



SACRAMENTO
STATE

FINANCIAL CONFLICT OF INTEREST:
INVESTIGATOR PROCEDURES

OFFICE OF RESEARCH, INNOVATION, AND ECONOMIC DEVELOPMENT
RESEARCH INTEGRITY AND COMPLIANCE

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Introduction

This document describes state and federal requirements for investigator disclosures of financial conflicts of interest when applying for funding from a non-governmental entity or from the National Science Foundation (NSF) or Public Health Services (PHS). The State of California requires investigators to disclose financial interests with non-governmental entities from which funding is requested to ensure public employees are not personally benefitting at the expense of the public interest. The NSF and PHS require investigators to disclose all financial interests that could potentially bias research outcomes. There are several other federal and non-federal funding agencies that have adopted the PHS policy on financial conflicts of interest. All investigator disclosures are managed by the Office of Research, Innovation, and Economic Development.

Private, Non-Governmental Funding Procedure

I. Financial Conflicts of Interest Requirements

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.”

This procedure applies to Principal Investigators (PI) in research requiring the disclosure of any financial interests an investigator, or the investigator’s spouse/domestic partner and dependent children, may have with a non-governmental funding entity.

Information requested on all FPPC forms is used by the FPPC 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.

Referenced regulations, code, and policy:

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>

A. Exempt Private Agencies

Research funding by certain nonprofit entities will not trigger disclosure. Exempt sponsors are listed in this document: [Sponsors Exempt from Financial Disclosure Requirement \(PDF\)](#) or in Title 2, Division 6, Section 18755 of the FPPC regulation.

B. Disclosure, Training, Review, and Management

1. Filing a Disclosure

Definitions and reporting requirements are described within the 700-U document, available here: <http://www.csus.edu/research/links/proposaldevelopment/700u.pdf#highlight>

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.

Disclosure is required prior to final acceptance of a contract or grant, or within 30 days after funding is renewed. The ORIED will monitor the submission of 700-U disclosure forms and retain ownership of the forms. Forms not submitted after the first notification from the Research Integrity and Compliance Officer will result in additional notifications to the PI and the PI's Department Chair. Subsequent notifications of delinquent disclosure will escalate notifications to the College Dean and the Provost.

2. Training Requirements

In accordance with the Fair Political Practices Commission requirements and consistent with ICSUAM, Principal Investigators must complete the CSU Ethics and Conflict of Interest training within six (6) months of receiving the grant. Subsequent training is required as least once each consecutive period of two calendar years that the grant is in place.

To gain access to the CSU Ethics and Conflict of Interest training, the Office of Research, Innovation, and Economic Development (OREID) must provide the Investigator's name and email address to the campus filing officer or designee in the Office of Human Resources (HR). In coordination with ORIED and HR, the Investigator will receive an email notification when they have been granted access to the training module. The Skillport software sends automated reminders monthly until the training is completed. ORIED will run monthly reports of training completion. If the training is incomplete four months post-initial notification, ORIED will send a notification to the PI and the PI's Department Chair. Reminders will be escalated to the College Dean and Provost if the training is incomplete after six months.

3. Review of Disclosed Conflicts

If a financial interest is disclosed on the 700-U form, the Research Integrity and Compliance Officer, with the Associate Vice President of ORIED and/or with the Associate Director of ORIED, 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, an ad hoc independent review committee will be formed to make recommendations for the management of the conflict(s) as necessary. The ad hoc committee may consist of the following: Research Integrity and Compliance Officer (for administrative purposes), the AVP of ORIED, liaison with the Academic Senate, and a faculty member that does not have a conflict of interest in the review.

4. Management of FCOIs

Management of financial interests will be set by the ad hoc independent review committee. Some examples of management are:

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
- Abstention from certain project segments or decisions;
- Modification of the external commitment or financial interest;
- Modification of the research plan (including the assignment of responsibilities);
- Divestiture or severance of an external commitment or financial interest;

Federal Funding Procedure

II. Financial Conflicts of Interest Requirements

Federal policy requires Sacramento 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.

A. Definitions

1. Investigator

The principal investigator or project director, co-principal investigator, and any other personnel who would be responsible for the design, conduct, or reporting of research or educational activities funded by the PHS/NSF or proposed for such funding, which may include, for example, consultants, investigators on subawards, and unpaid collaborators. *For purposes of this policy, regardless of funding source, "Investigator" also includes the investigator's spouse/domestic partner and dependent children.*

2. Disclosure

Disclosure is the process of a Sacramento State investigator, as defined above, completing and submitting a Financial Conflict of Interests form to ORIED 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

3. Significant Financial Interest

Public Health Services (PHS)

A Significant Financial Interest (SFI) related to the investigator's institutional responsibilities including:

- If publicly traded entity, total value of compensation and equity interest > \$5,000
- In non-publicly traded entity, total value of compensation > \$5,000 or any equity interest
- Income received related to intellectual property >\$5,000
- Any reimbursed or sponsored travel
 - Excluding (1) travel that is reimbursed or sponsored by a state or government agency, university, teaching hospital, medical center, or research institute affiliated with a university; or (2) travel for the investigator's spouse/domestic partner and/or dependent children.

