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SANTA BARBARA • SANTA CRUZ

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

June 4, 2020

## SUSAN CARLSON, VICE PROVOST ACADEMIC PERSONNEL

## **Re: Proposed Presidential Policy on Protection of Human Subjects in Research**

Dear Susan,

Kum-Kum Bhavnani

Telephone: (510) 987-9303

Email:kum-kum.bhavnani@ucop.edu

As you requested, I distributed for systemwide Senate review the proposed Presidential Policy on Human Subjects in Research. Nine Academic Senate divisions and one systemwide committee (UCAF) submitted comments. These comments were discussed at Academic Council's May 27, 2020 meeting and are attached for your reference.

We understand that the revisions are intended to update the responsibilities of the University, its campuses and researchers, in protecting the rights and welfare of human subjects, particularly in the context of changes made in 2018 to the "Common Rule" protections for human subjects mandated for federally-funded research that allows more research to be considered "exempt" from institutional review board (IRB) review. The policy defines key terms; explains the ethical principles UC follows for human subjects research; describes the responsibilities of the campuses, IRBs, other oversight offices, and researchers, for compliance with this Policy; states that UC's commitment to human subjects protection applies to all human subjects research, regardless of the funding source or institution that provided the IRB review; and explains that campuses have flexibility to replace specific Common Rule protections with commensurate protections for research not subject to the Common Rule, as long as they follow the ethical principles described in the policy.

Senate reviewers expressed support for efforts toward clearer and improved guidance for researchers and flexibility for campuses, along with more uniformity across UC campuses. Reviewers also noted some concerns about the policy and issues that would benefit from further clarification.

Among these is a concern that the overall tone of the policy has shifted from a visionary statement affirming the importance of protecting the rights of people who participate in research, towards a more legalistic statement about meeting minimum requirements. It is important for patients to understand the distinction between their treatment and their participation in a trial. It should be clear that an agreement to take part in a trial will not influence the manner of treatment. To avoid any appearance of conflict the University should consider the use of a third party who is not directly involved in the treatment of a patient to explain the nature of the investigation to the subject.

Another concern relates to the "officials of the University" mentioned in the policy who would have authority to subject an IRB-approved research project to additional review or controls. Further clarification is needed about who these "officials" are, and on what basis they would use their veto authority.

Another more general concern relates to how IRBs may infringe on academic freedom by erecting barriers to research in ways that have no relation to the rights and welfare of human subjects. The policy should explicitly acknowledge APM 010 (Academic Freedom), and list the Committee on Academic Freedom in the section "Other Campus Offices and Committees" on page 5 and among the "Resources" listed on page 7. The policy should encourage faculty and Senate involvement in the development and revision of local procedures for protection of human subjects, and note the need for IRBs to recognize faculty and disciplinary expertise. At a minimum, faculty should be offered the opportunity to object to nominees.

In addition, the 2018 changes to the Common Rule were seen by many humanities and social sciences faculty as a positive move to exempt more research from unnecessary IRB review, given that many forms of research do not expose human subjects to the kind of risks the Common Rule intends to address and/or prevent. However, reviewers note that pursuing this exemption has become a cumbersome and byzantine process on some campuses. For some reviewers, the policy does not go far enough to distinguish between Common Rule and non-Common Rule research and does not acknowledge the disciplinary-specific standards for protection of human subjects in research and creative work that are separate from the University's, particularly in the humanities and social sciences. Moreover, UC researchers who conduct behavioral studies with mentally competent, non-incarcerated adults, and do not collect protected health information, should continue to be able to self-declare such research as exempt under the 2018 revisions.

Finally, the policy does not take into account the ways in which future research on human subjects will be affected by pandemic conditions. This might be useful, given that the pandemic is likely to have long term consequences for human subjects in research.

We encourage you to incorporate these suggestions into the policy and would appreciate being apprised about progress. Thank you for the opportunity to opine. Please do not hesitate to contact me if you have additional questions.

Sincerely,

Kun Kun Bhawani .

Kum-Kum Bhavnani, Chair Academic Council

cc: Associate Director Demattos Research Policy Manager Balla Academic Council Senate Directors



May 19, 2020

KUM-KUM BHAVNANI Chair, Academic Council

Subject: Comments on the Proposed Presidential Policy "Protection of Human Subjects in Research"

Dear Kum-Kum,

On May 11, 2020, the Divisional Council (DIVCO) of the Berkeley Division discussed the *Proposed Presidential Policy on the Protection of Human Subjects in Research*, informed by the report of the Committee on Research (COR). DIVCO endorsed the report, which is appended in its entirety, and supports the proposed policy.

Thank you for the opportunity to comment. If you have any questions, please don't hesitate to contact me.

Sincerely,

Olliver O'M

Oliver O'Reilly Chair, Berkeley Division of the Academic Senate Professor of Mechanical Engineering

Enclosure

 cc: Jennifer Johnson-Hanks, Vice Chair, Berkeley Division of the Academic Senate John Colford, Committee on Research Jocelyn Surla Banaria, Executive Director, Berkeley Division of the Academic Senate Deborah Dobin, Senate Analyst, Committee on Research



UNIVERSITY OF CALIFORNIA

April 9, 2020

PROFESSOR OLIVER O'REILLY Chair, Berkeley Division of the Academic Senate

## *Re: COR Comments on Proposed Presidential Policy on Protection of Human Subjects in Research*

At its meeting on March 18, COR briefly discussed the Proposed Presidential Policy on the Protection of Human Subjects in Research. The committee endorses the revised policy, which provides clear and improved guidance for researchers.

Thank you for asking COR to comment on this proposed policy revision.

