UCLA Research & Creative Activities

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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

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
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