UNIVERSITY OF CALIFORNIA, ACADEMIC SENATE

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James Steintrager Telephone:(510) 987-9983 Email: james.steintrager@ucop.edu Chair of the Assembly of the Academic Senate Faculty Representative to the Regents University of California 1111 Franklin Street, 12th Floor Oakland, California 94607-5200

April 4, 2024

KEVIN CONFETTI ASSOCIATE VICE PRESIDENT & CHIEF RISK OFFICER

Re: Proposed Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

Dear Associate Vice President Confetti:

As requested, I distributed for systemwide Academic Senate review the proposed revisions to Presidential Policy BFB-BUS-50 (Controlled Substances Use in Research and Teaching). All ten Senate divisions and two systemwide committees (UCORP and UCFW) submitted comments. These were discussed at the Academic Council's March 27 meeting and are attached for your reference.

The proposed revisions aim to clarify UC's compliance standards around federal and state laws governing the use of controlled substances in research and teaching, including regulations pertaining to the acquisition, maintenance, storage, use, and disposal of controlled substances. We understand that the policy does not extend to the use of controlled substances in patient care settings, except to outline the responsible units and positions involved in such activities.

Overall, there is general support for the policy as a framework for navigating the complexities associated with using controlled substances for research and teaching. The revisions are seen to enhance the policy's clarity, scope, delineation of responsibilities, and procedures related to compliance with relevant laws and regulations. Reviewers appreciate the policy's adaptability to the specific needs of each location.

Reviewers also identified several areas where further clarification is needed. In particular, we encourage you to consider the comments made by the Merced and San Francisco divisions and by UCFW. Several of these concerns are summarized below:

1. Clarification of protocols for monitoring and securing controlled substances in a Principal Investigator's lab or a shared lab setting, and for maintaining "strict control over inventory and security of Controlled Substances."

- 2. Accountability standards for investigators and Controlled Substances Program Officers (CSPOs), including the CSPO's role in placing orders for controlled substances and the expected approval timeframes.
- 3. Expectations for researchers who collaborate with individuals in foreign countries with varying controlled substances policies.
- 4. Clarification of whether individual faculty are permitted to obtain a Schedule II-V controlled substances license; permissible activities under campus Schedule II-V policies; and the intermingling of controlled substances covered under a campus Drug Enforcement Administration (DEA) registration with those covered under an individual DEA registration.
- 5. The policy's applicability to clinical care.

Furthermore, reviewers emphasized the need for campus-based education and training to ensure that faculty and staff who work closely in this area understand the policy and receive accessible and regularly updated lists of controlled substances. In addition, faculty involved in research using controlled substances should have an opportunity to review the final policy before its implementation to ensure it does not hinder their scholarly pursuits. Finally, the Senate believes it will be important to implement the revised policy in a way that does not strain campus resources or overly burden faculty researchers and staff.

The Council appreciates the opportunity to comment. Please do not hesitate to contact me if you have additional questions.

Sincerely,

James Steintrager, Chair

Academic Council

Cc: Academic Council

Executive Director Smith, Environment, Health & Safety Vice Provost for Academic Policy and Programs Haynes

Senate Division Executive Directors Senate Executive Director Lin

Encl:



March 18, 2024

JAMES STEINTRAGER Chair, Academic Council

Subject – Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Chair Steintrager:

On March 4, 2024, the Council of the Berkeley Division (DIVCO) discussed the proposed revisions to the *Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching*, informed by written comments from the Committee on Research (COR). DIVCO endorsed the attached comments in full. Please see attached.

The proposed revisions enforce more regulations regarding controlled substances used in research and teaching. DIVCO is in favor of the revisions since some regulations in this area have been relaxed. Some members expressed concern that the revised policy will create more burden for faculty researchers. We strongly encourage to not increase undue burdens. Other members pointed out that this policy seemed to focus only on clinical settings, and asked that environment and non-medical research can be addressed.

Sincerely,

Maximilian Auffhammer, Avice M. Saint Professor

Professor of Agricultural & Resource Economics/Political Economy (ARE/PE)

Chair, Berkeley Division of the Academic Senate

Enclosure

cc: Amani Nuru-Jeter, Vice Chair, Berkeley Division of the Academic Senate Jocelyn Surla Banaria, Executive Director Lia Fernald, Chair, Committee on Research Patrick Allen, Senate Analyst, Committees on Research



February 27, 2024

CHAIR MAXIMILIAN AUFFHAMMER

Academic Senate

Re: Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Chair Auffhammer,

During our meeting held on February 8, 2024, the Committee on Research (COR) reviewed the proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching. COR extended an invitation to Professor Gül Dölen from the Department of Psychology, Berkeley Center for the Science of Psychedelics, and the Helen Wills Neuroscience Institute to discuss and share her insights on the policy due to her research in this area. Professor Dölen noted that the newer document's verbiage is concise, and she appreciated the adaptability of the UC policy to suit the specific research needs at each location.

COR supports enhancing the efficiency and transparency of the Campus Controlled Substances Programs by clarifying the detailed scope of duties assigned to Controlled Substances Program Officers. This clarification will contribute to a more streamlined and effective execution of responsibilities within the program. Additionally, defining the Campus Designation form of Drug Enforcement Agency (DEA) Registration and addressing specific requirements for other DEA Registrations, such as individual schedule I DEA Registrations, will foster a comprehensive understanding of registration processes.

COR also believes that offering additional guidance on the import, export, interstate, and intrastate use, transfer, and transport of Controlled Substances, along with Controlled Substances Analogues and DEA-exempt chemical preparations, is crucial for ensuring compliance and preventing misuse. Overall, COR supports this policy as currently written and understands the necessity of the policy; however, COR supports seeking less burdensome rules if and when possible.

Thank you for the opportunity to review this document.

Sincerely,

Lia Fernald, Chair Committee on Research

Groferall

LF/pga



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

March 11, 2024

James Steintrager

Chair, Academic Council

RE: Proposed Revisions Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

The proposed revisions to Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching were forwarded to all standing committees of the Davis Division of the Academic Senate. Eight committees responded: Graduate Council (GC), Research (COR), and the Faculty Executive Committees of the College of Biological Sciences (CBS), College of Engineering (COE), the College of Letters and Sciences (L&S), the School of Education (SOE), the School of Medicine (SOM), and the School of Nursing (SON).

