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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 disproportionally subjecting studies to SRC review in instances were 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
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
March 31, 2021

Shane White
Chair, UCLA Academic Senate

Re: Academic Senate Concerns re Scientific Review

Dear Chair White:

I am writing in response to your letter dated February 19, 2021 regarding the Academic Senate’s concerns about the role of the CTSI Scientific Review Committee (SRC) and about general access to information collected in webIRB, the system of record for the Office of the Human Research Protection Program (OHRPP).

We carefully reviewed and considered the Senate’s recommendations provided in January 2020 and January 2021. In January 2020, I asked the Office of Research Administration (ORA) and OHRPP to begin work immediately to inventory user access to the webIRB system and to review and make recommendations about the SRC process in webIRB.

As reported to COR by Associate Vice Chancellor Marcia Smith on June 3, 2020, ORA had by that date reviewed all user access to webIRB and immediately revoked access from any campus user who did not have documented Dean or Department head approval to access School or Department records. We also revoked nearly all access to grant or contract proposals submitted with IRB applications and stored in webIRB records. On average, about ten individuals outside ORA now have access, within their areas of responsibility, to grant proposals stored in webIRB. In these cases, ORA verified their need-to-know in order to perform their job responsibilities. These individuals include administrators from Hospital Billing, Billing Compliance, and Clinical Budget Development.

In addition, we changed the process for granting access to webIRB and webIRB tools so that no individual can grant access to webIRB without a second level of approval from ORA leadership. All requests for department-level access to webIRB will be forwarded to OHRPP leadership for review, and approval or disapproval. All requests for global access will be vetted by OHRPP Senior Director Kristin Craun and approved by AVC Marcia Smith.

I would like to highlight other tangible actions taken by our ORA technology team, beginning in early 2020 and continuing to the present, to improve security and limit access to the WebIRB online submission system and its related tools.
WebIRB Security and Access:
- Developed webIRB security capabilities to enable limiting user access at the School or Department level.
- Revoked global access from Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC) staff, to limit their access to cancer-related protocols.
- Revoked global access from CTSI staff, to limit their access to protocols from Health System organizations and those that propose to use Health System resources.
- Established a quarterly user access review process so OHRPP can proactively monitor and revoke user access as needed, such as when a user moves to a different job or department on campus.

ORA Data Feed to Clinical Research Management System (CRMS):
- Updated our web services to limit CRMS access to protocols from Health System organizations or those that propose to use Health System resources.
- Modified all reports to CRMS to limit data as above.
- IN PROGRESS – Working to identify the essential webIRB data elements required for CRMS operations and reduce the number of data elements provided by web service to CRMS to the minimum number required.

IRB Status Report Tool on ORA Portal:
- ORA technology group developed a tool that allows campus research administrators and fund managers to search for protocol approval dates when preparing a proposal or progress report. The tool provides a very limited set of data that includes PI name, Protocol Number and Title, and Approval Date. This tool has been enhanced to enable security at the department level.
- Revoked all global access to this tool and implemented department-level access on a per request basis.

OHRPP Senior Director Craun and ORA’s technology group carefully reviewed the SRC process in webIRB and discussed the process with CTSI, and CTSI conferred with Health System leadership. To help ensure patient safety and privacy, the Vice Chancellor of UCLA Health Sciences/CEO of UCLA Health will continue the Scientific Review process for research studies that fall under the purview of the UCLA Health Sciences (access UCLA patients, involve UCLA Health Sciences faculty, or use UCLA Health resources or medical records). The research studies subject to scientific review include the following:

1. Meet the NIH definition of a Clinical Trial
2. Non-cancer research (cancer research has mandatory scientific review requirements from the NCI independent of the IRB)
3. Without external documented scientific review
Research studies outside the scope of the Health Sciences will not be subject to review by the SRC and will be managed through the IRB review and approval process only.

I want to thank the Academic Senate for their time and consideration of this matter. I hope this letter brings resolution to any remaining concerns.

Sincerely,

Roger M. Wakimoto
Vice Chancellor for Research and Creative Activities

cc: Jody Kreiman, Vice Chair/Chair Elect, UCLA Academic Senate
    Michael Meranze, Immediate past Chair, UCLA Academic Senate
    Julian Martinez, Council on Research Chair, UCLA Academic Senate
    April de Stefano, Executive Director, UCLA Academic Senate
    Elizabeth Feller, Principal Policy Analyst, UCLA Academic Senate
    Marcia L. Smith, Associate Vice Chancellor for Research Administration
    Kristin Craun, Senior Director, Office of Human Research Protection Program