

Council on Research

UCLA Health System and Scientific Review Mandate 2021

Table of Contents

Exec Divisional Response	1
COR Final Response	3

June 15, 2021

Emily Carter
Executive Vice Chancellor and Provost

Re: Campus Governance

Dear EVCP Carter,

At its meeting on June 3, 2021, the Executive Board reviewed the attached letter of May 24, 2021, from the Council on Research (COR) expressing their concerns regarding the Health System's governance following a meeting among DGSOM VDR Steven Smale and COR leadership on April 26, 2021, to discuss issues surrounding a unilateral imposition of scientific review by the Clinical and Translational Science Institute (CTSI) leadership through their Scientific Review Committee (SRC). I have previously written to you about the issue of Health System's scientific review mandate, but this letter addresses a different topic, that of campus governance.

At the April 26 meeting, VDR Smale informed COR Chair Martinez and COR Vice Chair Iacoboni that the Vice Chancellor for Research (VCR) does not oversee patient privacy policies, and as a result, notwithstanding the federally defined role of the IRB, the health system may mandate its own scientific review to ensure patient privacy and safety. As represented by VDR Smale, the Health System appeared to believe it had the authority to set up a review process outside the purview of the VCR and the Academic Senate. When this was discussed at the May 12, 2021 COR meeting, members found this deeply problematic, and the above referenced letter of May 24 was transmitted to the Executive Board.

According to Regents' Bylaw 40.1, the Academic Senate has the responsibility to ensure the quality of instruction, research, and public service at the University and to protect academic freedom. The above refusal to engage the Academic Senate prevents it from fulfilling its duties in ensuring the quality of research and in protecting academic freedom. Failure of the Health System to engage with the Office of the Vice Chancellor for Research & Creative Activities (ORCA) or the Academic Senate when making a unilateral mandate undercuts campus governance, and undermines your and the Chancellor's Offices.

It is with regret that that I bring this matter to your attention. Perhaps VDR Smale overstated his position, or failed at that moment to appreciate the mechanisms of campus governance. Nonetheless, the incident cannot be overlooked. I look forward to your response, and to ensuring that such incidents are not repeated.

Sincerely,

Shane White
Chair, UCLA Academic Senate

Encl.

cc: Gene Block, Chancellor
April de Stefano, Executive Director, UCLA Academic Senate
Elizabeth Feller, Principal Policy Analyst, UCLA Academic Senate
Marco Iacoboni, Council on Research Vice Chair, UCLA Academic Senate
Jody Kreiman, Vice Chair/Chair Elect, UCLA Academic Senate
Julian Martinez, Council on Research Chair, UCLA Academic Senate
Michael Meranze, Immediate Past Chair, UCLA Academic Senate
Emily Rose, Assistant Provost and Chief of Staff to the EVCP
Roger Wakimoto, Vice Chancellor for Research and Creative Activities

May 24, 2021

Shane White, Chair
Academic Senate

Re: Health System Scientific Review Mandate

Dear Chair White,

On April 26, COR leadership met with Steve Smale to discuss issues surrounding role of the Scientific Review Committee (SRC) in the David Geffen School of Medicine and UCLA Health System studies. At that meeting, COR Chair Martinez and COR Vice Chair Iacoboni were informed that the Vice Chancellor for Research does not oversee patient privacy policies and that the health system mandates scientific review in instances where it is lacking to ensure patient privacy and safety. This was discussed at the May 12, 2021 COR meeting and members found this deeply problematic. A summary of the meeting, seen and approved by the attendees, is enclosed at the end of the letter.

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: Jody Kreiman, Vice Chair/Chair-Elect, Academic Senate
Michael Meranze, Immediate Past Chair, Academic Senate
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Principal Policy Analyst, Council on Research
Members of the Council on Research

Encl.

Meeting on Scientific Review

April 26, 2021

Attendees: Marco Iacoboni (COR Vice Chair), Julian Martinez (COR Chair), Steve Smale (VDR DGSOM)
Elizabeth Feller (COR Analyst)

Summary

Vice Dean for Research Smale requested a meeting with Dr. Martinez and Dr. Iacoboni after a discussion with Vice Chancellor Wakimoto, which led to the sense that it could be helpful for Dr. Smale to describe his perspective on the reasons for the Scientific Review mandate. These are not official statements, but rather Dr. Smale's personal perspective from being involved in some of the discussions. He shared the following on the scientific review process:

- 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.
- Council on Research (COR) and the Academic Senate may not have understood that it's being viewed primarily as a patient safety/privacy issue, and may feel it should instead be viewed as a research/academic freedom issue.
- The rationale for Scientific Review has two components:
 - UCLA Health has mandated Scientific Review for the small number of human subjects studies that have not undergone external peer review (e.g. by the NIH, FDA, etc.) and that require UCLA Health patients and patient data; the purpose is to help maintain patient safety and privacy. As stated by another university with mandated scientific review, "Ensuring scientific merit is a key component of protecting the rights and welfare of human research subjects."
 - The review mandate extends to all studies proposed by UCLA Health faculty, not just those that involve health system patients and data. The reason for extending the mandate is that it would be ethically inappropriate to consider scientific merit only when UCLA Health patients are involved, but not if faculty are able to recruit study participants from elsewhere (such as our partner hospitals, whose patients are skewed toward lower income and more ethnically diverse populations).

Many institutions, including UC Irvine, are implementing mandatory scientific review. While IRB looks at the safety of a study, scientific review evaluates its scientific merit.

- The Health System mandates Scientific Review. The issues of authority can be raised beyond the Health System.
- 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. If IRB Review occurs before Scientific Review, the IRB may need to re-review protocols that are modified after Scientific Review, which would be inefficient for the IRB and would delay final study approval for the faculty. Scientific Review could also be dissociated from webIRB, but this would only decrease efficiency and speed and would therefore be undesirable to PIs. Dissociating Scientific Review from webIRB would not change the mandate.

COR Leadership stated the following:

- COR's concerns have been clear:

- Given that the Vice Dean Smale acknowledged that the Health System unilaterally imposed this mandate, there are ongoing concerns about a process that is not federally mandated and that impinges on the work of the IRB. There is a perception that the Health System is trying to bypass the Senate and campus.
- The Scientific Review Committee's (SRC) process has not been explained to faculty. It is not transparent.
- Faculty have expressed concerns that can lead to quenching the pursuit of research efforts.
- In addition, why have there been studies submitted to the IRB with the unchecked box for the SRC's review but there has still been a review completed by the SRC? The perception is that this has been a unilateral decision from the Health System leadership. There is a need for more transparency.
- Additional concerns include:
 - Why does the SRC have access to research data? How does the IRB process feed to the SRC? This is unclear to COR and to faculty more broadly. SRC seems to be a mandatory process, which disproportionately affects faculty in the School of Medicine School.
 - How was this process established unilaterally without engaging the shared governance entities that represent faculty? This is most relevant in this context as it could create inequities to fund studies among faculty.
- Issues of authority: can the Health System impose a review? The HS unilaterally decided on this issue under the guise of patient safety. The existence of the SRC process adds another layer of review that is redundant given that there are other opportunities for scientific review, facilitated through the IRB process which unlike the SRC, is federally mandated.

Next Steps:

- Vice Dean Smale agreed that he would request detailed information about the process and flow of information that has been developed to allow Scientific Review and IRB Review to occur efficiently. He will then help to make sure the detailed process is clearly communicated to COR and faculty.
- COR will share main points of the discussion with members at their next meeting.