Committees support the proposed revisions. GC note that the clarity of the policy has been improved, however, it is difficult to determine whether the proposed revisions would increase faculty workload. COR and SOM provide three suggestions for the policyholders to consider: 1) adding "clinical" to the title to encompass all parties referenced in the policy; 2) including "Controlled Substance Analogues" in the "Scope" statement on the first page of the policy; and, 3) providing a summary of the policy with key points for those working in this field.

The Davis Division appreciates the opportunity to comment.

Sincerely,

Ahmet Palazoglu

Chair, Davis Division of the Academic Senate Distinguished Professor of Chemical Engineering 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

March 8, 2024

Ahmet Palazoglu

Chair, Davis Division of the Academic Senate

RE: Request for Consultation on the Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

Dear Ahmet:

The Committee on Research (COR) has reviewed the Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching. We note the following items to consider:

- A suggested change to the 'scope' statement on the first page, which suggests including 'controlled substance analogues' as defined on page 3. It is worth noting that there is no consideration of the substance amounts, which means that no exception will be made for people who use these substances for analytical purposes only.
- It would be helpful to provide a summary with key points for those working in this field.

Sincerely,

Paul D. Hastings

Chair, Committee on Research

February 23, 2024

Ahmet Palazoglu

Chair, Davis Division of the Academic Senate

RE: Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

As delegated by Graduate Council, the Academic Planning and Development (APD) Subcommittee has reviewed and discussed the proposed revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching. The proposed revisions improve the clarity of the policy and do not appear to substantively change the policy itself. Although the clarity of the policy has been improved, it was still difficult for APD to determine whether these revisions would increase faculty workload, which would be the committee's main concern.

Many thanks for the opportunity to review and comment.

Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

FEC: School of Medicine Committee Response

March 8, 2024

Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

- FEC members reviewed and discussed this item on February 28
- The committee suggested adding "clinical" in the title to encompass all the parties referenced in the document.

Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

FEC: College of Biological Sciences Committee Response

March 8, 2024

We have no comments and no concerns.

Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

FEC: College of Engineering Committee Response

March 8, 2024

COE FEC has no objections

Proposed Revisions to the Presidential Policy BFB-BUS-50, Controlled Substance Use in Research and Teaching

FEC: School of Nursing Committee Response

March 8, 2024

The SON FEC has no objection on the proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching.





March 20, 2024

Jim Steintrager, Chair Academic Council

Re: Proposed Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Chair Steintrager,

The Irvine Division Cabinet discussed the proposed revisions to Presidential Policy BFB-BUS-50 at its meeting on March 19, 2024. The Council on Teaching, Learning, and Student Experience (CTLSE) and Council on Research, Computing, and Libraries (CORCL) also reviewed the proposed revisions. The committees' comments are attached for your review.

The Irvine Division appreciates the opportunity to comment.

Sincerely,

Arvind Rajaraman, Chair

Academic Senate, Irvine Division

Enclosures: CTLSE & CORCL memos

Cc: Valerie Jenness, Chair Elect

Jisoo Kim, Executive Director Gina Anzivino, Associate Director





Academic Senate Council on Research, Computing & Libraries 307 Aldrich Hall Irvine, CA 92697-1325 (949) 824-7685 www.senate.uci.edu

March 4, 2024

ARVIND RAJARAMAN, CHAIR ACADEMIC SENATE, IRVINE DIVISION

RE: Proposed Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

At its meeting on February 15, 2024 meeting the Council on Research, Computing, and Libraries (CORCL) discussed the proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching.

Overall, the Council found that the proposed revisions to be reasonable. The revisions clearly define the scope, policy, responsibilities, and procedures.

One recommendation is to clarify whether it is permissible for any individual with a personal DEA registration for research purposes to submit controlled substance purchase requests under the University's Program. Council members were confused as to why "Authorized Individuals working in a research laboratory conducting Authorized University Activities with the use of Dangerous Drugs and/or Devices" are not covered under the Campus Controlled Substance Programs. These activities likely encompass most of the activities approved by UBA and/or IACUC. (III. Policy Text, A., 5., Page 7)

The Council appreciates the opportunity to comment.

On behalf of the Council,

Meal

James Weatherall, Chair

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





Academic Senate Council on Teaching, Learning & Student Experience 307 Aldrich Hall Irvine, CA 92697-1325 (949) 824-7685

February 12, 2024

ARVIND RAJARAMAN, CHAIR ACADEMIC SENATE – IRVINE DIVISION

Re: Systemwide Proposed Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Academic Council Chair Steintrager forwarded for review proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching.

The Council on Teaching, Learning, and Student Experience (CTLSE) discussed this issue at its meeting on February 5, 2024, and members had no concerns with the proposed revisions at this time.

Sincerely,

Sergio Gago-Masague, Chair Council on Teaching, Learning, and Student Experience

C:

Jisoo Kim, Executive Director Academic Senate

Gina Anzivino, Associate Director Academic Senate

Stephanie Makhlouf, Cabinet Analyst Academic Senate





March 19, 2024

James Steintrager Chair, UC Academic Senate

Re: (Systemwide Senate Review): Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Chair Steintrager,

At its meeting on March 14, 2024, the divisional Executive Board (EB) reviewed the Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching and the attached divisional committee and council responses.

EB members voted unanimously in favor of a motion to endorse the proposal with the proviso that faculty that work closely in this area should be consulted on the details going forward.

Members noted the importance of having faculty that frequently use controlled substances in their research review the proposal prior to finalization and implementation to ensure that the policy does not stymie their scholarly endeavors.

Sincerely,

Andrea Kasko

Chair

UCLA Academic Senate

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Encl.

