Policy.

Additionally, a systemwide UC High-Containment Laboratory Oversight Committee (UC HCLOC) provides overall coordination and oversight of High-Containment Laboratory management practices across all the UC campuses and affiliated laboratories.

In addition to the committees just specified that are directly related to HCLs, the policy involves other positions/committees that likely already exist in each campus, such as the Biosafety Officer and Biosafety Committee, the Export Control Officer, the Animal Care and Use Committee, the Institutional Review Entity (IRE, the committee that provides oversight for Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential), and the Official for Select Agents and Toxins. Here, we concentrate on the individual and groups dedicated to High-Containment Research, which constitute additional human resources that need to specifically be created to fulfill this policy.

The Office of Risk Services of UCOP is responsible for providing administrative support to the <u>systemwide</u> UC High-Containment Laboratory Oversight Committee (UC HCLOC). The UC HCLOC itself is responsible for providing oversight of management practices, establishing and reviewing policies and standards, ensuring that all UC Locations receive policies and guidance, and assessing effective implementation of policies across all sites. The UC HCLOC is ultimately responsible for enforcing this Policy. Finally, the UC HCLOC reviews annual UC Location HCLOG reports and prepares a triennial report on High-Containment Laboratory management practices that is submitted to the UC President. It is not clear how this position for each Campus is selected and if it can be occupied by either the HCLD or the chair of the HCLOG, but likely will involve the Office of Risk Services of UCOP. The UC Berkeley representative in this committee will have a significant task that will likely be at par with other UC-wide committee duties.

The HCLD is an administrative official for whom the title may vary at UC Locations, but the responsibilities remain the same: overseeing all aspects of the UC Location High-Containment Laboratory operations and management; developing and maintaining UC Location HCL Plan; coordinating with all other UC Location compliance groups and/or individuals, reviewing proposed research and providing recommendations for High-Containment Research to UC Location compliance committees, such as IBC, IRE and/or IACUC; and maintaining a record of High-Containment Laboratory operations. The staff hours dedicated to this position should be commensurate with the size of the High-Containment Research program at the UC Location, which may be seen as light at UC Berkeley.

The HCLOG must include technical and/or faculty experts and staff responsible for High-Containment Laboratories and Research. It must be chaired by a faculty member and include the HCLD. Additional membership may be drawn from units such as Facilities Management, Environmental Health & Safety, Occupational Health, Police, Finance, Research, Export Control, Information Technology, Planning and Administration. Berkeley may designate an existing committee to serve this function, if it includes representation from the relevant areas as specified. The HCLOG is responsible for: establishing a local HCLOG charter that includes the specific duties of the committee, reviewing their High-Containment Research activities for compliance with this Policy, implementing policies and procedures and halt research when necessary for safety, approving their UC Location HCL Plan, and submitting an annual report to the UC HCLOC. CAPRA anticipates that their task may not be more onerous than that for other campuswide committee duties.

HCLOG together with HCLD will contribute to developing and maintaining a HCL Program, and must solicit stakeholder engagement in both the development and revision processes.

This should establish a sustainable mechanism to support the ongoing operation and maintenance, including procedures for rapid resource distribution during emergencies affecting High-Containment Laboratories. The HCL Program must include: laboratory risk assessments with established review criteria, biosafety, biosecurity, facility operations & maintenance, occupational health requirements, medical surveillance, incident response and reporting, and training. The HCL Plan may be a collection of documents and must collectively contain the required information.

HCLOGs must prepare an annual report to be submitted to the UC HCLOC that summarizes the status of the HCL Program, including information on the HCLD, HCLOG activities, list of RG3 agents and biological materials that are identified to be handled in a High-Containment Laboratory at UC Berkeley, list of new, renovated, operational, inactive, and decommissioned HC Laboratories and their research overview, number of personnel trained by roles identified in the HCL Plan and any incidents

The UC HCLOC reviews the annual HCL Program reports from all locations and prepares a triennial report which summarizes High-Containment Laboratory and Research activities to be submitted to the UC Office of the President.

The work of the HCLOGs to create an HCL Program may be quite involved, even though the work in this area at UC Berkeley is not very significant (two multi-PI labs), CAPRA is concerned that this Program may add another layer of bureaucracy and official positions on top of those related to other safety-dedicated groups and policies, such as the Biosafety Officer and Biosafety Committee, Official for Select Agents and Toxins, the Animal Care and Use Committee, and the Institutional Review Entity, which provides oversight for Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

With the caveat expressed above, but in view both of the value of High-Containment Research and the seriousness of failures to have proper safety control, the participation of faculty and technical personnel as defined in the policy appears essential. On the other hand, CAPRA points out that, given that the cost associated with safety for High-Containment laboratories may be high, CAPRA considers that such costs should be, if they are not already, included in the direct costs of the grants funding this type of research.

