

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

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- FPPC Regulation 18755, and federal requirements of 2 CFR 200, and individual federal agency requirements regarding subrecipient Financial Conflicts of Interest.

Investigators are required to disclose Significant Financial Interest (SFI) whenever an investigator applies for funding from the National Science Foundation (NSF), Public Health Service (PHS) agencies (e.g., the National Institutes of Health), as well as several other agencies adopting federal requirements. The NSF and PHS require investigators to disclose all financial interests that could potentially bias research outcomes. Investigators must disclose SFI annually during the life of a sponsored research project, and within 30 days of discovering or acquiring a new SFI. All investigator disclosures are monitored and managed by the Office of Research and Sponsored Programs, Division of Research and Graduate Studies.

Definitions

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

Significant Financial Interest means anything of monetary value, including, but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria)
- equity interests (e.g., stocks, stock options, or other ownership interests)
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

The term does NOT include:

- salary, royalties, or other remuneration from the university;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities;
- an equity interest that, when aggregated for the Investigator and the Investigator’s spouse and dependent children meets both of the following tests:
 - (1) does not exceed \$10,000 (or \$5,000 for PHS projects) in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - (2) does not represent more than a 5% ownership interest in any single entity.
- salary, royalties or other payments that, when aggregated for the investigator and the investigator’s spouse and dependent children over the next twelve months, are not expected to exceed \$10,000 (or \$5,000 for PHS projects).

Financial Conflict of Interest (FCOI) is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the funded research. The following are examples of when an Investigator would be deemed to have a financial conflict of interest:

- a. If the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS/NSF-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or
- b. The Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University which has resulted in license income and that technology is the subject of a proposed PHS/NSF-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

Disclosure means the process of an investigator, as defined above, completing and submitting a Financial Conflict of Interest form to the Office of Research and Sponsored Programs when the following occur:

Public Health Services (PHS) disclosures:

- Initial proposal (prior to award)
- Non-competing continuations
- Renewals
- Supplemental funding
- New personnel added
- Must be reported within 60 days of addition
- New financial interests that would be considered "significant" according to PHS
- Must be reported within 30 days of acquiring or discovering new significant financial interests

National Science Foundation (NSF) disclosures:

- Initial proposal (prior to award)
- New personnel added
- Any change in an investigator's financial interest

PHS disclosure requirements: https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

NSF disclosure requirements: https://www.nsf.gov/pubs/policydocs/pappguide/nsf09_29/aag_4.jsp

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.

Designated Institutional Officials

The Research Compliance Officer (RCO) is the designated institutional official for the collection of Financial Conflict of Interest Forms. This person, in conjunction with the Director of Research and Sponsored Programs and the Dean of the Division of Research and Graduate Studies, are the designated officials for the review and identification of financial conflicts of interest.

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 within the Division of Research and Graduate Studies shall provide a copy of this policy statement to Investigators at the time of application for a project to be submitted to a non-governmental agency and/or a federal agency requiring such reporting.

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

The Recipient will notify PIs of annual deadlines for multi-year awards.

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 Research and Sponsored Programs within the Division of Research and Graduate Studies will review and store the originals of all disclosure forms. Copies of such forms will be filed in the submission folder and grant folder if awarded.

General Filing Procedure: Private, Non-Governmental Funding

Requirements for Financial Conflict of Interest Disclosure

The purpose for conflict of interest laws is to prohibit public employees from personally benefitting at the expense of the public interest. The Political Reform Act of 1974, administered by the Fair Political Practices Commission (FPPC), is often regarded as the principal conflict of interest law, and is the guiding regulation for the CSU Conflict of Interest Code (see CSU Conflict of Interest Handbook) and the Integrated CSU Administrative Manual (ICSUAM) Policy 11010.02. The ICSUAM defines a Significant Financial Interest as “anything of monetary value, including but not limited to salary or other payments for service; equity interests; being an owner, partner, director or officer in a non-publicly held company or entity; and, intellectual property rights and royalties from such rights.” The FPPC requests information on the CA-700U disclosure form to administer and enforce the Political Reform Act. Failure to provide all the information required by the Act is a violation subject to administrative, criminal or civil prosecution. All reports and statements provided are public records open for public inspection and reproduction.

