

Committee on Research
Stuart Gansky, MS, DrPH, Chair

ANNUAL REPORT
2017-2018

Issues reviewed and acted on by the Committee included:

- Presidential Policy on Export Controls
- Research Resource Identification
- Proposed Presidential Policy on Disclosure of Financial Interests and Management of COI in Private Sponsors of Research and Revised APM – 028
- Funding 23 Principal Investigators (PIs) through the Research Allocation Program (RAP)
- 2017-2018 Faculty Research Lectures in Basic, Clinical, and Translational Sciences
- Selection of 2018-2019 Faculty Research Lectures in Basic, Clinical, and Translational Sciences
- RMS Subaward Process
- RMS Funding Model
- T32 Trainees and Compensation
- Common Rule and the Institutional Review Board (IRB)
- Organized Research Unit (ORU) Review Process
- Conflict of Interest and UCSF "Rule 11"

Task Forces, Special Committees, and Sub-Committees:

- Office of Sponsored Research Advisory Group – Stuart Gansky
- RAP Executive Steering Committee – Stuart Gansky
- RAP Sub-Committee – Farid Chehab, Stuart Gansky, Parya Saberi

Issues for Next Year (2018-2019)

- Research Management Services (RMS) Funding Model
- Export Controls Policy
- Conflicts of Interest
- Organized Research Unit (ORU) Review Process
- Implementation of the Common Rule (human research protections)
- Selection of the 2019-2020 Faculty Research Lecturers in Basic, Clinical, and Translational Sciences
- Chancellor Funds

2017-2018 Members

Stuart Gansky, Chair	Heather Leutwyler
Lea Grinberg, Vice Chair	Marguerita Lightfoot
Adam Abate	Janel Long-Boyle
Joelle Brown	Janet Myers
Wenhan Chang	Sima Porten
Farid Chehab	Parya Saberi
Elena Flowers	Lei Wang
Benjamin Franc	Emmanuelle Waubant
Galen Joseph	Elad Ziv

Number of Meetings: 9

Senate Analyst: Kenneth Laslavic

Presidential Policy on Export Controls

Following the 2016-2017 systemwide review of the proposed Presidential Policy on Export Controls, which resulted in numerous questions and concerns from various divisions of the Academic Senate, UCOP initiated a second systemwide review of the proposed policy. The Committee on Research reviewed the revised proposed policy and found it made minimal changes with respect to the concerns expressed during the 2016-2017 systemwide review. In particular, during the 2016-2017 systemwide review, the UCSF Academic Senate's COR raised concerns about the policy's lack of specific information about the Openness in Research Policy, which the 2016-2017 proposed policy referenced as UCOP's primary strategy for compliance with federal laws and regulations pertaining to export controls. To address these concerns, the 2017-2018 proposed policy eliminated all references to the Openness in Research Policy because such a policy does not yet exist.

COR discussed this issue over several meetings. The committee recognized that UC is required to have an Export Control Policy, and, without such a policy, UC is currently out of compliance with federal laws and regulations. COR supported the establishment of an Export Control Policy. However, COR also noted that PIs are responsible for compliance with export control laws and are thus exposed to personal liability for potential violations. Thus, COR recommended that UCOP and UCSF provide comprehensive and clear guidance.

During 2018-2019, COR will work with the UCSF Office of Ethics and Compliance to ensure that UCSF develops local policies and procedures for Export Controls and Openness of Research.

Research Resource Identification

The Chair of UCORP brought this issue to the attention of the Chair of the San Francisco Division of the Academic Senate who referred the matter to COR.

The Research Resource Identification Initiative aims to promote rigor and transparency in the publication of academic research by establishing a system by which research resources are easily identified.

Members of COR agreed that this is an important issue, especially with respect to research resources that vary greatly such as antibodies. However, COR stated that this issue should be led by a funding agency such as the NIH. COR referred this issue directly to UCSF Vice Chancellor of Scientific Policy Keith Yamamoto.

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 Associate Director of Ethics and Compliance Joan Doherty-Campbell to understand how this proposed policy would impact UCSF. There was significant confusion about how UCSF administers the current policy and how the proposed revised policy would impact UCSF. In addition, it was unclear whether UCSF's current implementation is consistent with APM - 028.

UCSF Campus Administrative Policies 100-33, 100-34, and 100-35 may need to be revised and approved by the Chancellor after UC enacts the proposed Presidential Policy on Disclosure of Financial Interests and Management of COI.

COR will continue to address UCSF COI policies during the 2018-2019. In particular, COR will try to understand how the UCSF administers documented policies. In addition, COR will review the UCSF COI website for clear and accurate policies, procedures, and guidance materials.