With best regards,

John M. Cofford. Q.

John Colford, Chair Committee on 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, 2020

## Kum-Kum Bhavnani

Chair, Academic Council

RE: Proposed Presidential Policy on Protection of Human Subjects in Research

Dear Kum-Kum:

The proposed Presidential Policy on Protection of Human Subjects in Research was forwarded to all standing committees of the Davis Division of the Academic Senate. Four committees responded: Research (COR) and the Faculty Executive Committees of the College of Agricultural and Environmental Sciences (CAES), the School of Law (LAW), and the School of Medicine (SOM).

Committees support the revisions and have no serious concerns. Committees note two grammatical corrections needed:

- 1. The singular "IRB" and plural "IRBs" are used inconsistently throughout. It may be clearer to use only the singular form.
- 2. Likewise, page 5 should fix "an IRBs' requirements" to a grammatically correct form.

The Davis Division appreciates the opportunity to comment.

Sincerely,

Kinstin H. Lagettuta

Kristin H. Lagattuta, Ph.D. Chair, Davis Division of the Academic Senate Professor, Department of Psychology and Center for Mind and Brain

Enclosed: Davis Division Committee Responses

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

#### Committee on Research

Response to Request for Consultation: Proposed Presidential Policy on Protection of Human Subjects in Research

The Committee on Research has reviewed and discussed the Proposed Presidential Policy on Protection of Human Subjects in Research and has no concerns. The committee did, however, note a typo on page 5, "...an IRBs' requirements..." - either delete "an" or move apostrophe before the s.

The College of Agricultural and Environmental Sciences Faculty Executive Committee appreciates the opportunity to comment on revisions to this policy for human subjects in research. We agree with the revisions as presented and support the refinements proposed.

We suggest one minor emendation to address inconsistent use of singular "IRB" and plural "IRBs", so as to avoid any confusion the plural form might create.



May 20, 2020

Kum-Kum Bhavnani, Academic Council Chair 1111 Franklin Street, 12<sup>th</sup> Floor Oakland, CA 94607-5200

RE: Proposed Presidential Policy on Protection of Human Subjects in Research

At its May 19, 2020 meeting, the Irvine Division Senate Cabinet reviewed the Proposed Presidential Policy on Protection of Human Subjects in Research. Irvine's Council on Research, Computing, and Libraries (CORCL) also reviewed the proposed policy.

CORCL found that all the revisions made to the original policy are appropriate and will ensure uniformity across UC campuses. However, with respect to human subjects used in clinical trials, they noted some issues that would benefit from further clarification. These issues are described in the Council's memo, attached here.

The Cabinet unanimously endorsed CORCL's recommendations and urges consideration of these issues prior to finalization of the policy.

The Irvine Division appreciates the opportunity to comment.

Sincerely,

C:

James Steintrager, Chair Academic Senate, Irvine Division

Jeff Barrett, Chair-Elect Secretary Kate Brigman, Executive Director Gina Anzivino, Assistant Director Brandon Haskey-Valerius, Cabinet Analyst





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

May 11, 2020

## JAMES STEINTRAGER, CHAIR ACADEMIC SENATE, IRVINE DIVISION

## **RE:** Proposed Presidential Policy on Protection of Human Subjects in Research

At its meeting on April 16, 2020, the Council on Research, Computing, and Libraries (CORCL) reviewed the proposed Presidential Policy on Protection of Human Subjects in Research. The revisions are an update of a UCOP policy finalized in September 1, 1981. The main new features of this update include:

- 1. A new definition section for the policy that explicitly defines such relevant terms as Common Rule, Human Subject, Institutional Review Board (IRB), and Research.
- 2. An explanation of the ethical principles that the University follows for human subjects research. These describe how the University of California is committed to the ethical principles of respect for persons, benefice, and justice, which are set forth in the Belmont Report of the National Commission for the Protection of Human Subject of Biomedical and Behavioral Research.
- 3. A statement that the University's commitment to human subjects applies to all human subjects research in which the University is engaged, regardless of funding source or the institution provided by the IRB review.
- 4. The statement that campuses may replace specific Common Rule (required for federally funded research) with similar protections for Human Subjects when the University is engaged in non-federally funded research that is not subject to the Common Rule established by Federal Policy for the Protection of Human Subjects in federally-funded research. Each UC location may replace specific Common Rule requirements with commensurate protections for Human Subjects so long as the University follows the ethical principles described in the UCOP Policy document
- 5. A revised description of the responsibilities of the campuses, IRBs, other oversight offices, and researchers for ensuring compliance with this policy. The revisions specify that IRBs have the authority to approve, disapprove or require modifications to research proposals; suspend or terminate research not being conducted in accordance with IRB requirements; and establish written procedures for ensuring prompt reporting of any unanticipated problems involving risks to Human subjects.

CORCL found that all revisions made to the original document are appropriate and will ensure uniformity across UC campuses. However, with respect to human subjects used in clinical trials, there are some



issues that would benefit from further clarification.

1. The mental capacity of the subjects to agree to participation in trials should be unequivocally established, especially among seriously ill and frequently sedated subjects. The use of a wide range of others to give consent as outlined in the "Guidelines for IRB Approval of Surrogate Consent Use for Research" may not protect the interests of the subject adequately.

- 2. It is important that patients understand the distinction between their treatment and their participation in a trial. The fact that whether they agree to take part in a trial will not influence the manner of their treatment needs to be made very clear.
- 3. The use of a third party who is not directly involved in the treatment of a patient to explain the nature of the investigation to the subject should be required in order to avoid any appearance of conflict.
- 4. Researchers conducting behavioral studies with mentally competent, non-incarcerated adults, and not collecting protected health information, should continue to be able to self-declare such research as exempt. Streamlined tracks for such exempt research are needed in order to avoid the extensive delays associated with the approval process. Studies of economic or moral reasoning, decision-making, opinion surveys, and online research where participants have the option to remain anonymous carry a very minimal risk.