Cc: Kathleen Bawn, Vice Chair/Chair Elect, UCLA Academic Senate

Jessica Cattelino, Immediate Past Chair, UCLA Academic Senate April de Stefano, Executive Director, UCLA Academic Senate



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

March 5, 2024

To: Andrea Kasko, Chair, UCLA Academic Senate

From: Brooke Scelza, Chair, Graduate Council

Re: Systemwide Senate Review: Presidential Policy BFB-BUS-50: Controlled Substances Use in

Research and Teaching

Graduate Council members independently reviewed proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching. Most members did not have comments. One member who responded was in support of the revisions.

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 ele@senate.ucla.edu.

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OFFICE OF THE ACADEMIC SENATE

Matt Hibbing, Chair of the Academic Senate senatechair@ucmerced.edu

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

March 20, 2024

To: James Steintrager, Chair, Academic Council

From: UCM Divisional Council

Re: Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

The proposed revisions to Presidential Policy BFB-BUS-50 Controlled Substances Use in Research and Teaching were distributed for comment to the Merced Division Senate Committees and School Executive Committees The following committees offered comments for consideration. Their comments are appended to this memo.

- Committee on Research (CoR)
- Committee on Rules and Elections (CRE)
- Committee on Faculty Welfare and Academic Freedom (FWAF)
- Graduate Council (GC)

CoR sees the policy as a valuable tool for handling the complexities of obtaining controlled substances for research. It aims to simplify the understanding and compliance with laws and regulations, benefiting both Environmental Health and Safety (EHS) and faculty members. CoR offers some comments related to some aspects of the policy. Notably, a lack of clarity regarding how controlled substances will be monitored and secured in a Principal Investigator's lab or a shared lab setting. There is a need for further clarification on what "maintain strict control over inventory and security of Controlled Substances" entails. Strict control typically involves secure storage measures such as locking substances in separate cabinets or utilizing a secure lab door. In shared lab settings, it is crucial to establish clear protocols for access and monitoring to ensure compliance with regulations. It is unclear how one can maintain control and security over controlled substances in shared labs. Furthermore, the personnel screening requirements mandate that individuals with access to controlled substances must not have prior felony offenses and a background check will be necessary for all lab workers. It is unclear whether the Principal Investigators will cover this cost, especially considering the turnover of students and researchers throughout the year. The policy highlights the IRB's role in approving the use of controlled substances in research and training. Similarly, it would seem appropriate that the Institutional Animal Care and Use Committee (IACUC) also be included in this policy, as the IACUC reviews, approves, and monitors animal research protocols that often involve controlled substances.

CRE believes that minor edits to the language would improve accountability for investigators and the Controlled Substances Program Officers (CSPOs), as well as facilitate the registration process. Thus, CRE recommends edits to section III. A "Activities under the Campus Controlled Substance Programs".

Current Language:

Campus Controlled Substance Programs may provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

Suggested Language (in bold, underlined font):

Campus Controlled Substance Programs may shall provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices, in the form of checklists, guidance documents, and FAQ materials. In addition, the CSPO should be closely engaged with the DEA registration process, so that they are well prepared to facilitate the process and advise campus stakeholders.

FWAF supports the proposed policy revisions and deems them non-controversial. The committee has no substantive comments or proposed changes. However, FWAF has a minor concern regarding researchers collaborating with individuals in foreign countries with differing controlled substances policies. FWAF suggests detailing expectations for researchers in such situations to minimize liability and risk exposure for both the researchers and the University.

GC seeks more details about the CSPO's role in ordering the controlled substances and the expected approval timeframes. GC suggests including the ordering process in the policy for clarity and efficiency. Additionally, GC questions the removal of the forms appendix and recommends providing a link if the forms have been relocated.

DivCo members reviewed the committees' comments and support their various points and suggestions.

The Merced Division thanks you for the opportunity to comment on these proposed policy revisions.

CC: Divisional Council
Monica Lin. Executive

Monica Lin, Executive Director, Systemwide Academic Senate Michael LaBriola, Assistant Director, Systemwide Academic Senate UCM 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

February 23, 2024

To: Matt Hibbing, Senate Chair

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

Re: Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

The purpose of the revised Policy on Controlled Substances Use in Research and Teaching is to define the roles, procedures, and responsibilities for establishing and maintaining a Controlled Substances Program at each campus within the UC system. Overall, CoR believes that this is a welcome program that is needed to manage the complexity of acquiring Controlled Substances for research purposes. The laws and regulations are challenging for EHS and faculty to understand and keep track of and this program appears to help bridge that gap.

The main comments CoR has centers around the vague language over how the Controlled Substances will be monitored and secured in a PI's lab or shared lab setting:

- 1. PIs and DEA Registrants are required to "maintain strict control over inventory and security of Controlled Substances." This may need additional clarification. What exactly constitutes strict control? Do Controlled Substances need to be locked away in separate cabinets or does a secure lab door suffice? Furthermore, many labs are shared in which multiple research labs occupy the same lab. How can one maintain control and security over their Controlled Substances under those conditions? The answers to these questions may have a big impact on the day-to-day operation of a research lab.
- 2. Personnel screening requirements require all individuals who have access to Controlled Substances must have no prior felony offenses. A background check will be required to screen all individuals working in the lab. Will this be a cost that the PIs will be paying for? Many students come and go throughout the year (high school researchers, undergraduate researchers, graduate students and postdocs).
- 3. The policy mentions IRB considering their approving authority for use of controlled substances in research and training. In the same vein, we suggest that Institutional Animal Care and Use Committee (IACUC) be also involved in this policy. IACUC reviews, approves, and monitors animal research protocols which in many instances include controlled substances.

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

February 26, 2024

To: Matthew Hibbing, Chair, Divisional Council

From: Committee on Rules and Elections (CRE)

Re: Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

The Committee on Rules and Elections evaluated the Presidential Policy BFB-BUS-50: Controlled Substances in Research and Teaching and offers the following comments.

