Primary Focus Points for the Year:
- Institutional Review Board
- Faculty Research Lecture (FRL) Categories
- Office of Sponsored Research
- NIH Diversity Supplements

Task Forces, Special Committees, and Sub-Committees:
- Resource Allocation Program Committee – Penny Brennan
- Research Advisory Board – Vanessa Jacoby
- Office of Sponsored Research Advisory Board – Bin Liu
- NIH Diversity Supplement Sub-Committee – Vanessa Jacoby and Su Guo
- FRL Categories and Call Sub-Committee – Penny Brennan, Mary Helen Barcellos-Hoff, Vanessa Jacoby, and Sheri Lippman

Issues for Next Year (2022-2023)
- Institutional Review Board
- Chancellor’s Bridge Funding Program
- Research Z Payment Pilot Program
- NIH Diversity Supplements

2020-2021 Members
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<tr>
<th>Penny Brennan, Chair</th>
<th>Salomeh Keyhani</th>
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<tr>
<td>Vanessa Jacoby, Vice Chair</td>
<td>Kerstin Kolodzie</td>
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<td>Lea Grinberg, UCORP Rep</td>
<td>Sheri Lippman</td>
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<td>Mehrdad Arjomandi</td>
<td>Bin Liu</td>
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<td>Mary Helen Barcellos-Hoff</td>
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<td>Mallar Bhattacharya</td>
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<td>Myriam Chaumeil</td>
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<td>Daniel Fried</td>
<td>Glenn-Milo Santos</td>
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<td>Su Guo</td>
<td>Elliott Sherr</td>
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Number of Meetings: 8
Senate Analyst: Liz Greenwood
UCORP

Lea Grinberg reported on the work of the systemwide University Committee on Research Policy (UCORP). This year, UCORP focused on topics including innovation and entrepreneurship, foreign influence, outside research activities, IT operations, conflicts of interest, and graduate student unionization.

Systemwide Reviews

The Committee on Research (COR) commented on two systemwide reviews. Those comments are summarized below.

1. Research Data: The draft Presidential Policy on University of California Research Data was circulated for a second systemwide review. COR expressed appreciation that the new draft incorporated many of the comments on the previous draft. However, COR noted that some concerns remained. The policy delegated much of the responsibility for implementation to individual campuses, failed to acknowledge the potential costs of complying with the policy, had some unclear language, and could lead to potential conflicts with other research policies (e.g., human subjects protections). COR's comments are included as Appendix 1.

2. Affiliations: The Proposed Presidential Policy on Affiliations with Certain Healthcare Organizations laid out guidelines for affiliations between the University of California and organizations that have instituted policy-based restrictions on care. COR objected to the guideline that clinicians can only provide necessary and appropriate items or services in the event of an emergency, as this restriction limits the care that clinicians can provide and forces them to discriminate against patients. COR also expressed the concern that the policy could impede the progress of clinical research. Other divisional committees raised similar objections to the policy. COR's comments are included as Appendix 2.

Divisional Business

PROCESS TOPICS

Resource Allocation Program (RAP) Grant Funding

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<tr>
<td>Fall 2021</td>
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<tr>
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</tr>
<tr>
<td>Total</td>
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The Academic Senate funded 20 grants totaling $879,548 during the 2021-2022 RAP cycles.

Travel Grants
The Academic Senate Office, under the auspices of COR, awarded two travel grants to new and junior faculty during the 2021-2022 academic term totaling $985.98.

Chancellor’s Fund

The Committee awarded 21 Conference Registration Grants totaling $20,000 for travel to present the results of original research via the Chancellor’s Fund.

2021-2022 Faculty Research Lectures

COR hosted three Faculty Research Lectures. The 2021-2022 Faculty Research Lecture in Clinical Science was presented by Esteban G. Burchard, MD, MPH and was held on November 2, 2021, via Zoom. The 2021-2022 Faculty Research Lecture in Basic Science was presented by Jim Wells, PhD and was held on April 26, 2022, at Byers Auditorium and via Zoom. The 2021-2022 Faculty Research Lecture in Translational Science was presented by Diane Barber, PhD and was held on May 10, 2022, at Byers Auditorium and via Zoom.

COR Vice Chair Vanessa Jacoby hosted the Faculty Research Lectures in Clinical Science and Basic Science. COR Chair Penny Brennan and Committee member Su Guo co-hosted the Faculty Research Lecture in Translational Science. All three lectures were well-attended, and including a Zoom component enabled the lectures to reach a wide audience.

