

May 24, 2021

Shane White, Chair
Academic Senate

Re: IRB and Scientific Review Follow-up

Dear Chair White,

The Council on Research (COR) invited Professor Thomas Coates, Professor Todd Franke, and Professor James McGough to its April 7, 2021 meeting, to discuss the issue of scientific review. COR members had an opportunity to review VCR Wakimoto's March 31, 2021 response to the Senate in advance. COR Members and the IRB Chairs felt that the letter did not address the issues raised by the Council and the Academic Senate's Executive Board. The core of the issue is in the nuance and members felt this was not addressed by the reply. While the VCR's response was reassuring in that concrete steps have been taken to limit webIRB access to essential research study-related activities, the letter continues to justify disproportionately subjecting studies to SRC review in instances where there has not been outside peer review under the justification of patient privacy and safety.

On April 26, 2021, the Council's Leadership met with Steve Smale, Vice Dean for Research, DGSOM. Smale stated: "The Scientific Review mandate is considered by UCLA Health to be a patient safety and privacy issue rather than a research issue. The Vice Chancellor for Research generally does not oversee patient safety/privacy policies." This process appears to be happening at other UC campuses; UCI was pointed out as an example. This raises the issue of independence of UC Health from the UC enterprise.

COR members were briefed on the main points of the discussion with VDR Smale at the May 12, 2021 COR meeting. Earlier at that meeting, VCR Wakimoto acknowledged the continued implementation of the SRC process. He stated that only a small subset of applications, limited to clinical trials that have not undergone external peer review, is selected for review by the SRC, as part of a Health System mandate aimed at ensuring participant privacy and safety. COR members continue to be concerned with this issue, particularly the additional layer of scrutiny on studies and its effects on constraining research. COR members expressed concern given that patient safety and privacy are tenets and mandates of the IRB; requiring "scientific review" for the purposes of patient safety is redundant, unnecessary and open for misuse. Members find the statement that the Health System has authority, independent of the VCR's supervision, on issues of research study participant privacy and safety to also be deeply problematic. The lack of VCR supervision implies a lack of shared governance and therefore an absent role for the Senate in reviewing similar mandates. There are significant

consequences to the SRC mandate moving forward; COR members are concerned with the lack of checks and balances.

All along in this process, COR has attempted to engage all interested and relevant stakeholders to identify transparency and clarity and encouraged better communication of the SRC's roles and processes with faculty. A lack of transparency coupled with evolving criteria and roles for the SRC presents ongoing challenges in trying to preserve faculty research autonomy while at the same time ensuring proper checks and balances in all activities of the university. While there may be lingering questions regarding the SRC's role and opportunities to improve its process, the main concerns remain with undermining the role of the IRB and usurping the dedicated tasks of protecting participant privacy and safety of the IRB to non-IRB entities.

Another concern is the consideration of preserving the role of the SRC within the existing processes and infrastructure of the IRB. This is again redundant as there currently already exists a voluntary request for scientific review in those instances in which it is lacking. Smale also stated: "the Scientific Review/IRB Review path can be structured in any of a number of ways. However, it is considered to be of benefit to everyone for Scientific Review to occur before IRB Review, and to be integrated into the webIRB system." It is clear the SRC already has a role integrated within the IRB system in providing scientific review where necessary. It appears, though, that this role has expanded to IRB applications in which SRC involvement has not been triggered. This further emphasizes the concerns regarding the presence of a mandate without checks and balances, outside of the purview of the IRB's process.

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
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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
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