CRE welcomes the requirement to have written designations. Based on consultation with campus stakeholders, we suggest that accountability of investigators and the Controlled Substance Program Officer (CSPO), together with facilitation of the registration process, would be enhanced by edits to the language of the second paragraph of III.A, as follows:

Current Language:

Campus Controlled Substance Programs may provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

Suggested Language (in bold and underlined font):

Campus Controlled Substance Programs <u>may shall</u> provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices, in the form of checklists, guidance documents, and FAQ materials. <u>In addition, the CSPO should be closely engaged with the DEA registration process, so that they are well prepared to facilitate the process and advise campus <u>stakeholders.</u></u>

We thank you for the opportunity to review and comment.

CC: CRE Members Senate Office

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ACADEMIC SENATE, MERCED DIVISION COMMITTEE ON FACULTY WELFARE AND ACADEMIC FREEDOM (FWAF)

UNIVERSITY OF CALIFORNIA, MERCED 5200 NORTH LAKE ROAD MERCED, CA 95343

February 26, 2024

To: Matthew Hibbing, Chair, Divisional Council

From: Committee on Faculty Welfare and Academic Freedom (FWAF)

Re: Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

The Committee on Faculty Welfare and Academic Freedom evaluated the Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching and offers the following comments.

FWAF believes the proposed policy revisions are non-controversial and has no substantive comments or proposed revisions. However, FWAF does have one, largely minor concern. The policy highlights the importance of complying with state and federal laws on the use of controlled substances. This point is well taken. However, many researchers are involved in collaborations with researchers who maintain residency in foreign countries, and those countries frequently have a specific set of controlled substance policies that may not align with the policies of the United States or California. It may be useful to detail what researchers are expected to do in such situations, particularly to limit the liability and risk exposure of both the individual researchers and the University.

We thank you for the opportunity to review and comment.

Cc: FWAF Members Senate Office

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ACADEMIC SENATE, MERCED DIVISION GRADUATE COUNCIL (GC)

UNIVERSITY OF CALIFORNIA, MERCED

February 26, 2024

To: Matt Hibbing, Chair, Divisional Council

From: Michael Scheibner, Chair, Graduate Council (GC)

Re: Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Graduate Council (GC) reviewed the Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching and offers the following comments:

GC would like to gather additional information about the Controlled Substance Program Officer (CSPO) role in the process for ordering controlled substances and the expected average timeframes for approval processes for ordering such substances. GC wonders whether the timeframe and process for ordering controlled substances could be stated in the policy to result in a less complicated and timeconsuming process.

It is also unclear why the appendix with all the forms has been removed. GC wonders whether these forms have been relocated. If so, GC believes it may be useful to include a link.

GC thanks you for the opportunity to review the Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching.

Cc: Graduate Council
Senate Office

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CHAIR, ACADEMIC SENATE RIVERSIDE DIVISION UNIVERSITY OFFICE BUILDING, RM 225 SANG-HEE LEE PROFESSOR OF ANTHROPOLOGY RIVERSIDE, CA 92521-0217 TEL: (951) 827-4390 EMAIL: SANG-HEE.LEE@UCR.EDU

March 14, 2024

James A. Steintrager, Chair, Academic Council 1111 Franklin Street, 12th Floor Oakland, CA 94607-5200

RE: [Systemwide Review] Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Jim.

The Riverside Executive Council discussed the subject proposed policy during their March 11, 2024 meeting and had no comments to add to those provided by local committees. These comments are attached.

Several committees had no comments, concerns, or objections to the proposed changes. The Committee on Academic Personnel commends the effort in clarifying the scope of duties of the Campus Controlled Substances Programs and the Controlled Substances Program Officers as well as several DEA-related issues and appreciates its contextual coherence and definitional consistency. The faculty executive committee of the College of Humanities Arts and Social Sciences feels they lack the expertise to address the proposal but recognizes that controlled substance use in research and teaching occurs in their college and across the campus. For this reason, the Executive Committee encourages that CHASS faculty who use controlled substances in their research and teaching be directly consulted when there are significant proposed changes to policies regarding controlled substances.

The School of Medicine Faculty Executive Committee is in favor of the proposed changes and opined that the UC must have infrastructure in place that handles controlled substances (CS) for compliance; and noted that the Clinical component is not included in the policy except for the university's infrastructure related to CS. The SOM FEC also identified one proposed change in the document:

Section III Policy Text, A. Activities under the Campus Controlled Substance Programs: Campus Controlled Substance Programs may (change "may" to "shall") provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

Sincerely yours,

Sang Alu Lee_

Sang-Hee Lee

Professor of Anthropology and Chair of the Riverside Division

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



Academic Senate

COMMITTEE ON ACADEMIC PERSONNEL

February 6, 2024

To: Sang-Hee Lee, Chair

Riverside Division Academic Senate

From:

Jang-Ting Guo, Chair Jung Jud Committee on Academic Personnel

Re: Proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled

Substances Use In Research and Teaching

In its February 5, 2024 meeting, CAP discussed the proposed revisions to the systemwide Presidential Policy on Controlled Substances Use In Research and Teaching. The committee commends the effort in clarifying the scope of duties of the Campus Controlled Substances Programs and the Controlled Substances Program Officers as well as several DEA-related issues, and appreciates its contextual coherence and definitional consistency. Accordingly, CAP has no further comment on this revised systemwide Presidential Policy.



College of Humanities, Arts, and Social Sciences EXECUTIVE COMMITTEE

February 07, 2024

TO: Sang-Hee Lee, Chair

Riverside Division of the Academic Senate

FROM: Wesley Leonard, Chair

CHASS Executive Committee

RE: [Systemwide Review] Proposed Revised Policy: Presidential Policy BFB-BUS-

50: Controlled Substances Use In Research and Teaching

The CHASS Executive Committee reviewed the Proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching. The committee feels they lack the expertise to address the proposal but recognizes that controlled substance use in research and teaching occurs in CHASS and across the campus. For this reason, the Executive Committee encourages that CHASS faculty who use controlled substances in their research and teaching be directly consulted when there are significant proposed changes to policies regarding controlled substances.



