

Committee on Research
Lea Grinberg, MD, PhD, Chair

ANNUAL REPORT
2018-2019

Issues reviewed and acted on by the Committee included:

- Presidential Policy on Export Controls
- Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028
- UC MEXUS
- Funding 21 Principal Investigators (PIs) through the Research Allocation Program (RAP)
- Travel Grant for Junior Faculty
- Chancellor’s Fund Travel Grants
- 2018-2019 Faculty Research Lectures in Basic, Clinical, and Translational Sciences
- Selection of 2019-2020 Faculty Research Lectures in Basic, Clinical, and Translational Sciences
- Conflict of Interest “Rule 11”
- Office of Sponsored Research Funding Model
- Common Rule and the Institutional Review Board (IRB)
- Procedures for Changing Name of Academic Unit or Program
- Fetal Tissue Research
- Consultation with Office of Research

Task Forces, Special Committees, and Sub-Committees:

- Office of Sponsored Research Advisory Group – Stuart Gansky
- RAP Executive Steering Committee – Lea Grinberg
- Resource Advisory Board - Marguerita Lightfoot

Issues for Next Year (2019-2020)

- Research Management Services
- Institutional Review Board
- Export Controls Policy
- Conflict of Interest “Rule 11”
- Organized Research Unit (ORU) Review Process
- Intellectual Property, Technology Transfers and National Security
- Selection of the 2019-2020 Faculty Research Lecturers in Basic, Clinical, and Translational Sciences
- Chancellor Funds

2018-2019 Members

Lea Grinberg, Chair Marguerita Lightfoot, Vice Chair Adam Abate Penny Brennan Joelle Brown Wenhan Chang Farid Chehab Elena Flowers Stuart Gansky, UCORP Representative	Daniel Jones Janel Long-Boyle Sima Porten Peter Rechmann Parya Saberi Lei Wang Zhen Wang Emmanuelle Waubant Elad Ziv
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Number of Meetings: 9
Senate Analyst: Kenneth Laslavic

Systemwide Business

Presidential Policy on Export Controls

The committee reviewed and commented on the 2016-2017 and 2017-2018 systemwide review of the proposed Presidential Policy on Export Control. During both reviews, the committee noted that UCSF would need to create an Export Control Program. The committee also noted that faculty could be subject to civil and criminal penalties for violations of export control laws and regulations.

During 2018-2019 COR requested information from the UCSF Office of Ethics and Compliance about the creation of an Export Control Program at UCSF. The committee will continue efforts to engage staff from the Ethics and Compliance in order to gather information about the Export Control Program.

Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028

UCOP issued a proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research, which would define circumstances in which the substantive review of a disclosure of financial interests must be completed by the Independent Substantive Review Committee (ISRC), as opposed to a Designated Campus Reviewer (DCR).

COR reviewed the policy and conferred with the Ethics and Compliance to understand the impact of the new policy. The revision removes the policy from the APM and puts the policy within an official Presidential Policy. The new policy also requires a Designated Campus Reviewer to submit disclosures above \$10,000 to the COIAC.

UC MEXUS

UC proposed the consolidation of *UC MEXUS*, the *UC-Mexico Initiative*, and *Casa de California*. COR discussed the proposal and supported the proposal with the following caveats: (1) *UC-MEXUS* provide leadership for the now consolidated activities, (2) that the administrative home of the program remain at UC Riverside, and (3) UCOP investments match those of CONACYT.

COR submitted a letter to Executive Council regarding the proposed merger of *UC MEXUS*, *UC Mexico Initiative*, and *Casa de UC*.