The Council therefore recommends consideration of these issues prior to assembling a final policy document. The Council appreciates the opportunity to comment.

On behalf of the Council,

Jee Bandwell

Lee Bardwell, Chair

c: Kate Brigman, Executive Director Gina Anzivino, Assistant Director Michelle Chen, CORCL Analyst Brandon Haskey-Valerius, Senate Analyst

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OFFICE OF THE ACADEMIC SENATE TOM HANSFORD, CHAIR senatechair@ucmerced.edu UNIVERSITY OF CALIFORNIA, MERCED 5200 NORTH LAKE ROAD MERCED, CA 95343

May 19, 2020

## Kum-Kum Bhavnani, Chair, Academic Council

# Re: Systemwide Review of Proposed Revisions to the Presidential Policy on Protection of Human Subjects in Research

Dear Chair Bhavnani:

The <u>Proposed Revisions to Presidential Policy on Protection of Human Subjects in Research</u> were distributed for review and comment to the UCM Senate Committee on Research (CoR), the Graduate Council (GC), and the School Executive Committees<sup>1</sup>.

The Committee on Research supports the policy and raises some questions on the proposed revisions. The School of Natural Sciences Executive Committee offers some thoughts. All comments are appended to this memo for your reference.

The Merced Division thanks you for the opportunity to opine.

Sincerely,

-11-

Tom Hansford Chair, Divisional Council

CC: Divisional Council Hilary Baxter, Executive Director, Systemwide Academic Senate Fatima Paul, Interim Executive Director, Merced Senate Office

<sup>&</sup>lt;sup>1</sup> Graduate Council, the School of Engineering and the School of Social Sciences, Humanities and Arts Executive Committees declined to comment.

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ACADEMIC SENATE, MERCED DIVISION COMMITTEE ON RESEARCH MICHAEL SCHEIBNER, CHAIR mscheibner@ucmerced.edu UNIVERSITY OF CALIFORNIA, MERCED 5200 NORTH LAKE ROAD MERCED, CA 95343 (209) 228-4369

April 24, 2020

To: Tom Hansford, Chair, Division Council

From: Michael Scheibner, Chair, Committee on Research (COR)

**Re:** Proposed Revisions to Presidential Policy on Protection of Human Subjects in Research

CoR reviewed the attached, proposed revisions to the Presidential Policy on Protection of Human Subjects in Research. The committee supports the proposed revisions, but raises the below questions and comments.

- The statement, "...the risks and benefits of research should be distributed among subjects in a fair and equitable manner...," should be clarified. An FAQ document providing examples of how such a distribution may look like would be helpful.
- The section about, "...an Institutional Official who oversees Human Subject protections," seems to give a single individual the power to assign IRB members. Given the importance of the IRB to research activities this power should be distributed, and faculty should be able to participate. At a minimum, faculty should be offered the opportunity to object to nominees.
- In section "Other Campus Offices and Committees", we suggest the document be revised to use the word "extends" instead of "expands".
- Page 3 of the policy states "When engaged in Research that is not subject to the Common Rule (because, e.g., the Research is not federally funded), each UC location may replace specific Common Rule requirements with commensurate protections..." CoR is unclear why each campus may replace specific Common Rule requirements. This will result in a patchwork of protections, which may be problematic for multi-campus research programs.
- Page 4 states "Campuses may grant the IRBs additional authorities." What authorities or types of authorities might be granted? While CoR appreciates that it is likely difficult to include an exhaustive set of scope conditions, the statement should not be left open ended. An FAQ document providing examples would be helpful.

We appreciate the opportunity to opine.

cc: Senate Office

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SCHOOL OF NATUAL SCIENCES

UNIVERSITY OF CALIFORNIA, MERCED 5200 N. LAKE ROAD BLDG A MERCED, CA 95343

April 24, 2020

To: Tom Hansford, Chair, Merced Division of the Academic Senate

From: Kevin Mitchell, Chair, Natural Sciences Executive Committee

Re: Systemwide Review Item - Proposed Revisions to Presidential Policy on Protection of Human Subjects in Research

The SNS Executive Committee has reviewed the Presidential Policy on Protection of Human Subjects in Research. The revisions, which focus on adding detailed definitions and explanations, substantially improve the policy's clarity. We do not foresee any adverse impacts on SNS.

The new policy clearly defines key terms (*e.g.* "human subject"), explains the ethical principles that UC follows, and delineates the responsibilities of various groups, including the IRB, the campus, and PIs.

The new policy commits the UC to following ethical guidelines regardless of funding source or IRB review institution. The new policy allows UC some flexibility in how these guidelines are followed in the case that the research is not federally funded.

We have no further comments on the new Human Subjects policy and appreciate the opportunity to provide our thoughts.