February 2, 2024

TO: Sang-Hee Lee, Ph.D., Chair, Academic Senate, UCR Division

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

SUBJECT: Response to [Systemwide Review] Proposed Revised Policy: Presidential Policy BFB-BUS-50:

Controlled Substances Use in Research and Teaching

Dear Sang-Hee,

The SOM Faculty Executive Committee has reviewed the proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching.

The Committee identified one proposed change in the document:

• Section III Policy Text, A. Activities under the Campus Controlled Substance Programs Campus Controlled Substance Programs <u>may</u> (change "may" to "shall") provide assistance for individual DEA registration applicants and/or individuals working with Dangerous Drugs and/or Devices in the form of checklists, guidance documents, and FAQ materials.

The University must have infrastructure in place that handles controlled substances (CS) for compliance. The Clinical component is not included in the policy except for the university's infrastructure related to CS.

We approve of the proposed revised policy and have no additional comments.

Yours sincerely,

Marcus Kaul, Ph.D.

Chair, Faculty Executive Committee School of Medicine



Academic Senate

COMMITTEE ON ACADEMIC FREEDOM

January 18, 2024

To: Sang-Hee Lee, Chair

Riverside Division Academic Senate

From: Matt King, Chair

Committee on Academic Freedom

Re: Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in

Research and Teaching

The Committee on Academic Freedom reviewed the proposed Presidential Policy for Controlled Substances Use in Research and Teaching at their January 18, 2024 meeting and did not have any concerns related to Academic Freedom.



February 22, 2024

TO: Sang-Hee Lee, Ph.D., Chair, Academic Senate, UCR Division

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

SUBJECT: [Systemwide Review] Proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

Dear Sang-Hee,

The CNAS Faculty Executive Committee reviewed the Proposed Revised Policy on February 6, 2024, and has no comments or concerns with the proposed changes.

Sincerely,

Bahram Mobasher, Ph.D

Chair, Faculty Executive Committee College of Natural and Agricultural Sciences



Academic Senate

GRADUATE COUNCIL

February 15, 2024

To: Sang-Hee Lee, Chair

Riverside Division

From: David Oglesby, Chair

Graduate Council

Re: [Systemwide Review] Proposed Revised Policy: Presidential Policy

BFB-BUS-50: Controlled Substances Use In Research and Teaching

Graduate Council reviewed the proposed revised Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching at their February 15, 2024 meeting. The Council did not have any concerns with the revisions being proposed.



2/26/24

To: Sang-Hee Lee, 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] Proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

The SOE Executive Committee reviewed the [Systemwide Review] Proposed Revised Policy: Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching. Comments/feedback were solicited at our executive committee meeting and via email.

The SOE FEC did not have any comments on this proposed policy.

Thank you for the opportunity to provide feedback.

Sincerely,

Katherine Meltzoff Faculty Executive Committee Chair School of Education University of California, Riverside BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

OFFICE OF THE ACADEMIC SENATE

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

March 19, 2024

Professor James Steintrager Chair, Academic Senate University of California VIA EMAIL

Re: Divisional Review of Proposed Revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Chair Steintrager,

The revisions to BFB-BUS-50: Controlled Substances Use in Research and Teaching were distributed to San Diego Divisional Senate standing committees and discussed at the March 11, 2024 Divisional Senate Council meeting. Senate Council endorsed the proposal and had no comments.

The responses from the Divisional Committee on Faculty Welfare and Committee on Research are attached.

Sincerely,

John A. Hildebrand

Chair

San Diego Divisional Academic Senate

Attachment

cc: Olivia A. Graeve, 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 28, 2024

JOHN HILDEBRAND, CHAIR Academic Senate, San Diego Division

SUBJECT: Systemwide Review of Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

The Committee on Faculty Welfare discussed the proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching at its February meeting. The committee endorsed the proposed Presidential policy.

Sincerely,

Juan Pablo Pardo-Guerra, Chair Committee on Faculty Welfare

cc: O. Graeve

February 20, 2024

JOHN HILDEBRAND, Chair Academic Senate, San Diego Division

SUBJECT: Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

The Committee on Research (COR) discussed the Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching at their February 12, 2024 meeting. The Committee was generally supportive of the proposed revisions, and hopes that there will be clear guidelines on which version of the policy should be followed as the transition from the previous policy to the revised policy is enacted.

Sincerely yours,

George Fuller, Chair Committee on Research

cc: A. Chiba

K. Gonzalez

O. Graeve

L. Hullings





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 Thomas Chi, MD, Secretary Kathy Yang, PharmD, MPH, Parliamentarian March 18, 2024

James Steintrager
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 Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

Dear Chair Steintrager:

The San Francisco Division of the Academic Senate is pleased to opine on the Systemwide Review of Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching. The UCSF Senate committees acknowledge that many aspects of the policy are determined by federal and/or state regulations and believe that the policy is in line with practices at UCSF Health. Moreover, the UCSF Academic Senate appreciates the policy's efforts to clarify the use of controlled substances in UC research and teaching activities. Three UCSF committees submitted comments on this review: the Clinical Affairs Committee (CAC), the Committee on Research (COR), and the Committee on Rules & Jurisdiction (R&J).

Applicability to Clinical Care

CAC and R&J advise that the policy should clarify its applicability to clinical care. Presently, the cover sheet implies the policy excludes patient care activities involving controlled substances, yet Section IV, subsection (B) addresses these very activities. To rectify this inconsistency and dispel confusion, CAC and R&J propose adding introductory text to Section IV (Compliance/Responsibilities), providing necessary context and explanation, particularly for the *Patient Care and Clinical Controlled Substance Programs* section.

Inconsistencies in Policy Language and Clarity:

COR recommends that the policy explicitly outline its full scope in Section I (Policy Summary) or within the introductory portion of Section III (Policy Text) to prevent ambiguity. This should encompass the duties of individuals involved in research with any controlled substances and reference pertinent policies or guidelines concerning Schedule I substances.