Principal Investigators (PIs) requesting funding from nonexempt, non-governmental sources must file the one-page California Form 700-U.

References:

1. The FPPC regulation pertaining to PIs can be found in Title 2, Division 6, Section 18755: <http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/LegalDiv/Regulations/Index/Chapter7/Article3/18755.pdf>

2. CSU Conflict of Interest Handbook (COI code):
<http://www.calstate.edu/gc/Docs/ConflictofInterestHandbook.pdf>

3. ICSUAM Policy 11010.02: <https://csyou.calstate.edu/Policies/icsuam/Pages/11010-02.aspx>

I. Exempt Agencies

PIs requesting funds from state, county, and city government are exempt from filing conflict of interest forms. Exempt sponsors are listed in this document: [FPPC List of Exempt Agencies- List begins on Page 3](#) or in Title 2, Division 6, Section 18755 of the FPPC regulation.

II. Filing a Disclosure: California Form 700-U

The 700-U Statement of Economic Interests for Principal Investigators form is required by all persons employed by the CSU who have principle responsibility for a research project if the project is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental agency.

PIs requesting funding from nonexempt, non-governmental sources must file the one-page California form 700-U. Form link: https://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/Form%20700/2020-21/Form_700-U_2020.pdf

California regulations require:

- (1) Filing of form 700-U for an initial submission of a grant or contract (before the final acceptance of a contract, grant, or gift);
- (2) Filing of form 700-U within 30 days after the contract, grant, or gift is renewed. California State University, Fresno defines “renewal” as a competitive renewal (i.e., the PI must apply for the grant).
- (3) CSU’s ethics training must be completed within six (6) months of receiving the grant or contract. Subsequent training is required at least once within each two calendar-year period that the grant or contract is active.

The Office of Research and Sponsored Programs, Division of Research and Graduate Studies, will request and monitor the submission of 700-U disclosure forms and retain ownership of the forms.

III. Training

In accordance with the Fair Political Practices Commission requirements and consistent with ICSUAM, PIs must complete the CSU Ethics and Conflict of Interest training within six (6) months of receiving the grant. Subsequent training is required at least once within each two calendar-year period that the grant or contract is active.

The CSU Ethics and Conflict of Interest training is administered through the campus CSULearn system training portal. To gain access to CSULearn system, the Office of Research and Sponsored Programs must first provide a spreadsheet of PI names to the campus Human Resources (HR) department. The authorized HR CSULearn system representative will then send out email notifications to all PIs within the provided spreadsheet regarding the necessary training. The CSULearn system sends automated reminders monthly until the training is completed. The Office of Research and Sponsored Programs will receive notification from HR once training has been completed by PIs.

IV. Disclosure Review and Management

If a financial interest is disclosed on the 700-U form, the Research Compliance Officer will determine whether the disclosure meets the definition of significant financial interest (SFI). If a significant financial interest or the appearance of a significant financial interest is determined, it will be submitted to the Conflict of Interest Review Committee. 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 and make recommendations for the management of the conflict(s) as necessary.

When the Committee believes a “significant” conflict of interest exists under either State or Federal regulations, it shall:

- (1) inform the employee 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; 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:

- public disclosure of significant financial interests;
- monitoring of the project by independent reviewers;
- modification of the project plan;
- disqualification from participation in all or a portion of the project;
- divestiture of significant financial interests; and/or
- severance of relationships that create actual or potential conflicts.

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 three (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.

General Filing Procedure: Federal Funding

Federal policy requires Fresno State researchers and investigators submitting to NSF, PHS agencies, or agencies who have adopted the PHS policy to disclose any significant financial interest, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research proposed for funding. The review and management of significant financial interests promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from conflicts of interest.

When filing of the Conflict of Interest form is required for federal agencies, PIs must submit forms to the Office of Research and Sponsored Programs, Division of Research and Graduate Studies prior to submission of the grant application.