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

National Science Foundation (NSF)

A SFI related to the research project including:

- Income >\$10,000
- Equity (of any type) >\$10,000 or 5%
- Director, Officer, Employee, Partner, Trustee, Consultant or Management position
- Intellectual Property

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

4. Financial Conflict of Interest (FCOI)

A 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:

- (i) 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
- (ii) 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.

5. Designated Institutional Officials

The Research Integrity and Compliance Officer is the designated institutional official for the collection of a Financial Conflict of Interest Form. This person, in conjunction with the Associate Vice President for

Research, Innovation, and Economic Development and the Associate Director for Research, Innovation, and Economic Development, are the designated officials for the review and identification of financial conflicts of interest.

B. Training Requirement

The ORIED shall be responsible for ensuring that each Investigator is informed about (i) the PHS and NSF financial conflict of Interest policies, (ii) the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and (iii) the Sacramento State FCOI Procedures. The ORIED, through the designated institutional official, shall require each Investigator to complete training:

1. Prior to engaging in research related to any PHS funded grant, cooperative agreement or contract;
2. At least every four (4) years thereafter; or
3. Immediately (within 10 business days following the event that triggers the training requirement) when any of the following applies:
 - a. Sacramento State revises this policy that affects requirements of Investigators,
 - b. An Investigator is newly appointed at the University and transfers their PHS funding, to CSUS; or
 - c. An Investigator is newly appointed to a PHS funded research grant as the PI or key personnel; or
 - d. The University finds that an Investigator is not in compliance with this Policy or their management plan.

The PHS Conflict of Interest course can be accessed on our Collaborative Institutional Training Initiative (CITI) site:

1. Link: <https://www.citiprogram.org/>
2. Click *Register* under *Create an Account*
3. Create a profile with California State University, Sacramento
4. Under *Select Curriculum*, Question 4, select *PHS Investigators and Key Personnel* course and select *Not at this time* for all other course options.

At the time ORIED is notified of a PHS award, the PI and key personnel will be notified of the training requirement. ORIED 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 SPA administrator will be notified to not draw funds until it is completed. See our webpage for a CITI registration guide: <http://www.csus.edu/research/researchintegritycompliance/coi.html>

C. Disclosure, Review and Management Requirements

1. Making a Disclosure

Disclosures occur through the action of an Investigator completing and submitting a Sacramento State Financial Disclosure Form as a component of the Proposal Approval Form. These forms can be located on the ORIED Conflict of Interest website:

<http://www.csus.edu/research/researchintegritycompliance/coi.html>.

- a) Disclosures must be submitted when seeking PHS funding (or funding from other agencies that have adopted the PHS policy) in accordance with the following milestones:

- No later than at the time of application for funding;
- At least annually during the period of the award;
- Within 30 days of discovering or acquiring a new SFI;
- Within 60 days of the addition of an Investigator new to participating in the research project or transferring a project to Sacramento State from another institution.

b) Disclosures must be submitted when seeking NSF funding in accordance with the following milestones:

- No later than at the time of application for funding;
- At least annually during the period of award;
- Or as new reportable significant financial interests are obtained.

In the interest of reducing administrative burden and confusion, conflict of interest forms for PHS and NSF funding will be requested annually. If new SFI is disclosed prior to an annual deadline, the deadline will be extended to a year from the most recent disclosure.

Forms not submitted after the first notification from the Research Integrity and Compliance Officer will result in an additional notification to the PI and the PI's Department Chair. Subsequent notifications of delinquent disclosure will escalate notifications to the College Dean and the Provost. The SPA administrator will be notified to not draw funds until disclosures are completed at the initial or annual stage.

2. Review of Disclosures

Identified conflicts of interest are reviewed prior to expenditure of funds by the Research Integrity and Compliance Officer, the AVP of Research, Innovation, and Economic Development and/or Associate Director of Research, Innovation, and Economic Development to determine whether an Investigator has a Significant Financial Interest (SFI) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definitions of SFI.

Identified SFI results in further disclosure to the AVP of Research, Innovation, and Economic Development, AVP of Human Resources, and Vice Provost, with the Investigator, to reasonably determine whether the SFI is a Financial Conflict of Interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of the funded research.

Following the determination of an FCOI, the Associate Vice President for Research, Innovation, and Economic Development, Associate Vice President for Human Resources, and the Vice Provost shall make a final determination involving one of the following administrative actions:

1. Accepting the sponsored project award subject to suitable modification in the award documentation or in the investigator's, or his/her family's, affiliation with the external constituencies involved. Possible modifications are explained below in Management of FCOI;
2. Implement a management plan within sixty days whenever an SFI is identified that was not disclosed timely by the Investigator or not previously reviewed by the campus; or
3. Not accepting the sponsored project award.