Elaboration of Procedures:

COR finds the appendices in the original policy useful for determining research procedures and suggests retaining them, as long as the information in the appendices is still current. Furthermore, COR suggests enhancing the clarity of procedures in various subsections of Section III of the policy. Specifically:

- Section III.C should detail the process for researchers handling controlled substances in non-clinical areas or indicate that they must adhere to their respective campus policies, urging campuses to establish and disseminate clear guidelines.
- Section III.C.3 could benefit from more explicit storage requirements for controlled substances, particularly for Schedule II-V drugs, potentially setting a systemwide standard for lab management of these substances.



http://senate.ucsf.edu

- For Section III.D.2.b, COR advises specifying if UC researchers at non-UC California locations
 using controlled substances under that location's DEA registration require a Controlled Substance
 Program Officer (CSPO)'s prior written approval. COR suggests providing guidance on the
 procedures for such situations.
- Relevant to Section III.D.6, COR notes that the Research Advisory Panel of California (RAPC) also
 requires researchers to obtain the RAPC's review and approval of study protocols that involve DEA
 schedule III-V controlled substances, in addition to non-scheduled drugs, when they are used in
 Substance Use Disorder treatment research. It may be useful to mention this requirement in this section,
 as not all researchers may be aware of this requirement.

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

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

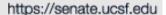
Enclosures (2)

Si w Hum

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

Spencer Behr, Chair, Committee on Rules & Jurisdiction (R&J)

Malini Singh, Chair, Clinical Affairs Committee (CAC)





Clinical Affairs Committee Malini Singh, MD, MPH, MBA, Chair

Rules & Jurisdiction Committee Spencer Behr, MD, Chair

March 8, 2024

Steven Hetts, MD Division Chair UCSF Academic Senate

Re: Comments on Controlled Substances Use in Research and Teaching Systemwide Review

Dear Chair Hetts:

The Clinical Affairs Committee (CAC) and Rules and Jurisdiction (R&J) write to comment on Revised Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching that is out for systemwide review. Specifically, the committees write to recommend clarification about whether and how the policy applies to clinical care.

The policy cover sheet begins with a scope section that explicitly states, "This Policy does not apply to Controlled Substance use in connection with patient care activities performed by a UC health system, veterinary teaching hospital, pharmacy except to establish the units and positions responsible for such activities (see section IV)." Then, in Section IV on Compliance/Responsibilities, there is a subsection (B) on Patient Care and Clinical Controlled Substance Programs. Presumably, this section is there to "establish the units and positions responsible for such activities" as referenced in the scope section, but CAC and R&J still found this confusing.

If this policy is not applicable to patient care and clinical programs, why is there a section on *Patient Care and Clinical Controlled Substance Programs*? Shouldn't the information be in a policy that is applicable to patient care and clinical programs? Why would people look for this information in a policy that expressly says it is not appliable to patient care and clinical programs?

CAC and R&J also believe the language of Section IV would benefit from introductory text. The section includes job titles and responsibilities, but it is missing an explanation, even a short one, for why those job titles are responsibilities are being listed. CAC and R&J believe an explanation and context would be especially helpful for the section on *Patient Care and Clinical Controlled Substance Programs* since the policy otherwise does not apply to those settings.

CAC and R&J recommend the University consider adding introductory and explanatory language to the *Compliance/Responsibilities* section. CAC and R&J further recommend the University consider whether the section on *Patient Care and Clinical Controlled Substance Programs* will be found and followed by the appropriate parties when the larger policy signals that it is not applicable to patient care and clinical programs.

Setting aside those considerations, CAC had no substantive concerns about the policy. CAC reached out to colleagues in the School of Pharmacy and understands the policy is in line with

practices at UCSF Health. The proposed revisions did not raise concerns among those familiar with how these policies work in practice.

If you have questions about CAC's and R&J's joint comments, please contact the committees' analysts Kristie.Tappan@ucsf.edu and Sophia.Root@ucsf.edu. Thank you for the opportunity to comment.

Sincerely,

Malini Singh, MD, MPH, MBA Clinical Affairs Committee Chair

Malini Kligh

Spencer Behr, MD

Committee on Rules and Jurisdiction Chair





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

March 14, 2024

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: Revised Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and

Teaching

Dear Chair Hetts:

The Committee on Research (COR) writes to comment on the Systemwide Review of Revised Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching. As an advocate for researchers at UCSF, COR appreciates the opportunity to provide feedback on this policy. COR understands that many aspects of the policy are determined by federal and/or state regulations. However, COR has a few suggestions to improve the policy's clarity.

- 1. The full scope of the policy should be clearly stated in either Section I (Policy Summary) or the introductory text of Section III (Policy Text). Currently, Section I states, "The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program within the University of California." The policy goes on to state that Campus Controlled Substance Programs do not cover the use of schedule I drugs. Thus, a reader may assume that schedule I drugs are outside the scope of this policy. However, later parts of the policy (e.g., III.C on Responsibilities of Individual / Other DEA Registrants) do discuss schedule I drugs. To avoid confusion, it may be helpful to state upfront that the policy's scope includes not only Controlled Substances Programs but also the responsibilities of individuals conducting research using controlled substances of any kind. It would also be helpful to reference the other policies or guidelines related to schedule I drugs if this policy does not comprehensively list all policies and procedures regarding the use of these drugs.
- 2. Research faculty found the appendices to the previous version of the policy helpful for determining research procedures, and COR was surprised to see them removed without explanation. Assuming that the information in the appendices is still current, COR recommends that the appendices be retained either in this policy or in an alternative policy or systemwide document that is easy for researchers to access. If the appendices are moved to another document, their location should be identified within this policy.
- 3. Section III.C states that researchers must notify the Controlled Substance Program Officer (CSPO) before handling controlled substances in a non-clinical area, but it does not provide further details about procedures for doing so. COR understands that the intention may be to allow individual campuses to determine the procedures that work best for them. If so, COR supports that intention but suggests that to improve clarity, the policy should state that researchers are expected to follow their campus's policies and should require that campuses develop clear policies and procedures that are easily accessible to researchers. Additionally, it would be helpful to either state whether this notification must take a certain form (e.g., email or formal letter) or explain that the required form of the notification is determined by campus guidelines.