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CHAIR, ACADEMIC SENATE RIVERSIDE DIVISION UNIVERSITY OFFICE BUILDING, RM 225

DYLAN RODRIGUEZ PROFESSOR OF MEDIA & CULTURAL STUDIES RIVERSIDE, CA 92521-0217 TEL: (951) 827-6193 EMAIL: DYLAN.RODRIGUEZ@UCR.EDU

May 18, 2020

Kum-Kum Bhavnani, Chair, Academic Council 1111 Franklin Street, 12th Floor Oakland, CA 94607-5200

## **RE: Presidential Policy on Protection of Human Subjects in Research**

Dear Kum-Kum,

The UCR Academic Senate's Executive Council engaged in an animated discussion regarding the Presidential Policy on Protection of Human Subjects in Research. In addition to supporting the existing sets of comments from the attached standing committee response memos, Council members added that it may be unduly cumbersome to require *all* humans for *all* research to be addressed by the terms of such a policy. Many forms of research do not subject human subjects to the kind of risk that is intended to be addressed and/or prevented by this policy, but such a distinction is not present in the current draft. Other Council members elaborated on this point, suggesting that the policy should be revised to eliminate any other forms of unintended ambiguity. Executive Council also raised the question as to whether the policy is intended to create another layer of approval beyond existing IRB processes. Some members voiced concerns about giving effective veto power on research plans to administrators who do not have the training or academic background to make such decisions—this concern arose from the lack of a clear definition of who in the university falls under the vague term "officials of the University."

As always, the UCR Senate is proud to participate in this review and encourages the proposers to study the attached feedback from standing committees.

Sincerely yours,

Dylan Rodríguez Professor of Media & Cultural Studies and Chair of the Riverside Division

CC: Hilary Baxter, Executive Director of the Academic Senate Cherysa Cortez, Executive Director of UCR Academic Senate Office

## UCRIVERSITY OF CALIFORNIA Academic Senate COMMITTEE ON ACADEMIC FREEDOM

May 4, 2020

To:	Dylan Rodriguez, Chair
	Riverside Division of the Academic Senate

- From: Dmitri Maslov, Chair D. Mas Committee on Academic Freedom (CAF)
- Re: Proposed Policy: Presidential Policy on Protection of Human Subjects in Research

The Committee on Academic Freedom considered the document "Proposed Policy: Presidential Policy on Protection of Human Subjects in Research" submitted for a systemwide review on March 18, 2020.

This proposed Presidential Policy on use of human subjects in research is relevant for Academic Freedom. Essentially, it sets the ethical boundaries to the freedom of pursuing such research. Such boundaries are justified and necessary. In each case the exact limits to how far such research can go would be set differently, but, paraphrasing the old principle, the freedom of a researcher would end where the freedom of his/her human research subject would begin. The transition zone between the two freedoms is determined by ethics. The policy proclaims that the University prioritizes ethics. Thus, the CAF suggests to endorse this policy.

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EXECUTIVE COMMITTEE: COLLEGE OF HUMANITIES, ARTS, AND SOCIAL SCIENCES

RIVERSIDE, CALIFORNIA 92521-0132

May 1, 2020

TO: Dylan Rodriguez, Chair Academic Senate

Lucille Chia, Chair Luille Chia FROM: **CHASS Executive Committee** 

RE: Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research

The CHASS Executive Committee discussed the Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research via email. There were no objections and our committee approved the proposed policy.

## UCRIVERSITY OF CALIFORNIA Academic Senate COMMITTEE ON DIVERSITY, EQUITY, AND INCLUSION

## April 6, 2020

To:	Dylan Rodriguez Riverside Division Academic Senate
From:	Xuan Liu, Chair Committee on Diversity, Equity, and Inclusion
Re:	Proposed Policy: Presidential Policy on Protection of Human Subjects in Research

The Committee on Diversity, Equity and Inclusion (CODEI) reviewed the proposed Presidential Policy on Protection of Human Subjects in Research at its April 2 meeting. We noted that the proposal didn't discuss diversity issues in human subjects participating in research. This would be essential since the whole reason we have these protections is the violations of diverse populations in research. We must also ensure the diversity of participants in research, so that everyone can benefit from research.

## UCRIVERSITY OF CALIFORNIA Academic Senate

April 1, 2020

To: Dylan Rodriguez, Chair Riverside Division

From: Djurdjica Coss, Chair Committee on Research

RE: Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research

The Committee on Research reviewed the proposed revisions to Presidential Policy on Protection of Human Subjects in Research during the meeting on 03/20/2020.

The Committee members were generally supportive of proposed revisions, except for the paragraph delineated below that requires further consideration and clarification prior to approval:

Under IV. COMPLIANCE / RESPONSIBILITIES; Campus Responsibilities: "Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve Human Subjects Research if it has not been approved by an IRB."

1) Additional information is needed to define who are "officials of the institution", who appoints these officials and to who they report a decision to disapprove proposed research that has IRB approval.

2) Clarifications are needed to specify rules or guidelines that aforementioned official will be using as a premise to approve or disapprove the proposed research.



## **GRADUATE COUNCIL**

May 4, 2020

To: Dylan Rodriguez, Chair Riverside Division

From: Jason Stajich, Chair Graduate Council

## Re: Proposed Presidential Policy on Protection of Human Subjects in Research

Graduate Council reviewed the Proposed Presidential Policy on Protection of Human Subjects in Research at their April 16, 2020 meeting. The Council noted that Page 5 includes a statement that indicates that an institution can still review and disapprove a research project that already has IRB approval. The members of the committee are concerned this is open ended and appears very broad in scope. There are no guidelines about when this option by an institution might be executed. A clear rationale for this in the document needs to be indicated.

The committee raised concerns that there are campus-by-campus variations in how offcampus and exempt human projects are administered. It would be helpful to have more coordination in an effort to improve assessment of how these procedures are implemented.

# UCRUNIVERSITY OF CALIFORNIA

School of Medicine Division of Biomedical Sciences Riverside, CA, 92521

April 24, 2020

То:	Dylan Rodriquez, Ph.D., Chair, Academic Senate, UCR Division
From:	Declan McCole, Ph.D., Chair, Faculty Executive Committee, UCR School of Medicine
Subject:	SOM FEC Response to Proposed Policy: Presidential Policy on Protection of Human
	Subjects in Research

Dear Dylan,

The School of Medicine Faculty Executive Committee discussed the Proposed Policy: Presidential Policy on Protection of Human Subjects in Research today. The committee has 4 concerns relating to Page 4; Section IV (Compliance/Responsibilities); Campus responsibilities, paragraph 2, which states: Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution.

