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
- Animal Subjects
- Technical Committees

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

Awards involving human subjects’ research require coverage analysis and budgets review. UCSF currently has three units that are qualified and approved to perform a CA.

For questions regarding the Coverage Analysis process, please contact:
1. For Cancer related studies: Cancer Center Investigational Trial Resource (ITR) - Greg Nalbandian, ITR Coverage Analyst: nalbandiang@cc.ucsf.edu
2. For Division of Cardiology: Carol Maguire, Administrative Director of Clinical Research: carol.maguire@ucsf.edu
3. For all others: Clinical Trials Business Support Center (CTBSC): 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.
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 HRPP website for instructions to add a funding source, or Key Personnel.

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.

Technical Committees

Technical 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