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 2018-2019 Faculty Research Lectures Recipients*
 - FRL – Clinical Science (Donna Ferriero, MD)*
 - FRL – Basic Science (Carol Gross, PhD)*
 - FRL – Translational Science (Kathleen Giacomini, PhD)*

Policy Topics:

- RMS Subaward Process*
- RMS Funding Model*
- T32 Trainees and Compensation*
- Common Rule and the Institutional Review Board (IRB)*
- Organized Research Unit (ORU) Review Process*
- Conflict of Interest and UCSF "Rule 11"*

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 2017	5	4	1	1	0	1	2	1	1	16
Spring 2018	4	1	0	0	0	0	0	1	1	7
Total	9	5	1	1	0	1	2	2	2	23

The Academic Senate funded 23 grants during the 2017-2018 RAP cycles totaling \$963,761 - a decrease of six grants from the prior year. The decrease is largely due to the increased budget of various grant mechanisms. COR intentionally funded more Fall cycle than Spring cycle grants to offset the Fall decrease in participating RAP funders based on NIH sources.

The Committee on Research discussed the possibility of requesting an amendment to the endowment funds managed by the Senate so that COR may have more flexibility when selecting grant recipients. COR is currently limited by the research areas to which a particular endowment is restricted, however COR does not have any disease or organ system specific funds with large balances. Whether the terms of endowments can be changed will be explored during the 2018-2019 academic year. COR will need to consult with Legal Affairs to determine if this is possible.

COR would also like to see the University dedicate additional funding to the Academic Senate for the Resource Allocation Program. The Academic Senate is one of the largest funding agencies that participates in RAP. In addition, the Senate has more flexibility than other funding agencies because the funds are not restricted to a particular school. Moreover, the cost of research continues to increase but the Senate's funding sources have not increased commensurately. COR will explore potential ways to increase the reach of its RAP awards during the 2018-2019 academic year. For example, COR may recommend the Chancellor allocate a portion of contributions from the UCSF Campaign to the Senate specifically to support more RAP grants.

Travel Grants

The Academic Senate Office, under the auspices of the Committee of Research, granted 20 travel grants during the 2017-2018 academic term. These grants are funded from Opportunity Funds. The Senate office awarded grants in the amount of \$8,833.

Chancellor's Fund

COR awarded \$20,000 in travel grant funding to faculty via the Chancellor's Fund program.

2017-2018 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 Ruth Greenblatt, MD

2017-2018 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 Robert Stroud, PhD

2017-2018 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 John Featherstone, PhD

Selection of the 2018-2019 Faculty Research Lecture Recipients

Committee members reviewed nomination packets of eight candidates, met with nominators, and voted to honor three lecturers during the 2018-2019 term. Those to be recognized are:

- Faculty Research Lecture - Clinical Science is Donna Ferriero, MD
- Faculty Research Lecture - Translational Science is Kathleen Giacomini, PhD
- Faculty Research Lecture - Basic Science is Carol Gross, PhD

COR Town Hall

COR sponsored a Town Hall on March 28. The Town Hall brought together senior administrators to present updates to an audience of faculty researchers and staff research administrators and answer questions. The event was moderated by COR Chair Stuart Gansky and the panel included David Odato, Associate Vice Chancellor, HR; Jenny Schreiber, Assistant Vice Chancellor, HR; Winona Ward, Director, Office of Sponsored Research; Gretchen Kiser, Executive Director, Research Development Office; Laurie Herraiz, Director, Human Research Protection Program; and Elizabeth Sinclair, Director, Research Resource Program (RRP)

The COR Town Hall was a part of a series of town halls organized by the Academic Senate in a strategic effort to increase faculty engagement and improve communication across various functions of UCSF. The Senate will host a series of town halls during the 2018-2019 Academic Year.

POLICY TOPICS

Research Management Services (RMS)

During 2017-2018, COR continued to work with Winona Ward, Director of the Office of Sponsored Research, which oversees Research Management Services. COR focused on the outcomes of the subaward business process improvement (BPI) effort and the RMS funding model.

Following a BPI initiative that examined the subaward process within RMS, COR heard from RMS staff about the current status of the subaward process. Members of COR were encouraged to see that RMS significantly reduced the backlog of subaward requests and decreased the average time for processing a subaward request. COR found that RMS received additional resources to hire temporary staff to achieve these outcomes. However, without a permanent commitment of resources from the administration, RMS began to see a reversal, with the average time to process a subaward slowly increasing again. COR successfully advocated to the administration, submitting a formal letter to EVCP Lowenstein advising on the need to increase staffing resources for RMS.