• Given that human subjects research at UCR is hampered by often lengthy negotiations and approvals by outside IRBs (i.e. partner hospitals/clinics each of which have their own IRBs) it is important to clarify which UCR officials have this veto power over IRB approvals as this can have long term consequences for research partnerships with local hospitals.

• What qualifications do these officials need to have in order to properly evaluate and potentially veto an IRB approval?

- Under what conditions would IRB approval be over-ruled by said officials?
- What is the time line for this over-ruling action by a UCR official?

Yours sincerely,

Declar Milde

Declan F. McCole, Ph.D. Chair, Faculty Executive Committee School of Medicine

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ACADEMIC SENATE Santa Barbara Division 1233 Girvetz Hall Santa Barbara, CA 93106-3050

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Henning Bohn, Chair Debra Blake, Executive Director

May 11, 2020

To: Kum-Kum Bhavnani, Chair Academic Council

Academic Senate

From: Henning Bohn, Chair Henning Kohn

Re: Proposed Revised Presidential Policy on Protection of Human Subjects in Research

The Santa Barbara Division delegated its Committee on Research Policy and Procedures to review the proposed revisions to the Presidential Policy on Protection of Human Subjects in Research. The Committee found the policy to be reasonable and did not see any issues that would substantially alter the manner in which research activities are executed now.

Members noted a potential discrepancy regarding the policy's reference to UCOP's Research Policy website. The policy states, "Implementing procedures or additional guidance related to this Policy may be found on the UCOP Research Policy Analysis and Coordination website." However, the only procedural guidance regarding human subjects provided at the site is a copy of the 2012 version of the policy itself. If additional procedural guidance is actually available, CRPP recommends that it be made readily accessible to faculty.

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OFFICE OF THE ACADEMIC SENATE

9500 GILMAN DRIVE LA JOLLA, CALIFORNIA 92093-0002 TELEPHONE: (858) 534-364 FAX: (858) 534-4528

May 18, 2020

Professor Kum-Kum Bhavnani Chair, Academic Senate University of California 1111 Franklin Street, 12<sup>th</sup> Floor Oakland, CA 94607

Re: Proposed Revisions to UC Human Subjects in Research Policy

Dear Professor Bhavnani:

The proposed revisions to the UC Human Subjects in Research Policy was circulated to Divisional standing Senate committees for review. Responses were received from the Committee on Research (COR) and Graduate Council (GC). The proposed policy revisions and committee responses were discussed at the Divisional Senate Council meeting on May 11, 2020. Senate Council endorsed the revisions.

Sincerely,

Maripat Corr, Chair San Diego Divisional Academic Senate

Cc: Steven Constable, Vice Chair, San Diego Divisional Academic Senate Ray Rodriguez, Director, San Diego Divisional Academic Senate Hilary Baxter, Executive Director, Systemwide Academic Senate

UCSD



http://senate.ucsf.edu

Office of the Academic Senate 500 Parnassus Ave, MUE 230 San Francisco, CA 94143-0764 Campus Box 0764 tel: 415/514-2696 academic.senate@ucsf.edu https://senate.ucsf.edu

Sharmila Majumdar, PhD, Chair Steven Cheung, MD, Vice Chair Vineeta Singh, MD, Secretary Jae Woo Lee, MD, Parliamentarian May 20, 2020

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

Re: Protection of Human Subjects in Research

Dear Kum-Kum:

The San Francisco Division of the Academic Senate supports the proposed revisions to the UCOP policy on Protection of Human Subjects in Research.

Our Committee on Research endorsed the inclusion of a section on definitions.

Sincerely,

S. Majundar\_\_\_

Sharmila Majumdar, PhD, 2019-21 Chair UCSF Academic Senate

Enclosure (1) Cc: Lea Grinberg, MD, PhD, UCSF COR Chair

http://senate.ucsf.edu



May 20, 2020

Professor Sharmila Majumdar, PhD Chair, UCSF Academic Senate

RE: Protection of Human Subjects in Research

Dear Chair Majumdar,

On March 6, 2020, UCOP disseminated for systemwide review the proposed revisions to the Protection of Human Subjects in Research.

We have reviewed the proposed revisions as they are germane to the business of the Committee on Research (COR).

We support the proposed revisions to the policy on the Protection of Human Subjects in Research. We especially appreciate the inclusion a section with definitions. Moreover, we support the language that identifies the principles set forth in the Belmont Report which include respect for persons, beneficence, and justice.

Sincerely,

eapliner

Lea Grinberg, MD, PhD Chair, Committee on Research UCSF Academic Senate 2019-2020

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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

May 20, 2020

KUM-KUM BHAVNANI, Chair Academic Council

### Re: Presidential Policy on Protection of Human Subjects in Research

Dear Chair Bhavnani,

The Santa Cruz Division of the Academic Senate has reviewed and discussed the proposed revisions to Presidential Policy on Protection of Human Subjects in Research. Our Committees on Affirmative Action and Diversity (CAAD), Academic Freedom (CAF), Academic Personnel (CAP), and Faculty Welfare (CFW) have responded.

