

Regulatory/Compliance Requirements

Overview

UCSF faculty members are required to conduct research and manage the financial aspects of research in compliance with University policy, federal and state laws, and sponsor requirements. Principal Investigators must ensure that they, their fellow investigators, students and staff meet compliance requirements, including any necessary training.

Below are the frequent areas of compliance to consider when preparing a proposal and before an award can be accepted.

- Conflict of Interest (COI)
 - Coverage Analysis
 - Cost Sharing
 - Harassment and Discrimination Protections
 - Human Subjects
 - Human Fetal Tissue Research (HFT)
 - Animal Subjects
 - Foreign Influence and Export Control
 - Safety Committees
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Conflict of Interest (COI)

Researchers may have financial interests in research sponsors and/or entities with business interests closely related to their research. These interests must be disclosed. Before an award can be setup and transmitted to CGA, it must be released by the Conflict of Interest Division (COI). The RSC requests this release either at the Just-in-Time stage, or during Award Set-Up. This release can only occur after the PI makes the proper disclosures and COI approves them. If required, the type of grant or contract will determine the kind of disclosure necessary.

Visit UCSF's Conflict of Interest division website for detailed information.

Coverage Analysis

Coverage analysis is the independent review of a human research study to determine which patient care costs are billable to insurance and which are not. Learn more about coverage analysis here. Awards involving human subjects? research require coverage analysis and budgets review. To initiate Coverage analysis email: clinicaltrials@ucsf.edu

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Cost Sharing

Cost sharing is a financial commitment to an external sponsor to augment its sponsored project budget. Cost sharing is tracked by CGA. More information can be found on the Controller?s Office website.

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Harassment and Discrimination Protections

In accordance with Title IX of the Education Amendments of 1972, Federally-supported research and training must occur in a civil, safe, and respectful environment, free from discrimination and unlawful harassment, sexual or otherwise. Harassment of any kind including sexual harassment is not tolerated at institutions that receive Federal funding or anywhere that Federally-funded activities are conducted.

NOT-OD-19-029 implemented the requirement of an additional institutional **Letter of Support** in NIH Training Grant Applications, ensuring that the University has proper policies, procedures, oversight, and practices in place to prevent discriminatory harassment and other discriminatory practices, and ensuring that the institution has adopted procedures to request prior approval of a change in the status of the PD/PI or other senior/key personnel if administrative or disciplinary action is taken that impacts their ability to continue in their role on the NIH award as described in the application.

The RPAC Policies & Guidance webpage for Discrimination and Sexual Harassment is available to provide links to polices and resources necessary to meet specific sponsor requirements.

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Human Subjects

The UCSF Human Research Protection Program (HRPP) is responsible for ensuring the

ethical and equitable treatment of human research subjects, as well as ensuring compliance with Federal Regulations, State Statutes and Guidance.

The Institutional Review Board (IRB) - formerly known as the Committee on Human Research (CHR) - reviews and makes decisions on all research involving human subjects performed by UCSF faculty, staff and students, regardless of funding source or the location of the research.

Awards that require these types of approvals may be processed before the IRB has issued an approval number. However, in such cases, research is restricted to activities not involving human subjects. Research activities involving human subjects may only proceed after IRB has given a final approval and number. In order for the approval to be valid the Sponsor (or funding source), and Key Personnel must be listed on the IRB applications. See the HRP website for instructions to add a funding source, or Key Personnel.

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Human Fetal Tissue Research (HFT)

NIH Requirements:

On July 26, 2019, NIH modified the policy on Human Fetal Tissue Research (NIH GPS 4.1.14) to include the HHS requirements and review considerations for NIH research applications (e.g. grants, cooperative agreements, and R&D contracts) that involve the proposed use of human fetal tissue obtained from elective abortions (HFT). See Human Fetal Tissue Research, Human Fetal Tissue from Elective Abortions (NIH GPS 4.1.14.2).

These requirements apply to competing grant applications submitted for due dates on or after September 25, 2019 and in response to R&D contract solicitations published on or after September 25, 2019 and grant and cooperative agreement awards with HFT or that add HFT made on or after September 25, 2019.

NOTE: Please refer to the General Application Guide for specific instructions when preparing competing applications proposing research involving HFT. In the SF424 (R&R) Version F , HFT are called-out in the Cover Letter (Section G.200), Cover Page Supplement Form (G.210), Detailed Budget and Justification (Section G.300), and Research Plan (Section G.400). Page limits **will not** be increased to accommodate these requirements. The Modular Budget Form cannot be used (Section G.320). For R&D contract proposals, please refer to the specific solicitation for proposal instructions.

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Animal Subjects

The Institutional Animal Care and Use Committee (IACUC) oversees all UCSF research and instruction that involves vertebrate animals. The IACUC ensures that the highest ethical and animal welfare standards are met.

Awards that require these types of approvals may be processed before the IACUC has

issued an approval number. However, in such cases, research is restricted to activities not involving animal subjects. Research activities involving animal subjects may only proceed after IACUC has given a final approval and number. In order for the approval to be valid the Sponsor (or funding source), and personnel must be listed on the applications. See the IACUC website for further instructions.

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Foreign Influence and Export Control

The Office of Ethics and Compliance collaborates with the UCSF community and senior leadership to coordinate and guide compliance efforts across the campus. The foreign Influence and export control page provides information to assist researchers in satisfying certain reporting and disclosure obligations.

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Safety Committees

Safety Committees are campus committees that are mandated by regulatory and policy requirements.

- Chemical & Environmental Safety Committee
- Human Gamete, Embryo and Stem Cell Research Committee (GESCR)
- Institutional Biosafety Committee
- Radiation Safety Committee
- Radioactive Drug Research Committee

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Human Resources Administration

- Protecting Your Grant: Affirmative Action and Non-Discrimination: Hiring for grants at UCSF must follow laws regarding Affirmative Action and Equal Opportunity Employment.
- Personnel Policies for Staff Members
- A&PS and Staff Title and Pay Plans

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Resources:

UCSF Policies

There are many campus policies involved in the research administration process. These policies are primarily located in the *Academic Administration* (100), *Financial Administration* (300), and *Contracts and Grants* (400) sections of the Campus Administrative Policies.

Following are other UCSF policy links:

- Campus Code of Conduct
- Social Media Guidelines
- Export Control

In addition to actual shipment of a commodity out of the United States, export regulations also control the transfer, release or disclosure of technical data about controlled commodities to foreign persons in the United States.

- Integrity of Research: Along with the Integrity of Research campus policy (100-29), Academic Affairs offers further procedures on Integrity of Research.

UCOP and Regents? Policies

- Contracts and Grants Manual
- Academic Personnel Manual
- Accounting Manual
- Standing Orders
- UCOP Policies and Guidance Main Menu
- Business and Finance Bulletins

Federal Policies and Regulations

- Uniform Guidance effective December 26, 2014
- OMB Circular A-21: Cost Principles
- OMB Circular A-110: Administrative Principles
- OMB Circular A-133: Audit Principles
- Code of Federal Regulations
- NIH - Grants and Funding
 - Responsible Conduct of Research: NIH provides guidance and training resources in the Responsible Conduct of Research (RCR). RCR training is mandatory for the recipients of some NIH awards.
- Federal Register

San Francisco and Bay Area Counties

- Alameda County
- Contra Costa County

- [County of Marin](#)
- [Napa County](#)
- [City and County of San Francisco](#)
- [County of San Mateo](#)
- [County of Santa Clara](#)
- [Solano County](#)
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Keywords

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