2022-2023 Faculty Research Lecture - Basic Science

Since 1957, this award has been bestowed on an individual member of the UCSF faculty with a distinguished record in basic science. Nominations are made by UCSF faculty, who consider the scientific research contributions of their colleagues and submit nominations for this prestigious award to COR. COR selected Alexander Johnson, PhD as the recipient of the 2022-2023 Faculty Research Lecture in Basic Science.

2022-2023 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 COR. COR selected Diane Havlir, MD as the recipient of the 2022-2023 Faculty Research Lecture in Clinical Science.

2022-2023 Faculty Research Lecture - Translational Science

Since 2010, this award has been bestowed on an individual member of the UCSF faculty with a distinguished record in 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 benefitting both patients and legions of other clinicians worldwide. COR received no nominations for this award, and no winner was selected for 2022-2023.

POLICY & PROGRAM TOPICS

Institutional Review Board
Ed Kuczynski, Director of the Human Research Protection Program, met with COR twice to discuss the Institutional Review Board (IRB). Director Kuczynski shared metrics regarding the IRB’s volumes of work, factors that impact review times, and satisfaction survey results. The IRB has recently developed new tools for consenting non-English speakers and now provides exemplary applications to improve the quality of submissions. Director Kuczynski provided the same information to the Academic Senate’s Executive Council.

Following the meetings with COR and the Executive Council, the Executive Council wrote a letter to Director Kuczynski describing the concerns raised by COR members and other Senate members and providing some recommendations to address those concerns (Appendix 3). Specifically, the Senate recommended breaking out the performance metrics into quartiles to better understand performance among the bottom time-to-approval quartile and reduce these studies’ duration in the system. The Senate also recommended using technologies to ease the application process and reduce submission errors, increase transparency, automate certain review activities, and collect feedback.

After the Senate’s letter was sent, Chair Brennan and Vice Chair Jacoby met with Director Kuczynski to discuss the recommendations further. Director Kuczynski shared that he had made some improvements to the management of the IRB application queue, including hiring a new analyst with expertise to handle more complex applications. He and his teams also investigated technologies designed to ease the application process, reduce submission errors, and collect feedback for users. His team considered several options for providing a dashboard to allow faculty to check the progress of submissions, such as creating a dashboard internally or leveraging existing software. He noted that any standalone software developed by UCSF would need to be layered on and integrated with software already in use by UCSF’s Human Research Protection Program for IRB application processing. Finally, Director Kuczynski shared that he was working on a proposal for increased funding and hoped that COR would support that proposal once it was completed.

COR members also asked Director Kuczynski about the July 2021 changes in the IRB fee structure for UCSF affiliate research faculty, but there was insufficient information and meeting time for Director Kuczynski to answer questions about the changes. COR plans to revisit this issue in the coming academic year.

**Faculty Research Lecture Categories**

Chair Penny Brennan, Vice Chair Vanessa Jacoby, and Committee Members Mary Helen Barcellos-Hoff and Sheri Lippman formed a sub-committee to revisit the Faculty Research Lecture (FRL) categories and call for nominations. In 2019, the Academic Senate received a letter from faculty members and EVCP Dan Lowenstein requesting that a fourth FRL be added to recognize work in areas related to social, population, and health policy sciences. In 2020, COR voted to maintain the same slate of FRLs, representing basic, clinical, and translational sciences, and to add wording to make the call for nominations more welcoming to applicants in the social, population, and health policy sciences. This year, COR decided to revisit the question of whether to add a fourth category to the current three FRL categories.

The sub-committee proposed adding a fourth FRL category titled “Social, Behavioral and Health Policy Sciences” and holding two FRLs per year. The proposal suggested that the categories be rotated such that FRLs in each category were held every other year. The sub-committee also suggested revising the call for nominations to provide more clarity regarding the definitions of translational research and social, behavioral, and health policy research and to explicitly encourage nominations of historically excluded and underrepresented faculty. Finally, the sub-committee recommended simplifying the application process.
The recommendations to revise the call for nominations and simplify the application process were straightforwardly approved and were adopted in the 2022-2023 call for nominations. The proposal to add a fourth category and hold two FRLs per year involved more discussion. Some members expressed concerns that holding each category's lecture every other year would decrease engagement by reducing the frequency of lectures in faculty members' areas of interest. Others felt that holding four lectures in one year would decrease engagement by creating fatigue. Ultimately, members voted to propose adding a fourth category titled “Social, Behavioral and Health Policy Sciences” and holding four FRLs per year. The proposal was sent to the Senate Chair Steven Cheung and Executive Council (Appendix 4) but has not yet been voted on.

