NOTE: 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 longer applies to those sponsors that have adopted the 2011 PHS regulations. For proposals to and awards from the PHS or sponsors that have adopted the 2011 PHS regulations, please refer to Disclosure of Financial Interests Related to Public Health Service Sponsored Projects for Promoting Objectivity in Research (Effective 8/24/12).

This policy remains in effect for National Science Foundation funded research, University of California-funded research programs and California Institution for Regenerative Medicine funded research.

UCI ADMINISTRATIVE POLICIES & PROCEDURES

RESEARCH AND SPONSORED ACTIVITIES
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 Administration
Revised: May 2006

References / Resources

University of California, Office of the President: UC Policies
Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects
Business and Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest

A. Introduction

In October 1995, the Public Health Service (PHS) and the National Science Foundation (NSF) developed common policies similar to those in place within the State of California 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.

B. Policy

Investigators responsible for the design, conduct, or reporting of a project funded by the National Science Foundation or the Public Health Service 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. Investigators must disclose all significant financial interests for themselves, their spouses 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. 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 Public Health Service regulations, “Objectivity in Research,” 42 CFR Part 50 and 45 CFR Part 94, and the “Investigator Financial Disclosure Policy” of the National Science Foundation. The University also applies this policy to proposals from other extramural sponsors as required.

C. Definitions

1. **Conflict of Interest Oversight Committee (COIOC):** The faculty advisory committee appointed by the Vice Chancellor for Research to review financial disclosures where there is the possibility of a conflict of interest. This group is also referred to as the Independent Substantive Review Committee in UC policies.

2. **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, the term also includes the investigator’s spouse 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.

3. **Related Financial Interest:** Interests of the investigator, their spouse 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. The following are considered “related” financial interests by UC:

   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 or dependent children have a financial interest;

   b. The investigator, their spouse 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 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 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 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.

4. Significant Financial Interest: Significant financial interests are anything of monetary value, including but not limited to the following:

a. **Income** exceeding $10,000 from a single entity including salary, consultant payments, honoraria, royalty payments, dividends, 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 or anticipated over the next twelve months when aggregated for an investigator, their spouse 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 (publicly-traded stock or stock options, real estate, or any other investment or ownership interest)** that exceeds $10,000 (current market value) and is greater than a 5% ownership interest, for any one enterprise when aggregated for the investigator, their spouse and dependent children.

   Note: An investment in a mutual fund, pension fund or other investment fund over which the investigator or his/her immediate family member does not exercise any control is excluded.

c. **Equity (non-publicly-traded stock or stock options, or any other investment or ownership interest):**

   1. For research involving human subjects, all equity in privately-held stock or stock options must be disclosed regardless of the dollar value.
2. For research that does not involve human subjects, disclosure is required for privately-held stock or stock options that exceed $10,000 (internal estimate of value or the amount of investment, whichever is greater) and are greater than a 5% ownership interest, for any one enterprise when aggregated for an investigator, their spouse and dependent children.

   Note: Disclosure is not required of investigators who hold interests in applicants for Small Business Innovation Research (SBIR) or a Small Business Technology Transfer (STTR) awards through the Public Health Service. However, disclosure may be required under the State of California statute affecting awards from non-governmental entities.

d. Management position, such as board member, director, officer, partner or trustee, held by the Investigator, their spouse and/or dependent children.

e. Intellectual property interest held by the Investigator, their spouse 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

1. The Vice Chancellor for Research is responsible for implementing this policy, for the final decisions regarding the acceptability of disclosures, and for approval of any required management plan.

2. Investigators (i.e., any University employee responsible for the design, conduct or reporting) are responsible for disclosing their financial interests as defined by this policy. Principal Investigators are responsible for obtaining disclosures of all research personnel at the time of proposal submission.

3. The Conflict of Interest Oversight Committee is responsible for reviewing financial disclosures of investigators and recommending management to the Vice Chancellor for Research.

4. The Office of Research Administration 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. Scope

This policy applies to any University employee responsible for the design, conduct, or reporting of a project submitted to the U.S. Public Health Service (PHS), which includes the National
Institutes of Health (NIH), and the National Science Foundation (NSF), and to financial disclosure requirements imposed by other research sponsors. This policy supplements but does not supplant the State requirements for disclosure of financial interests issued as the “University Policy on Disclosure of Financial Interests in Private Sponsors of Research” (APM-028-0).

Note: This policy applies to PHS research projects and NSF research and education projects.