Thank you for the opportunity to comment.

With best regards,

En Villeber

J. Miguel Villas-Boas Chair, Committee on Academic Planning and Resource Allocation



Dorothy Hashimoto <dhashimoto@berkeley.edu>

COR Committee comments RE: (Systemwide Senate Review) Proposed New Presidential Policy on High-Containment Research

Patrick G Allen <pgallen@berkeley.edu>

Wed, May 7, 2025 at 3:48 PM noto@berkeley.edu>

To: Jocelyn Surla Banaria <jocelynbanaria@berkeley.edu>, Dorothy Hashimoto <dhashimoto@berkeley.edu> Cc: Abby F Dernburg <afdernburg@berkeley.edu>

Dear Jocelyn and Dory-

COR Chair Dernburg and the Committee, reviewed the *Proposed New Presidential Policy on High-Containment Research*. COR supports the proposed policy. COR expressed a concern about potential increases in research costs and administrative burdens; however, it was unclear whether the proposed policy would, in fact, contribute to these impacts.

Please let me know if you have any questions for COR. Thank you.

Best regards, Patrick

On Mon, Mar 17, 2025 at 11:44 AM Jocelyn Surla Banaria <<u>jocelynbanaria@berkeley.edu</u>> wrote: Dear Professors Dernburg, Villas-Boas, Gilless, and Wallace, – Committee Chairs of COR, CAPRA, and FWEL,

On behalf of Division Chair Amani Nuru-Jeter, committee comments are requested on the proposed new Presidential Policy on High-Containment Research.

Please send committee comments to Dory Hashimoto (dhashimoto@berkeley.edu) and me by Tuesday, May 6, 2025 for discussion at the May 12th DIVCO meeting.

Sincerely, Jocelyn

----- Forwarded message ------

From: Michael LaBriola < Michael.LaBriola@ucop.edu>

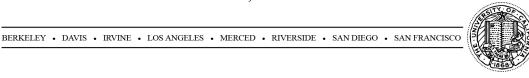
Date: Wed, Mar 12, 2025 at 9:26AM

Subject: (Systemwide Senate Review) Proposed New Presidential Policy on High-Containment Research To: UCACOUN-L@LISTSERV.UCOP.EDU <UCACOUN-L@listserv.ucop.edu>, jenson.wong@ucsf.edu <jenson.wong@ucsf.edu>, valdevit@uci.edu <valdevit@uci.edu>, David Volz <david.volz@ucr.edu>, gailmard@berkeley.edu <gailmard@berkeley.edu>, Robin Nabi <nabi@comm.ucsb.edu>, bngweno@ucdavis.edu <bngweno@ucdavis.edu>, jmleslie@ucmerced.edu <jmleslie@ucmerced.edu>, m1hanna@ucsd.edu <m1hanna@ucsd.edu>, po-ning.chen@ucr.edu <po-ning.chen@ucr.edu>, irenet@uci.edu <irenet@uci.edu> Cc: adestefano@senate.ucla.edu <adestefano@senate.ucla.edu>, cherysa.cortez@ucr.edu <cherysa.cortez@ucr.edu>, emarevalo@ucdavis.edu <emarevalo@ucdavis.edu>, fpaul@ucmerced.edu <fpaul@ucmerced.edu>, jisoo.kim@uci.edu <jisoo.kim@uci.edu>, jocelynbanaria@berkeley.edu <jocelynbanaria@berkeley.edu>, lhullings@ucsd.edu<immednick@ucsc.edu</mmednick@ucsc.edu</mmednick@ucsc.edu>, shasta.delp@senate.ucsb.edu>, Fredye Harms<Fredye.Harms@ucop.edu>, Joanne Miller <Joanne.Miller@ucop.edu>, Kenneth Feer <Kenneth.Feer@ucop.edu>, Stefani Leto <Stefani.Leto@ucop.edu>

CHAIRS OF SENATE DIVISIONS

CHAIRS OF SYSTEMWIDE SENATE COMMITTEES

On behalf of Academic Senate Chair Cheung, I am forwarding for systemwide Senate review a proposed new Presidential Policy on High-Containment Research.



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DAVIS DIVISION OF THE ACADEMIC SENATE ONE SHIELDS AVENUE DAVIS, CALIFORNIA 95616-8502 (530) 752-2220 academicsenate.ucdavis.edu

May 20, 2025

Steven Cheung

Chair, Academic Council

RE: Proposed New Presidential Policy on High-Containment Research

The proposed new Presidential Policy on High-Containment Research was forwarded to all standing committees of the Davis Division of the Academic Senate. Three committees responded: the Faculty Executive Committees of the College of Biological Sciences (CBS), the College of Letters and Science (L&S), and the School of Medicine (SOM).