We begin by calling attention to the fact that these proposed revisions obviously preceded the current state of affairs presented by the COVID-19 pandemic, which introduces another set of considerations related to human subjects in research. As CAAD notes, the proposed revisions are thus necessarily "incomplete, or possibly obsolete, because it hasn't taken into account the ways in which future research on human subjects will be affected by pandemic conditions." Although CAAD does not call for specific allowances based on this context, it seems important to consider the related questions since this pandemic is likely to have long term consequences for human subjects in research.

Both CAF and CAP are concerned about the barriers to research presented by Institutional Review Boards (IRB). CAF specifically notes that IRBs create "barriers to research that conforms to disciplinary ethical standards, follows conventional research procedures and presents little to no risk of harm to human subjects." This is despite 2018 changes to the Common Rule that allowed for exemptions, which has often proven to be more of a burden to researchers, particularly those conducting research in the arts, humanities, and social sciences. CAAD reiterates this point in calling attention to disciplinary specific standards for the protection of human subjects in research and creative work: "Disciplines such as psychology and film, however, have their own codes of conduct and protocols regarding human subjects in research, separate from the university's." In addition, the committee recommends "that the policy acknowledge the existence of these." CAP notes that this issue also arises in the proposed revisions to the subsection of the policy related to Campus Responsibilities that provides "Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution." CAP acknowledges that this relates to ethical standards; however, the lack of language limiting oversight opens the door to the possibility that IRB administrators could disapprove of any research for any reason. When considered with the comments provided by CAF, this is cause for concern for those disciplines whose research protocols do not fit neatly within the Common Rule. Somewhat related, the revisions to Institutional Responsibilities calling for direct observation of research activities by IRB administrators can impact not only the work itself, CAP notes, but this impact could be amplified if the observed research processes and protocols

themselves are campus-centric. It places researchers from some disciplines in a position of having to operate under the shadow of a rebuttable presumption: that they must legitimize their research processes in the eyes of the observer while they are conducting it.

CAP also raises a question about the framing of the proposed revised policy, noting that the proposed revision shifts the emphasis from "a visionary statement affirming the importance of protecting the rights of human beings who participate in our research" to "a more legalistic statement about meeting minimum requirements." Furthermore, as CAP points out, "Rather than implying that the protection of the rights of human subjects is solely in the hands of IRBs and Institutional Officers, the policy could acknowledge the vitally important role that faculty/researcher expertise plays in protecting human subjects." CAF agrees and adds that while faculty researchers must follow ethical standards in their interaction with human subjects, "it is vital to ensure that IRB oversight that may not necessarily protect human subjects' rights and welfare does not also limit researchers' academic freedom."

Finally, CAF and CAAD offer the following specific recommendations:

- Explicit acknowledgement of academic freedom and the need for IRBs to recognize faculty and disciplinary expertise (CAF)
- Faculty and Senate involvement in development and revision of all local procedures related to the protection of human subjects (CAF)
- Divisional or Departmental Responsibility for Review of Non-Common Rule Human Subjects Research (CAF)
- Add "and others" to the third principle of the introduction to Section III so as to make clear that the list is not exhaustive (CAAD):

Justice requires that the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition--as children, prisoners, patients, impoverished persons, **and others**--places them in a vulnerable or dependent position.

As always, thank you for the opportunity to comment. I am enclosing the committee responses and hope these observations prove useful in the continued development of this important policy.

Sincerely,

Kimberly Lau, Chair Academic Senate, Santa Cruz Division

cc: Jessica Taft, Chair, Committee on Academic Freedom Elizabeth Abrams, Chair, Committee on Affirmative Action and Diversity Lynn Westerkamp, Chair, Committee on Academic Personnel Grant McGuire, Chair, Committee on Faculty Welfare Paul Roth, Chair, Committee on Research

May 11, 2020

## Kimberly Lau, Chair Academic Senate

## **RE: Proposed Presidential Policy on Protection of Human Subjects in Research**

Dear Kim,

The Committee on Academic Freedom (CAF) has reviewed the proposed changes to the UC Policy on Protection of Human Subjects of Research.

The AAUP and many scholarly associations have identified consistent problems with Institutional Review Boards (IRBs) stifling academic freedom and creating undue barriers to research -- -- even if that research conforms to disciplinary ethical standards, follows conventional research procedures, and presents little to no risk of harm to human subjects.<sup>1</sup> Further, CAF has heard increased reports from colleagues regarding our own IRB creating barriers to research that are unnecessary and that have no effects on the rights or welfare of research subjects, such as using specific analytic software or requiring rewording of interview questions.

While the 2018 changes to the Common Rule were originally seen by many in the humanities and social sciences as a positive shift that would allow more research could be considered "exempt" from IRB review, the experience of scholars has been that pursuing this exemption has become an incredibly arduous process, even for research activities that represent minimal risk and that involve only standard disciplinary research practices. Additionally, the local approach to what is now called "Limited Review" has actually made the IRB process *more* burdensome for some researchers. In particular, faculty in the Arts, Humanities, and Social Sciences, deeply committed to the ethical treatment of those with whom they work, have found in IRB standards insufficient recognition of the particular character of their research protocols. This can needlessly inhibit their ability to do research.

Given this frequently reported tendency at both the national and local level, CAF wants to take this opportunity to reiterate that when the IRB engages in its review, it should recognize faculty and disciplinary expertise regarding field-appropriate ethical practices so long as the research is in line with the principles outlined in the attached policy. The IRB could support academic freedom by making its procedures as minimally intrusive and streamlined as possible. Therefore, with these dynamics in mind, CAF makes the following recommendations to the proposed policy:

- 1. <u>Explicit acknowledgement of academic freedom and the need for IRBs to recognize faculty</u> <u>and disciplinary expertise</u>. This acknowledgement could be incorporated into the Introduction to the policy (alongside the excellent ethical principals).
- 2. <u>Faculty and Senate involvement in development and revision of all local procedures related</u> to the protection of human subjects. The policy notes that campuses may produce their own

<sup>&</sup>lt;sup>1</sup> <u>https://www.aaup.org/file/IRB-Final-Report.pdf;</u>

https://cdn.ymaws.com/www.ethnomusicology.org/resource/resmgr/ethics/irb\_statement\_2018.pdf;

guidance to supplement the implementation of the policy. Responsibility for any such guidance regarding local IRB procedures should be specified to include significant faculty consultation, including with the Divisional Senate and its Divisional Committee on Academic Freedom.