**Office of Sponsored Research**

Assistant Vice Chancellor Winona Ward and Jim Kiriakis, Executive Director of Industry Contracts, joined a COR meeting to discuss several topics pertinent to COR.

- **Industry contracts** – Executive Director Kiriakis described the scope of the Industry Contracts Division’s (ICD) work and noted that although the volume of clinical trials at UCSF continues to grow, the ICD staff and budget have not increased commensurately. Members expressed concerns about the start-up time for funded research projects, noting that in some cases, the time to activation has interfered with a researcher’s ability to complete a study by the sponsor’s deadline and has at times resulted in sponsors rescinding awarded funds. The ICD is working to reduce turnaround time but noted that other steps (e.g., IRB approval) also affect start-up time and suggested providing more transparent information to faculty regarding the statuses of studies awaiting various approvals. Executive Director Kiriakis said that more staff are needed to reduce the ICD's turn-around time and asked for COR's support when he next requests more resources from leadership.

- **De-identified data sharing** – Faculty have requested an official UCSF policy regarding de-identified data sharing to improve clarity. Executive Director Kiriakis explained the proposed policy. For incoming data from an outside entity, the outside entity shall determine whether an agreement is required. If the outside entity requires an agreement, then the agreement required by the outside entity will be used to facilitate the data transfer. For outgoing clinical data provided by UCSF to a third party for a distinct research project, a data use agreement must be executed prior to the transfer of any data, including deidentified data, limited data sets, and protected health information. The terms of the agreement that will be executed shall be determined by the appropriate contracting office and will depend on the type of data being provided.

- **T32 data tables** – Assistant Vice Chancellor Ward shared that the T32 Trainee Tracking System (3TS) would be sunsetted because the newly required NIH xTRACT system is duplicative to the 3TS. Members were informed that the Office of Sponsored Research would update its website to provide transparent information to faculty regarding processes and requirements for completing these tables, ways to obtain the necessary data for these tables, and other tools. The Office of Sponsored Research also planned to set up a T32 community network.

**NIH Diversity Supplements**

COR members raised the issue that NIH Diversity Supplements are insufficient to cover the stipends and benefits paid to UCSF graduate students but that, under the current rules, other federal funds cannot be used to bridge the gap. In practice, faculty use their discretionary funds to cover this gap, which means that only faculty with discretionary funding can receive these awards. Nevertheless, these awards seem to be in alignment with UCSF’s institutional goals. Reports from the departments to the Dean of the School of Medicine include information on the number of diversity supplements applied for and received. Additionally, both UCSF’s Research Development Office and Office of Diversity and Outreach encourage
UCSF faculty to apply for NIH Diversity Supplements, and contributions to diversity, equity, and inclusion are factored into the advancement and promotion process.

COR members raised this issue in conversations with EVCP Dan Lowenstein and Assistant Vice Chancellor Winona Ward and found that UCSF does not have a clear mechanism to address this issue. Vice Chair Vanessa Jacoby and Committee Member Su Guo formed a sub-committee to develop institutional mechanisms for closing the gap and increasing the accessibility of NIH Diversity Supplements. The sub-committee has met with Graduate Division Dean Nicole Blake and Assistant Vice Chancellor Winona Ward and will continue to work toward solutions in the coming academic year.

**Bridge Funding**

COR was one of several Academic Senate committees that contributed to the development of a faculty survey regarding awareness and use of the UCSF Chancellor’s Office’s Bridge Funding Program. The survey was initiated because a review of the Chancellor’s budget for faculty bridge funding revealed substantial unexpended balances across all the schools despite faculty reporting an increased need for such funding following the COVID-19 pandemic. Although the five-year program was launched in 2018, only 5% and 7% of the available funds for the School of Nursing (SON) and School of Dentistry (SOD) had been spent as of Fall 2021. The Senate aimed to better understand the reasons for the discrepancy between faculty’s stated need for bridge funding and the underutilization of the Chancellor’s Bridge Funding Program.

Around 11% of faculty responded to the survey. The survey’s findings were presented to leadership, including the Deans of the Schools and the Graduate Division, the Vice Chancellor, and the EVCP. The survey identified a lack of awareness of the Bridge Funding Program within the SON and a perception that the SON and SOD cannot provide matching funds. Leadership agreed to work with the Deans of the SON and SOD to improve messaging and awareness. The survey also found widespread support for expanding the criteria for the Bridge Funding Program and suggested that expanded criteria would increase applications from women faculty.

