1.0 Purpose

The San Jose State University Research Foundation (SJSURF) Financial Conflict of Interest Policy establishes guidelines for the disclosure, identification, and management of financial conflict of interests (FCOI) for investigators responsible for the design, conduct, or reporting of research under a sponsored research project or when proposing a sponsored project. SJSURF and SJSU follow all federal, state, and California State University regulations for reviewing, identifying, and managing FCOI disclosures.

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

This policy is set in place to ensure that investigators involved in a sponsored research project that is externally funded by contracts or grants from non-governmental sponsors, the National Science Foundation, or the Public Health Service disclose all significant financial interests (SFI) related to the proposed research. Prior to proposal submission SJSURF and SJSU review FCOI disclosures to determine if investigators have potential significant financial conflicts of interests. Any significant financial conflicts of interest are further reviewed by the SJSU institutional official and a management plan is implemented to manage, reduce, or eliminate the FCOI. Records of financial disclosures and all actions taken to resolve conflicts of interest are maintained for three years beyond the termination or completion of the grant to which they relate or until the resolution of any sponsor action involving those records, whichever is longer.

2.0 Responsibility

- SJSURF is responsible for reviewing proposals and awards for FCOI compliance and to assist SJSU and its investigators and collaborators with FCOI compliance.

- SJSU has designated the Associate Vice President for Graduate Studies and Research as the Institutional Official who reviews disclosures of SFIs of the investigator (s) (and those of the investigator’s spouse and dependent children as required on the FCOI forms) related to an Investigator’s institutional responsibilities.
• SJSU’s designated Institutional Official is responsible for reviewing FCOI disclosures to ensure that no financial conflict of interest exists and that any disclosed significant financial conflict of interest is managed, reduced, or eliminated.

• SJSURF Sponsored Programs Managers are responsible for supplying each investigator with the applicable Financial Conflict of Interest Form prior to submitting a proposal for external funding from the National Science Foundation, the Public Health Service (PHS), a private non-governmental sponsor, or a governmental sponsor with contractual COI requirements.

• Each investigator is responsible for completing mandatory FCOI training prior to engaging in research funded by the Public Health Service. Each PHS funded investigator must complete refresher training every four (4) years after the initial training, or when the SJSURF or SJSU FCOI policy, procedures, or forms are revised in any manner that affects the requirements of investigators; when new investigators are appointed to SJSU; and when SJSU or SJSURF finds that an investigator is not in compliance with the FCOI regulations or management plan.

• Each investigator must complete the applicable Financial Conflict of Interest Form and return it promptly to the SJSU Research Foundation. Each investigator must disclose significant financial conflicts of interest before a proposal is submitted, within thirty (30) days of discovering or acquiring a new significant financial interest, and on an annual basis.

• SJSURF is required to make this FCOI policy publicly accessible on a web site or to provide it to any requestor within five business days of a request for the policy.

• Prior to expenditure of any funds under a PHS-funded research project SJSURF is required to ensure public accessibility to information concerning disclosures that have been determined to be financial conflicts of interest related to the PHS funded project.

• SJSURF is responsible for maintaining FCOI records for three years beyond the termination or completion of the grant to which they relate or until the resolution of any NSF or PHS action involving those records, whichever is longer.

3.0 Policy
3.1 Financial Disclosure
Significant Financial Interest
Investigators are required to disclose Significant Financial Interests (SFI) whenever an investigator applies for funding from the National Science Foundation, Public Health Service, from non-governmental contract or grant sources, or from a governmental entity with a contractual conflict of interest requirement. In addition investigators must disclose significant financial interests annually during the life of a sponsored research project, and within 30 days of discovering or acquiring a new SFI.
Significant financial disclosures are defined as follows:

“(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $1,000. For purposes of this definition, 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;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $1,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) PHS funded investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that 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, however, 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 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. Travel disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The SJSU institutional official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by an Investigator’s 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; 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; income from seminars, lectures, or teaching engagements sponsored by 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; or 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.”

**Investigator**

*Investigator* is defined as the Principal Investigator (PI) or Project Director (PD), the Co-PI or Co-PD, and any other person, regardless of title or position, who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, including non-SJSU investigators, consultants, and unpaid collaborators. SJSURF is required to consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

**Specific Sponsored Program Funders**

Sponsored program funders for which FCOI disclosure is required by investigators before a proposal is submitted or an award is accepted include the following:

- National Science Foundation (NSF), Public Health Service (PHS) funds (NIH, FDA, CDC, HIS, HRSA, SAMHSA, AHRQ, ATSDR), including any other agency issuing PHS funds; as well as subcontracts made through another institution for the flow down of NSF or PHS funds.
- Any government agency that prescribes conflict of interest requirements in a contract or grant, such as the County of Santa Clara.

**Forms**

An investigator must make a financial disclosure using a specific financial conflict of interest disclosure form.

