

UCI ADMINISTRATIVE POLICIES & PROCEDURES

OFFICE OF RESEARCH

Conflict of Interest

Sec. 481-2: Disclosure of Financial Interests Related to Sponsored Projects for Assurance of Objectivity in Research

Responsible Office: Office of Research

Revised: May 2006; July 2015; April 2016

Implemented: June 23, 2016

References / Resources

University of California, Office of the President: UC Policies

[Policy on Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards](#)

Business and Finance Bulletin G-39, [Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest](#)

Contact: Office of Research- Conflict of Interest Administrator (949)824-0012

A. Purpose and Scope

In October 1995, the National Science Foundation (NSF) developed policy to ensure that the public trust and federal financial support are not compromised to advantage the personal gain of Investigators. The University of California issued its “Policy on Disclosure of Financial Interests and Management of Conflicts of Interests Related to Sponsored Projects” on October 15, 1997, to implement the federal requirements with an update on December 23, 2014. This policy also applies to University of California-funded research programs and California Institution for Regenerative Medicine funded research.

This policy no longer applies to Public Health Service (PHS) proposals submitted on or after August 24, 2012 or PHS research awards with Notice of Grant Award dates of August 24, 2012 or later. Likewise, this policy no longer applies to those sponsors adopting the 2011 PHS regulations. For proposals to and awards from the PHS or sponsors adopting the 2011 PHS regulations, please refer to [Disclosure of Financial Interests Related to Public Health Service Sponsored Projects for Promoting Objectivity in Research](#).

B. Applicability

This policy applies to all individuals (faculty, staff, students, non-UCI collaborators, etc.) that are applying for or participating in a project that complies with the NSF conflict of interest policy who meet NSF’s definition of an Investigator.

C. Definitions

Annual Disclosure: The annual electronic financial disclosure all UCI Investigators on National Science Foundation proposals and awards are required to complete prior to proposal submission.

Conflict of Interest Oversight Committee (COIOC): The faculty advisory committee is appointed by the Vice Chancellor for Research or the Associate Vice Chancellor for Research Administration to review financial disclosures based on conflict of interest policies and regulations. This group is also referred to as the Independent Substantive Review Committee in UC policies.

COI Addendum: Form used to collect additional information on the financial entity and the research project for the COIOC review.

Institutional Official: Vice Chancellor for Research or designee

Investigator: Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project. Investigator includes but is not limited to the Principal Investigator, Co-Investigators, and any other individual (including personnel from other institutions). For purposes of this policy, Investigator also includes the investigator's spouse/registered domestic partner and dependent children.

Note: Reporting includes authorship on publications resulting from the research. Thus, graduate and undergraduate students may be required to disclose, even if they are not paid from the project.

NSF Disclosure: All UCI Investigators that disclosed a financial interest (excluding travel) in their Annual Disclosure are required to complete an additional electronic disclosure for each NSF proposal to identify any significant financial interests related to their NSF-funded project(s).

Related Financial Interest: Interests of the Investigator, their spouse/registered domestic partner or dependent children, or interests of the company in which these individuals have an interest, that would reasonably appear to be affected by the research to be done or currently ongoing in the associated grant or contract. Related financial interests include but are not limited to the following:

- a. The research results could be relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator, their spouse/registered domestic partner or dependent children have a financial interest;
- b. The Investigator, their spouse/registered domestic partner or dependent children have a financial interest in an entity that might manufacture or commercialize a drug, device, procedure or any other product used in the project or that will predictably result from the project;
- c. The Investigator, their spouse/registered domestic partner or dependent children have cumulative consulting income exceeding \$10,000 during the prior twelve

months from a single entity, which would reasonably appear to be affected by the research;

Note: Disclosure of consulting income is encouraged so that an independent assessment of the relatedness can be made by the COIOC chair and staff.

Consulting based on an individual's academic expertise is considered related.

- d. The Investigator, their spouse/registered domestic partner or dependent children have a financial interest in an entity and the sponsored project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity; or
- e. The Investigator, their spouse/registered domestic partner or dependent children have a financial interest in an entity that is part of a consortium or that will otherwise participate in the sponsored project.

Significant Financial Interest (SFI): Significant financial interests are anything of monetary value, including but not limited to the following:

- a. **Income** exceeding \$10,000 from a single public or nonprofit entity including salary, consultant payments, honoraria, royalty payments, dividends, loans from the entity, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans, during the prior twelve months when aggregated for an Investigator, their spouse/registered domestic partner and dependent children.

Note: Income from a public or nonprofit entity for seminars, lectures, teaching engagements, or service on advisory committees or review panels is exempt. Salary, royalties, stipends, honoraria, reimbursement of expenses, or any other remuneration from The Regents is also excluded.

- b. **Equity interest**, in the form of stock, stock options, real estate, or any other investment or ownership interest that when aggregated for an Investigator and the Investigator's spouse/registered domestic partner and dependent children, either exceeds \$10,000 in value (market value if publicly traded; internal reasonable estimate of value if not publicly traded) for any single entity or exceeds a 5% ownership interest in any single entity.
- c. **Intellectual property** interest held by the Investigator, their spouse/registered domestic partner or dependent children in a patent, patent application, or a copyright of software assigned or to be assigned to a party other than The Regents.

D. Responsibilities

The Vice Chancellor for Research is responsible for implementing this policy, for making final decisions regarding the acceptability of disclosures, and for approving any required management plan. The Vice Chancellor for Research may delegate the responsibilities of

reviewing and approving financial disclosures and proposed management plans to the Associate Vice Chancellor for Research Administration, the Vice Chancellor for Research's designee for conflict of interest.

