

# **Financial Conflict of Interest Policy**

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#### **POLICY**

San Francisco State University (SF State) requires Principal Investigators (PIs) and, if required, Key Personnel, on a sponsored project to disclose a listing of significant financial interests (and those of their spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project. All PIs and if required Co-PIs and Key Personnel listed in a proposal for external funding must complete a disclosure form. According to the University Executive Directive #UED 96-20, it is the responsibility of the Office of Research and Sponsored Programs to maintain documentation on all possible conflict of interest issues.

#### **DEFINITIONS**

**PI:** Defined as Principal Investigator (PI), co-Principal Investigator (Co-PI), and any other person who is responsible for the design, conduct or reporting of the sponsored project or of any related agreement. Disclosures must also be made for each PI's spouse and dependent children.

**Significant Financial Interest (SFI):** The term "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 interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

#### **SCOPE**

#### A. Financial Conflict of Interest (FCOI) Disclosure Forms

<u>Federal Awards and other governmental awards</u>: SF State has developed a form entitled *Disclosure of Financial Interests Certification for* National Science Foundation (NSF), the Public Health Service (PHS), and other sponsors that have adopted the requirements for financial disclosure.

#### PIs are required to complete and submit at the following times:

- i. At the time of pre-award/proposal submission
- ii. At the time of post-award
- iii. Annually
- iv. Within 30 days of acquiring or discovering a new FCOI

<u>Non-Governmental Awards</u>: SF State uses *California Form 700-U (Statement of Economic Interests For Principal Investigators)* for disclosure of financial interest for all non-governmental sponsors.

# PIs are required to complete and submit at the following times:

- i. At the time of pre-award/proposal submission
- ii. At the time of post-award
- iii. Renewal of award (within 30 days)

### B. Financial Conflict of Interest (FCOI) Exemption Policy

- <u>Non-governmental Entities Exempt from Disclosure requirements</u>: PIs are not required to complete a disclosure form if their project is sponsored by a non-governmental agency listed in Appendix A.
- PIs are not required to complete a disclosure form if their project is funded by internal University funds.

## C. California State University Conflict of Interest Policy

In addition, SF State requires the annual completion of the California Form 700 (Statement of Economic Interests) for all University positions whose decisions "may foreseeably have a material effect on financial interests" of the University. Some faculty and MPP directors at SF State may be required to complete both a project-specific disclosure form for ORSP and a California Form 700 (Statement of Economic Interests) for Human Resources. Further information on the annual SF State requirement can be found on the SF State Human Resources website:

http://www.SF State.edu/~hrwww/Labor\_Compliance\_ProfDev/emp\_relations/hr\_Directives/P203.html

### D. Subrecipients

- SF State requires subrecipients to identify whether they will follow SF State's FCOI policy or if they have their own in place. If following their own FCOI policy, they must also verify that their policy complies with all appropriate regulations.
- SF State requires that the subrecipient report identified FCOIs for its PIs within a timeframe that in turn allows SF State to report FCOIs to the appropriate funding agency.

#### E. Institutional Certification and Review

- The Associate Vice President, Office of Research and Sponsored Programs (AVP of ORSP) is the designated institutional official who will determine whether a PI's SFI is a FCOI:
  - 1. The AVP of ORSP or his/her designee performs the initial review of all FCOI Disclosure Forms submitted by PIs.
  - 2. The AVP of ORSP is responsible for the following:
    - i. Determining whether a PI's SFI is a FCOI.
    - ii. Developing and implementing any Management/Resolution plans (referred to hereafter as Resolution Plans) needed to manage identified FCOIs.
    - iii. Taking necessary action to manage FCOIs, including those of subrecipient PIs, and monitoring a PI's compliance with the established Resolution Plan through completion of the project.
    - iv. If a FCOI is discovered that was not disclosed in a timely manner by the PI or was not previously reviewed by SF State, developing a Resolution Plan within 60 days of discovering the FCOI.
- Certification will be performed by the AVP of ORSP or his/her designee and will be based on information
  provided by the PI on the FCOI Disclosure form for each entity that may be involved. The AVP of ORSP or
  his/her designee will review the disclosures, assess their potential for a FCOI, and develop resolution
  strategies with the PI to manage, reduce, or eliminate such conflicts.
- SF State will notify the sponsor if required of any FCOI and provide a Resolution Plan to address the
  conflict. If a FCOI is identified after an award has started, SF State will follow sponsor's guidelines for
  handling.