- For NSF- and PHS-funded research projects the investigator completes a *Conflict of Interest Disclosure Form – 1* provided by SJSURF.
- For all nonexempt private sponsors the investigator completes a *Form 700U* provided by SJSURF or found at [http://www.fppc.ca.gov/Pdf/Form700-UInteractive02-03.pdf](http://www.fppc.ca.gov/Pdf/Form700-UInteractive02-03.pdf).
- For any government agency that prescribes conflict of interest requirements in a contract or grant the investigator completes a *Conflict of Interest Form COI -2 SJSURF*. 
4. Procedures Overview

4.1 Pre-Award

For all proposal submissions for a non-governmental contract or grant, or for funding from the National Science Foundation or Public Health Service funds, Sponsored Programs Managers will provide the Conflict of Interest Form – 1, Conflict of Interest Form – 2, or 700u Form and guidelines for completion to each investigator before proposal submittal.

Investigators will also submit FCOI forms annually and when SFI status changes. Upon receipt of a COI disclosure form from an investigator, the Sponsored Programs Manager will ensure the form is completed and signed by the investigator.

The Sponsored Programs Manager will include the FCOI disclosure form in the proposal routing package for review by SJSURF and campus administrators or if subsequent to proposal submittal will forward the FCOI disclosure form to the AVP GS&R for review.

When an investigator discloses a significant financial interest the SJSU chair, dean, and AVP GS&R will review the disclosure to determine whether the SFI is related to the sponsored research and whether the SFI is an FCOI. The SJSU chair, dean, and AVP GS&R work with the Investigator to create a management plan to mitigate and manage the potential conflict of interest and will provide a copy of the approved mitigation and management plan to the SJSURF Sponsored Programs Manager for inclusion in an FCOI file within the proposal file.

4.2 Post-Award

Prior to transmitting an award file to the post-award Sponsored Programs Analyst, the pre-award Sponsored Programs Manager will ensure that each investigator receiving an award for funding from the National Science Foundation, a Public Health Service-funded agency, a non-governmental contract or grant sources, or from a governmental entity with a contractual conflict of interest requirement has an unexpired disclosure form (Conflict of Interest Form – 1, Conflict of Interest Form – 2, or 700u Form) in place.

When an investigator has disclosed a significant financial interest on a disclosure form the Sponsored Programs Manager and Sponsored Programs Analyst will confirm that the form has been countersigned by the Associate Vice President of Graduate Studies and Research to indicate acknowledgement of the disclosure, and that a copy of an approved FCOI management plan accompanies the disclosure form signed by the investigator and the AVP of Graduate Studies and Research, and that a training completion certificate is on file for any investigator subject to mandatory FCOI training (PHS funded research projects).

4.3 Mandatory FCOI Training for PHS-Funded Research Projects

Investigators must complete mandatory FCOI training before engaging in research funded by Public Health Service (PHS), and must also complete refresher training every four (4) years thereafter; when SJSURF or SJSU FCOI policy, procedures, or forms are revised in any manner that affects the requirements of investigators; when the investigator is new to a university; and when SJSU or SJSURF finds that an investigator is not in compliance with the FCOI regulations or management plan.
SJSURF Sponsored Programs Managers provide the NIH FCOI tutorial link to investigators when research projects are being proposed for PHS-funding. http://grants.nih.gov/grants/policy/doi/tutorial2011/fcoi.htm.

Once investigators complete the mandatory training they request the issuance of the training completion certificate and provide a copy of the certificate to their designated SJSURF Sponsored Programs Manager.

4.4 Management of Financial Conflicts of Interest

Prior to the expenditure of awarded funds, the SJSU AVP GS&R reviews all Investigator disclosures of significant financial interests, determines whether any significant financial interests relate to the funded award, determines whether a financial conflict of interest exists, and if so, creates and implements a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

At the discretion of SJSU, examples of 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);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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 shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the funded award.

4.5 Reporting Financial Conflicts of Interest to PHS

SJSURF will submit a report to NIH or other PHS-funded agency regarding any Investigator Significant Financial Interest found by the Institution to be a Financial Conflict of Interest in accordance with the regulation prior to expenditure of any funds under a PHS-funded research project. SJSURF will also provide an FCOI report whenever an Investigator does
not timely disclose a Significant Financial Interest or whenever SJSU, for whatever reason, does not review a disclosed Significant Financial Interest and the Institution then determines that a Financial Conflict of Interest exists.

SJSURF will submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award. SJSU will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward and submit an FCOI report to the NIH or other PHS-funded agency.

SJSU and SJSURF will also, within 120 days of the determination of noncompliance, 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 time period of the noncompliance, was biased in the design, conduct or reporting of such research. Based on the results of the retrospective review, if appropriate, SJSURF will update the previously submitted FCOI report, specify the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, SJSURF will notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effects of the bias.

