

I. Introduction:

UCSF faculty, students and staff conduct research and scholarly activity to develop new knowledge and translate new discoveries into practical applications for the public good. To support this activity, the University permits these investigators to establish industry partnerships to translate new discoveries through sponsored research support, consulting, and entrepreneurship. However, UCSF also aims to establish standards by which investigators can engage in industry collaborations while managing Significant Financial Interests (SFIs) that could potentially detract from the real and perceived objectivity of research. This document provides guidelines for disclosure of reportable financial interests and management of SFIs for UCSF investigators. These guidelines describe the legal and ethical requirements that bind UCSF investigators.

II. Conflict of Interest

A conflict of interest exists when an investigator's financial or personal considerations have the potential to compromise or bias the investigator's professional judgment or objectivity in the design, conduct, reporting, review, or oversight of a research project. An *investigator* is anyone responsible for the design, conduct, or reporting of the project, regardless of title

III. Reportable Financial Interests

In order to support management of conflicts of interest among investigators, UC policies establish criteria by which investigators must disclose their financial interests. According to University of California policies, the threshold above which a **related** financial interest is considered **reportable** depends on the source of funding:

Public Health Service (PHS): A reportable financial interest exists if any of the following conditions apply:

- Income and/or equity in a publicly-held entity exceeds \$5,000;
- Income or any amount of equity in a privately-held entity exceeds \$5,000; AND/OR
- Income from intellectual property rights exceeds \$5,000 in the previous 12 months, excluding royalties received from the University of California Regents.

National Science Foundation: A reportable financial interest is defined if any of the following conditions apply:

- Income exceeding \$10,000 from either a publicly traded, private or non-profit entity.
- Equity exceeding \$5,000 or 5% of the value of the entity
- Any intellectual property not held by the UC Regents.

Non-PHS Federal Sponsors: A financial interest is reportable if any of the following conditions apply:

- Income and/or equity in publicly-held entity exceeds \$10,000;
- 5% ownership interest in any entity;

- A management position, whether paid or unpaid, such as a board member, director, officer, partner, or trustee, held by the investigator; AND/OR
- Intellectual property interest in the form of a patent, patent application or copyright held by the Investigator, or the Investigator's spouse or registered domestic partner, or dependent children on a patent, patent application, assigned or to be assigned to a party other than The Regents.
- Specifically excluded are payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University. Also excluded is income from public or nonprofit entities for seminars, lectures, teaching engagements, or service on advisory committees or review panels.

Private Sponsors: A financial interest is reportable if any of the following conditions apply:

- The investigator is a board member, consultant or has a management position with the sponsor;
- The investigator has equity exceeding \$2000 or more in the sponsor.
- The investigator has income or loans from the sponsor exceeding \$500.
- The investigator has received gifts exceeding \$50 in value.
- The entity has sponsored travel exceeding \$500 in income or gifted more than \$50 in travel costs to the investigator.
- The investigator has any other disclosures that meet the PHS requirements of a reportable financial interest.

IV. Significant Financial Interest

A reportable financial interest that is **related*** to the research will be considered a Significant Financial Interest (SFI) that requires a Conflict of Interest Management Plan at UCSF if any of the following conditions apply:

- The individual is an *investigator* on the project. An *investigator* is anyone responsible for the design, conduct, or reporting of the project, regardless of title.
- It meets the definition of a reportable financial interest related to a PHS, NSF, or other federally-funded project as described in section III.
- For privately-funded projects:
 - Exceeds \$5,000 in income and/or equity in a publicly-held entity.
 - Exceeds \$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.

*A financial interest is **related** to the research if either of the following conditions apply:

- The value of the interest (e.g. material or intellectual property) could be affected by the outcome of the project.

- The investigator has financial interests in an entity of which the value could be affected by the outcome of the project.

V. Financial Conflict of Interest (PHS only)

A Financial Conflict of Interest (FCOI) exists when the University reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of a research project funded by a PHS agency. FCOIs are reportable to the PHS agency.

VI. Disclosure of Reportable Financial Interests

All reportable financial interests as described in Section III above must be disclosed to UCSF COIAC as follows:

- All PHS-funded investigators are required to disclose their respective reportable financial interests within the COI-SMART application on an annual basis, or within 30 days of incurring a new reportable financial interest.
- All principal investigators are required to disclose their respective reportable financial interests in non-governmental sponsors using the 700-U form both at time of proposal submission and when the project is funded.
- All principal investigators are required to disclose the respective reportable financial interests in non-PHS federal sponsors on the PI certification form.
- At time of submission to the Institutional Review Board (IRB), principal investigators conducting human subject studies must disclose whether they or any of the co-investigators have reportable financial interests (varies by sponsor as described in section III) related to the project.

VII. Review of Reportable Financial Interests

Per UC Policy, reportable financial interests must be reviewed by an Independent Substantive Review Committee. At UCSF, this role is carried out by the Conflict of Interest Advisory Committee (COIAC). These reviews take place upon submission of a research project for funding, upon funding of the project, and at time of submission of an IRB application. Based on the disclosures referenced in III above, the COIAC reviews an investigator's reportable financial interests in relation to research projects at time of submission and at time of funding. The review considers the aims of research project, determines if the reportable financial interests are significant, determines if the interests are related to the project and determines if there is a Financial Conflict of Interest (PHS projects). If the COIAC determines a financial interest is significant, it will determine whether the conflict is manageable. If so, the COIAC will devise a plan for managing that conflict of interest to reduce or eliminate the impact of the Significant Financial Interest on the conduct and reporting of the research. That plan, or an amended version of that plan based on consideration of an appeal, must be signed off by the principal investigator for the funding to be accepted.

Relevant links and policies:

[UCSF Policy 100-34](#): Disclosure of Financial Interests & Management of Conflicts of Interests, Public Health Service (PHS) Research Awards

[UCSF Policy 100-35](#): Disclosure of Financial Interests & Management of Conflicts of Interests, Non-Public Health Service (Non-PHS) Research Awards

[UCSF Policy 100-33](#): Disclosure of Financial Interests & Management of Conflicts of Interests, Private Sponsors of Research