

INTERIM POLICY ON CONFLICT OF INTEREST IN GRANTS AND CONTRACTS FOR PRINCIPAL INVESTIGATORS

I. Introduction

This policy sets institutional Conflict of Interest standards and practices applicable to Investigators on grants and contracts. This policy is intended to strengthen, and where appropriate, be consistent with the CSU Conflict of Interest Code, California Government Code 87302, and federal requirements of 42 CFR Part 50, Subpart F.

II. Definitions

Investigator means the Principal Investigator, Co-Investigators, Project Directors, collaborators, consultants, and any other person who is responsible for the design, conduct, or reporting of research activities funded or proposed for funding. For reporting of Significant Financial Interest, “investigator” includes the investigator’s spouse and dependent children.

Institution means California State University, Fresno (University) or California State University Fresno, Foundation (Foundation).

Significant Financial Interest (SFI) means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

For investigator’s funded by the Public Health Service (PHS)¹, an SFI includes a de minimis threshold of \$5,000 for disclosure which generally applies to payments for services and equity interests. This includes *any* equity interest in non-publicly traded entities. A reportable SFI is related to the investigator’s institutional responsibilities.

The term *does not* include:

1. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
2. intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
3. any ownership interests in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
4. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
5. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
6. income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Financial Conflict of Interest (FCOI) exists when an SFI could directly and significantly affect the design, conduct, or reporting of the research.

¹ Public Health Services means any agency under the U.S. Public Health Service, including: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA).

Recipient means the legal entity awarded a contract or grant. At California State University, Fresno, the Recipient is either the University or one of its recognized auxiliary organizations and shall not be an individual, department, or other constituent unit.

III. Reporting Requirements

Investigators are required to complete and submit Conflict of Interest forms to the Office of Human Resources reporting an SFI at the following times:

1. At the time of proposal submission
2. Annually, during the period of the award
3. Within 30 days of discovering or acquiring a new FCOI

The Conflict of Interest forms shall include:

1. Grant/contract number;
2. Name of Investigator with SFI;
3. Name of entity with which Investigator has SFI;
4. Nature of SFI (e.g., equity, consulting fees, etc.);
5. Plans to manage SFI.

When filing of the Conflict of Interest form is required, an Investigator must submit the forms with the Project Information Form to the Office of Research and Sponsored Programs **prior to submission** of the grant application.

California Form 700-U. An Investigator requesting funding from non-governmental sources must file the one-page California form 700-U. California regulations require: (1) an annual update of form 700-U; (2) California state ethics training in the first year and each two years thereafter; and (3) a final form 700-U submitted within 90-days after the project ends. The following link gives a list of private non-profit agencies that have been determined to be **EXEMPT** by the California Fair Political Practices Commission: <http://www.fppc.ca.gov>.

Federal Form. An Investigator applying to federal agencies requiring Financial Conflict of Interest disclosure (e.g. NIH, NSF) must complete the Federal Disclosure form available on the Office of Research and Sponsored Programs website (www.csufresno.edu/grants).

IV. Responsibilities

It is the responsibility of the **Principal Investigator** of a grant or contract to identify all investigators (as defined above) -- that is, all persons with design, conduct or reporting responsibilities on the grant or contract -- whether or not they are identified in the proposal, grant or contract, and ensure that they follow the provisions of this policy.

It is the responsibility of each **Investigator** (as defined above) to disclose any changes or newly identified financial conflicts that arise during the course of the funded project.

The **Office of Research and Sponsored Programs** shall make available a copy of this policy statement to the public on an accessible website. The Office shall make an initial review of the conflict of interest documents and determine if there are any issues. The Office shall keep and store original conflict of interest forms.

The **Recipient** (Foundation or University) will include information about Conflict of Interest disclosure in the Principal Investigator handbook.

The **Recipient** will notify Principal Investigators of annual deadlines for multi-year awards and annual/final reporting.

The **Recipient** will notify subrecipients of the Conflict of Interest requirements. Subrecipients of externally funded projects from nongovernmental and specified federal agencies will be asked to submit Conflict of Interest declarations or proof of an acceptable Conflict of Interest policy prior to receiving funding. The recipient will ask the subrecipient to complete disclosure forms prior to full execution of any subcontract.