Thereafter SJSURF will submit FCOI Reports to NIH or other PHS-funded agency annually for any Financial Conflict of Interest previously reported. The annual FCOI report shall address the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports will be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable), but is not to be submitted as part of the annual progress report.

The annual FCOI report will be submitted to NIH separately through the eRA Commons FCOI Module and will 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; and
SJSURF and SJSU follow all federal, state, and California State University regulations for reviewing SFIs and for identifying, managing, reducing, eliminating, and reporting FCOIs.

4.6 Enforcement Mechanisms and Remedies for Non-Compliance for PHS-funded Sponsored Research

As required by PHS regulations, SJSURF will notify the sponsoring agency promptly of the corrective action taken or to be taken for non-compliance by an Investigator and the non-compliance appears to have biased the design, conduct, or reporting of the PHS-funded research. PHS FCOI regulations will be followed for the conduct of retrospective reviews and management and mitigation reports.

As required by PHS regulations, SJSURF will require the Investigator(s) to disclose an FCOI in each public presentation of the research results and to request and addendum to previously published presentations for any clinical research projects supported by the PHS, should the Department of Health and Human Services determine that the PHS-funded project of clinical research, whose purpose is to evaluate that 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.

SJSURF will complete and document retrospective reviews within 120 days of a determination of noncompliance for SFIs not disclosed timely by the investigator, not initially identified when previously reviewed, or whenever an FCOI is not identified or managed in a timely manner, and will document the reviews as required by the regulation.

4.7 Subrecipient Requirements

Prior to including a subrecipient in a PHS-funded research proposal, the SJSURF Sponsored Programs Manager will confirm, through use of the written subrecipient information form, that all proposed subrecipients have a FCOI interest policy that complies with FCOI regulations and that the subrecipient will report identified FCOIs for its investigators in a timeframe that allows SJSURF to report identified FCOIs as required by the regulation. http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

SJSURF will report to the PHS-funding agency any FCOI that is identified by any subrecipient, subcontractor, collaborator, or consultant in the manner required under FCOI regulations prior to expenditure of funds and within sixty (60) days of any subsequently identified FCOI.
5.0 Required Forms

These are the referenced and required form of the Conflict of Interest Policy.

<table>
<thead>
<tr>
<th>Form</th>
<th>Description of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>700u Form</td>
<td>Must be completed by Investigator for financial disclosure when Investigator is proposing to or receiving sponsored funding from a non-governmental entity.</td>
</tr>
<tr>
<td>Conflict of Interest Form – 1</td>
<td>Must be completed by Investigator for financial disclosure when Investigator is proposing to or receiving sponsored funding from a government agency that requires disclosure of Significant Financial Interests such as NSF and PHS-funded research.</td>
</tr>
<tr>
<td>Conflict of Interest Form – 2</td>
<td>Must be completed by Investigator for financial disclosure when proposing to or receiving sponsored funding from a governmental entity with a contractual conflict of interest requirement.</td>
</tr>
<tr>
<td>Subrecipient Information Form</td>
<td>Must be completed by potential subrecipients or subcontractors to provide contact and regulatory compliance information and disclosures.</td>
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</tbody>
</table>

6.0 Record Retention

All documents and records are maintained in accordance with the SJSURF Record Retention Policy.

<table>
<thead>
<tr>
<th>Record</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCOI disclosure forms and all documents related to the management of an FCOI</td>
<td>Three years</td>
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</tbody>
</table>

7.0 Definitions

Refer to the following table for definitions as used in Conflict of Interest Policy.

<table>
<thead>
<tr>
<th>Term or Acronym/Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>Financial Conflict of Interest</td>
<td>A Financial Conflict of Interest (FCOI) exists when the Institution, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to an NSF-, PHS-, or other funded research project and could directly and significantly affect the design, conduct, or reporting of the NSF-, PHS- or other- funded research.</td>
</tr>
<tr>
<td>Institutional Responsibilities</td>
<td>Institutional responsibilities are defined by the 2011 revised PHS regulation as an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the institution in FCOI policy, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, or Data and Safety Monitoring Boards.</td>
</tr>
</tbody>
</table>
In this policy investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NSF, PHS, or proposed for such funding, which may include, for example, collaborators or consultants. For sponsored projects funded by non-governmental agencies or government agencies with contractual conflict of interest clauses the institution officials may determine that investigators are limited to the PI or Co-PIs of the sponsored program.

Interest that would create a conflict of interest is defined as any financial interest that a principal investigator would have that would reasonably appear to be directly and significantly affected by sponsored activities or any interest that a principal investigator would have in entities whose financial interest would reasonably appear to be directly and significantly affected by sponsored activities.

Travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available.

8.0 References and Related Policy Information

These are the referenced or related documents for the Conflict of Interest Policy.


