

January 11, 2021

Shane White, Chair
Academic Senate

Re: IRB and Scientific Review

Dear Chair White,

At its meeting on November 4, 2020, the Council on Research (COR) met with Professor Thomas Coates, Professor Todd Franke, and Professor James McGough. After an initial overview of what has transpired up to date between the IRB and the Scientific Review Committee (SRC), since COR issued its first letter to the Vice Chancellor for Research on January 16, 2020, members expressed the following comments and concerns.

Professors Coates, Franke, and McGough unequivocally praised COR's analysis and recommendations. COR members are distressed by the fact that nothing appears to have changed in one year. After COR and Senate Leadership issued its recommendations, there has not been transparency in the SRC's practices. It has come to COR's attention that the SRC continues to push and proceed with its activities, despite multiple discussions with the IRB and the OVCR. In particular, there are persistent concerns about the SRC imposing its review process on IRB applicants.

Even if COR members agree that there might be a benefit to the SRC's service, there is a concern that the overall involvement of the SRC has shifted from a voluntarily available resource to an imposition. The SRC's service is a recommendation and not a regulation. It could be a useful consultation service but as a voluntary consultation and not a mandatory process. COR wishes to emphasize the importance of protecting the rights of people who participate in research. The involvement of another body other than the IRB is redundant and not mandated by Federal regulations. This is not a question of value but of principle. COR members and Senate leadership understand that the SRC should not have the power to mandate to the PI, both in terms of research confidentiality and in terms of academic freedom. It is disappointing that after the Council issued recommendations, these were ignored.

COR issued a set of principles that we understood we had agreed upon. The following issues still persist: confidentiality in research, intellectual property and preservation of academic freedom.

COR members are troubled by the fact that this independent process without a mandate is dictating to faculty how to design research proposals and in the process defining which research should be supported, and all of this

occurs without communicating to the IRB. It appears that the SRC has been allowed unrestricted access to confidential information, although not vetted by any Senate body or the IRB. What we found in October 2019 and communicated in January 2020, appears to be still happening. COR wishes to underscore that the IRB is the only federally mandated body that evaluates scientific studies. Furthermore, COR also has been informed that the infrastructure that supports the existence of the SRC may be dependent on completing these reviews, even without official permission. This creates the appearance of a conflict of interest if indeed financial support of its efforts is dependent on their funding renewal and progress reports on SRC performance.

If you have any questions for us, please do not hesitate to contact me at julianmartinez@mednet.ucla.edu or via the Council's analyst, Elizabeth Feller, at efeller@senate.ucla.edu.

Sincerely,

Julian Martinez, Chair
Council on Research

cc: Thomas Coates, Chair, South General Institutional Review Board
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Principal Policy Analyst, Council on Research
Todd Franke, Chair, North General Institutional Review Board
Jody Kreiman, Vice Chair/Chair-Elect, Academic Senate
James McGough, Chair, Medical Institutional Review Board #3
Michael Meranze, Immediate Past Chair, Academic Senate
Roger Wakimoto, Vice Chancellor for Research and Creative Activities
Members of the Council on Research