Purpose

The federal Department of Health And Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F [3] and 45 C.F.R. Part 94 [4], as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Services (PHS)-sponsored investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored Activities will be conducted free of bias resulting from Investigator financial conflicts of interest.

These regulations require the University to maintain a written policy on conflict of interest disclosure as a condition for receiving PHS awards. Therefore, this Policy implements the 2011 PHS regulations on Promoting Objectivity in Research and applies to all Investigators supported by PHS [National Institutes of Health (NIH), Centers for Disease Control (CDC), Food and Drug Administration (FDA), etc.] awards and other non-federal sponsors that adopt the PHS policy. (See Guidance Table of PHS Organizations and Agencies following PHS regulations [5]).

This policy applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

Consistent with PHS regulations, this policy will be made available via a publicly-accessible website. All University of California Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS Activities, and Investigators seeking PHS support) shall be informed where this policy and relevant reporting requirements may be accessed via the web.

The University of California [6] and UCSF [7] maintain a separate conflict of interest policy applicable to sponsors and programs, including the National Science Foundation (NSF) who continue to follow the 1995 regulations on Objectivity of Research.

Definitions

Conflict of Interest Advisory Committee (COIAC)
The UCSF faculty committee charged with determining whether Significant Financial Interests are related to the proposed research and whether they constitute Financial Conflicts of Interest. The COIAC is appointed and is advisory to the Executive Vice Chancellor and Provost. The Chancellor designated the Executive Vice Chancellor and Provost as the official who receives and approves recommendations from the COIAC regarding Financial Conflicts of Interest.

Designated Official

Campus official (or designee) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in a PHS Activity. The Designated Official at UCSF is the Associate Vice Chancellor, Ethics and Compliance.

Financial Conflict of Interest (FCOI)

A Significant Financial Interest that is related to the PHS-funded activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct or reporting of PHS Activity.

Institutional Responsibilities

Teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California which are in the course and scope of the Investigator’s University of California appointment/employment.

Investigator

Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project. This includes the Principal Investigator, Co-Investigators, Collaborators, Consultants, and any other individual who has responsibility for designing, conducting, or reporting of funded research or proposed such funding.

Key Personnel

A PHS research Project Director, Principal Investigator and any other personnel considered
essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.

PHS Activity(ies)

Any activity for which funding is available from PHS awarding agency including but not limited to research contracts, cooperative agreements, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, conference grants, and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

Principal Investigator (PI)

The individual ultimately responsible for the appropriate scientific and financial conduct of a sponsored research project. On occasion, co-principal investigators who share responsibility for a project.

Significant Financial Interest (PHS)

Consistent with the University of California’s definition (See University of California Policy Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards), Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator’s spouse or registered domestic partner and any dependent children for the following categories:

A. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph E, below) received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are salary (other than salary described in Paragraph E, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.

B. With regard to any non-publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph E, below) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse, registered domestic partner, or dependent children) holds any equity interest (including stocks, options, etc.)

C. Receipt of income from intellectual property rights and interests exceeding $5,000 during the twelve months preceding disclosure. However, Significant Financial Interests do not include royalties received from the University of California Regents.

D. Travel reimbursements made to, or on behalf of, the Investigator, regardless of the amount,
by a for-profit or nonprofit entity, excluding a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute. Only the Investigator’s travel reimbursements are included in the definition of Significant Financial Interest. Therefore, the Investigator’s spouse or registered domestic partner, or dependent children’s travel reimbursements are not considered to be a Significant Financial Interest in this policy.

E. The term “Significant Financial Interest” does not include the following types of financial interests:

1. Mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles;
2. Salary, stipends, royalties, honoraria, reimbursement of expenses, or any other payments made by the University of California Regents to a University of California Investigator who is currently employed or otherwise appointed by the University;
3. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education;
4. Travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.

Policy

A. Disclosure

1. Investigators seeking PHS funding or receiving PHS support are required to disclose all Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall electronically submit disclosure of Significant Financial Interests form(s) in accordance with the COIAC process.

B. Training/Education

1. Investigators must complete required training/education program(s) on Financial Conflicts of Interest, the responsibilities to disclose, and the PHS regulations prior to the expenditure of PHS funds and every 4 years during the award.

C. Reporting to PHS

1. Financial Conflict of Interest(s) (FCOIs) are reported to PHS by the Designated Official (or designee) prior to expenditure of PHS funds, upon subsequent disclosure or discovery, and on an ongoing basis as required under the federal regulations.

Responsibilities

- Responsibilities and Procedures for 100-34 Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service (PHS) Research Awards

Related Policies

- 100-33 - Disclosure of Financial Interests & Management of Conflicts of Interests, Private Sponsors of Research
References

- NIH Financial Conflict of Interest Website [20] with Revised Regulations and 1995 Regulations
- Retention and Access Requirements for Records See 45 C.F.R. 74.53 [21](b) and 45 C.F.R. 92.42 [22](b)
- UCSF Conflict of Interest in Research [8]
- UCSF Conflict of Interest Advisory Committee [23]
- University Conflict of Interest Policy Related to State Public Records Act Conflict of Interest Requirements See University of California's Conflict of Interest Code [27]
- University Policy on Conflict of Commitment and Outside Activities of Faculty Members (APM 025) See http://www.ucop.edu/acadpersonnel/apm/apm-025-07-01.pdf [28]
- Related forms, templates and guidance, please access the UCOP Research Policy Analysis and Coordination website [29]