UCLA Academic Senate

January 22, 2020

Roger Wakimoto
Vice Chancellor for Research

Re: Academic Senate Leadership's Response to the Scientific Review Issue

Dear Roger:

Because we think that this issue is of fundamental importance to the research environment and the academic freedom of UCLA researchers, Academic Senate Leadership discussed the Council on Research's (COR's) January 16, 2020 letter [enclosed] opposing the compulsory subjection of human subjects clinical trial research to a UCLA Clinical and Translational Science Institute (CTSI) review at our January 21, 2020 meeting. We are writing to make clear that we concur with COR's conclusion.

To assist in putting into context several issues that undergird the CTSI's request to subject proposals to preview, it is useful to include some local history that underlies our thinking. In the late 1990s, the U.S. government issued oversight of the Institutional Review Board (IRB) to the Chancellor, who delegated it to the then EVC/P Daniel Neuman. It is the Academic Senate Leadership's understanding that this line of responsibility is still in existence as an agreement with the Federal Government's Office of Human Research Protection. The reason this agreement occurred is that there were concerns at the time about both our IRB specifically and about the entire research procedures on campus more generally. Unless there has been rescinding of this designation, EVC/P Carter currently remains responsible for ensuring oversight of the IRB process. When this oversight designation occurred, the Academic Senate, in partnership with the administration, participated in several activities to revamp the entire process. Critical to this history is that at any juncture in which major changes have been requested to the IRB, previous EVC/Ps put into motion a process of a full investigation (one typically engaging the Huron Group) to ensure best practices and to project costs and personnel needs for the proposed changes. The costs of the review process have always been a large budget item for the campus. It is critical that these costs are adequately covered in order to be responsive to faculty and to manage the workload of the staff in support of timely review. I share this history in the interest of not only making clear the lines of authority but also to clarify what is at stake in the current requests from CTSI and how these matters have historically been handled.

The recent CTSI request to institute a pre-review, as presented to COR, raises a several issues that the Academic Senate Leadership wishes to emphasize here. First, we are writing as a follow-up to COR's letter [enclosed] in order to make clear that we concur and fully support COR's conclusion. The Academic Senate Leadership expects that such an expansion of the type requested by CTSI is not going forward either as a mandate or an imposition on our colleagues in Medicine as an obligatory recommendation. COR has not supported this expansion of the review process. We also note from examining the CTSI website that there are several institutions that have not moved forward with mandatory pre-reviews, those that have are neither the size nor the complexity of our institution.

The IRB process is a legally mandated review to ensure that harm is not done to human subjects. According to federal policy, the IRB is responsible for scientific review unless someone else has completed it. For UCLA, that other body is either NIH or JCCC ISPRC. For students, their faculty sponsor typically provides the scientific review. There is a related guidance/procedure document:

http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf. Our IRB is AAHRPP-accredited. It is the Senate Leadership's understanding that the process and expectations for the UCLA IRB mirror those of other IRBs nationally. UCLA IRB submissions already have a question in the application that asks the researcher to indicate if they want the IRB to conduct a scientific review or another entity (Section 2.1/Item 7.0). Therefore, any faculty member who may want additional review has always been at liberty to request it. Like other IRBs nationally, the UCLA IRB possesses the ability to provide any member who wants an additional review the opportunity to receive it. In general, however, our IRB follows the Federal regulations (45 CFR 46.111) that require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review seamlessly. (See http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Scientific_Review.pdf for additional details.)

Under the procedures as we understand them, the request for any additional reviews goes directly to the IRB which is bound by a number of regulations and statues in how they are to conduct that review and provide expertise that meets the Federal requirements in doing reviews (e.g., inclusion of community members, careful consideration of subjects drawn from vulnerable populations such as prisoners). We also are ensured that there is a process in place to protect and act in accordance with confidentiality and not to provide any competitive insights into research