3. Divisional or Departmental Responsibility for Review of Non-Common Rule Human Subjects Research. The Committee appreciates that the policy acknowledges that "when engaged in Research that is not subject to the Common Rule (because, e.g., the Research is not federally funded), each UC location may replace specific Common Rule requirements with commensurate protections for Human Subjects so long as the University follows the ethical principles referenced above and that those commensurate protections are consistent with other applicable federal or state laws." However, by later stating that "officials may not approve Human Subjects Research if it has not been approved by an IRB" and IRBs are "charged with the review and continuing oversight of Research involving Human Subjects" it requires that all research also be authorized by the IRB, rather than another institutional body. In contrast to this model, the AAUP (and others) have proposed that departmental (disciplinary) oversight should be sufficient for research that uses surveys, interviews, other minimal risk methodologies because this is more protective of academic freedom and faculty are more informed regarding the ethical standards for their discipline than an IRB.<sup>2</sup> CAF supports development of a policy that would leave certain non-Common Rule research practices at UCSC subject to departmental or disciplinary oversight, rather than IRB review.

CAF certainly believes that researchers must follow ethical principals in their interaction with human subjects (this isn't a constraint on academic freedom). However, we feel that it is vital to ensure that IRB oversight that may not necessarily protect human subjects' rights and welfare does not also limit researchers' academic freedom. We would hope to see both systemwide and local policies that are more responsive to these longstanding concerns.

Thank you for the opportunity to comment.

Sincerely,

Jessier K. Topt

Jessica K. Taft, Chair Committee on Academic Freedom

cc: Lynn Westerkamp, Chair, Committee on Academic Personnel Elizabeth Abrams, Chair, Committee on Affirmative Action and Diversity Grant McGuire, Chair, Committee on Faculty Welfare Paul Roth, Chair, Committee on Research

<sup>&</sup>lt;sup>2</sup> https://www.aaup.org/file/IRB-Final-Report.pdf

May 13, 2020

Kimberly Lau, Chair Academic Senate

# **Re:** Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research

Dear Kim,

The Committee on Academic Personnel (CAP) reviewed the proposed Presidential Policy on Protection of Human Subjects in Research during its meeting of April 2, 2020. CAP members see this policy as being mostly in the purview of the Committee on Academic Freedom (CAF) and the Committee on Research (COR) but relates to CAP's charge in that the ability to conduct research is fundamental to career advancement for faculty.

CAP members were supportive of many of the proposed changes but also have some suggestions and several concerns. In the service of enhanced communication and to support careful review, CAP members ask whether additional context could be provided as to the timing and purpose of the proposed revision. For example, is this revision partly a response to changes by the federal government in its requirements for human subjects protection in funded research?

Some of the changes were seen as positive by CAP members. A clear statement that each campus must designate a person responsible for ensuring that IRBs "remain free from undue influence" helps to ensure that the IRB is conducting a rigorous and independent review of proposals. The explicit statement that this individual is also responsible for ensuring "adequate resources" for the IRB is also a positive change. If adequate resources are not available, the review process is likely to be lengthened, leading to delays in starting research projects. Delays are detrimental to all researchers, but especially to junior faculty and graduate students who are on tight timelines for their next career milestone (tenure and dissertation/job search, respectively).

Although generally supportive of the proposed changes, CAP members felt there were some areas of concern. Under *Campus Responsibilities* it is stated that "The Institutional Official appoints members of the IRBs." It is our understanding that this is the current practice (at least at UCSC)

and that these appointments are made only after faculty consultation. As far as we are aware, the current practice is working well on our campus. However, given that the "formal authority" part of the appointment process will now be made explicit in the (system-wide) policy, members felt that it would be appropriate to also make explicit that these appointments should be made only after appropriate consultation with faculty (e.g., relevant Senate committees, current IRB members, faculty who conduct research on Human Subjects).

More worrisome are two additions related to institutional authority, one under *Institutional Review Board Responsibilities* and the other under *Campus Responsibilities*. Under *Institutional Review Board Responsibilities*, the statement that the IRB has the authority to "Observe, or have a third party observe, the consent process and/or the conduct of Research" has the potential for overreach. Presumably this authority would be used only in extreme situations, but in extreme situations other policies (e.g., regarding faculty misconduct) might be more applicable and provide better processes for investigation and correction. The insertion of this statement contributes to a change in a tone (that we discuss further, below) that frames Human Subjects Protection as administration monitoring of possible research misconduct, rather than as a shared priority for (and value of) administration and researchers. Members also note that observation would be especially intrusive in some disciplines (e.g., Anthropology) or for some methodologies (e.g., interviews). Observation can change behavior, thus leading to inaccurate or inconclusive research results.

In *Campus Responsibilities*, a new statement reads "Research in which the University is engaged that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution." CAP members felt that this was both broad and vague, and has the potential for overreach and abuse of institutional authority. In the context of this policy, one might assume that the "further appropriate review" would be limited to ethical review, but that is not stated. Could this further review be based on financial considerations or perceived political fallout? Could the "officials" (who are they?) decide to disapprove research for any reason they please? Mindful of the fact that research is at the heart of faculty career advancement, CAP is concerned about oversight and the lack of an appeal process, but also believes that a statement giving such broad powers to the administration does not belong in a policy that should rightly be focused only on the ethical conduct of research with human subjects.