CBS expresses concern regarding staffing, noting that UC locations may struggle to allocate sufficient resources to the High-Containment Laboratory Director role which requires specialized training. CBS notes that this may lead to uneven policy application across UC locations. SOM supports the proposed Presidential Policy. L&S has no comments.

The Davis Division appreciates the opportunity to comment.

Sincerely,

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Katheryn Niles Russ, Ph.D. Chair, Davis Division of the Academic Senate Professor of Economics University of California, Davis

Enclosed: Davis Division Committee Responses

c: Monica Lin, Executive Director, Systemwide Academic Senate Michael LaBriola, Assistant Director, Systemwide Academic Senate Edwin M. Arevalo, Executive Director, Davis Division of the Academic Senate

Proposed New Presidential Policy on High-Containment Research

FEC: College of Biological Sciences Committee Response

May 14, 2025

The CBS FEC has reviewed and discussed the RFC Proposed New Presidential Policy on High-Containment Research and had one concern regarding staffing. The HCLD role requires specialized training, but UC locations may struggle to allocate sufficient resources, especially smaller campuses. US GAO has previously highlighted understaffing as a systemic issue in lab oversight. Inconsistent Local Enforcement: Variability in HCLOG composition (e.g., faculty expertise, stakeholder representation) could lead to uneven policy application across UC locations.

Proposed New Presidential Policy on High-Containment Research

FEC: School of Medicine Committee Response

May 14, 2025

The SOM Committee on Research Affairs reviewed this proposal on behalf of the SOM FEC. It is supported. A parallel effort is underway, lead by Dr. Hamed Pirsiavash from the Computer Science department, to apply for Department of Defense funding to enhance GPU clusters for research at UCD main and health campuses, and for teaching.



307 Aldrich Hall Irvine, CA 92697-1325 senate@uci.edu www.senate.uci.edu

May 7, 2025

Steven Cheung, Chair Academic Council

Re: Proposed Presidential Policy on High-Containment Research

The Irvine Division Cabinet discussed the proposed Presidential Policy on High-Containment Research at its meeting on May 6, 2025. The Council on Planning and Budget (CPB) and Council on Research, Computing, and Libraries (CORCL) also reviewed the policy. The councils' feedback is attached for your review.

The Irvine Division appreciates the opportunity to comment.

Sincerely,

Vale

Valerie Jenness, Chair Academic Senate, Irvine Division

Cc: Jane Stoever, Chair Elect-Secretary Jisoo Kim, Executive Director Gina Anzivino, Associate Director



April 28, 2025

VALERIE JENNESS, CHAIR ACADEMIC SENATE, IRVINE DIVISION

RE: Presidential Policy on High-Containment Research

At its April 17, 2025 meeting, the Council on Research, Computing, and Libraries (CORCL) discussed the proposed Presidential Policy on High-Containment Research.

The proposed policy aims to enhance consistency, accountability, and safety across all UC highcontainment research activities. CORCL noted that it effectively defines its scope, policies, responsibilities, and procedures in a clear and reasonable manner. Applying to all high-containment facilities and research activities at University-owned and/or operated locations, the policy establishes a comprehensive framework for oversight, safety, and accountability in high-containment research. It addresses the following key issues:

- Formalization of the authority of the UC High-Containment Laboratory Oversight Committee (UC HCLOC), solidifying its role in ensuring compliance with safety standards, regulatory requirements, and best practices across UC's high-containment laboratories
- Outline of the essential components of a High-Containment Research Program, which include a local High-Containment Laboratory Oversight Group responsible for site-specific governance and compliance, a designated High-Containment Laboratory Director tasked with overseeing daily operations and safety protocols, and a High-Containment Laboratory Plan that serves as a detailed management and operational safety guide for each facility.

CORCL offers the following recommendations:

- 1. To maintain continuity and ensure compliance with NIH Guidelines, it is highly recommended that each UC location designate an alternate administrative official for the role of Biosafety Officer or/and High-Containment Laboratory Director (HCLD) to oversee recombinant or synthetic nucleic acid molecule research in High-Containment Laboratories if the primary responsible individual is unavailable.
- 2. A hierarchical organizational chart (or reporting flow chart) can help clarify the roles, responsibilities, and reporting structures among the personnel, groups, and committees involved in overseeing high-containment research.

On behalf of the Council,

qweath

James Weatherall, Chair

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



April 25, 2025

VAL JENNESS, CHAIR ACADEMIC SENATE, IRVINE DIVISION

RE: Proposed Presidential Policy on High-Containment Research

At its April 9, 2025 meeting, the Council on Planning and Budget (CPB) discussed the proposed Presidential Policy on High-Containment Research.