Investigators are responsible for disclosing their financial interests as defined by this policy. Principal Investigators are responsible for obtaining disclosures of all Investigators at the time of proposal submission.

The Conflict of Interest Oversight Committee is responsible for reviewing financial disclosures of Investigators and making recommendations related to those disclosures to the Institutional Official. If an individual is being added to a study and meets the definition of an Investigator, the Principal Investigator is responsible to notify the Conflict of Interest team in the Office of Research.

The Office of Research staff receive disclosures and additional information, support the COIOC in regular and ad hoc meetings, maintain the Conflict of Interest website, and provide advice and information on policies and procedures to faculty and staff.

E. Policy

Investigators on a project funded by the National Science Foundation are required to disclose certain personal financial interests related to that project at the time a proposal is submitted or as soon as a financial interest becomes known. All Investigators are responsible for completing and maintaining their Annual Disclosure. Those Investigators with financial interests will also need to complete an NSF Disclosure that identifies any SFI related to each NSF funded project or project funded by a sponsor that has adopted the NSF policy. Investigators must disclose all SFI for themselves, their spouses/registered domestic partners and dependent children (i) that would reasonably appear to be affected by the activities funded or proposed for funding; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

Investigators from other institutions who share responsibility for the design, conduct or reporting of the research, and who will be conducting research under a subaward from UCI are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by UCI will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if the subrecipient organization is unable to satisfactorily manage a financial conflict of interest, for sending UCI notification in accordance with NSF requirements. If a subrecipient organization does not have a policy that complies with the NSF policy, the subrecipient's authorized institutional official must agree in writing that UCI's policy will apply to the subrecipient's Investigators until such time as the subrecipient organization implements a policy that complies with the NSF policy. A subrecipient organization's failure to comply with its policy or the NSF policy may result in the termination of the subaward.

If an individual is performing under an independent consulting agreement issued by UCI and the nature of their work, duties and responsibilities satisfy the definition of Investigator, the UCI Principal Investigator must identify the consultant as an Investigator and the consultant must complete the UCI disclosure forms. If, upon review, UCI determines that a consultant's SFI is a financial conflict of interest, the consultant will be expected to comply with a management plan to eliminate, reduce or manage the conflict of interest. Failure of a consultant to comply with a management plan may result in the termination of the consulting agreement.

This policy establishes a process of disclosure and independent review to identify potentially harmful conflicts of interest between an Investigator's obligations related to the sponsored project and their personal financial interests or obligations, and a process to reduce, manage or eliminate such conflicts in order to preserve objectivity in the design, conduct, or reporting of research.

The policy is consistent with the "Investigator Financial Disclosure Policy" of the National Science Foundation. The University also applies this policy to proposals from other extramural sponsors as required.

F. Overview of Disclosure Review Process

With each new NSF proposal, all Investigators with Annual Disclosures indicating they have a financial interest (i.e., a positive disclosure) are required to disclose whether or not they have a SFI related to the proposed project by completing their NSF Disclosure. At the just-in-time stage or notice of award, all Investigators who disclosed a SFI related to the project on the NSF Disclosure will be asked to provide additional information about the SFI. The SFI will be reviewed by the COIOC or a Designated Official to determine whether the SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the NSF funded research and thereby constitute a financial conflict of interest ("FCOI") that may need to be managed, reduced or eliminated.

Investigators from Other Institutions (Non-UCI Personnel)

At the time of proposal submission, non-UCI Investigators on a subaward complying with UCI's NSF COI policy and procedures and non-UCI Investigators on UCI's NSF award are required to submit their disclosure forms for review.

All Investigators (at UCI and from other institutions) are also required to disclose when they acquire a new SFI related to a NSF funded project during the duration of the project by submitting the COI Addendum to the Conflict of Interest team.

G. Management, Reduction or Elimination of Conflicts of Interest

Under certain circumstances, the COIOC or the Institutional Official may recommend special conditions or restrictions to manage, reduce or eliminate the effect of the financial interests on

the design, conduct or reporting of the project. Examples of conditions or restrictions that may be imposed upon the Investigator include the following:

1. publicly disclosing the related financial interest(s);
2. project monitoring by independent reviewers appointed by the Institutional Official;
3. modifying the research or project plan;
4. disqualification from participation in all or a portion of the project;
5. divesting part or all of the related financial interest;
6. severing relationships that create actual or potential conflicts.

Adopting conditions or restrictions to manage or eliminate a conflict of interest must be agreed to by the Investigator and the Institutional Official prior to the expenditure of any funds under the award.

Alternatively, if the COIOC determines that an Investigator's financial interests could affect the sponsored project and the conflict cannot be managed, the COIOC may recommend to the Vice Chancellor that the project not proceed.

H. Records Access and Maintenance

The Annual Disclosure, NSF Disclosure, COI Addendum and additional information about the SFI received by the Office of Research are public documents and subject to the Federal Freedom of Information Act (FOIA) and the California Public Records Act (CPRA).

Under federal requirements, the Disclosure information must be retained for three years following the termination or completion of the award to which the records relate, or the resolution of any government action involving the records, whichever comes last. Records relating to unfunded projects need not be retained.

I. Sanctions

Failure to complete the Annual Disclosure or the NSF Disclosure or the COI Addendum or to comply with any conditions or restrictions imposed on the conduct of, or any plans for managing, the project under this Policy is grounds for discipline pursuant to the Policy on Faculty Conduct and the Administration of Discipline or other applicable employee disciplinary policies. In addition, federal regulations may require UCI to report violations of its policy to the NSF. The NSF or any federal sponsor following the NSF policy may pursue non-compliance remedies in accordance with its own policies and 2 CFR 200.338 – Remedies for Noncompliance, which include suspending or terminating the award and/or debarring an Investigator from receiving future awards.