Council on Research

Scientific Review and IRB

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UCLA Academic Senate
Council on Research

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 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
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UCLA Research & Creative Activities

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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

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

UCLA Academic Senate

February 19, 2021

Roger Wakimoto
Vice Chancellor for Research & Creative Activities

Re: **IRB and Scientific Review Committee**

Dear Vice Chancellor Wakimoto,

On behalf of the Executive Board, I am writing to follow up about on-going concerns of the Academic Senate about the role of the Scientific Review Committee (SRC).

In a letter to you dated January 22, 2020, my predecessor indicated the Academic Senate's alarm about the SRC's practices, which were detailed in the Council on Research (COR)'s accompanying letter dated January 16, 2020. COR sent a follow-up letter to the Executive Board dated January 11, 2021, which reiterated its continued concerns as well as its dismay that no change had occurred in the preceding year.

At its meeting on February 18, 2021, the Executive Board unanimously endorsed the new COR letter of January 11, 2021. Members concurred that the current practices of the SRC have a pernicious effect on confidentiality in research, intellectual property and preservation of academic freedom.

We respectfully request a written response to this letter and the enclosed materials by the end of March 2021. As always, we appreciate the opportunity to advise your office on the crucial issues facing the campus and look forward to working with you to address them.

Sincerely,

Shane White
Chair, UCLA Academic Senate

Encl.

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

UCLA Academic Senate
Council on Research

January 11, 2021

Shane White, Chair
Academic Senate

Re: IRB and Scientific Review

Dear Chair White,

At its meeting on November 4, 2020, the Council on Research (COR) met with Professor Thomas Coates, Professor Todd Franke, and Professor James McGough. After an initial overview of what has transpired up to date between the IRB and the Scientific Review Committee (SRC), since COR issued its first letter to the Vice Chancellor for Research on January 16, 2020, members expressed the following comments and concerns.

Professors Coates, Franke, and McGough unequivocally praised COR's analysis and recommendations. COR members are distressed by the fact that nothing appears to have changed in one year. After COR and Senate Leadership issued its recommendations, there has not been transparency in the SRC's practices. It has come to COR's attention that the SRC continues to push and proceed with its activities, despite multiple discussions with the IRB and the OVCR. In particular, there are persistent concerns about the SRC imposing its review process on IRB applicants.

Even if COR members agree that there might be a benefit to the SRC's service, there is a concern that the overall involvement of the SRC has shifted from a voluntarily available resource to an imposition. The SRC's service is a recommendation and not a regulation. It could be a useful consultation service but as a voluntary consultation and not a mandatory process. COR wishes to emphasize the importance of protecting the rights of people who participate in research. The involvement of another body other than the IRB is redundant and not mandated by Federal regulations. This is not a question of value but of principle. COR members and Senate leadership understand that the SRC should not have the power to mandate to the PI, both in terms of research confidentiality and in terms of academic freedom. It is disappointing that after the Council issued recommendations, these were ignored.

COR issued a set of principles that we understood we had agreed upon. The following issues still persist: confidentiality in research, intellectual property and preservation of academic freedom.

COR members are troubled by the fact that this independent process without a mandate is dictating to faculty how to design research proposals and in the process defining which research should be supported, and all of this

occurs without communicating to the IRB. It appears that the SRC has been allowed unrestricted access to confidential information, although not vetted by any Senate body or the IRB. What we found in October 2019 and communicated in January 2020, appears to be still happening. COR wishes to underscore that the IRB is the only federally mandated body that evaluates scientific studies. Furthermore, COR also has been informed that the infrastructure that supports the existence of the SRC may be dependent on completing these reviews, even without official permission. This creates the appearance of a conflict of interest if indeed financial support of its efforts is dependent on their funding renewal and progress reports on SRC performance.

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
Members of the Council on Research

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
Tzung Hsiai, Chair, Faculty Welfare Committee
Moira Inkelas, Chair, Committee on Academic Freedom
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Principal Policy Analyst, Council on Research
Todd Franke, Chair, North General Institutional Review Board
Thomas Coates, Chair, South General Institutional Review Board
Daniel Clemens, Chair, Medical Institutional Review Board 1
Allan Pantuck, Chair, Medical Institutional Review Board 2
James McGough, Chair, Medical Institutional Review Board 3

Ronald Brookmeyer, Dean, the UCLA Jonathan and Karin Fielding School of Public Health

Robin Garrell, Vice Provost/Dean, Graduate Division

Paul H. Krebsbach, Dean, School of Dentistry

Kelsey Martin, Dean, David Geffen School of Medicine

Linda Sarna, Dean, School of Nursing

Steven M. Dubinett, Director, UCLA Clinical and Translational Science Institute

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
Michael Meranze, Chair, Academic Senate
Marcia Smith, Associate Vice Chancellor, Office of Research Administration
Shane White, Vice Chair/Chair-Elect, Academic Senate
Members of the Council on Research