The proposed policy applies to all high-containment facilities and research activities at all University owned and/or operated locations. It formalizes the authority of the UC High-Containment Laboratory Oversight Committee and identifies the required elements of a High-Containment Research Program the local High-Containment Laboratory Oversight Group (HCLOG), the designated High-Containment Laboratory Director, and the High-Containment Laboratory Plan, which details the management and operational safety plan for each high-containment facility.

CPB observed that the policy involves multiple administrative roles including a director of HCDP and a faculty who chairs HCLOG, among other entities. Facilities will also have a role in the HCLOG committee. However, it is unclear whether these positions already exist or need to be created. Given the current hiring freeze, information on the resources needed for this initiative, including estimated costs, is needed.

Furthermore, CPB recommends that future proposed policies include information on budget implications in their review materials. Without this critical financial context, the Council is unable to provide a meaningful evaluation of the proposals.

On behalf of the Council,

Alyssa a. Brewer

Alyssa Brewer, Chair Council on Planning and Budget

CC: Jisoo Kim, Executive Director Gina Anzivino, Associate Director Michelle Chen, CPB Analyst



UCLA Academic Senate Executive Board

May 8, 2025

Steven Cheung Chair, UC Academic Senate

Re: (Systemwide Senate Review) Proposed New Presidential Policy on High-Containment Research

Dear Chair Cheung,

The divisional Executive Board (EB) reviewed the Proposed New Presidential Policy on High-Containment Research and divisional council feedback at its meeting on May 8, 2025. Members advised that when individual campuses develop plans to implement the new policy, they should consult with the faculty who will be most affected by the implementation in order to do so in a way that supports their research.

Thank you for the opportunity to advise on this matter.

Sincerely,

KBain

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

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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

May 9, 2025

To: Steven Cheung, Chair, Academic Council

From: UCM Divisional Council (DivCo)

Re: <u>New Presidential Policy on High-Containment Research</u>

The proposed Presidential Policy on High-Containment Research 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)
- School of Natural Sciences Executive Committee (NSEC)

CoR notes that this policy sets systemwide standards for the operation and oversight of High-Containment Laboratories (HCLs) at UC locations. By setting clear requirements for safe handling of high-risk biological agents, including RG3 materials, the policy strengthens research safety and compliance. CoR particularly appreciates the structured approach to oversight, including the creation of a UC-wide committee and local High-Containment Laboratory Oversight Committees (HCLOG), as well as mandates for qualified personnel and comprehensive management plans. However, CoR also notes that smaller campuses such as UCM may face resource and staffing challenges in meeting the policy's demands. Importantly, the policy provides flexibility by allowing existing institutional biosafety committees or similar bodies to fulfill oversight responsibilities, provided they possess the requisite expertise. This pragmatic approach will be critical for successful implementation at resource-limited campuses.

CRE confirms that a UCM Natural Sciences faculty is currently serving as both the faculty chair and representative for the systemwide HCLOG, meeting the policy requirement. Additionally, the campus has recently appointed a High-Containment Laboratory Director, futher aligning with policy expectations. At present, the only planned HCR Level 3 lab is in the BSP Building, though it is not yet operational. CRE also noted a minor typo on page 8 of the draft policy (an extraneous period), which should be corrected in the final version. The **NSEC** affirms that faculty in Molecular and Cell Biology Department are the primary stakeholders in the proposed policy. The NSEC views the policy as a well-structured and much-needed framework that will support the School's growing emphasis on infectious disease research. By clarifying governance roles, enhancing oversight mechanisms, and improving institutional accountability, the policy offers a strong foundation to safely advance high-containment research at UCM. Moreover, it provides a timely opportunity to resolve longstanding barriers to activating the campus's BSL-3 facility. Active engagement in the policy implementation process will further empower faculty to advocate for necessary resources and advance the campus's growth in high-containment research.

DivCo discussed this policy during its May 6 meeting and supports the committees' various points and suggestions.

We thank you for the opportunity to review this policy.

Cc: DivCo Members NSEC Chair Manilay UCM Senate Office Monica Lin, Executive Director, Systemwide Senate Office Michael LaBriola, Assistant Director, Systemwide Senate Office

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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

April 25, 2025

To: Kevin Mitchell, Senate Chair

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

Re: Presidential Policy on High-Containment Research

CoR reviewed the Presidential Policy on High-Containment Research and offers the following comments.

This policy establishes system-wide standards for High-Containment Laboratories across UC locations. It ensures safe and secure research involving Risk Group 3 (RG3) infectious materials and other high-risk biological agents in compliance with laws and regulations. The policy requires the establishment of a system-wide oversight committee. The policy also requires each of the UC locations to establish a High-Containment Laboratory Oversight Group (HCLOG), appoint a qualified HCLD, and develop a High-Containment Laboratory Management Plan (HCL Plan). The policy also clarifies the responsibilities of involved individuals and units. A potential challenge for a smaller campus such as UC Merced is to find enough people with required expertise to serve on multiple biosafety-related committees, including HCLOG, IBC, IRE, and IACUC. The policy allows UC Locations to designate an existing committee to serve this function if the committee has the required representation of expertise. This could be a more practical option for UC Merced.