- 4. In Section III.C.3, it may be helpful to include more details as to the types of storage requirements necessary for different controlled substances when handled in settings that are not under the jurisdiction of the Campus Controlled Substances Program. Schedule I substances require a schedule I safe, but the requirements for the storage and handling of schedule II-V drugs are less well-defined, and it may be helpful to set a systemwide standard for individual labs working with these substances.
- 5. In Section III.D.2.b, COR recommends clarifying whether a UC researcher who conducts research at a non-UC location within California and uses controlled substances obtained through that location's DEA registration, as described in Section III.A.4, must obtain prior written approval by the CSPO. This situation may apply to many UC researchers, such as active collaborators with the San Francisco Department of Public Health's Center on Substance Use and Health, and, thus, it would be helpful to provide guidance regarding appropriate procedures in this situation.
- 6. Relevant to Section III.D.6, COR notes that the Research Advisory Panel of California (RAPC) also requires researchers to obtain the RAPC's review and approval of study protocols that involve DEA schedule III-V controlled substances, in addition to non-scheduled drugs, when they are used in Substance Use Disorder treatment research. It may be useful to mention this requirement in this section, as not all researchers may be aware of this requirement.

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 Susannah Scott, Chair Shasta Delp, Executive Director

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

March 20, 2024

To: Jim Steintrager, Chair

Academic Senate

From: Susannah Scott, Divisional Chair

Academic Senate

Re: Systemwide Review of Proposed Presidential Policy BFB-BUS-50: Controlled Substances

Susannah L Swott

Use in Research and Teaching

The Santa Barbara Division distributed the Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching to the Council on Faculty Welfare, Academic Freedom, and Awards (CFW), the Council on Planning and Budget (CPB), the Committee on Research Policies and Procedures (CRPP), and the Graduate Council (GC). GC opted not to opine. The Faculty Executive Committee (FEC) of the Gevirtz Graduate School of Education (EDUC) received the proposed policy as an information item, and opted to opine.

Overall, the revised version of the proposed policy was well received by the Santa Barbara Division. The reviewing groups note that the policy is reasonable and comprehensive. They offer a number of suggestions for consideration, which are summarized below. All of the individual responses are attached for your reference.

In terms of the policy's implementation, campuses or locations will need to make a considerable effort to raise awareness of the policy and ensure that it is thoroughly understood. Individuals who use controlled substances in their research and/or teaching should be provided with adequate training, including additional guidance on where federal law might differ from state law, along with a well-maintained list of controlled substances. Campuses and locations should also consider the additional workload that will be borne by faculty, staff, and administrators as the policy is implemented, and take care to manage the approval process in a manner that does not delay research progress.

The EDUC FEC offers a minor note related to the use of the acronym "DEA" in the proposed policy. In the red line version, it appears that DEA is used for both "Drug Enforcement Agency" and "Drug Enforcement Administration," which has the potential to create confusion (please see red line version p. 2 and p. 4).

Thank you for the opportunity to comment.

Academic Senate Santa Barbara Division

March 14, 2024

To: Susannah Scott, Divisional Chair

Academic Senate

From: John W.I. Lee, Chair

Council on Faculty Welfare, Academic Freedom and Awards

1 W.A. L_

Re: Proposed Revised Presidential Policy BFB-BUS-50: Controlled Substances Use in

Research and Teaching

At its meeting of March 6, 2024, the Council on Faculty Welfare, Academic Freedom and Awards (CFW) discussed the proposed revised Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching. The Council suggests a focus on faculty, staff, and researcher awareness so that any new policies are thoroughly advertised and clearly understood. Council members in departments where controlled substances are used in research and/or teaching emphasized the importance of providing training modules for faculty, and of providing easily accessible and continuously updated lists of controlled substances. The Council also would like more explicit guidance for research situations that may involve controlled substances for which California law differs from federal law.

CC: Shasta Delp, Executive Director, Academic Senate

University of California ACADEMIC SENATE SANTA BARBARA DIVISION

Council on Planning & Budget

March 8, 2024

To: Susannah Scott, Divisional Chair

UCSB Academic Senate

France Winddance Twine, Chair France Winddance June
Council on Planning & Budget From:

BFB-BUS-50: Controlled Substances Use in Research & Teaching Re:

The Council on Planning & Budget (CPB) has reviewed the proposed revisions to Policy BFB-BUS-50: Controlled Substances Use in Research & Teaching. The proposed revisions are important for ensuring the safe use of controlled substances in teaching and research, and for ensuring compliance with Federal and State regulations. The proposed revisions are seen by CPB as both necessary and reasonable. However, the Council does note that where additional duties, documentation, personnel screening, and training are to be implemented, the additional workload on staff and faculty should be considered. This is particularly relevant with regards to the scope of the newly detailed duties for the campus Controlled Substance Program Officer (CSPO). Moreover, because the approval process for use of controlled substances in research can be very time consuming, resulting in delayed research progress, CPB is concerned that the new policy should not add additional delays, and that the campus will work to expedite the approval process.

Shasta Delp, Academic Senate Executive Director

cc:

Academic Senate Santa Barbara Division

March 5, 2024

To: Susannah Scott, Divisional Chair

Academic Senate

From: Alan Murray, Chair

Committee on Research Policy and Procedures

Re: Proposed Revised Presidential Policy BFB-BUS-50: Controlled Substances Use in

Research and Teaching

At its meeting of March 1, 2024, the Committee on Research Policy and Procedures (CRPP) discussed the proposed revised Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching. CRPP thought this was a thoughtful and comprehensive revision of the policy to clarify details that may have been ambiguous in the previous version.