activities of faculty through the reviewing of their intellectual property. In carefully reading the CTSI website, there is a matter that is troubling to us that we would like to close the loop on. We have reason to believe that CTSI has access through the IRB portal to applications. This belief arises from the CTSI website, which indicates that investigators do not need to submit protocols to them (https://www.researchgo.ucla.edu/regulatory-scientific-review-committee): "Investigators are not required to initiate SRC reviews and there is no application process. All study documentation is collected by Office of Regulatory Affairs (ORA) staff and provided to the SRC for review" (https://www.researchgo.ucla.edu/office-regulatory-affairs). This apparent ability to access research protocols directly is significantly concerning and appears to have been allowed through an administrative an overreach without full disclosure to the Senate or campus researchers. The Senate Leadership is requesting that this process of providing unsupervised access and permission-less access to the intellectual property of the faculty be stopped at once. Going forward, if anyone funded by CTSI wishes to request a CTSI review or anyone elsewhere on campus wishes to engage the services of CTSI, these individuals must submit directly to CTSI and not commingle systems. As far as we understand, CTSI has no legal standing in the university review process. Moreover, there are no articulated and transparent rules in place for the conduct for their activities.

I think that we can all agree that preventing harm for human research participants is of the utmost responsibility for us as a campus. We are mandated to meet this goal by Federal regulations. Still, it is also the responsibility of both the university administration and the Academic Senate (in the spirit of shared governance) to ensure that our procedures inflict no damage upon the faculty. Although distinct scientific review procedures have been mandated for Federal funding at the Cancer Center, the government has not chosen to make this a more general requirement. For UCLA to do so unilaterally, in fact, raises serious questions about administrative interference in research and in the academic freedom of researchers. Indeed, at COR's October 2, 2019 meeting (which Vice Chair Shane White and myself attended, due to our recognition of the importance of this proposal), it was clear that CTSI could inevitably impose a particular sense of research validity and appropriateness on disparate and differing fields of research. I think that all of us can agree that there are already enough bureaucratic processes that researchers need to pass through without adding an additional layer, especially one that is likely to impose a particular sense of what research is. The proposed approach will likely result in persistent use of grievance procedures on the part of individual faculty who, to my mind, will appropriately believe that they are being subject to unnecessary administrative interference in their work.

In summary, the Academic Senate Leadership stands firmly behind COR's recommendations. If EVC/P Carter elects to undertake a major review of this matter along with its budget implications, faculty and staff burden, mandates by the Federal Office of Human Research Protection, and faculty perspectives, the Academic Senate will of course be prepared to work with the Administration. Until then, however, we are sharing our concurrence with COR's decision with various entities, including the movers of the request, our faculty IRB chairs, and EVC/P Carter.

Please let us know if you have any questions. We would also appreciate indication from your office apprising COR that you have informed both the IRB and the CTSI that the latter's proposal will not be enacted.

Sincerely,

Michael Meranze
Chair, UCLA Academic Senate

Encl. COR to VCR_Scientific Review Issue_1-16-2020.pdf

Cc: Emily Carter, Executive Vice Chancellor and Provost
Marcia Smith, Associate Vice Chancellor, Office of Research Administration
Shane White, Vice Chair/Chair Elect, UCLA Academic Senate
Joseph Bristow, Immediate Past Chair, UCLA Academic Senate
Richard Desjardins, Chair, Council on Research
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UCLA Academic Senate
Council on Research

January 16, 2020

Roger Wakimoto
Vice Chancellor for Research

Re: Scientific Review Issue

Dear Vice Chancellor Wakimoto,

At its meeting on October 2, 2019, the Council on Research (COR) met with the Research Administration leadership, Human Research Policy Board (HRPB) members, and the CTSI Scientific Review Committee (SRC) members, to discuss the issue of incorporating a more formal scientific review into approvals of human subjects clinical trials research. The Council on Research focused on substantive differences in the arguments presented by both groups. After a consultation with each group, the Council had an opportunity to discuss in an executive session, without guests present, and considered the issue again at its meeting on November 13, 2019 as well as via several subsequent email communications.

The Council's understanding of the background is as follows:

- The Institutional Review Board (IRB) review process is based on a federal legal mandate to mitigate safety risks involving human research subjects. As part of this process, the IRB recruits appropriate experts based on subject matter to review research proposals. The IRB is committed to constantly reviewing and improving its research review process. Furthermore, the IRB is willing to incorporate a further SRC review process for research involving clinical trials with human subjects on a voluntary basis so as to provide additional support, but this must be rationalized through the IRB review process and follow appropriate protocols regarding confidentiality, permissions to access the proposals; any additional review for support must be voluntary.