COR is still concerned about the RMS funding model, which charges departments on the basis of the number of PIs submitting grant proposals. The funding model has impacted smaller schools and departments more sharply than larger ones, often increasing their costs. COR will continue to monitor the funding model and advocate for an equitable funding model that balances the needs of RMS (which operates entirely on user fees) and the need to promote equitable cost sharing across schools and departments with varied resources.

T32 Grants

The Research Advisory Board (RAB) brought to COR's attention an issue concerning compensation of federally-sponsored trainees.

T32 grants are NIH Institutional National Research Service Award (NRSA) training grants which enable institutions to support individuals they select for predoctoral and postdoctoral research training. According to NIH Grants Policy Statement 11.3.10.2 (Compensation), clinical trainees may seek employment coincidental to their work on a T32 grant on several conditions. In particular, "compensation may not be paid from a research grant that supports the same research that is part of the trainee's planned training experience as approved in the Kirschstein-NRSA institutional research training grant application."

RAB developed a form to facilitate properly vetting employment on federal grants. COR reviewed the form and met with representatives from RAB. The form's purpose is to approve employment coincidental to

their work on an NIH grant while ensuring that the research is not similar and with overlapping aims. COR endorsed the form RAB developed.

Common Rule and the Institutional Review Board (IRB)

On January 18, 2017, the federal government issued the final update to the Common Rule. Most regulations were originally scheduled to go into effect on January 18, 2018 with some provisions scheduled to go into effect on January 20, 2020. However, on January 17, 2018, the federal government issued an Interim Final Rule delaying the implementation until July 19, 2018. On June 18, 2018, the US Department of Health and Human Services and 16 other federal agencies issued a Final Rule delaying the compliance date of the regulations an additional six months. The current deadline for compliance is January 20, 2019.

The final revisions to the Common Rule require consent forms to provide better understanding of the research's purpose, risks and benefits, and appropriate alternate treatments. The final revisions to the Common Rule require, in many but not all cases, using a single IRB for multi-institutional research studies. Substantial flexibility is written into the rule, allowing broad groups of studies (instead of specific studies) to be removed from this requirement. The Final Rule expands the definition of human subjects to include identifiable biospecimens.

In addition, NIH implemented a separate requirement that all multi-site NIH funded studies must use a single IRB (sIRB).

COR met with UCSF Human Research Protection Program (HRPP) then-Interim Director Michael Roach and HRPP's then-Director of Operations and Quality Improvement Laurie Herraiz. Roach and Herraiz discussed efforts UCSF is taking to implement the regulations. Herraiz was subsequently appointed Director of UCSF's HRPP. COR will continue to confer with HRPP Director Herraiz as UCSF works to implement the Common Rule and the NIH sIRB mandate.

Organized Research Units (ORUs)

COR has continued to monitor and track the development of local policies and procedures for establishing, reviewing, and disestablishing ORUs. Brian Smith, Associate Vice Chancellor of Research Infrastructure and Operations has been developing an ORU Review Process. The policy development was delayed due to limited capacity as the UCSF research administration underwent leadership changes. COR will continue tracking the policy development and provide input when a draft is completed.

COR surveyed ORU policies, procedures, guidance materials, and resources from all other UC campuses and found a variety of tools available to faculty and stakeholders. During the 2018-2019 academic year, COR will advocate for expanded resources modeled after other UC campuses.

Conflict of Interest and UCSF "Rule 11"

A faculty member contacted the Senate about their experience with UCSF Office of Ethics and Compliance - Conflict of Interest Office. On the UCSF Conflict of Interest website, there was a subsection titled "Academic Senate Rule 11" which stated: *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 (such as service on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the clinical study. If you have questions about this, please contact coiac@ucsf.edu*

COR researched the history of the so-called Rule 11 and found that the Academic Senate recommended the administration eliminate Rule 11 from UCSF COI Guidelines.

COR met with Associate Director of Ethics and Compliance Joan Doherty-Campbell. She presented information about Rule 11 and proposed her office assumes ownership over Rule 11 which was erroneously named Academic Senate Rule 11 on the Ethics and Compliance website. The committee voted to endorse the proposal from the Office of Ethics and Compliance and requested a follow up meeting with Ethics and Compliance in October of 2018.

Going Forward

Ongoing issues under review or actions which the committee will continue into 2018-2019:

- Research Management Services (RMS) Funding Model
- Export Controls Policy
- Conflict of Interest Policy
- Organized Research Unit (ORU) Review Process
- Implementation of the Common Rule (human research protections)
- Implementation of the NIH sIRB mandate
- Selection of the 2019-2020 Faculty Research Lecturers in Basic, Clinical, and Translational Sciences
- Chancellor Funds