3. Management of FCOI

Management plans developed to mitigate FCOIs will be overseen by the designated institutional officials. The ORIED, in conjunction with the investigator(s), the College Dean, Department Chair, and

the Provost, will finalize the management plan and communicate it to the affected research personnel. Management measures may include, as appropriate, but are not limited to:

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
- Research personnel's abstention from certain project segments or decisions;
- Modification of the external commitment or financial interest;
- Modification of the research plan (including the assignment of responsibilities);
- Monitoring of the potentially affected research activity by an independent individual or subcommittee;
- Divestiture or severance of an external commitment or financial interest;
- Independent review of student research progress;
- Discontinuation of advisee's or subordinate employee's participation in External Entity.

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting compliance at pre-determined intervals until the completion of the project. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the ORIED.

4. 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 Provost 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 Provost will be guided by the following principles:

- 1) Assure adherence to all relevant Sacramento 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.

D. Reporting Financial Conflicts of Interests

1. NIH Reporting Requirements

Reports will be sent to NIH during the circumstances and deadlines specified below:

- 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 Requirements

In the event of discovering an FCOI that cannot be satisfactorily managed, either by the Investigator, the ORIED, or the Institution, the Research Integrity and Compliance Officer will work with Sponsored Program Administration to keep the NSF's Office of the General Counsel appropriately informed of the situation and seek assistance.

E. Subrecipient Compliance and Reporting

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, or follow Sacramento State's FCOI Policy. If the subrecipient individual(s) have an identified FCOI, it should be revealed, by their employing institution, to Sacramento State's ORIED before proposal submission.

If the subrecipient individuals will be following Sacramento State's Policy, they will be required to disclose their Significant Financial Interests directly to the ORIED at Sacramento State. If it is determined that there is an FCOI, they will be subject to the same requirements as are Sacramento State-employed investigators.

Sacramento State, through the ORIED, will report to the NIH funding agency any FCOI in accordance with Section D. of this procedure.

F. Remedies and Noncompliance

If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS/NSF funded research, the University, through the ORIED, as required under federal regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the ORIED shall 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.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under 42 CFR 50, the University, through the ORIED, must require the Investigator(s) to disclose the FCOI in each public

presentation (such as articles, manuscripts and the ORIED presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

G. Enforcement and Sanctions

All persons subject to this FCOI Policy are expected to comply with it fully and promptly. Whenever an Investigator has violated the Policy, for example by a failure to disclose a Significant Financial Interest, the ORIED may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.

Violations of this policy and the PHS/NSF Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective University policy and procedures governing allegations of research misconduct.

In addition, with respect to conflicts of interest that are not properly disclosed and handled, State of California ethics laws may apply. Violations of the State ethics laws can lead to civil fines and criminal prosecution.

H. Records

The University, through the ORIED, is required to maintain all Disclosures and all related records of actions taken by the University with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS/NSF or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

I. Federal and non-Federal sponsors that have adopted PHS regulations

U.S. Public Health Services Agencies include:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health, including
 - Office of Minority Health Resources Center (OMH)
 - Office of Population Affairs (OPA)
 - Office of Research Integrity (ORI)
 - Office of Research on Women's Health (OWH)
- Office of the Assistant Secretary for Preparedness and Response, including
 - Biomedical Advanced Research and Development Authority (BARDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

This list of PHS agencies is taken from the FDP Institutional Clearinghouse website:
http://nrc59.nas.edu/pub/fcoi_agencies_phs_regs.html.

J. Non-PHS organizations that have adopted PHS regulations:

Alliance for Lupus Research
 Arthritis Foundation
 American Heart Association
 American Cancer Society
 Susan G. Komen for the Cure
 California Institute for Regenerative Medicine (CIRM)
 University of California, Office of the President (UCOP) Special Programs:
 University AIDS Program
 California Breast Cancer Program
 Tobacco-Related Disease Research Program

This list of PHS agencies is taken from the FDP Institutional Clearinghouse website:
http://nrc59.nas.edu/pub/fcoi_agencies_phs_regs.html and from the ICSUAM Section 11010.02.

K. PHS Public Accessibility Requirements

The University, through the ORIED, will make the Sacramento State Financial Conflict of Interest Policy publicly accessible through presence on a publicly accessible website:
<http://www.csus.edu/research/researchintegritycompliance/coi.html>.

Requests for information concerning identified FCOIs (a Significant Financial Interest which is a Financial Conflict of Interest (FCOI) which could directly and significantly affect the design, conduct, or reporting of the funded research) held by senior/key personnel (as defined by the regulation) will be made available to the requestor in writing within five (5) business days of a 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.