

Purpose

 This training provides guidance regarding Subrecipient Investigators' responsibilities under the <u>Public Health System</u> <u>Objectivity in Research regulations</u>.







Applicability

When the University of California, San Francisco (UCSF) receives an award from the Public Health Service (PHS) or Certain Federal Agencies, Foundations or Extramural Sponsors naming subrecipients, those subrecipients must comply with the PHS regulations regarding Objectivity in Research.



Timing

- Federal regulations and policies require UCSF, as the prime applicant, to collect certain information from PHS subrecipients at the time of award. Subrecipient Investigators who are subject to the UCSF Financial Conflict of Interest Policy must complete a Significant Financial Interest (SFI) Disclosure:
 - At Notice of Award;
 - Within 30 days of discovering or acquiring a new SFI
 - Annually



Disclosure Requirements

 Subrecipient Investigators subject to the UCSF Financial Conflict of Interest Policy are required to disclose whether they or an Immediate Family Member have a Significant Financial Interest that is directly related to their work under the subrecipient agreement.



Disclosures: Forms A and B

Form A

Subrecipient Investigators complete
 Form A to confirm whether or not
 their institution has a conflict of
 interest policy that is compliant with
 the PHS regulation. If yes, they must
 agree to follow it, and no other steps
 are required. If not, they must provide
 the names of all investigators to
 complete Form B.

Form B

 SFI disclosures must be made on Form B for any subrecipient without a compliant institutional PHS policy.
Form B must be sent to each person listed as an Investigator on Form A.



Review of Financial Conflicts of Interest

- At Notice of Award, the UCSF Conflict of Interest Office will review each subrecipient Investigator's Significant Financial Interest Disclosure (Form B), determine whether a Financial Conflict of Interest (FCOI) exists, and if so, whether it is possible to manage the FCOI.
- When a FCOI is identified, UCSF will report its existence and all required details of the FCOI to the PHS awarding component as required by regulation.



SFI Disclosure Requirements

- **SFI**: Any one or more of the following four types of financial interests that you or your Immediate Family have would be considered an SFI according to the UCSF COI Policy:
 - Exceeding \$5,000 in income and/or equity in a publicly-held entity.
 - Exceeding \$5,000 in income or any amount of equity in a privately-held entity.
 - Income from intellectual property rights exceeding \$5,000 in the previous 12 months, excluding royalties received from the University of California Regents.
 - A management position, whether paid or unpaid, such as a board member, director, officer, partner, or trustee, held by the investigator.



Public Accessibility to FCOI Information

- The PHS regulation mandates that institutions receiving SFI disclosures shall, upon request, ensure public accessibility of information concerning any SFI disclosed to the recipient institution that meets the following criteria:
 - The SFI was disclosed and is still held by key personnel;
 - 2. The institution determines that the SFI is related to the PHS-funded research; and
 - 3. The institution determines that the SFI is a FCOI.



Public Accessibility to FCOI Information

- To comply with this requirement, UCSF will make certain FCOI information publicly available by responding in writing to requests for such information within five business days of receipt by the UCSF Conflict of Interest Office of such requests. Public disclosures of a subrecipient Investigator's FCOI information will include the following information:
 - Name, title, and role of the subrecipient Investigator on the UCSF Research Project;
 - 2. Name of the entity in which the SFI is held (if applicable); and
 - 3. Nature and approximate dollar value or range of the SFI, or a statement that the value cannot be readily determined.



Glossary of Terms

- Financial Conflict of Interest: An SFI that could directly and significantly affect the design, conduct, or reporting of the research.
- Investigator: The project director or principal investigator and any other person (faculty, staff, students, and collaborators or consultants outside of UCSF), regardless of title or position, who is responsible for the design, conduct, or reporting of a UCSF Research Project.
- Immediate Family Member: Spouse, domestic partner, or dependent child.
- <u>UCSF Research Project:</u> Any systematic investigation (i.e., the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, whether or not it is made available to the general public, involving a UCSF employee, student, or other person where the UCSF is responsible for the oversight and/or administration of the activity.



Training Completion

You have completed the required training, please submit your subrecipient disclosure form using **Form B**.

If you have any questions, please email coiac@ucsf.edu.