I. Filing a Disclosure: Federal Disclosure Form

PIs applying to federal agencies requiring Financial Conflict of Interest disclosure (e.g., NIH, NSF) must complete the Federal Disclosure Form available on the Division of Research and Graduate Studies website: <http://www.fresnostate.edu/academics/grants/forms/conflict.html>

Federal Disclosure Requirement:

- (1) Principal Investigators and key personnel are required to submit a disclosure statement at the proposal submission stage and every year during the life of the grant or contract, unless disclosure is triggered by another event prior to an annual disclosure (i.e., within 30 days of discovering or acquiring a new SFI and within 60 days of the addition of an Investigator new to participating in the research project or transferring a project to Fresno State from another institution.
- (2) Principal investigators and key personnel are required to complete Financial Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and every four (4) years after award for the life of the grant or contract. Training is offered through Collaborative Institutional Training Initiative (CITI) Program (<http://www.fresnostate.edu/academics/grants/citi/citi.html>). CITI Program's conflict of interest courses cover the U.S. Public Health Service (PHS) regulations on financial conflicts of interest and an investigator's responsibilities related to the disclosure of Significant Financial Interests.

II. Training

The Office of Research and Sponsored Programs shall be responsible for ensuring that each Investigator is informed about the PHS and NSF financial conflict of Interest policies, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, as well as the Fresno State FCOI procedures. Investigators shall be required to complete training prior to engaging in research related to any PHS funded grant, cooperative agreement or contract; at least every four (4) years thereafter; or immediately when any of the following applies:

1. Fresno State revises this policy that affects requirements of Investigators,
2. An Investigator is newly appointed at the University and transfers their PHS funding to Fresno State;
3. An Investigator is newly appointed to a PHS funded research grant as the PI or key personnel; or
4. The University finds that an Investigator does not comply with this policy or management plan.

Fresno State utilizes Collaborative Institutional Training Initiative (CITI) to fulfill PHS training requirements. Instructions are as follows:

Step 1. Follow Link: <https://www.citiprogram.org/>

Step 2. Click *Register* under *Create an Account*

Step 3. Create a profile with California State University, Fresno

Step 4. Under *Select Curriculum*, Question 4, select *PHS Investigators and Key Personnel* course and select *Not at this time* for all other course options.

The PI and key personnel will be notified by the Research Compliance Officer (RCO), Office of Research and Sponsored Programs, of the training requirement. The RCO will track certification completion administratively and will continue to notify PI's of the requirement weekly until it is completed. In the event PHS training is incomplete at the time of award, the Post-Award administrator will be notified to not draw funds until it is completed. For full CITI COI Training registration instructions, visit our webpage: <http://www.fresnostate.edu/academics/grants/forms/conflict.html>

III. Disclosure Review and Management

If a financial interest is disclosed on the federal form, the Research Compliance Officer will determine whether the disclosure meets the definition of significant financial interest (SFI). If a significant financial interest or the appearance of a significant financial interest is determined, it will be submitted to the Conflict of Interest Review Committee. 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 and make recommendations for the management of the conflict(s) as necessary.

When the Committee believes a “significant” conflict of interest exists under either State or Federal regulations, it shall:

- (1) inform the employee 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; 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:

- public disclosure of significant financial interests;
- monitoring of the project by independent reviewers;
- modification of the project plan;
- disqualification from participation in all or a portion of the project;
- divestiture of significant financial interests; and/or
- severance of relationships that create actual or potential conflicts.

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 three (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.

IV. Appeals to FCOI Determinations

Appeals to a positive finding of a FCOI determination that results in declination of the sponsored project award, or a FCOI determination that results in the implementation of a management plan can be made to the Dean of the Division of Research and Graduate Studies for final review, discussion, and determination. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award.

In reviewing positive findings that are appealed, the Dean of the Division of Research and Graduate Studies will be guided by the following principles:

- 1) Assure adherence to all relevant Fresno State policies and provisions of collective bargaining agreements;
- 2) Give full consideration to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator’s family members, with the external constituencies;
- 3) Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and

- 4) Consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent FCOI.