Divisional Business

Topics Explored during 2017-2018

Process Topics:

- Resource Allocation Program (RAP) Grant Funding*
- Travel grants for faculty appointed within last five years*
- Selection of the 2019-2020 Faculty Research Lectures Recipients*
 - FRL – Clinical Science (Rebecca Smith-Bindman, MD)*
 - FRL – Basic Science (Kevin Shannon, MD)*
 - FRL – Translational Science (John Fahy, MD)*

Policy Topics:

*Conflict of Interest "Rule 11"
Office of Sponsored Research Funding Model
Common Rule and the Institutional Review Board (IRB)
Procedures for Changing Name of Academic Unit or Program*

PROCESS TOPICS

Resource Allocation Program (RAP) Grant Funding

	Est. Pilot	Jr. Pilot	Shared Instrument	Family Support	Re-Entry	Hardship	Independent Support	Team Science	URM	Total
Fall 2018	3	7	1	0	0	0	0	1	0	12
Spring 2019	3	2	2	0	1	0	0	1	0	9
Total	6	9	3	9	1	0	0	2	0	21

The Academic Senate funded 21 grants during the 2018-2019 RAP cycles totaling \$925,000 - a decrease of two grants from the prior year..

Travel Grants

The Academic Senate Office, under the auspices of the Committee of Research, granted 10 travel grants during the 2018-2019 academic term. These grants are funded from Opportunity Funds. The Senate office awarded grants in the amount of \$5,000.

Chancellor's Fund

The Committee agreed to reduce the amount of available funding per award from \$2,000 last cycle to \$1,500 this cycle in order to support more applicants. In addition, the committee agreed to enact a new review criteria. Funding will only be awarded for oral presentations and not a poster presentation of original research results. If possible, COR suggested the Senate use a single application for all travel grants. In addition, the travel grants should be awarded in cycles in order to preserve funding for applicants who travel later in the year.

\$30,000 of the Chancellor's Fund has been set aside for this purpose. COR will award one half of the total beginning in February and it will award the other half later in the year. COR expects the demand for these grants to be extremely high based on prior years' experience. During the two cycles the committee awarded \$24,248.71 in travel grants.

2018-2019 Faculty Research Lecture - Clinical Science

Since 2001, this award has been bestowed on an individual member or members of the UCSF faculty with outstanding achievements in clinical research. Nominations are made by UCSF faculty, who consider the clinical research contributions of their colleagues and submit nominations for this prestigious award to the Academic Senate Committee on Research. Each year, the Committee on Research selects the recipient of this award. Faculty Research Lecture - Clinical Science was Donna Ferriero, MD, MS.

2018-2019 Faculty Research Lecture - Basic Science

Since 1957, this award has been bestowed on an individual member of the UCSF faculty who has made a distinguished record in basic science. Nominations are made by UCSF faculty, who consider scientific research contributions of their colleagues and submit nominations for this prestigious award to the Academic Senate Committee on Research. Each year, the Committee on Research selects the recipient of this award. Faculty Research Lecture - Basic Science was Carol Gross, PhD

2018-2019 Faculty Research Lecture - Translational Science

In selecting faculty to receive this award, the Senate recognizes the immense value of those who translate bench science to a bedside clinical practice directly benefiting both patients and legions of other clinicians worldwide. Faculty Research Lecture - Translational Science was Kathleen Giacomini, PhD

Selection of the 2019-2020 Faculty Research Lecture Recipients

Committee members reviewed nomination packets of eight candidates, met with nominators, and voted to honor three lecturers. Those to be recognized are:

- Faculty Research Lecture - Clinical Science is Rebecca Smith-Bindman, MD
- Faculty Research Lecture - Translational Science is John Fahy, MD
- Faculty Research Lecture - Basic Science is Kevin Shannon, MD

Attendance at Faculty Research Lectures

During the 2018-2019 academic year COR directed efforts toward increasing attendance at the FRL lecture series. In addition to digital and print advertising, COR used targeted communications to departments. COR observed an increase in attendance as a result of its efforts.