The **Office of Human Resources** at the university shall review conflict of interest forms where issues are identified by the Office of Research and Sponsored Programs and determine if there is a SFI covered by this policy, and if so, will submit it to the Conflict of Interest Committee.

V. Managing Conflicts of Significant Financial Interest

After the Office of Research and Sponsored Programs' initial review of the disclosure form, the Office of Research and Sponsored Programs will refer issues to the **Office of Human Resources** to determine if there is any SFI covered by this policy, and if so, will submit it to the **Conflict of Interest Review Committee**.

SFI disclosure forms referred by the Office of Human Resources will be reviewed by the Committee to determine if they are related to an investigator's Public Health Services related research, and if related, to determine whether they create any FCOI. An SFI is "related" if the research could affect the value of the SFI or the entity in which there is an SFI. A financial conflict of interest exists when an SFI could directly and significantly affect the design, conduct, or reporting of the research.

The Committee shall be composed of:

The Associate Provost, the AVP for Financial Services, and the AVP for Academic Personnel.

Each member of the Committee is to be familiar with the State and Federal regulations governing conflicts of interest.

The Committee shall review all statements regarding potential conflicts of interest submitted by the Office of Human Resources.

When the Committee believes a FCOI exists under either State or Federal regulations, it shall:

1. inform the Investigator and Office of Human Resources;
2. with the appropriate Dean, draft a Resolution Plan that details steps that will be taken to manage, reduce, or eliminate the conflict of interest prior to acceptance of funding, or if appropriate, to disclose the FCOI in papers and presentations; and
3. enter into an MOU between the university and investigator that details the conditions or restrictions imposed upon the investigator in the conduct of the project or in the relationship with the business entity.

Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential conflicts of interest include, but are not limited to:

1. public disclosure of FCOI;
2. monitoring of the project by independent reviewers;
3. modification of the project plan;
4. disqualification from participation in all or a portion of the project;
5. divestiture of FCOI; and/or
6. severance of relationships that create actual or potential FCOI.

Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Recipient (Foundation or University) until 3 years after the date of termination or completion of the award to which the documents relate, or the resolution of any government action involving these records.

The Recipient will notify the awarding agency with details of each FCOI, including the name of the individual with the conflict of interest, the name of the entity with which the entity has the financial interest, the nature and magnitude of the interest, the basis for the financial conflict of interest determination, and the key elements of the management plan.

VI. Actions for Noncompliance

Anyone found to be noncompliant with the University Independent Review Committee requests and/or in violation of this policy will be reported to the Provost for further action. If sanctions are imposed, they may range from a formal reprimand to the imposition of disciplinary action as defined in Article 19 of the Memorandum of Understanding (MOU) between The California State University and the California Faculty Association.

VII. Requirements Specific to PHS Funds

Reporting Requirements to the NIH: The Associate Vice President for Research and Sponsored Programs or his designee will send initial, annual and revised FCOI reports, as required by 42 CFR 50.604(h) and 42 CFR 50.605(b) to the National Institutes of Health and any subrecipients at the following times:

1. Prior to the expenditure of funds
2. Within 60 days of identification of a PI new to the project
3. Within 60 days for new, or newly identified, FCOI's for existing PIs
4. Annually to provide the status of the FCOI and any changes to the management plan until completion of the project

Travel Reimbursements and Sponsored Travel: Investigators with PHS funding are required to disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Disclosure of travel reimbursements and Sponsored Travel does not include travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

VIII. Training

Conflict of Interest training is required of all Principal Investigators as stated in the Principal Investigator Handbook.

In addition, any and all Principal Investigators submitting a proposal to any PHS entity also must complete the NIH on-line training tutorial, found at the following link:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

All Principal Investigators who complete the NIH on-line training tutorial must send a copy of the program generated certificate of completion to Office of Research and Sponsored Programs prior to award acceptance.

Interim policy approved by the President

January 10, 2013