

<u>Subject:</u> Sponsored Programs Financial Conflict of Interest Policy	<u>Division Name:</u> Business and Finance	<u>Approval:</u>  Joseph/F. Sheley, President <u>Date:</u> 10/2/15
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**A. Purpose**

At California State University, Stanislaus (University) all grant and contract awards are made to and accepted by the University. It is the policy of the California State University (CSU) that each campus shall develop and maintain policies and procedures that comply with conflict of interest regulations related to Principal Investigators (PIs), key personnel, students, and research staff engaged in sponsored research activities. This policy establishes compliance with this requirement by the University.

**B. Scope of Policy**

The CSU requires that each campus will, at minimum:

- Assist PIs, students and research staff in determining whether and to what extent outside financial relationships and interest may conflict with their primary research and academic activities or other institutional responsibilities.
- Maintain procedures for:
  - Managing and resolving individual financial conflicts of interest.
  - Complying with the regulations applicable to grants and contracts received from sponsors, as summarized below.

All University departments conducting research, instruction, and/or other sponsored work under grants, and other agreements are required to comply with the Financial Conflict of Interest Policy. The intention of the policy set forth below is to establish a uniform policy which covers state and federal laws and regulations currently in place and those anticipated and to provide the public with accountability in the University's dealings with external organizations.

**C. Definitions**

Refer to *Glossary of Commonly-Used Terms in Sponsored Programs*.

**D. Policy**

This policy is based upon the principle that institutions of higher education operate for the common good. Advancement of this mission requires that employees avoid conflicts of interest that may impair public trust and conflicts of commitment that may compromise their performance effectiveness. California State University, Stanislaus has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest involving activities conducted under the authority of the University. For the purpose of this policy, when referring to the "PI", it is understood this means "PI and/or key personnel who have program authority".

**For federally-funded grants and contracts** the University must certify with NSF, DHHS and other federal grant sponsors for each proposal that a formal procedure for managing any conflict of interest that could bias a funded project are in place. Disclosure requirements are applicable to any person who will work on the proposed federal grant or contract, and who is responsible for the design, conduct, or reporting of work performed on the project. This includes the PI and other individuals with independent responsibility for accomplishing project objectives, including investigators working for sub-grantees.

- When the faculty member states on the form that there are no reportable financial interests, the form will be filed with Post Award Grant Administration in conformance with standard campus procedure, and no further action is required.
- If a significant financial interest is reported, the disclosure must be reviewed by an Internal Review Committee (IRC) to determine whether such a financial interest could directly and significantly affect the project and if a true conflict of interest exists.

**For privately-funded grants and contracts** there is no “annual” filing requirement for PIs; however, the Fair Political Practices Commission (FPPC) requires PIs to file a statement of economic interest before the final acceptance of a contract, grant or gift, and when funding for such a contract or grant is renewed. In addition to FPPC requirements and consistent with CSU policy:

- PIs who are employed by the University must complete the CSU Ethics and Conflict of Interest Training within 6 months of receiving the grant. Subsequent training is required at least once each consecutive period of two calendar years that the grant is in place.
- When a conflict of interest appears to be present, the IRC shall determine what conditions or restrictions, if any, should be imposed on the research or PI in order to manage, reduce, or eliminate the conflict(s). The committee may consult with the PI and others to develop a plan to resolve any real or apparent conflict of interest issues. The committee shall then recommend that the University take one of the following actions: (1) acceptance of the project award, (2) withdrawal of the proposal or disapprove acceptance of the award, or (3) acceptance of the award subject to modifications in either the proposal or in the external affiliations or economic interest of the PI. Recommended actions to resolve conflict may include:
  - public disclosure of significant financial interests;
  - monitoring of research by independent reviewers;
  - modification of the research plan (with sponsor approval);
  - disqualification from participation in all or a portion of the research funded by the sponsor;
  - divestiture of significant financial interests; or
  - severance of relationship that create actual or potential conflicts.
- If required by the sponsoring agency, prior to the expenditure of any funds under the award, the University shall report to the sponsoring agency the existence of any conflict of interest (but not the nature of the interest) and provide assurance that the conflict has been managed, reduced, or eliminated.

