PURPOSE

It is the policy of the California State University (CSU) that each campus shall have procedures in place to comply with conflict of interest regulations related to Principal Investigators (PIs), students, and staff engaged in sponsored research activities. This procedure governs the manner and extent to which California State University, Stanislaus (University) manages financial conflicts of interest while conforming to Integrated CSU Administrative Manual (ICSUAM) Sponsored Programs (SP) policy number 11010.02.

DEFINITIONS

For definitions, refer to ICSUAM SP Policy 11001.01 SP Policy Definitions.

OVERVIEW

For the purpose of this document, PIs, Co-PIs, and key personnel will be referred to hereafter as “investigator”. This procedure 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 Service (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. NSF and PHS, as well as several other federal and non-federal funding agencies that have adopted the PHS policy on financial conflicts of interest, require investigators to disclose all financial interests that could potentially bias research outcomes. ICSUAM 11001.01 defines Significant Financial Interest as “anything of monetary value, including but not limited to salary or other payments for service such as consulting fees or honoraria; 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”. All University departments and organizations conducting research, instruction, and/or other sponsored work under grants, and other agreements are required to comply with these procedures.

PROCEDURE

I. Private, Non-Governmental Funding

   A. Financial Conflict of Interest Requirements
The purpose of conflict of interest laws is to prohibit public employees from personally benefitting at the expense of the public trust. While the Political Reform Act of 1974 (Government Code §§ 81000 et seq.), administered by the Fair Political Practices Commission (FPPC), is often regarded as the principal conflict of interest law, it is also the guiding regulation for the CSU Conflict of Interest Code and ICSUAM Policy 11010.02.

This section of the procedure applies to investigators 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:

- The FPPC regulation pertaining to investigators can be found in Title 2, Division 6, Section 18755.
- CSU Conflict of Interest Handbook (COI Code)
- ICSUAM Policy 11010.02

1. Exempt Private Agencies

Research funding by certain nonprofit entities will not elicit disclosure. Exempt sponsors are listed in Section 18755 of the FPPC regulation at the following link:

2. Disclosure, Training, Review, and Management

a. Filing a Disclosure

Definitions and reporting requirements are described within the 700-U document.

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 non-governmental agency.

Disclosure is required prior to final acceptance of a contract or grant, or within 30 days after funding is renewed or a new conflict arises during the course of
the project. Working in conjunction with the Office of Research and Sponsored Programs (ORSP), Post Award will monitor the submission of 700-U disclosure forms and retain the forms for audit purposes. Delinquent submission of signed forms will result in additional notifications to the investigator and the investigator’s department chair. Subsequent notifications will escalate to the college dean and/or Provost.

b. Training Requirements

In accordance with FPPC requirements and consistent with CSU policy, investigators must complete the CSU Ethics & Conflict of Interest training within 6 months of receiving the grant. Subsequent training is required at least once each consecutive period of 2 calendar years that the grant is in place.

To gain access to the CSU Ethics & Conflict of Interest training, Post Award will provide the investigator’s name and email address to the campus training administrator who will assign the training. The investigator will receive an email notification when they have been granted access to the training module. Periodic automated reminders will be sent until the training has been completed. Delinquent completion of training will result in additional notifications to the investigator and the investigator’s department chair. Subsequent notifications will escalate to the college dean and/or Provost.

c. Review of Disclosed Conflicts

If a financial interest is disclosed on the 700-U form, a determination will be made as to whether the disclosure meets the definition of significant financial interest (SFI). If a SFI or the appearance of one is concluded, 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: VP/AVP for Financial & Support Services, Campus Compliance Officer, ORSP Director, liaison with the Academic Senate, and/or a faculty member that does not have a conflict of interest in the review.

d. Management of Financial Conflicts of Interest

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, etc.
- 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.
II. Federal Funding

A. Financial Conflict of Interest Requirements

Federal policy requires the campus researchers and investigators submitting to NSF, PHS agencies, or agencies who have adopted the PHS policy to disclose any SFI, 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 SFIs promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and the reporting of research will be free from bias resulting from conflicts of interest.

