

SJSU Research Foundation Financial Conflict of Interest Policy

Office of Sponsored Programs

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1.0 Purpose

This document sets forth the San José State University Research Foundation's guidelines regarding avoidance, disclosure, management, and resolution of financial conflicts of interest in San José State University research and sponsored programs.

2.0 Responsibility

San José State University campus administrators, in collaboration with Research Foundation Office of Sponsored Programs directors, managers, and analysts, are responsible for the oversight and implementation of this policy. All investigators engaged in research at San José State University are responsible for adhering to this policy.

3.0 Scope

This policy applies to all San José State University research and sponsored programs.

4.0 Definitions

This table provides definitions for special terms, acronyms, and abbreviations used in this policy.

Term, Acronym, or Abbreviation	Description
Financial Conflict of Interest	A financial conflict of interest exists when the institution, through its designated official(s), reasonably determines that an investigator's significant financial interest is related to National Science Foundation (NSF), Public Health Service (PHS), or other sponsoring agency that funded the research project and which directly or indirectly affects the design, conduct, or reporting of the funded research project.
Investigator	Principal investigator (PI) or Co-PI, or project director (PD), Co-PD, and any other person, irrespective of title or position, who is responsible for the design, conduct, or reporting of research funded by the sponsoring agency or who is proposed to be responsible for such funding, including non-SJSU investigators, consultants, and unpaid collaborators.
Significant Financial Interest (SFI)	An SFI exists if, in the twelve months preceding the disclosure, the value of any remuneration received from the entity and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$1,000.

Dependent	Includes spouse, registered domestic partner, and dependent children.
Remuneration	Includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship).
Equity Interest	Includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

5.0 Policy

The SJSU Research Foundation and San José State University actively encourage collaboration between academic researchers and educators and industry in the development of private entrepreneurial ventures. Such endeavors can create an increased risk of financial conflicts between the private interests of individuals, the entities with which they are involved, and the public interest that governmental funding serves.

Principal investigators seeking private or non-governmental contracts or grants, or funding from state or federal agencies, must make every effort to avoid financial conflicts of interests—actual or perceived—and make appropriate disclosures. When a conflict does exist, the investigator must annually disclose any significant financial interests (SFI) related to their university responsibilities during the life of a sponsored research project, and within 30 calendar days of discovering or acquiring a new SFI.

Significant financial interests will be reviewed by designated campus administrators to determine whether a financial conflict of interest (FCOI) exists. The Research Foundation and San José State University will follow all federal, state, and California State University (CSU) regulations for reviewing SFIs and for identifying, managing, reducing, eliminating, and reporting FCOIs.

If it is determined that an FCOI exists, investigators will work collaboratively with a chair, dean, and other SJSU and Research Foundation administrators in preparation and implementation of a management plan to reduce or eliminate the FCOI. The associate vice president for the Office of Research has final approval of the management plan. The PIs and Co-PIs must adhere to the management plan and provide updated information to the Office of Research, as required.

5.1 Disclosures

A disclosure of significant financial interest must be provided to the SJSU Research Foundation by PIs, Co-PIs, and all personnel deemed as investigators, for all proposals submitted to any of the types of agencies listed below:

- Federal government agencies such as NSF, DHHS, or NASA
- California State and local government agencies
- Private industries such as IBM or Cisco, as well as small businesses
- Private, nonprofit, or foundation – Please note that applications to some sponsors are exempt from the financial disclosure process. Visit the CSU website for further details: <http://calstate.edu/hradm/pdf2005/hr2005-38.pdf>
- Private organizations such as the Rotary Club or the Petroleum Research Fund

- Subcontracts – If the proposal involves a subcontract through another educational institution for the flow down of NSF or DHHS funds, a financial conflict of interest form must also be on file for the personnel from the subrecipient institution.

Disclosure is required if financial interests of the investigator (or those of the investigator's spouse, domestic partner, or dependent children) fall into any of the following areas that reasonably appear to be related to the investigator's institutional responsibilities:

- (i) Any publicly traded entity – A **significant financial interest** exists if, in the twelve months preceding the disclosure, the value of any **remuneration** received from the entity and the value of any **equity interest** in the entity as of the date of disclosure, when aggregated, exceeds \$1,000.
- (ii) Any non-publicly traded entity – A **significant financial interest** exists if, in the twelve months preceding the disclosure, the value of any **remuneration** received from the entity when aggregated, exceeds \$1,000, or when the investigator (or the investigator's spouse, domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- (iii) Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (iv) **PHS-funded investigators** must also disclose the occurrence of any reimbursed or sponsored travel (i.e., travel which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined in **General Definition Of Institution Of Higher Education 20 U.S.C. Section 1001** (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. For definition details, visit the [U.S. Government Office of Publishing website](#).

The disclosure of travel must include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. In accordance with the institution's FCOI policy, the institutional official(s) will value, in order to determine whether the travel constitutes an FCOI with the U.S. PHS-funded research.

5.2 Exclusions

The term "significant financial interest" does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;
- (ii) Any ownership interest in the institution held by the investigator, if the institution is a commercial or for profit organization; 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;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, and institution of higher education as defined in **General Definition Of Institution Of Higher Education 20 U.S.C. Section 1001**

- (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- (iv) Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 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.