Overall, this is a clear and reasonable policy that is needed to mitigate the risks involved in BSL-3 research.

We appreciate the opportunity to opine.

cc: Senate Office

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

April 21, 2025

То:	Kevin Mitchell, Chair, Divisional Council
From:	Committee on Rules and Elections (CRE)
Re:	Proposed New Presidential Policy on High-Containment Research

The Committee on Rules and Elections (CRE) has reviewed the Proposed New Presidential Policy on High-Containment Research, and offer the following comments.

The Presidential Policy on High-Containment Research (HCR) was solicited in 2022 "to formalize the elements of UC high-containment research programs to support this vital work in a manner that maintains the health and safety of UC faculty". As a result, this proposed new systemwide policy "sets the minimum standards for the design, construction, operation, maintenance, training, and oversight of these [HCR] laboratories."

In consultation with the UC Merced Interim Director of Environmental Health & Safety, it was confirmed that Professor Katrina Hoyer (Molecular & Cell Biology) is the UC Merced chair and representative for the systemwide <u>UC High-Containment Laboratory Oversight Committee</u>, which satisfies the requirement that a faculty member chair that committee. Also, the UC Merced High Containment Laboratory Director position has recently been filled. Moreover, it is noted that the Biomedical Sciences and Physics (BSP) Building is the only planned campus laboratory to operate at HCR Level 3, but that it is not presently operational.

CRE would like to point out a typo on page 8 of the proposed new systemwide policy, where there is an extra period: "A faculty member must chair the HCLOG..".

We thank you for the opportunity to review and comment.

CC: CRE Members Senate Office From: Jennifer Manilay <jmanilay@ucmerced.edu>
Sent: Thursday, April 24, 2025 8:24 PM
Subject: RE: [Systemwide Senate Review] Proposed New Presidential Policy on High-Containment Research - Deadline for Comments: Friday, April 25, 2025

Dear Fatima and Kevin:

NSEC has reviewed the Proposed New Presidential Policy on High-Containment Research. Given the nature of the research involved, we identified the Molecular and Cell Biology (MCB) faculty within the School of Natural Sciences as the primary stakeholders. Accordingly, NSEC's feedback is primarily focused on aspects relevant to MCB.

The proposed UC Presidential Policy on High-Containment Research offers UC Merced a valuable framework for advancing our biosafety goals, particularly supporting the MCB Department's efforts to expand research capacity in infectious diseases. This policy clearly defines roles, enhances oversight through campus-level committees, and establishes systematic reporting to strengthen accountability and safety across all UC campuses. For UC Merced, these guidelines present an excellent opportunity to address longstanding challenges with activating our Biosafety Level 3 (BSL-3) facility by providing clear pathways and resources to facilitate high-containment research. Engaging actively in the current systemwide review will enable our faculty, especially those in MCB, to highlight specific research needs and advocate effectively for necessary support, ultimately contributing to UC Merced's growth as a center of excellence in infectious disease research.

Thank you for the opportunity to comment.

Sincerely,

Jennifer O. Manilay, PhD (pronounced mah-NEE-lie, sounds like "money-lie") Professor, Dept. of Molecular and Cell Biology Chair, Natural Sciences Executive Committee AY-24-25 School of Natural Sciences University of California, Merced jmanilay@ucmerced.edu

Pronouns: she/her/hers

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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

May 16, 2025

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

RE: Proposed New Presidential Policy on High-Containment Research

Dear Steven,

On May 12, 2025 the Riverside Academic Senate Executive Council discussed the *Proposed New Presidential Policy on High-Containment Research* along with comments received from divisional committees and had no comments to add to those from responding committees.

As you'll find from the attached memos, comments are generally supportive of the proposed policy.

Sincerely yours,

Kennett. Bar

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



PHYSICAL RESOURCES PLANNING

April 30, 2025

To: Kenneth Barish, Chair, Academic Senate Elizabeth Watkins. Provost and Executive Vice Chancellor

From: Brian Siana, Physical Resources Planning Committee Chair

Re: [Systemwide Review] (Proposed Policy) Proposed New Presidential Policy on High-Containment Research

The Physical Resources Planning Committee reviewed the March 2025 [Systemwide Review] (Proposed Policy) Proposed New Presidential Policy on High-Containment Research document that will formalize the elements of the high-containment research programs across the UC system. The Committee agrees that risk assessment for such high-risk research is most appropriately assessed by individuals outside of the laboratory, though policy implementation impacts are unclear. It is advisable for the UCR Environmental Health & Safety unit to utilize currently utilized infrastructure to carry out this new policy, though the number of labs at UCR fitting policy criteria for will likely determine the application effects on this campus. Committee expectation is that this policy will impact personnel requirements instead of space requirements for implementation.