1. Definitions

a. **Investigator**: The PI or project director, Co-PI, and any other personnel who would be responsible for the design, conduct, or reporting of research or educational activities funded by PHS/NSF or proposed for such funding, which may include, for example, consultants, investigators on subawards, and unpaid collaborators. For the purpose of this procedure, regardless of funding source, “investigator” also includes the investigator’s spouse/domestic partner and dependent children.

b. **Disclosure**: Is the process of a campus investigator, as defined above, completing and submitting an FCOI form to ORSP or Post Award when the following occur:

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

NSF disclosures:
- Initial proposal (prior to award)
- New personnel added
- Any change in an investigator’s financial interest

c. **Significant Financial Interest (SFI):**

*Public Health Service (PHS)*
A SFI related to the investigator’s institutional responsibilities including:

- If publicly traded entity, total value of compensation and equity interest > $5,000
- If 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**

**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**

d. **Financial Conflict of Interest (FCOI):**

A FCOI is a 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 FCOI:

i. If the investigator (together with the investigator’s spouse/domestic partner and dependent children) has a SFI 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 the investigator’s spouse/domestic partner and dependent children) has a SFI 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.

e. **Designated Institutional Officials:**
ORSP and Post Award are the two institutional areas designated to collect FCOI forms. The Post Award Manager, working with the AVP for Financial & Support Services when needed, is responsible for the review and identification of financial conflicts of interest.

2. Training Requirements

Post Award, working in conjunction with ORSP, shall be responsible for ensuring that each investigator is informed about:
- The University’s FCOI policies and/or procedures
- Investigator’s disclosure responsibilities regarding SFIs
- Federal regulations; PHS and NSF policies

Post Award and/or ORSP shall require each investigator 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, if:
  - The University revises its FCOI policy/procedure that affects requirements of investigators
  - Investigator is new to the University
  - Investigator is not in compliance with the policy/procedure or management plan.

The PHS Conflict of Interest training can be accessed on the campus Collaborative Institutional Training Initiative (CITI) site:
- Link:  https://www.citiprogram.org/
- Click the “Register” box
- Under Organization Affiliation, find and select California State University, Stanislaus
- Check the “I agree” box
- Check the “I affirm” box
- Click on “Continue” to create a CITI Program username/password
- Once in, select the training for Financial Conflict of Interest

Investigator will be provided with a deadline date for completion of the training and will be requested to provide Post Award with a copy of the Certificate of Completion. If the training is not completed by the deadline date provided, Post Award will continue to follow-up with the investigator until it has been completed. Grant funds cannot be drawn down until completion of training has been confirmed.

a. The PI or project director, Co-PI, and any other personnel who would be responsible for the design, conduct, or reporting of research or educational activities funded by PHS/NSF or proposed for such funding, which may include, for example, consultants, investigators on subawards, and unpaid
collaborators. For the purpose of this procedure, regardless of funding source, “investigator” also includes the investigator’s spouse/domestic partner and dependent children.

3. Disclosure, Review, and Management Requirements

a. Making a Disclosure:

Disclosures occur through the action of an investigator completing and submitting a Disclosure of Financial Interests Certification Form as a component of the proposal routing and approval process.

i. 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 the University from another institution

ii. 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 the award
   - As new reportable SFIs are obtained

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

Delinquent submission of signed forms will result in additional notifications to the investigator and the investigator’s department chair. Subsequent notifications will escalate to the college dean and/or Provost. Grant funds cannot be drawn down until initial and/or annual signed disclosure forms have been received.

b. Disclosure Review:

Prior to expenditure of funds, identified conflicts of interest will be reviewed by the AVP for Financial & Support Services and Post Award Manager to determine whether an investigator has a SFI related to the investigator’s institutional responsibilities that meets or exceeds the regulatory definition of SFI. If it’s concluded there is a SFI, an ad hoc independent review committee (see section I.A.2.c.), along with the investigator, will be convened to reasonably determine whether the SFI is a FCOI that could directly and
significantly affect the design, conduct, or reporting of the funded research. Following the determination of a FCOI, the independent review committee will make a final determination involving one of the following administrative actions:

i. 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 in the Management of Financial Conflicts of Interest below.

ii. Implement a management plan within 60 days of a SFI being identified that was not disclosed timely by the investigator or not previously reviewed by the campus.

iii. Not accepting the sponsored project award.

c. Management of Financial Conflicts of Interest (FCOI):