Finally, members were disappointed that the overall tone of the policy has shifted away from a visionary statement affirming the importance of protecting the rights of human beings who participate in our research and shifted towards a more legalistic statement about meeting minimum requirements. For example, why was the statement "The University of California is committed to the ethical principles for the protection of human subjects in research ..." removed and replaced with "This policy describes the responsibilities of the University ... in protecting the rights and welfare of Human Subjects"? Instead of a statement of commitment to an ethical principle, the

policy now merely acknowledges a responsibility (imposed by others?) to meet this goal. Rather than gutting the statement of commitment, this revision could be an opportunity to expand it. Rather than implying that the protection of the rights of human subjects is solely in the hands of IRBs and Institutional Officers, the policy could acknowledge the vitally important role that faculty/researcher expertise plays in protecting human subjects. Only the people deeply involved in research and its methods know the full range of risks and the full set of mitigations that can be employed. Risks and best practices are the subject of continued professional discussion and standards in different fields evolve over time. Transmitting this knowledge is an important part of graduate education. The policy as written seems to transform the protection of human subjects and the conduct of ethical research into a set of bureaucratic procedures rather than a shared commitment to an important value, one that is mostly upheld and realized by faculty.

Thank you for the opportunity to opine.

Sincerely,

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Lynn Westerkamp, Chair Committee on Academic Personnel

 cc: Elizabeth Abrams, Chair, Committee on Affirmative Action and Diversity Grant McGuire, Chair, Committee on Faculty Welfare Paul Roth, Chair, Committee on Research Jessica Taft, Chair, Committee on Academic Freedom

May 13, 2020

Kimberly Lau, Chair Academic Senate, Santa Cruz Division

## **Re:** Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research

Dear Kim,

During its meeting of April 16, 2019, the Committee on Faculty Welfare (CFW) reviewed the proposed revisions to the Presidential Policy on Protection of Human Subjects in Research. CFW supports the revisions and has no further comments.

Sincerely, /s/ Grant McGuire, Chair Committee on Faculty Welfare

 cc: Elizabeth Abrams, Chair, Committee on Affirmative Action and Diversity Lynn Westerkamp, Chair, Committee on Academic Personnel Paul Roth, Chair, Committee on Research Jessica Taft, Chair, Committee on Academic Freedom

May 11, 2020

Kimberly Lau, Chair Academic Senate

## Re: Review of Proposed Presidential Policy on Protection of Human Subjects in Research

Dear Kim,

The Committee on Affirmative Action and Diversity (CAAD) reviewed the Proposed Presidential Policy on Protection of Human Subjects in Research. CAAD recognizes that this draft was created prior to our current COVID-19 circumstances, rendering it incomplete, or possibly obsolete, because it hasn't taken into account the ways in which future research on human subjects will be affected by pandemic conditions. It is highly likely that research will be conducted remotely when feasible, requiring a re-thinking of the consent process for human subjects when studies are conducted online. For those experiments requiring human subjects to be physically present, ethical risks of potentially exposing human subjects to COVID-19 must be considered in the risk-benefit analysis when determining whether the experiment is appropriate.

CAAD noted that the policy seems to have been written as if the same approach were consistently applicable across all disciplines. Disciplines such as psychology and film, however, have their own codes of conduct and protocols regarding human subjects in research, separate from the university's. CAAD recommends that the policy acknowledge the existence of these.

CAAD also discussed the ethical principles outlined in the introduction in Section III, which were drawn from the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The third principle notes:

Justice requires that the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition--as children, prisoners, patients, impoverished persons--places them in a vulnerable or dependent position.

CAAD concurs that justice is a principle the policy must heed. To ensure the broadest application of this principle, we suggest adding the phrase "and others" after the short list of potentially vulnerable subjects ("children, prisoners, patients, impoverished persons") included. This would acknowledge that the list provided is not exhaustive.

Thank you for the opportunity to respond on this matter.

Sincerely,

\s\ Elizabeth Abrams, Chair Committee on Affirmative Action and Diversity Grant McGuire, Chair, Committee on Faculty Welfare Paul Roth, Chair, Committee on Research Jessica Taft, Chair, Committee on Academic Freedom

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UNIVERSITY COMMITTEE ON ACADEMIC FREEDOM (UCAF) Sarah Schneewind, Chair sschneewind@ucsd.edu Assembly of the Academic Senate 1111 Franklin Street, 12<sup>th</sup> Floor Oakland, CA 94607-5200 Phone: (510) 987-9466 Fax: (510) 763-0309

May 26, 2020

## KUM-KUM BHAVNANI, CHAIR ACADEMIC SENATE

# **RE: SYSTEMWIDE REVIEW OF PROPOSED PRESIDENTIAL POLICY PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

Dear Kum-Kum,

UCAF has discussed the Systemwide Review of Proposed Presidential Policy Protection of Human Subjects in Research and we have the following feedback.

Is there a process by which researchers can appeal Institutional Review Board decisions?

The Committee on Academic Freedom should also be listed in the as relevant to the process in the section on Other Campus Offices and Committees on page 5 of the proposed revisions and among the resources listed on page 7, the APM provisions on Academic Freedom should be included.

UCAF appreciates the opportunity to comment on this matter. Please feel free to contact me with any questions.

Sincerely,

Sarah Schneemind

Sarah Schneewind, Chair UCAF