5.3 Management of Financial Conflicts of Interest

Prior to the expenditure of awarded funds, the SJSU associate vice president for the Office of Research reviews all investigator disclosures of significant financial interests, determines whether any significant financial interests relate to the funded award, and determines whether a financial conflict of interest exists. If it is determined that a financial conflict exists the AVP for the Office of Research creates and implements a management plan that will specify the actions that have been, or will be taken to manage such financial conflict of interest.

At the discretion of SJSU, conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- Disclosure of financial conflicts of interest directly to participants (for research projects involving human subjects research);
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or severance of relationships that create financial conflicts.

Upon implementation of the management plan, SJSU will monitor investigator compliance with the management plan on an ongoing basis until the completion of the funded award.

5.4 PHS-Funded Research Projects

Prior to expenditure of funds on a PHS-funded research project, the Research Foundation is required to ensure public accessibility to the disclosed FCOI information when the disclosed FCOI is still held by the senior or key personnel identified by SJSU in the grant application, progress report, or any other required report submitted to a PHS-agency.

5.4.1 Mandatory Training

Investigators must complete mandatory FCOI training through the SJSU CITI Training portal before engaging in research funded by PHS. Visit the SJSU Office of Research website for details.

<http://www.sjsu.edu/research/faculty-training/>

Investigators must also complete refresher training every four (4) years thereafter when any of the following occurs:

- The Research Foundation or SJSU FCOI policy, procedures, or forms are revised in any manner that affects the requirements of investigators;
- The investigator is new to a university;
- SJSU or SJSURF finds that an investigator is not in compliance with FCOI regulations or a required management plan.

Once investigators complete the mandatory training they are to request issuance of the training completion certificate and provide a copy of the certificate to their designated Research Foundation sponsored programs manager.

5.4.2 Disclosing Significant Financial Interest

The Research Foundation requires the following from each investigator for the disclosure of SFIs at the specified intervals:

- **At Time of Application:** NIH requires that each investigator (including subrecipient investigators), planning to participate in PHS/NIH-funded research disclose to the designated official(s) at time of application.
- **Within 30 Calendar Days:** If there is a new SFI resulting from changes in circumstances such as marriage or inheritance, the investigator is required to submit an updated disclosure within 30 calendar days.
- **Annually:** As required by the sponsor, all investigators, including subrecipient investigators, are to submit an updated disclosure of SFI annually, in accordance with the specific time period prescribed by SJSU or the Research Foundation during the award period.

5.4.3 Reporting Financial Conflicts of Interest

In accordance with current regulations, when it is determined that a financial conflict of interest exists, the Research foundation will submit a report to NIH or other PHS-funded agency prior to the expenditure of any funds. The Research Foundation will also provide an FCOI report when an investigator does not disclose an SFI in a timely manner, as well as in instances where SJSU later discovers that a financial conflict of interest exists.

- **Within 60 Calendar Days:** The Research Foundation will submit an FCOI report within sixty (60) calendar days after it is determined that an FCOI exists for an investigator who is newly participating in the project or for an existing investigator who discloses a new SFI to the institution during the award period. SJSU will implement, at least on an interim basis, a management plan that will specify the actions that have been, or will be taken to manage such financial conflict of interest and will submit an FCOI report to NIH or other PHS-funded agency.
- **Within 120 Calendar Days:** SJSU and the Research Foundation will also complete a retrospective review of the investigator's research activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- Based on the results of the retrospective review, the Research Foundation will update the previously submitted FCOI report and specify the actions that will be taken to manage the financial conflict of interest, if appropriate. If bias

is discovered the Research Foundation will promptly notify NIH and will submit a mitigation report that includes the following:

- a) The key elements documented in the retrospective review,
 - b) A description of the impact of the bias on the research project,
 - c) Actions taken by the institution, or the institution's plan of action to eliminate or mitigate the effects of the bias.
- **Annually:** The Research Foundation will submit FCOI reports to NIH or other PHS-funded agency on an annual basis for any financial conflict of interest previously reported. The annual FCOI report will address the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the financial conflict of interest is still being managed or will explain why the financial conflict of interest no longer exists.
 - Annual FCOI reports (including multi-year funded progress reports) will be submitted to NIH through the eRA Commons FCOI module for the duration of the project—including extensions—with or without funds. The report is to be submitted at the same time as the annual progress report, i.e., two months prior to the start date for competitive proposals and 45 days prior to the start date of the noncompeting continuation award, or at the time of the extension. This report is not to be submitted as part of the annual progress report.
 - The annual FCOI report should include the following key elements:
 - a) The 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,
 - f) Other information as needed.

6.0 Related Policy Information

Not applicable.

7.0 Required Forms

This table contains a list of forms and special tools referenced in this document.

Form	Description of Use
California Form 700-U	Use for proposals funded by private, non-profit, industry sponsors.
Financial Conflict of Interest Form-1 Disclosure Form	Use for proposals funded by NSF, NASA, or PHS–funded agencies.
Financial Conflict of Interest Disclosure Form-2	Use for all other government sponsors or entities.

8.0 References and Related Information

[Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractor.](#)

[NSF Conflict of Interest guidance](#)

9.0 Record Retention

All documents and records are maintained in accordance with SJSU Research Foundation *Record Retention* requirements.

Record	Retention
<i>Financial Conflict of Interest Policy</i>	This document is effective until further revised or updated. Outdated or revised documents will be maintained in accordance with Research Foundation Record Retention requirements. The Research Foundation will maintain the signed original and electronic copies of the approved policy and all updates and replacements.