#### F. Resolution Plan

- If the designated official(s) determines that a FCOI exists, a Resolution Plan must be developed with the PI and implemented prior to the award being activated. The Resolution Plan must be in writing and approved by the Conflict of Interest Oversight Committee, which includes the Internal Auditor, AVP of ORSP, Director of ORSP, the Compliance Officer, and the Dean of the affected PI's College.
- Resolution options may include but are not limited to:
  - i. Public disclosure of significant financial interests
  - ii. Monitoring of research by independent reviewers
  - iii. Modification of the research plan
  - iv. Disqualification from participation in the portion of the project that is affected by the significant financial interest
  - v. Divestiture of significant financial interests
  - vi. Severance of relationships that create actual or potential conflicts

#### **G.** Enforcement Mechanisms and Sanctions

Potential violations of the Financial Conflict of Interest Resolution Plan shall be handled by the Conflict of Interest Oversight Committee. This committee will establish and enforce appropriate sanctions based on the specific conduct of a PI failing to follow the agreed upon Resolution Plan.

# H. Reporting

- For National Science Foundation (NSF) awards, the AVP of ORSP or his/her designee will inform the NSF's Office of the General Counsel if SF State is unable to satisfactorily manage a financial conflict of interest.
- For National Institutes of Health (NIH) & Public Health Service (PHS) awards, the AVP of ORSP or his/her designee will notify the PHS Awarding Component of the following information:
  - i. Award number;
  - ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
  - iii. Name of the Investigator with the Financial Conflict of Interest;
  - iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
  - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - vi. Value of the 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;
  - vii. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
  - viii. A description of the key elements of the Institution's management plan, including:
    - (A) Role and principal duties of the conflicted Investigator in the research project;
    - (B) Conditions of the management plan
    - (C) How the management plan is designed to safeguard objectivity in the research project;
    - (D) Confirmation of the Investigator's agreement to the management plan;
    - (E) How the management plan will be monitored to ensure Investigator compliance; and
    - (F) Other information as needed.

Reporting Requirements to the NIH & PHS: The AVP of ORSP or his/her 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 NIH & PHS for SF State and any subrecipients at the following times:

- i. Prior to expenditure of funds
- ii. Within 60 days of identified FCOI
- iii. Annually to provide the status of the FCOI and any changes to the management plan until completion of the project
- For other federal awards, the AVP of ORSP or his/her designee will follow the sponsor's instructions for handling and reporting.
- For other governmental and non-governmental awards, the AVP of ORSP or his/her designee will follow SF State and/or sponsor's instructions for handling and reporting.

#### I. Documentation and Records Maintenance

Office of Research and Sponsored Programs, and when appropriate, the University Corporation, will maintain records of all financial disclosures and of all actions taken to resolve financial conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any action involving those records, whichever is longer.

## J. Conflict of Interest Trainings

National Institutes of Health (NIH) & Public Health Service (PHS) Funding

PIs with NIH or PHS funding will also be required to complete an online FCOI training at the following times:

- i. Prior to engaging in research and expenditure of funds related to any NIH or PHS funded grant
- ii. At least every 4 years
- iii. Immediately, if:
  - o SF State revises its FCOI policy in such a way that it affects the requirements of PIs
  - PI is new to an Institution
  - o PI is not in compliance with the policy or management plan

## Non-Governmental Funding

PIs are identified and contacted by SF State's Human Resources to complete the Conflict of Interest/Ethics Training as required by California State University. This needs to be completed:

- i. within 6 months
- ii. retake every two year

## K. Financial Disclosure Requirements Specific to Sponsors

## • National Institutes of Health (NIH) & Public Health Service (PHS) Agencies

The de minimis disclosure threshold for a Significant Financial Interest is \$5,000 in the twelve months preceding for disclosure which generally applies to payments for services (e.g., consulting fees, honoraria, or paid authorship), equity interest (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights). This includes any equity interest in non-publicly traded entities. Investigators must disclose the occurrence of any reimbursed or sponsored travel. A reportable SFI is related to the PI's institutional responsibilities.

