The following policy on *Disclosure of Financial Interests Related to Public Health Service (PHS) Sponsored Projects for Promoting Objectivity in Research* is mandated by the Department of Health and Human Services and will become effective on **August 24, 2012**. It applies to all investigators and institutions that apply for and receive funding from PHS agencies as well as organizations that follow PHS regulations.

**UCI ADMINISTRATIVE POLICIES & PROCEDURES**

**RESEARCH AND SPONSORED ACTIVITIES**

**Conflict of Interest**

Sec. 481-2A: *Disclosure of Financial Interests Related to Public Health Service Sponsored Projects for Promoting Objectivity in Research*

**Responsible Office:** Office of Research  
**Issued:** August 15, 2012  
**Effective Date:** August 24, 2012

**References / Resources**

- UC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards Policy
- 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. Purpose and Scope**

This policy implements the 2011 Public Health Service regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (PHS regulations). These regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of Public Health Service funded research will be free from bias resulting from any Investigator’s financial conflicts of interest.

This policy is applicable to all research funded by the Public Health Service and other sponsors that adopt the Public Health Service regulations with an award issue date of August 24, 2012, or later and to proposals for research activities submitted on or after August 24, 2012. This policy applies to the Principal Investigator and to any individual responsible for the design, conduct, or reporting of Public Health Service funded research or research supported by entities adopting the Public Health Service regulations.

**B. Definitions**

**Conflict of Interest Oversight Committee (COIOC):** The faculty advisory committee appointed by the Vice Chancellor for Research to review disclosures of significant financial interests related to the PHS (as defined below) funded research and determine whether any of the
significant financial interests constitute a financial conflict of interest (as defined below). This group is also referred to as the Independent Substantive Review Committee in UC policies.

**Designated Official:** The campus official(s) designated to solicit and review disclosures of significant financial interests. This includes the Vice Chancellor for Research, Associate Vice Chancellor for Research, Assistant Vice Chancellor for Research Administration, conflict of interest staff in the Office of Research and COIOC members.

**Financial Conflict of Interest (FCOI):** A significant financial interest that is related to research (as defined below) funded by PHS (as defined below) in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS funded research.

**Institutional Responsibilities:** Teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California which are in the course and scope of the Investigator’s University of California appointment/employment. For the purpose of this definition only, research is defined as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge.

**Investigator:** Any individual responsible for the design, conduct, or reporting of research (as defined below) performed or to be performed with PHS (as defined below) funding, regardless of whether the Investigator receives compensation from the funding source supporting the research. Investigator includes but is not limited to the Principal Investigator, co-investigators and any other individual (including non-UCI personnel) responsible for the design, conduct, or reporting of the PHS funded research.

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.

**Principal Investigator:** An Investigator who is a UCI employee and who has primary responsibility for the scientific and technical conduct, reporting, and administrative and financial management of a sponsored research project.

**Public Health Service (PHS):** Any organizational unit, agency or entity of the Department of Health and Human Services (DHHS) designated by the DHHS as being part of the PHS, as well as any non-PHS entity adopting the PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.

**Research:** Any activity for which research funding is available from the PHS, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, Institutional training grants, program projects or research resources awards, conference grants and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this policy, consistent with the underlying PHS regulations, are Phase I SBIR awards and Phase I STTR awards.
**Significant Financial Interest (SFI):** Significant financial interests are anything of monetary value, consisting of one or more of the following interests of the Investigator or the Investigator’s spouse or registered domestic partner and dependent children that reasonably appear related to the Investigator’s Institutional Responsibilities:

1. For a publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments received during the prior twelve months and the value of any equity interests (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds $5,000.

2. For a non-publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including, but not limited to, consulting payments, honoraria, paid authorship, any other payments received during the prior twelve months, which when aggregated, exceeds $5,000 or any equity interest (regardless of valuation) including, but not limited to stock, stock options, or ownership interest in the entity.

3. Intellectual property rights and interests: Income from each organization that exceeds $5,000 during the twelve months preceding disclosure from such rights and interests.

4. Travel: Reimbursement of any amount received during the prior twelve months made to, or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity.

**C. Responsibilities**

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

Investigators are responsible for disclosing their financial interests as defined by this policy. Investigators who are collaborators at subrecipient institutions are responsible for disclosing their financial interests in accordance with the arrangement agreed upon between UCI and the subrecipient institution prior to submission of a proposal to the PHS and/or in accordance with the terms and conditions of the subaward issued by UCI. Investigators who are not UCI employees and not a collaborator at a subrecipient institution are subject to this policy as if they were UCI employees. Principal Investigators are responsible for ensuring that all investigators provide their disclosures in a timely manner and in accordance with this policy.

The Conflict of Interest Oversight Committee is responsible for reviewing financial disclosures of investigators, making recommendations and proposing management plans to the Vice Chancellor for Research or his/her designee.
The Office of Research staff are responsible for receiving disclosures and additional information, conducting administrative reviews of disclosures, supporting the COIOC in regular and ad hoc meetings, maintaining the Conflict of Interest website, providing advice and information on policies and procedures, reporting information about financial conflicts of interest and how such interests are being managed to PHS, and responding to public requests for information regarding financial conflicts of interest.