Reporting Requirements for FCOI

1. NIH Reporting Requirements

Reports will be sent to NIH for the following:

- When the designated institutional officials have discovered an initial SFI and implemented a management plan, reporting will be completed prior to the expenditure of funds;
- Within 60 days of identification of SFI for an Investigator who is newly participating in the project;
- Within 60 days for new, or newly identified, SFIs for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, or at time of extension) to provide the status of the SFI and any changes to the management plan, if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report, if appropriate;
- Promptly upon discovery of bias with the design, conduct or reporting of NIH-funded research with a mitigation report in accordance with the regulation;
- Promptly upon discovery of an Investigator failing to comply with the Institution's FCOI policy or if a FCOI management plan appears to have biased the design, conducts, or reporting of the NIH-funded research.
- A management plan will be implemented and reported within sixty days of discovering a failure to comply.

2. NSF Reporting Requirement

If an FCOI is discovered and cannot be managed appropriately by the Investigator, the Office of Research and Sponsored Programs or the Institution, the Research Compliance Officer will seek management guidance from the NSF's Office of the General Counsel.

Subrecipient Compliance Requirements

All proposed subrecipients under PHS/NSF funded research of the University shall have a financial conflict of interest policy that conforms to the requirements of the PHS and NSF financial conflict of interest regulations. 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.

All identified FCOI will be reported to Fresno State's Office of Research and Sponsored Programs before proposal submission. The Office of Research and Sponsored Programs will report to the NIH funding agency any FCOI in accordance with this policy.

Enforcement Mechanisms and Remedies and Actions of Noncompliance

Failure to comply with this FCOI policy, as well as the prescribed management plan, will result in corrective action. If actions of non-compliance by an investigator appears to have biased the design, conduct or reporting of the PHS/NSF funded research, the University, through the Office of Research and Sponsored Programs, as required under federal regulations, shall promptly notify the agency of the corrective actions to be implemented.

The Office of Research and Sponsored Programs will ensure compliance with the requirements for retrospective review, to be completed within 120 days of identification, and prepare a mitigation report, if needed, for submission to the applicable funding agency. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University to take further action to maintain the objectivity of the research.

If the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required by the regulation, the University, through the Office of Research and Sponsored Programs, shall require the Investigator involved to: (1) Disclose the FCOI in each public presentation of the results of the research, and (2) To request an addendum to previously published presentations.

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.

Maintenance of Records

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 three (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.

Agencies and Sponsors Following the PHS FCOI Regulations

Below is a list of federal agencies that are part of the U.S. Public Health Service (PHS) and that require compliance with the PHS FCOI requirement for grants and contracts.

Public Health Service (PHS) Agencies

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Centers for Disease Control and Prevention (CDC)
4. Food and Drug Administration (FDA)
5. Health Resources and Services Administration (HRSA)
6. Indian Health Service (IHS)
7. National Institutes of Health (NIH)
8. Office of Global Affairs (OG)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Planning and Evaluation
11. Office of the Assistant Secretary for Preparedness and Response (ASPR)
12. Office of Public Health and Science
13. Substance Abuse and Mental Health Services Administration (SAMHSA)

References:

<https://thefdp.org/default/fcoi-clearinghouse/fcoi-agencies/>

Public Accessibility Requirements

The University's FCOI policy is publicly accessible. The policy is posted on the Fresno State public website: <http://www.fresnostate.edu/academics/grants/forms/conflict.html>

Information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), will be made publicly accessible prior to the expenditure of funds. Requests for information will be made available to the requesting party in writing within five (5) business days of a written request. The minimum elements as required by the regulation will be included, which are:

1. the Investigator's name;
2. the Investigator's title and role with respect to the research project;
3. the name of the entity in which the significant financial interest is held;
4. the nature of the significant financial interest;
5. the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
6. the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor;
7. The information provided will remain available for three years from the date the information was most recently updated.

**Recommended by
Academic Senate**

September 11, 2017

Approved by President

Interim January 10, 2013

Interim October 4, 2017