



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

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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,

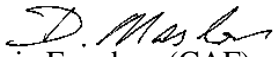
Dylan Rodríguez
Professor of Media & Cultural Studies and Chair of the Riverside Division

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

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COMMITTEE ON ACADEMIC FREEDOM

May 4, 2020

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

From: Dmitri Maslov, Chair 
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

FROM: Lucille Chia, Chair *Lucille Chia*
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.



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.



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 off-campus 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.

April 24, 2020

To: 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,



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