Each PI, as defined above, is required to file the appropriate disclosure form and any related information before expenses can be charged to an award as specified in this policy. In no case shall the University accept funds from an external agency or individual on behalf of an employee or project in the absence of the disclosures required in this policy and the satisfactory completion of actions required by the provisions of this policy, the applicable regulations and any findings approved by the President to manage, reduce or eliminate any conflicts of interest.

Department chairs, deans, or other administrators will disqualify themselves from approving a proposal for a project to be funded in whole or in part by a nongovernmental entity in which they have a financial interest. Also in keeping with CSU regulations, PIs will not make, participate in, or in any way attempt to use their position to influence the making of any governmental decision that foreseeably will have a material financial effect as specified in HR 2005-38 and any subsequent regulations.

It is the responsibility of Post Award Grant Administration to maintain documentation and monitor compliance for all possible conflict of interest issues.

## **E. Roles and Responsibilities**

### **Pre-Award**

#### **Office of Research and Sponsored Programs (ORSP)**

- Works with the PI to obtain the disclosure forms and then submits the documentation to the sponsor if a sponsor requires disclosure of financial conflict of interest before making an award.
- If a financial conflict of interest does exist, ORSP brings this information to the attention of the IRC.

### **Post Award**

#### **Principal Investigator (PI)**

- Discloses any financial conflict of interest on a sponsored project by completing and submitting the appropriate disclosure form prior to expending funds.
- Notifies Post Award Grant Administration (GA) immediately of any change in disclosure.
- Recertifies disclosure form on an annual basis.
- Assists GA in obtaining disclosure forms from key project personnel and, if necessary, with obtaining verification of disclosure forms from subrecipient personnel.
- Works with GA to develop a plan of action to address the conflict of interest if one exists.

#### **Co-Principal Investigator/Key Personnel and/or Professional Staff (if applicable)**

- Discloses any financial conflict of interest on a sponsored project by completing and submitting the appropriate disclosure form prior to expending funds.
- Notifies GA immediately of any change in disclosure.
- Recertifies disclosure form on an annual basis.
- Works with GA to develop a plan of action to address the conflict of interest if one exists.

#### **Post Award Grant Administration (GA)**

- Ensures that disclosure forms are completed for all projects for which they are required.
- Ensures that appropriate conflict of interest procedures are being followed.
- Distributes annual disclosure forms to PIs whose projects require annual recertification.
- Ensures that disclosure forms have been completed or revised by the PI, if appropriate, prior to expending funds on new awards.
- Works with the PI to ensure that disclosure forms have been completed and received from subrecipients.
- Notifies the AVP for Financial Services or designee of any emerging conflicts of interest on the project.
- Requests proof of resolution when conflict has been addressed.
- Maintains documentation on all possible conflict of interest issues for at least three years following IRC's decision or at the end of the project, whichever occurs last.
- Working in conjunction with ORSP and Human Resources, ensures that PIs and key personnel complete FCOI/Ethics training within 6 months of receiving a grant and then recertify every other year (24 months) thereafter.
- Maintains logs to monitor and document receipt of FCOI forms and dates of when FCOI/Ethics training has been completed by PIs and key personnel.

Associate Vice President (AVP) for Financial Services or Designee

- Reviews and certifies all FCOI disclosure forms.
- Works with the PI to develop a resolution plan to manage, eliminate, or reduce FCOI if one exists.
- Forwards a written resolution plan to the IRC for approval.
- Serves as liaison to sponsor agencies regarding unresolved conflicts of interest.

Independent Review Committee (IRC)

- Reviews and approves any resolution plan developed by the PI and GA/Financial Services.
- May consult with administrators, faculty and others involved in the research review process and the academic discipline in question.
- May consult with PIs and department chairs in order to gain information and seek modification to research projects, if necessary.
- Establishes and enforces appropriate sanctions based on the specific conduct of a PI failing to follow an agreed upon resolution plan.
- If a plan of action to address a financial conflict of interest has legal ramifications, works with General Counsel to review the plan and provide assistance with any legal matters.
- Maintains records of its deliberations, which shall be made available to the public upon request.

College Dean

- Participates as a member of the IRC.

Vice President for Faculty Affairs or Designee

- Participates as a member of the IRC.

Provost/Vice President for Academic Affairs

- Participates as a member of the IRC.