CC: Shasta Delp, Executive Director, Academic Senate

UC SANTA BARBARA

Faculty Executive Committee Gevirtz Graduate School of Education

March 4, 2024

To: Susannah Scott, Chair

Academic Senate

From: Tarek Azzam, Chair

Faculty Executive Committee, GGSE

Docusigned by:

Re: Proposed Revised Presidential Policy BFB-BUS-50: Controlled Substances Use in

Research and Training

To whom it may concern,

The GGSE FEC wants to thank those who were involved in the drafting of the Proposed Revised Presidential Policy BFB-BUS-50. We believe that this was a reasonable policy clarification. We would like to make a minor note related to the use of DEA in the document. The document changed the Drug Enforcement Administration to an agency. We believe that the document was referring to local versions of the DEA. It appears that the DEA can't be used for both agency and administration (please see red line version pgs. 2 & 4)

Tarek Azzam, Professor

Faculty Executive Committee Chair
Gevirtz Graduate School of Education

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1156 HIGH STREET SANTA CRUZ, CALIFORNIA 95064

Office of the Academic Senate SANTA CRUZ DIVISION 125 CLARK KERR HALL (831) 459 - 2086

March 20, 2024

JAMES STEINTRAGER Chair, Academic Council

Re: Systemwide Review of Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

Dear James,

The Santa Cruz Division of the Academic Senate has completed its review of the proposed Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching with the Committee on Rules, Jurisdiction, and Elections (CRJE) responding. The committee found the proposed policy reasonable and deems that it presents no conflict with existing policy.

On behalf of the Santa Cruz Division, I thank you for the opportunity to comment on this proposed policy.

Sincerely,

Patty Gallagher, Chair

Academic Senate, Santa Cruz Division

cc: Amanda Rysling, Chair, Committee on Courses of Instruction Michael Hance, Chair, Committee on Research Eleonora Pasotti, Chair, Committee on Rules, Jurisdiction and Elections Onuttom Narayan, Chair, Committee on Privilege and Tenure Elisabeth Cameron, Chair, Committee on Teaching Matthew Mednick, Executive Director, Academic Senate

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UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP) Cynthia Schumann, Chair Email: cschumann@ucdavis.edu University of California Academic Senate 1111 Franklin Street, 12th Fl. Oakland, California 94607

March 20, 2024

JAMES STEINTRAGER
CHAIR, ACADEMIC COUNCIL

RE: Revised Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching

Dear Jim,

UCORP members discussed the proposed revisions to Presidential Policy BFB-BUS-50: Controlled Substances Use In Research and Teaching at the UCORP meeting on March 11th. Several reported that their campus CORs had discussed the revised policy and had minor suggestions around editorial clarity and details regarding a quantity threshold:

- UC Davis suggested adding "controlled substance analogues" to the first paragraph of the scope statement.
- UC Merced suggested that there be more clarity around standards for maintaining "strict control over inventory and security" of the controlled substances and that the Institutional Animal Care and Use Committee (IACUC), which reviews, approves, and monitors animal research protocols, also be involved in this policy.
- UC San Diego thought there could be more clarity about substance quantity.

Overall, UCORP supports the changes to the policy and appreciates having a policy in place. Thank you for providing the opportunity to comment on the revisions.

Sincerely,

Cynthia Schumann Chair, University Committee on Research Policy

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UNIVERSITY COMMITTEE ON FACULTY WELFARE (UCFW) John Heraty, Chair heraty@ucr.edu

Assembly of the Academic Senate 1111 Franklin Street, 12th Floor Oakland, CA 94607-5200

March 19, 2024

JAMES STEINTRAGER, CHAIR ACADEMIC COUNCIL

RE: Proposed Presidential Policy BFB-BUS-50: Controlled Substances Use in Research and Teaching

Dear Jim.

The University Committee on Faculty Welfare (UCFW) has discussed the proposed Presidential policy BFB-BUS-50: Controlled Substances Use in Research and Teaching, and we have several comments.

1) The policy needs clarity whether individual faculty are allowed to obtain a Schedule II-V controlled substances license. For example, section 3.A states that

"departmental DEA registrations do not cover: 1. Activities conducted under an individual schedule II-V DEA registration obtained outside of the Campus Controlled Substance Program. In accordance with their individual DEA registration, such persons conducting activities under their personal DEA registration are responsible for proper purchasing, recordkeeping, disposal, and other regulated practices;"

However, on at least one campus, faculty are not allowed to hold an individual schedule II-V controlled substances license; therefore, the need for clarification of the policy. In addition, the policy should clarify which activities are allowable on campus schedule II-V policies. For instance, faculty have been told that synthesis is not allowed on the campus DEA registration, but also that they could not get their own II-V license. However, synthesis is allowed (of the more dangerous compounds) on individual Schedule I licenses.

2) Under C.3.b, it states that individuals/DEA registrants must "Ensure that Controlled Substances covered under an individual DEA registration are not intermingled in any manner with Controlled Substances covered under separate DEA registrations and/or owned by the University or by other individuals or entities."

The vagueness of the phrase "are not intermingled in any manner" becomes problematic when a faculty member has an individual Schedule I DEA license, as well as drugs covered under the campus Schedule II-V license. As stated, it could be interpreted to require completely separate storage facilities for both schedules of drugs. These storage facilities can be very expensive and impractical to duplicate within a faculty member's lab. For instance, the Schedule I storage used by the faculty member may involve taking a safe and bolting it to the floor so that the bolts are inaccessible; then

retrofitting a freezer by cutting a hole in it to fit over the safe that's bolted to the floor. While storage for Schedules II-V would be less extensive, it would include doubling a great many of the precautions and would actually be less safe. The same goal can be reached by just clearly separating the drugs within the Schedule I containment.

3) Controlled substance analogues must be clarified. Section D.3 states that "Controlled Substance Analogues must commonly be treated as schedule I or II Controlled Substances absent applicability of an exception which depends on a number of factors, including but not limited to the chemical structure of the compound and whether the compound is intended for human consumption."

The actual law states that the controlled substance analogues do NOT need to be treated as schedule I or II if they are not intended for human consumption. Furthermore, having a chemical structure similar to a schedule I or II compound is a vague categorization that would be difficult to apply in practice and would include a great many commonly used chemicals.

Others have no doubt uncovered other implementation obstacles. Pending redress of these and similar issues, we offer conditional support for the proposal.

Thank you for your attention to this important matter.

Sincerely,

John Heraty, UCFW Chair

Copy: UCFW

Monica Lin, Executive Director, Academic Senate Steven W. Cheung, Academic Council Vice Chair