**Office of Research**

The committee met with representatives of several administrative offices within the Office of Research at the start of the academic year to hear updates on their activities. Christy Anton, Director of the Office of Clinical Trials Activation (OCTA), shared that OCTA is striving to reduce the activation timeline from submission to opening enrollment from around 160-190 days to 120 days. Natalie Nardone provided information about the Clinical Trials Operation Office, which is an institutional advocate for researchers performing clinical trials. Tung Nguyen shared information about a new anti-racism and equity task force.

**Library**

COR consulted with several representatives from the UCSF Library. Anneliese Taylor, Head of Scholarly Communication, presented on the library’s data initiatives. The library offers data classes and courses for analysis and programming, workshops, and tools related to bioinformatics and statistical analysis. Chris Shaffer, University Librarian, provided a briefing on Open Access and highlighted that UCSF Open Access Funds were still available to support researchers seeking to publish in Open Access journals.

In the discussion on Open Access, COR members provided the feedback that faculty lack awareness of these agreements and the availability of funding. COR members recommended increasing awareness and clarification at the department level by, for example, arranging for librarians to meet with each department and provide department-specific information (e.g., highlighting the most relevant journals for a department that are covered by Open Access agreements).
Research Analysis Environment

Rick Larsen, Director of Research Informatics, and Rhett Hillary, Research Systems Team Lead, met with COR to provide information about the Research Analysis Environment (RAE). RAE is a secure virtual desktop for running analytics applications and storing data, allowing the removal of sensitive data from end-user devices. It has 1,200 active users at UCSF. Three tiers of RAE are offered: RAE Free, RAE Premium, and RAE Cloud. Members provided the feedback that additional advertising and outreach could be useful, as many researchers and even IT staff are unfamiliar with these tools. Members also expressed concerns about possible upcoming price increases and learned that RAE Free and consultations with the RAE team will continue to remain free for faculty.

Conflict of Interest Advisory Committee

Conflict of Interest Manager Ivana Neff shared updates from the Conflict of Interest Advisory Committee (COIAC) with COR members. The committee was charged with evaluating regulations and procedures to enhance relationships with industry and make it easier to disseminate innovations, and the guidelines for conflicts of interest were updated in early 2022. Faculty members were previously disallowed from serving on boards of directors, investing in companies, or holding a financial interest in the sponsor of a clinical study; now, these activities may be permissible in some circumstances, although they will still be vetted by the COIAC. The thresholds for disclosure requirements and COI management for privately funded research were also revised. Members recommended that the updated guidelines be disseminated widely once they are finalized.

Procedures for Research Misconduct Cases

COR reviewed revised procedures for research misconduct cases provided by the Office of Ethics and Compliance and provided feedback. Members noted that the procedures could come into conflict with human subjects protections, but the revised procedures did not address this issue. Members also noted that although some consent forms mention that a study may be audited, this language is not standardized. They suggested providing standardized language that accounts for the possibility of a university audit.

Finance

Chief Financial Officer Mike Clune presented the updated internal website, "UCSF Finance Explained," to COR members. The website focuses on UCSF’s campuswide financial activities and provides the latest finance news, basic information about finance, the sources and uses of funds, funds flows, and financial plans and results. CFO Clune highlighted information on facilities and administration (F&A) cost recovery, which is particularly relevant to researchers and is provided on the Source of Funds, Campuswide Funds Flows, and Core Financial Plan pages. Members noted that a perception remains that revenue supports the research enterprise, but not vice versa, although F&A cost recovery supports multiple campus core functions, including campus police, library, EVCP initiatives, and so on. This perception of the financial drain from research in clinical departments can create a challenging dynamic in which researchers may not feel fully supported. Members suggested that a chart showing how one dollar of NIH funding is spent, including F&A, may help demonstrate researchers’ contributions to the university.

Appendices

Appendix 1: Communication to S. Cheung re Second Systemwide Review of the Proposed Presidential Policy on University of California Research Data

Appendix 2: Communication to S. Cheung re Systemwide Review of the Proposed Presidential Policy on Affiliations with Certain Healthcare Organizations
Appendix 3: Communication to E. Kuczynski re HRPP/IRB Metrics and Processes

Appendix 4: Communication to S. Cheung re Proposed Change to Faculty Research Lectures Starting in Academic Year 2023-24