D. Policy

Investigators seeking PHS research funding or receiving PHS research support are required to disclose SFIs related to their Institutional Responsibilities at the following times:

(1) Initial disclosures must be made by all Investigators no later than at the time of application for PHS funding.
(2) Investigators who are engaged in PHS funded research have an ongoing responsibility to update their disclosures through the period of the PHS award within thirty (30) days of acquiring or discovering a new SFI and at least annually.
(3) New Investigators must complete a disclosure of SFI before engaging in ongoing PHS funded research.

Investigators do not need to disclose:

(1) Financial interests in mutual funds or other investment vehicles such as retirement funds where the Investigator or the Investigator’s spouse, registered domestic partner or dependent children does not directly control the investment decisions made for these investment vehicles.
(2) Payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of California.
(3) Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Investigators must disclose sponsored or reimbursed travel either as a prospective estimate of all planned or anticipated travel for the twelve month period following the filing of the Investigator’s disclosure form or within thirty (30) days of the occurrence of the travel event if the travel was not included in the prospective disclosure. Spouses, registered domestic partners and dependent children of Investigators are exempt from this disclosure requirement. In addition, Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
Investigators must complete a training/education program on financial conflicts of interest, the Investigator’s responsibilities regarding disclosure of SFI, and the PHS regulations prior to engaging in the PHS funded research and at least every four years thereafter, and when an Investigator is not in compliance with this policy or has failed to comply with a plan to manage or mitigate a FCOI.

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 a FCOI is identified, for sending UCI notification of their ability to manage, reduce or eliminate the FCOI, in accordance with PHS requirements. If a subrecipient organization does not have a policy that complies with the PHS regulations, 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 PHS regulations. A subrecipient organization’s failure to comply with its policy or the PHS regulations 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 FCOI, the consultant will be expected to comply with a management plan to eliminate, reduce or manage the FCOI. Failure of a consultant to comply with a management plan may result in the termination of the consulting agreement.

E. Overview of Disclosure Review Process

With each PHS proposal, progress report, supplemental or incremental funding or extension, all Investigators who disclosed a SFI at the time a funding application was submitted to PHS will be asked, at the just-in-time stage of the awarding process (if applicable), to provide additional information about the SFI. This information will be used by UCI to conduct a preliminary review to reasonably determine whether any of the Investigator’s SFI is related to the PHS funded research. A SFI is related to the PHS funded research if the SFI could be affected by the PHS funded research; or is in an entity whose financial interest could be affected by the research. If an Investigator did not disclose a SFI at the time the funding application was submitted, the Investigator must disclose the SFI.

If after review, it is determined that a SFI is related to the PHS funded research, there will be a second review conducted 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 PHS funded research and thereby constitute a FCOI that may need to be managed, reduced or eliminated.
Plans for managing identified a FCOI will be monitored for compliance until the completion of the PHS funded research. Each management plan will specify

- Role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the management plan will safeguard objectivity in the research;
- Confirmation of the Investigator’s agreement to the management plan; and
- How the management plan will be monitored to ensure compliance.

F. Reporting to PHS

Initial reports of FCOIs must be made to PHS prior to UCI’s expenditure of any funds under a PHS funded research project. Additional FCOI reports must be submitted to PHS under the following circumstances:

1. Throughout the lifetime of an award when progress reports are submitted, or at the time that an award is extended. When during the course of an ongoing PHS funded research a FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
2. Within sixty (60) days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS funded research project.
3. Within sixty (60) days of determining that a FCOI exists for an Investigator who joins an ongoing PHS funded research project.

However, if FCOIs are eliminated before research funds are expended, UCI is not required to submit a report to PHS.

G. Retrospective Review

When during the course of an ongoing PHS research project, UCI identifies a SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, a Designated Official will review the SFI within sixty (60) days to determine whether it is related to the PHS funded research and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever a FCOI is not identified or not managed in a timely manner (regardless of whether the Investigator did not disclose a SFI that was later determined to be a FCOI, or UCI failed to review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan) UCI must complete a retrospective review of the Investigator’s activities and the PHS funded research project within 120 days of the determination of non-compliance. The purpose of the retrospective review is to determine if the ongoing PHS funded research project 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, any previously submitted FCOI report must be updated to specify the actions that UCI will take to manage the identified FCOI.
If bias was found during the retrospective review, UCI will promptly notify PHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines UCI’s plans to eliminate or mitigate the effect of the bias.

H. Records Access and Retention

UCI is required to respond to within five (5) business days to any request for information about SFIs held by Key Personnel when UCI has determined that the disclosed SFIs are related to the PHS funded research and constitute FCOIs.

Records of financial disclosures, Designated Official’s determinations, COIOC recommendations, and University action regarding management of a FCOI will be retained for at least three (3) years beyond the date of submission of the award’s final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

I. 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 (Academic Personnel Manual, APM-016) and/or all other applicable employee disciplinary policies. In addition, UCI is required to report violations of this policy to the PHS and other applicable federal regulatory oversight agencies and/or offices. Sponsors may suspend or terminate an award and/or debar an Investigator from receipt of future awards in the event an Investigator fails to comply with the PHS regulations. Finally, an Investigator’s failure to disclose may also subject the Investigator to civil or criminal legal action.