**F. Procedure**

Financial Conflict of Interest Procedures and documents are identified below:

- Sponsored Programs Financial Conflict of Interest Procedure
- CSU Stanislaus Disclosure of Financial Interests Certification Form (Sponsor = Governmental)
- California Form 700-U Statement of Economic Interests for Principal Investigators (Sponsor = Non-Governmental)

## G. Laws, State Codes, Regulations and Mandates

Research Sponsor	Applicable Regulations and Links
Public Health Service Agencies and others adopting the PHS Policy*	<p><b>42 CFR Part 50</b>, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." COGR (Council on Government Relations) – Managing Externally Funded Research Programs: A Guide to Effective Management Practices – <a href="http://www.cogr.edu">http://www.cogr.edu</a></p>
National Science Foundation	<p><b>NSF Award and Administration Guide</b> – NSF April 2009; Chapter IV - Grantee Standards  <a href="http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_29/aag_4.jsp">http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_29/aag_4.jsp</a></p>
Non-Governmental agencies (CSU Policy and Fair Political Practices Commission {FPPC} - Guidelines)	<p><b>Regulations of the Fair Political Practices Commission (FPPC)</b>, Title 2, Division 6, California Code of Regulations; §18755. Statements of Economic Interests: Person or Persons at an Institution of Higher Education with Principal Responsibility for a Research Project  <a href="http://www.fppc.ca.gov/legal/regs/current/18755.pdf">http://www.fppc.ca.gov/legal/regs/current/18755.pdf</a>  <b>Exempt Organization List:</b>  <a href="http://www.ucop.edu/research/policies/exempt.html">http://www.ucop.edu/research/policies/exempt.html</a>            California State University, Office of the Chancellor</p> <ul style="list-style-type: none"> <li>• HR – Conflict of Interest Policies  <a href="http://www.ucop.edu/research/policies/exempt.html">http://www.ucop.edu/research/policies/exempt.html</a></li> <li>• CSU Ethics Training  <a href="http://www.calstate.edu/hrs/policies/policies_coi_training.shtml">http://www.calstate.edu/hrs/policies/policies_coi_training.shtml</a></li> </ul>
CSU Policy	<p>This policy provides more specific direction toward implementation of section 3.5.5 of Executive Order 890, dated January 7, 2014 – <a href="http://calstate.edu/eo/EO-890.pdf">http://calstate.edu/eo/EO-890.pdf</a></p>

## H. Resources and Reference Materials

- Glossary of Commonly-Used Terms in Sponsored Programs
- Summary of Disclosure Requirements:

CSU FCOI Disclosure Chart – Requirements by Funding Source		
STATE LAW (FPPC – Nongovernmental Funding)	FEDERAL POLICY (NSF Funding)	FEDERAL REGULATIONS (PHS Funding)
<b>REPORTING TRIGGERS</b>		
<ul style="list-style-type: none"> <li>• Research contract/grant from a non-governmental entity</li> <li>• Research Gifts earmarked for a specific individual or a specific research project</li> <li>• Material Transfer Agreement</li> </ul> <p><i>Note: Exclude all <a href="#">exempt sponsors on FPPC approved list</a> and all non-profit, tax-exempt educational institutions.</i> <i>However, researchers must disclose for the prime sponsor if the educational institution received its funds from a non-governmental entity.</i></p>	<ul style="list-style-type: none"> <li>• NSF research contract/grant</li> <li>• Non-governmental entity which flows down NSF funds</li> <li>• UC Discovery Grant</li> <li>• California Institute for Regenerative Medicine (CIRM) Grant</li> <li>• UC Special Research Programs (HIV/AIDS, breast cancer and tobacco related disease)</li> </ul> <p><i>Note: Exclude Phase 1 SBIR or STTR grants</i></p>	<ul style="list-style-type: none"> <li>• PHS research contract/grant from <a href="#">PHS designated agencies within the DHHS</a></li> <li>• Non-governmental entity which flows down PHS funds</li> <li>• Research Funding from organizations that follow PHS disclosure requirements (i.e., American Cancer Society, American Heart Association). Complete list at FDP (Federal Demonstration Partnership) website: <a href="http://nrc59.nms.edu/pub/fcoi_agencies_phs_reqs.html">http://nrc59.nms.edu/pub/fcoi_agencies_phs_reqs.html</a></li> </ul> <p><i>Note: Exclude Phase 1 SBIR or STTR grants. List of PHS compliant institutions and entities is available at the FDP site: <a href="http://nrc59.nas.edu/pub/fcoi_home.html">http://nrc59.nas.edu/pub/fcoi_home.html</a></i></p>
<b>WHO MUST DISCLOSE?</b>		
CSU Principal Investigator	CSU Investigator(s) – Individuals responsible for the design, conduct, or reporting of the funded research project	CSU Investigator(s) – Individuals responsible for the design, conduct, or reporting of the funded research project
<b>WHAT TO DISCLOSE- FINANCIAL INTEREST</b>		
<p>A financial interest in the non-governmental sponsor of the research including:</p> <ul style="list-style-type: none"> <li>• Income ≥ \$500</li> <li>• Investments ≥ \$2,000</li> <li>• Director, Officer, Employee, Partner, Trustee, Consultant or Management position</li> <li>• Loan Balances ≥ \$500</li> <li>• Personal Gifts Valued at ≥ \$50</li> <li>• Travel Reimbursements</li> </ul>	<p>A significant financial interest related to the research project including:</p> <ul style="list-style-type: none"> <li>• Income &gt; \$10,000</li> <li>• Equity (of any type) &gt; \$10,000 or 5%</li> <li>• Director, Officer, Employee, Partner, Trustee, Consultant or Management position</li> <li>• Intellectual Property</li> </ul>	<p>A significant financial interest related to the investigator's institutional responsibilities including:</p> <ul style="list-style-type: none"> <li>• If publicly traded entity, total value of compensation and equity interest &gt; \$5,000</li> <li>• If non-publicly traded entity, total value of compensation &gt; \$5,000 or any equity interest</li> <li>• Income received related to intellectual property &gt; \$5,000</li> <li>• Any reimbursed or sponsored travel (excluding (1) travel that is reimbursed or sponsored by a Federal, state, local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; or (2) sponsored or reimbursed travel for the Investigator's spouse/registered domestic partner and/or dependent children.)</li> </ul>
<i>Note for all sources: Financial interests received within 12 months prior to submission must be reported for the disclosing individual and his/her spouse or registered domestic partner, and dependent children.</i>		
<b>WHEN TO DISCLOSE</b>		
<ul style="list-style-type: none"> <li>• With the initial proposal</li> <li>• With additional funding</li> </ul> <p><i>Note: All positive disclosures must be reviewed and approved prior to acceptance of the award or additional funding.</i></p>	<ul style="list-style-type: none"> <li>• With the initial proposal</li> <li>• When new personnel are added</li> <li>• With any change in an investigator's financial interest</li> </ul> <p><i>Note: All positive disclosures must be reviewed and approved prior to acceptance of the award or additional funding.</i></p>	<ul style="list-style-type: none"> <li>• With the initial proposal</li> <li>• With non-competing continuations</li> <li>• With renewals</li> <li>• With supplemental funding</li> <li>• When new personnel are added</li> <li>• With any new significant financial interest (New significant financial interests must be reported within 30 days of acquiring or discovering the new SFI for the disclosing individual and his/her spouse/registered domestic partner and dependent children.)</li> </ul> <p><i>Note: All positive disclosures must be reviewed and approved prior to expenditure of funds.</i></p>
<b>DISCLOSURE FORMS TO SUBMIT</b>		
<ul style="list-style-type: none"> <li>• State Disclosure (<a href="#">Form 700-U</a>)</li> <li>• Campus addendum forms, if applicable</li> </ul>	<ul style="list-style-type: none"> <li>• NSF/Federal Disclosure (CSU or compliant campus form)</li> <li>• Campus addendum forms, if applicable</li> </ul>	<ul style="list-style-type: none"> <li>• PHS/Federal Disclosure (CSU or compliant campus form)</li> <li>• Campus addendum forms, if applicable</li> </ul>
<b>TRAINING REQUIREMENTS</b>		
<ul style="list-style-type: none"> <li>• Ethics Training (CSU for University investigators; CITI or campus-based training for auxiliary investigators)</li> </ul>	<ul style="list-style-type: none"> <li>• NA</li> </ul>	<ul style="list-style-type: none"> <li>• PHS Training and/or campus based training modules or programs (including CITI FCOI Training and campus in-person training/workshops)</li> </ul>