The term significant financial interest *does not* include:

- 1. Salary, royalties, or other remuneration from the applicant 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 as defined in 20 U.S.C. 1001(a), 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 as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- 7. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- 8. Salary, royalties, or other remuneration that when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$5,000 in the twelve months preceding for disclosure

For more information, go to NIH's COI website: <a href="https://grants.nih.gov/grants/policy/coi/index.htm">https://grants.nih.gov/grants/policy/coi/index.htm</a>

### National Science Foundation (NSF)

The de minimis disclosure threshold for a Significant Financial Interest is \$10,000 in the twelve months preceding for disclosure which generally applies to 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). A reportable SFI is related to the PI's institutional responsibilities.

The term significant financial interest *does not* include:

- 1. Salary, royalties, or other remuneration from the applicant institution;
- 2. Any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- 3. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities:
- 4. Income from service on advisory committees or review panels for public or non-profit entities;
- 5. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests:
  - (i) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and
  - (ii) does not represent more than a 5% ownership interest in any single entity;
- 6. Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve month period

For more information, go to NSF's website: <a href="https://www.nsf.gov/bfa/dias/policy/">https://www.nsf.gov/bfa/dias/policy/</a>

#### **ROLES AND RESPONSIBILITIES**

## Grant Support Coordinator (GSC) and Grant Administrator (GA)

 Ensures that FCOI disclosure forms are completed for all projects for which they are required during pre-award/proposal and post-award

### **Compliance Unit (CU)**

- Ensures that FCOI disclosure forms are completed for all projects for which they are required
- Ensures that appropriate FCOI documentation procedures are being followed
- Distributes annual FCOI forms to PIs whose projects require annual recertification
- Participates as a member of the Conflict of Interest Oversight Committee

### Director for the Office of Research and Sponsored Programs (Director of ORSP)

- Reviews FCOI forms
- Participates as a member of the Conflict of Interest Oversight Committee
- Serves as liaison to agencies regarding unresolved financial conflicts of interest

## Associate Vice President for the Office of Research and Sponsored Programs (AVP of ORSP)

- Reviews FCOI forms
- Develops resolution strategies with the PI to manage, eliminate, or reduce conflicts of interest
- Participates as a member of the Conflict of Interest Oversight Committee
- Serves as liaison to agencies regarding unresolved financial conflicts of interest
- Contacts the University Counsel when legal questions arise related to an identified conflict of interest

#### **Internal Auditor**

- Develops resolution strategies with the PI to manage, eliminate, or reduce conflicts of interest
- Participates as a member of the Conflict of Interest Oversight Committee

## **University Counsel**

• If a plan of action to address a financial conflict of interest has legal ramifications, the University Counsel coordinates with the AVP of ORSP to review the plan and provide assistance with any legal questions.

## **Principal Investigator (PI)**

- Discloses any FCOI on a sponsored project by completing and submitting a disclosure form to ORSP;
   resubmits/recertifies on an annual basis
- Notifies ORSP immediately of any change in disclosure
- Works with the AVP of ORSP to develop a plan of action to address the conflict of interest if one exists
- Completes COI training as required by funder and/or SF State
- Assists ORSP in obtaining disclosure forms from key project personnel and if necessary assists with obtaining verification of disclosure forms from sub-contract personnel

#### **Key Personnel on the Project**

- Discloses any FCOI on a sponsored project by completing and submitting a disclosure form to ORSP;
   resubmits/recertifies on an annual basis
- Notifies ORSP immediately of any change in disclosure
- Works with the AVP of ORSP to develop a plan of action to address the conflict of interest if one exists

Completes COI training as required by funder and/or SF State

# **College Dean**

- Reviews and approves any resolution plan developed by the PI and the AVP of ORSP
- Participates as a member of the Conflict of Interest Oversight Committee

#### **Human Resources**

• Assist with Conflict of Interest resolution plan if needed

## **RELATED DOCUMENTS**

- UED 96-20: Policies and Procedures Regarding Disclosure of Conflict of Interest for Principal Investigators
- <u>Disclosure of Financial Interests Certification Form</u>
- California Form 700 U-Statement of Economic Interest for Principal Investigators
- SF STATE HR Directive
- Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F
- Title 45 CFR Part 94 (Research Contracts)