- The SRC currently conducts scientific review of oncology clinical trials following the National Cancer Institute (NCI) requirement for Internal Scientific Peer Review Committee (ISPRC) reviews of clinical oncology protocols. The SRC requests a mandate to add an additional SRC review process for any research involving clinical trials with human subjects including non-oncology clinical trials, which has not received external scientific review. The rationale is that two years of quantitative data on 400 clinical trials reveals that a number of studies with significant issues could be addressed by SRC review, and that the difference

between oncology and non-oncology clinical trials is not substantial enough to warrant different review standards.

The Council's deliberations resulted in the following observations:

1) COR noted an important distinction between the rationale for IRB and SRC review processes, specifically that the former is based on a federal legal mandate. In contrast, the latter is a requirement by a federal agency to follow specific review protocols to qualify for federal funding for specific types of studies (i.e. oncology clinical trials).

2) CTSI's Scientific Review Committee is going beyond the IRB's legal mandate. The CTSI mission involves a number of things that are not scientific, but rather about defining what is a public good. There is considerable risk that the two end up conflated. If we are only talking about risks to research subjects, then IRB already has the mandate and process to deal with that.

3) Most COR members believe that SRC's added requirement implies that IRB is not fulfilling its role. There is no evidence that this is the case. Members agreed that data presented by SRC in support of the additional review was not compelling.

4) Most COR members believe that SRC's argument that differences between oncology and non-oncology clinical trials are not substantial enough to warrant different review standards is unwarranted and potentially problematic in many ways. For example, how is the value of science determined? Who decides what is "good science"? Most members believe that the SRC is not the correct body to decide what is "good science" beyond its specific disciplinary boundaries or in establishing criteria for research other than for specific types of research (i.e. oncology clinical trials). Non-oncology clinical trials are conducted outside the health and medical sciences and thus it is not clear if SRC's intention is to impose a particular approach or criteria beyond medical research. Moreover, it was not clear whether a particular approach should be imposed even within medical research since there are examples of relational type research between doctors and patients that do not necessarily align well with the biomedical approach to research. Most COR members believe that the peer review process including requirements outlined by a federal agency must be rooted in a community of peers that are directly relevant to the specific area of research and believe that IRB processes currently reflect this approach.

5) Most COR members believe that SRC's added requirement of a peer review process rooted in one disciplinary or established perspective (i.e. oncology clinical trials) could be a potential violation of academic freedom for those who conduct research from a different disciplinary perspective (i.e. non-oncology clinical trials). Moreover, this could stifle innovation and the discovery of alternative paradigms. Most members were particularly concerned with the potential of overreach and mission creep by SRC in imposing a particular model of science on other disciplines. For these reasons, most COR members believe that any added SRC review process should be transparent and voluntary. A few members thought it should be mandated for clinical trials of a specific nature such as those involving

biomedical interventions which pose risks to patients. One recommendation is to encourage a voluntary process whereby principal investigators are strongly encouraged to seek additional scientific review and support (from SRC) and provided with a clear and concise explanation of the risks involved and potential benefits. It is COR's recommendation that any further deliberation about mandating SRC's review process be referred to the Academic Senate's Standing Committee on Academic Freedom.

6) Most COR members believe that SRC's request for the added SRC review requirement involves additional faculty and administrative burden including financial costs, even if it involves no explicit financial outlay. It is therefore also COR's recommendation that any further deliberation about mandating SRC's review process be referred to the Academic Senate's Standing Committee on Faculty Welfare as well as the Council on Planning and Budget.

In summary, while faculty can and should be encouraged to seek additional review by the Scientific Review Committee if their research is not otherwise exposed to peer review and involves risks to research subjects, it is COR's view that this additional review should not be mandatory.

If you have any questions for us, please do not hesitate to contact me at desjardins@ucla.edu or via the Council's analyst, Elizabeth Feller, at efeller@senate.ucla.edu or x62470.

Sincerely,

Richard Desjardins, Chair
Council on Research

cc: Joseph Bristow, Immediate Past Chair, Academic Senate
Elizabeth Feller, Principal Policy Analyst, Council on Research
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Marcia Smith, Associate Vice Chancellor, Office of Research Administration
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