May 6th, 2025

TO: Kenneth N. Barish, Ph.D., Chair, Academic Senate, UCR Division

FROM: Harry Tom, Ph.D., Chair, Faculty Executive Committee, College of Natural and Agricultural Sciences

SUBJECT: [Systemwide Review] Proposed Policy: Proposed New Presidential Policy on High-Containment Research

Prof. Barish,

The CNAS FEC has reviewed the proposed changes. After consulting with the potential impacted departments, they feel the changes are reasonable and have no objections.

Sincerely,

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Harry Tom, Ph.D Chair, Faculty Executive Committee, College of Natural and Agricultural Sciences



Academic Senate

Committee on Research

April 30, 2025

- To: Kenneth Barish, Chair Riverside Division
- From: Rachel Wu, Chair Committee on Research

Re: Proposed New Presidential Policy on High-Containment Research

The committee on research reviewed the policy and believe the policy is a good idea to help harmonize the discrepancies between similar facilities.



April 28, 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] Proposed Policy: Proposed New Presidential Policy on High-Containment Research

Dear Ken,

The Committee reviewed the Proposed New Presidential Policy on High-Containment Research.

The FEC concluded that it supports the policy and had no additional comments.

Yours sincerely,

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

UNIVERSITY OF CALIFORNIA, SAN DIEGO

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OFFICE OF THE ACADEMIC SENATE

May 16, 2025

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

Re: Divisional Review of Proposed Presidential Policy on High-Containment Research

Dear Chair Cheung,

The proposed Presidential Policy on High-Containment Research was distributed to San Diego Divisional Senate standing committees and discussed at the May 12, 2025 Divisional Senate Council meeting. Senate Council had questions that they would like to see addressed prior to the policy being implemented. Council offered the following comments for consideration.

Reviewers did not identify any major concerns with the proposed policy but raised several questions regarding the classification of high-containment research and the responsibilities associated with monitoring and tracking such activities. Further clarification is needed on the High-Containment Laboratory Director (HCLD) role, including how this position will be funded, what the consequences are for not filling this role, and what resources will be provided to support the role's responsibilities. It was unclear if the establishment of the HCLD role would be at a cost to Principal Investigators or be funded by some other mechanism. Additionally, the classification criteria for high-containment research should be more clearly defined and include ways to identify at an early stage whether proposed research falls into the category or not. A clear process should also be established for Principal Investigators to appeal decisions regarding the classification of their research if they disagree with it. Moreover, the policy lacks guidance on how to enforce standards in shared laboratory spaces where multiple researchers and Principal Investigators are working together, which poses a challenge for ensuring compliance and safety in these collaborative environments.

The response from the Divisional Committee on Research is attached.

Sincerely,

Olivia bruve

Olivia A. Graeve 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



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UCSD

April 30, 2025

OLIVIA GRAEVE, Chair Academic Senate, San Diego Division

SUBJECT: Proposed Presidential Policy on High-Containment Research

The Committee on Research (COR) discussed the Proposed Presidential Policy on High-Containment Research at their April 21, 2025 meeting. The Committee saw no issues with the proposed policy, but had questions on more granular details about the classification of highcontainment research and the duties involved with tracking this. Their questions and comments are listed below:

High-Containment Laboratory Director role

- 1. The Committee would like to see specific language on what the High-Containment Laboratory Director (HCLD) will be in charge of keeping track of or enforcing.
- 2. Will the role of HCLD be established at a cost to PIs, or will the role be funded by some other mechanism?
- 3. What would the mechanism be for the HCLD to track and deal with issues of high-containment research when they arise?
- 4. What are the consequences of not fulfilling the HCLD role?

Classification of research

- 1. Will there be a way to determine at an early stage whether proposed research falls into the category of high-containment research?
- 2. Will there be an appeal process if a Principal Investigator's (PI's) research is deemed to be high-containment research, but the PI feels their research does not meet the criteria for high-containment research?

Shared laboratory spaces

1. In instances of shared lab spaces, responsibility may be delegated to one person even though there are multiple groups of researchers conducting different research. What will the liability be given the complexity of shared spaces with multiple PIs performing very distinct and unique research?

We thank you for the opportunity to respond to the Proposed Presidential Policy on High-Containment Research.

