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**
- **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
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

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.

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 the 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 the IACUC 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 IACUC applications. See the IACUC website for instructions to add a funding source, or Key Personnel.
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