POLICY TOPICS

Conflict of Interest "Rule 11"

In response to faculty concerns, the COI Advisory Council (COIAC) began reviewing Rule 11 and whether it should be revised or discarded. Rule 11 provides: "Faculty who have, or participate in, a privately sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study. In addition, they shall not have any investment in, or serve in a decision making capacity for (such as service on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the study." COIAC had a preliminary policy discussion on May 17, 2018. On June 21, 2018, the COIAC heard from faculty stakeholders and determined Rule 11 should not be eliminated but aspects of Rule 11 should be clarified. On July 18, 2018, COIAC members voted on proposed clarifications to Rule 11. The proposed changes will be sent to the Academic Senate and the EVCP for review and comment. One proposal for purposes of Rule 11 is to exclude research-related travel payments from the definition of "compensation." Another proposal is to limit the meaning of "clinical study" to anything that requires approval by the IR

Office of Sponsored Research – Funding Model

COR discussed the OSR funding model, which is a per PI charge. COR is concerned about the cost sharing burden imposed on departments where PIs submit grant proposals at a low frequency. In addition, smaller departments may incur higher costs under this funding model.

Common Rule Presentation – Laurie Herraiz, HRPP Director

Laurie Herraiz presented to COR on the Common Rule revisions, the single IRB mandate for NIH sponsored research, and general updates within HRPP.

The Common Rule, originally promulgated in 1991, applies to human research sponsored by the NIH, DoD, DoE, and NSF. The Common Rule revisions have changed rules and regulations governing the review and conduct of biomedical and social behavioral research involving human subjects. Under the changes, more research may qualify for Exemptions. In addition, the changes include new informed consent requirements. Continuing review of expedited research may not be required. Overall, the Common Rule revisions will have a lot of impact for investigators. The changes go into effect on January 21, 2020.

The NIH mandate for a single IRB for multi-site studies went into effect on January 25, 2018. At UCSF, 50 grant submissions were impacted by this mandate. We received 43 requests to be the Reviewing IRB.

HRPP has filled eight of its 10 vacancies. It has also appointed a new quality improvement director.

Procedures for Changing Name of Academic Units or Program

The Committee on Research reviewed and discussed the proposed procedures for changing the name of an academic unit or program. Members of the committee expressed support for the proposed procedures. The procedures were placed on the consent calendar of the Executive Council.

Fetal Tissue Research

During the second half of 2018 the federal government increased its attention and apparent opposition to the use of legally acquired fetal tissue in biomedical research. COR authored a letter urging the University of California Office of the President to coordinate a response to the federal government's recent threats to fetal tissue research. It made the following recommendations:

- UCOP should create a network of scientists who engage in research that may be subject to political opposition. The network should amplify the voices of subject matter experts in the process of developing public policy including but not limited to federal legislation and regulations. We offer the UCSF Program on Reproductive Health and the Environment as an example of a rapid response network that operates at the intersection of science, medicine, policy, and community.
- UCOP should sponsor a forum for academics from the humanities, social sciences, and health sciences to consider key questions of bioethics. UC could expand its support of the UC North Bioethics Collaboratory as a first step.
- UCOP should engage UC researchers who conduct fetal tissue research to develop a white paper defending the use of legally acquired fetal tissue in biomedical research.
- UCOP should organize direct action to engage policymakers and advocate for federal sponsorship of research using fetal tissue. UC Advocacy Network could be the platform for this effort.

Academic Council delivered a letter to President Napolitano unanimously endorsing the letter from the San Francisco Senate Division urging the Academic Senate and UCOP to speak out against new federal-level restrictions on NIH funding for legally-acquired fetal tissue in biomedical research.

In June 2019 the National Institutes of Health issued instructions for how scientists seeking grants for research using fetal tissue must comply with recent Trump administration restrictions on federal funding of such studies.

Consultation with Office of Research

With the appointment of Lindsey Criswell as the new Vice Chancellor for Research (VCR) COR has re-engaged with the Office of Research and the Vice Chancellor for Research. In addition to having a Senate representative on the Research Advisory Board, the VCR attends meetings of COR. COR will continue to coordinate and consult with the Office of Research and VCR.

Going Forward

Ongoing issues under review or actions which the committee will continue into 2019-2020:

- Research Management Services
- Institutional Review Board
- Export Controls Policy

- Conflict of Interest “Rule 11”
- Organized Research Unit (ORU) Review Process
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