Sincerely yours,

Julie Burelle, Chair Committee on Research

cc: J. Coomer L. Hullings R. Plant



http://senate.ucsf.edu

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 May 21, 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: Systemwide Review of Proposed New Presidential Policy on High Containment Research

Dear Chair Cheung:

The San Francisco Division of the Academic Senate is pleased to comment on the proposed new Presidential Policy on High Containment Research. The UCSF Committee on Rules and Jurisdiction (R&J) has reviewed the proposed policy and acknowledges the importance of establishing comprehensive biosafety and biosecurity practices for effectively managing High-Containment Laboratories. This policy is crucial for ensuring safe research activities that protect public health and the environment while complying with relevant regulations and guidelines.

R&J has identified a couple of areas where the policy could benefit from further revision:

- Campus-Level Regulatory Review: R&J recommends that the policy undergo review by pertinent regulatory entities at UCSF. Currently, the stakeholders involved in the development of this policy appear to be exclusively at the UC systemwide level, suggesting that campus-level regulatory bodies were not consulted. It is crucial for campus-level stakeholders to examine this policy to ensure its alignment with existing campus-level systems and practices.
- 2. Applicability to Affiliates: R&J expressed concerns regarding the applicability of the policy to affiliates such as the San Francisco Veterans Affairs Medical Center and San Francisco General Hospital. The policy text in section III.D. stipulates, "Non-UC personnel who work in or visit UC High-Containment Laboratories must comply with all UC policies and standards." However, there is ambiguity concerning which policies would take precedence in the event of a conflict with the regulations of affiliate sites. Clarification is needed to determine which policies would take precedence and how potential conflicts would be managed.

Thank you for considering the comments provided by R&J. We believe that addressing these points will enhance the effectiveness and clarity of the policy.

Sincerely,

Steven Hetts, MD, 2023-25 Chair UCSF Academic Senate

Enclosures (1) Cc: Irfan Kathiriya, MD, PhD, Chair, Rules & Jurisdiction



Committee on Rules and Jurisdiction (R&J) Irfan Kathiriya, MD, PhD, Chair

May 21, 2025

Steven Hetts, MD Division Chair UCSF Academic Senate

Re: Systemwide Review of Proposed New Presidential Policy on High-Containment Research

Dear Chair Hetts:

The Committee on Rules and Jurisdiction (R&J) writes to comment on the <u>Systemwide Review of</u> <u>Proposed New Presidential Policy on High-Containment Research</u>. R&J acknowledges the need for a University of California (UC) policy that establishes necessary biosafety and biosecurity practices to manage these High-Containment Laboratories effectively, ensuring safe research activities that protect public health and the environment while complying with relevant regulations and guidelines. In reviewing this policy, R&J identified a couple of areas that could use some revision.

First, R&J recommends that this policy undergo review by the pertinent regulatory entities at UCSF. At present, the stakeholders involved in the development of this policy are exclusively at the UC level, suggesting that campus-level regulatory bodies were not consulted. R&J asserts that it is crucial for campus-level stakeholders to examine this policy to ensure its alignment with the current campus-level systems and practices.

Second, R&J expressed concerns regarding the applicability of the policy to affiliates such as the San Francisco Veterans Affairs Medical Center and San Francisco General Hospital. Specifically, we questioned whether the policy might conflict with the local regulations of these affiliates, which have their own regulatory bodies. The policy text in section III.D. stipulates, "Non-UC personnel who work in or visit UC High-Containment Laboratories must comply with all UC policies and standards." However, there is ambiguity concerning which policies would take precedence in the event of a conflict with the regulations of affiliate sites.

Thank you for taking the time to review R&J's comments. Please contact me or our committee's analyst, Sophia Root (Sophia.root@ucsf.edu), if there are questions.

Sincerely,

Irfan Kathiriya, MD, PhD Committee on Rules and Jurisdiction Chair



UC SANTA BARBARA

Academic Senate Rita Raley, Chair Shasta Delp, Executive Director

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

May 20, 2025

To: Steven Cheung, Chair Academic Senate

From: Rita Raley, Divisional Chair Academic Senate

Re: Proposed New Presidential Policy on High Containment Research

The Santa Barbara Division distributed the Proposed New Presidential Policy on High Containment Research to the Council on Planning and Budget (CPB), Committee on Research Policy and Procedures (CRPP), and the Faculty Executive Committees (FECs) of the College of Letters and Science (L&S), College of Engineering (COE), College of Creative Studies (CCS), Bren School of Environmental Science and Management (BREN), and Gevirtz Graduate School of Education (EDUC). CPB, and the L&S, CCS, BREN, and GGSE FECs opted not to opine.

The comments from CRPP and the COE FEC are attached for your review and consideration.

We thank you for the opportunity to comment.