Management plans developed to mitigate FCOIs will be designated by the ad hoc independent review committee in conjunction with the investigator. Once the management plan has been finalized, it will be communicated to the affected research and campus 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, student 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 the 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 specifically provide how the monitoring will be performed, who will perform it, what records are to be kept, what type of reporting is required, and to whom.

d. Appeals to Financial Conflict of Interest (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:

i. Assure adherence to all relevant University policies and provisions of collective bargaining agreements.

ii. Give full consideration to the nature and extent of the financial interest as it relates to the relationship of the investigator, and/or the investigator’s family members, with the external constituencies.

iii. Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation.

iv. Consult fully with and obtain additional information from the investigator as deemed appropriate to the management of the apparent FCOI.

4. Reporting Financial Conflicts of Interest (FCOI)

a. National Institutes of Health (NIH) Reporting Requirements:

(NIH is an agency within the U.S. Department of Health and Human Services (DHHS), and is part of PHS.)

Notification will be provided by ORSP to NIH as specified below:

- When a SFI has been discovered and the designated institutional officials have implemented a management plan, NIH will be notified prior to the expenditure of funds.
- Within 60 days of identification of a SFI for an investigator who is new to the project.
- Within 60 days of identification of a new, or newly identified, SFI for existing investigators.
- At least annually, preferably at the same time as when the University is required to submit the annual progress report, multi-year progress report, or at time of award extension, to provide the status of the SFI and any changes to the management plan, if applicable, until the project is completed.
- 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 University’s policy/procedure or if a FCOI management plan appears to have biased the design, conducts, or reporting of the NIH-funded research.
  o A management plan will be implemented and reported within 60 days of discovering a failure to comply.

b. NSF Reporting Requirements:

In the event of discovering a FCOI that cannot be satisfactorily managed either by the investigator or the University, Post Award, working in conjunction with ORSP, will keep NSF’s Office of the General Counsel appropriately informed of the situation and seek assistance.

5. Subrecipient Compliance and Reporting

All proposed subrecipients under PHS/NSF-funded research of the University shall have a FCOI policy that conforms to the requirements of the PHS and NSF financial conflict of interest regulations; otherwise, they are required to adopt the University’s FCOI policy/procedure. If a subrecipient individual has an identified FCOI, the subrecipient agency must make the FCOI known to the University’s ORSP Director prior to proposal submission.

If the subrecipient individuals will be following the University’s policy/procedure, they will be required to disclose SFIs directly to the University’s ORSP Director. If it is determined that there is a FCOI, they will be subject to the same requirements as investigators employed by the University.

The University, through ORSP, will report to the NIH funding agency any FCOI in accordance with Section 4. of this procedure.

6. Remedies and Noncompliance

If an investigator fails to comply with the University’s FCOI policy/procedure 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 (Post Award working in conjunction with ORSP), as required under federal regulations, shall promptly notify the sponsor of the corrective action taken or to be taken. In every respect, the University 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 sponsor 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 PHS, if the DHHS 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, subpart F, the University must require the investigator involved to disclose the conflicting interest in each public presentation of the results of the research.

7. **Enforcement and Sanctions**

All persons subject to the University’s FCOI policy/procedure are expected to comply with it fully and promptly. If an investigator is found to be in violation by failing to disclose a SFI, the matter will be referred to the appropriate University official or committee for disciplinary or other appropriate action.

Violations of this policy/procedure 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/procedures governing allegations of research misconduct.

In addition, with respect to COIs 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.

8. **Records**

The University 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 PHS/NSF or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

9. **Federal Agencies Following Public Health Service (PHS) Regulations**

Following is a listing of Public Health Service Agencies that have been reported to be following PHS regulations:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDC)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs (OG)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Office of Public Health and Science
- Substance Abuse and Mental Health Services Administration (SAMHSA)
This list of agencies was obtained from the Federal Demonstration Partnership website.

RESOURCES AND REFERENCE MATERIALS

- 2 CFR 200, Subpart B §200.112 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards: Conflict of Interest
- 42 CFR 50, Subpart F – Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- 42 CFR 74.53(b) & 42 CFR 92.42(b) – DHHS Retention and Access Requirements for Records
- HR-2015-05: Principal Investigators – Non-governmental
- CSU FCOI Disclosure Requirements by Funding Source Chart