On occasion, Investigators may have questions about whether proposed or on-going financial arrangements or relationships that would not require disclosure under the terms of this Policy appear to constitute an actual or potential conflict of interest with respect to a sponsored project. In such circumstances, Investigators may voluntarily choose to disclose the relationship in accordance with this Policy. Should the University subsequently determine that the voluntarily disclosed interest might reasonably appear to be directly and significantly affected by the sponsored project, the University may take steps to manage or to eliminate the conflict.

Investigators who are members of the faculty are reminded of their separate obligation, pursuant to the “University Policy on Outside Professional Activities of Faculty Members” (Academic Personnel Policy 025), to provide descriptive information regarding time and effort devoted to all outside professional activities related to their academic specialty in annual reports to department chairpersons or equivalent unit heads.

F. Disclosure Forms and the Disclosure Process

1. Disclosure of Financial Interests (Disclosure Form for NSF Conflict of Interest Policy, Form 900): The PI and all investigators are required to sign the Disclosure form, reporting any personal significant financial interests related to a project as defined above. Disclosure is required:

   a. At the time of proposal submission or, when funding appears likely, prior to award acceptance;
   b. Annually with non-competing continuation funding;
   c. As new investigators are added to the project;
   d. As investigator’s financial interests change.

   It is the responsibility of the PI to submit the Disclosure form, signed by all project investigators, in sufficient time to allow for COIOC review of projects in which an investigator has disclosed a significant financial interest. The COIOC review must be completed and the award deemed acceptable by the Vice Chancellor for Research prior to the acceptance of the award and any expenditure of funds.

2. Investigator’s Disclosure of Economic Interests Addendum (Form COI-1): The Addendum is to be completed by those investigators who have a significant financial
interest related to the project. The Addendum should be forwarded with the Disclosure to
the Office of Research Administration. The form solicits additional facts from the
investigator to facilitate review by the COIOC. Investigators complete a separate
Addendum for each entity in which they have a significant financial interest related to the
project.

G. Review Process

Under supervision of the Assistant Vice Chancellor for Research, the COIOC Administrator is
responsible for reviewing all disclosures, ensuring completeness and consistency with prior
disclosures, and performing the initial analysis of the disclosed information. The Administrator
also confirms the necessity for review under this policy.

The Disclosure, Addendum, and other appropriate documentation are forwarded to the COIOC
for review at its monthly meeting. The COIOC considers whether the project could affect the
financial interests of the entity or the investigator’s financial interests could affect the design,
conduct, or reporting of the project. A direct impact occurs when the project results would be
directly relevant to the development, manufacturing, or improvement of the products or services
of the organization in which the investigator has a financial interest, or when the organization is a
proposed subcontractor or participant in the project. A significant impact on the financial
interest is one which will materially affect the value of the organization, its earnings, or the sales
of its product, or when the organization is a proposed subcontractor or participant in the project.

On the basis of its evaluation, the COIOC forwards a recommendation to the Vice Chancellor for
Research indicating one of the following outcomes:

1. the financial interests pose little or no probability for bias in objectivity in the
   sponsored project; or
2. the conflict of interest requires management, elimination, or reduction; or
3. for NSF proposals only, the conflict exists but conditions to manage, reduce, or
   eliminate the situation would be ineffective or inequitable, and any possible bias is
   offset by interests of scientific progress, technology transfer, or public health and
   welfare.

The Vice Chancellor for Research, acting within authority delegated by the Chancellor, reviews
the recommendations from the COIOC and determines whether to accept the recommendations.
The Vice Chancellor for Research is responsible for the final decision.

The COIOC Administrator prepares the Vice Chancellor’s communications to the investigators
regarding each disclosure, and messages to Sponsored Projects staff who serves as the official
communication link with the sponsors.

H. Management, Reduction or Elimination of Conflicts of Interest
Under certain circumstances, the COIOC or the Vice Chancellor 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. public disclosure of the related financial interest(s);
2. monitoring of the project by independent reviewers appointed by the Vice Chancellor;
3. modification of the research or project plan;
4. disqualification from participation in all or a portion of the project;
5. divestiture of the related financial interest;
6. severance of relationships that create actual or potential conflicts.

Adoption of conditions or restrictions to manage or eliminate the conflict of interest must be agreed to in writing by the investigator and the Vice Chancellor prior to the expenditure of any funds under the award.

Alternatively, if the COIOC determines that an investigator’s financial interests could be directly and significantly affected by the sponsored project or could affect the sponsored project and the conflict cannot be managed, the COIOC may recommend to the Vice Chancellor that the project not proceed.

I. Records Access and Maintenance

The Disclosure and Addendum information are open to the public 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.

J. Sanctions

Failure to complete the Disclosure or the Addendum or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be 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 reports to the federal sponsor of any violations of University policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receipt of future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally-sponsored projects.