CC: Monica Lin, Executive Director, Systemwide Academic Senate Shasta Delp, Executive Director, Santa Barbara Division

Academic Senate Santa Barbara Division

May 12, 2025

To: Rita Raley, Divisional Chair Academic Senate

Segla . Han

From: Stephanie Malia Hom, Chair Committee on Research Policy and Procedures

Re: Proposed New Presidential Policy on High-Containment Research

At its meeting of May 9, 2025, the Committee on Research Policy and Procedures (CRPP) discussed the proposed new Presidential Policy on High Containment Research. CRPP supports seeing a revised policy that specifies that this would only apply to campuses with Biosafety-Level 3 (BSL-3) facilities. Implementing this policy at all UC locations, including those without BSL-3 facilities, will place an undue burden on faculty and staff to manage.

CC: Shasta Delp, Executive Director, Academic Senate

May 13, 2025

TO:

Rita Raley Divisional Chair, Academic Senate

FROM: Carl Meinhart, College of Engineering, Faculty Executive Committee

RE: Proposed New Presidential Policy on High-Containment Research

The College of Engineering FEC met on Monday, May 5th and reviewed the Proposed New Presidential Policy on High-Containment Research.

Signed by:

While there is currently no BSL-3 research being conducted at UCSB, it remains a possibility that such research could be undertaken in the future. In light of this potential and considering the broader implications for all UC campuses, committee members with relevant expertise provided an overview of the nature of BSL-3 research and the proposed policy amendments. The members expressed support for the proposed changes, commending the policy for enhancing comprehensibility and clarity compared to previous versions.



Academic Senate	COORDINATING COMMITTEE ON GRADUATE AFFAIRS
Office of the President	James Bisley, Chair
1111 Franklin Street	jbisley@mednet.ucla.edu
Oakland, CA 94607	
senate.universityofcalifornia.edu	May 2, 2025
_	
CAMPUSES	Steven W. Cheung
Berkeley	Academic Senate Chair
Davis	
Irvine	RE: Proposed Presidential Policy on High-Containment Research
UCLA	
Merced	Dear Chair Cheung,
Riverside	Dear Onan Oneang,
San Diego	
San Francisco	At its April 9 meeting, CCGA discussed the new proposed Presidential
Santa Barbara	Policy on High-Containment Research.
Santa Cruz	
MEDICAL CENTERS	In several places, the policy refers to staff who use High-Containment
Davis	Laboratories, but it does not refer to trainees or students, who are typically
Irvine	not considered to be staff. We recommend that trainees and/or students
UCLA	are called out in sections 4.K.d and 4.L.b.
San Diego	
San Francisco	Thank you for allowing CCGA to weigh in on this matter. Please feel free to
NATIONAL LABORATORIES	contact me if you have any questions.
Lawrence Berkeley	
Lawrence Livermore	Sincerely,
Los Alamos	Shule

James Bisley Chair, CCGA

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



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Academic Senate	UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP) Susanne B. Nicholas
Office of the President	Email: sunicholas@mednet.ucla.edu
1111 Franklin Street	
Oakland, CA 94607	May 21, 2025
senate.universityofcalifornia.edu	STEVEN CHEUNG
	CHAIR, ACADEMIC COUNCIL
CAMPUSES	RE: Proposed New Presidential Policy on High-Containment Research
Berkeley	
Davis	Dear Chair Cheung,
Irvine	
UCLA	UCORP appreciates this effort to align governance and operations of High
Merced	Containment Labs (HCL) across the UC system. UCORP members
Riverside	acknowledge the importance of HCL research and heightened scrutiny by
San Diego	federal agencies; the new policy provides reasonable guidelines that
San Francisco	ensure compliance with federal regulations and minimize risks. With
Santa Barbara	discrepancies in how similar facilities at UC locations are operated, a
Santa Cruz	standardized framework will be beneficial. Because some HCLs may be
	-
MEDICAL CENTERS	owned by an outside entity and operated by the campus, there is concern
Davis	about authority for operation and maintenance responsibilities assigned
Irvine	to an oversight group and director. This will need to be worked out.
UCLA See Diego	
San Diego San Francisco	The policy is unclear regarding whether the directives apply to each "UC
	Location" or just those with the high containment facilities. While the
NATIONAL LABORATORIES	Scope is: "University-owned, -operated and/or leased locations," the first
Lawrence Berkeley	sentence of the policy text is: "Each UC Location must implement a HCL
Lawrence Livermore	Program." If the policy applies to <i>all</i> UC locations, this will create an
Los Alamos	undue and unnecessary administrative burden for those locations that do not have HCL facilities. Further, for campuses <i>with</i> BSL-3 labs, UCORP members wanted to know if there would be additional compensation for

Thank you for the opportunity to comment on this proposed policy.

members of the new oversight committee, staff, and faculty director for

Sincerely,

Susanne B. Nicholas Chair, University Committee on Research Policy

taking on this extra administrative work.