

UCI ADMINISTRATIVE POLICIES & PROCEDURES

OFFICE OF RESEARCH

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: June 1, 2016

Effective Date: June 23, 2016

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](#)
- Public Health Service (PHS) "Objectivity in Research," Code of Federal Regulations ([42 C.F.R. Part 50, Subpart F](#))

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

A. Purpose and Scope

This policy implements the 2011 Public Health Service (PHS) 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 PHS 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 PHS and [other sponsors that adopt the PHS 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 all individuals responsible for the design, conduct, or reporting of PHS funded research or research supported by entities adopting the PHS regulations.

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 PHS's definition of an Investigator.

C. Definitions

Annual Disclosure: The annual electronic financial disclosure all UCI Investigators on PHS proposals and awards are required to: 1) complete prior to proposal submission, and 2) keep updated throughout the duration of their active PHS awards.

Annual Form 810: Form used to collect additional information about the significant financial interest and the financial entity.

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.

Institutional Official: Vice Chancellor for Research or designee.

Financial Conflict of Interest (FCOI): A significant financial interest (as defined below) that is related to research funded by PHS 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 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.

New Significant Financial Interest (SFI): A new significant financial interest is a new different type of SFI (e.g., royalty payment versus income) than what had previously been disclosed for the same source/entity or the same type or nature of SFI (e.g. royalty payment) from a different source/entity (e.g., company A versus company B).

PHS Travel Log: An electronic records of travel disclosures.

Principal Investigator: An Investigator who is a UCI employee with 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 (STTR) awards. Excluded from this policy, consistent with the underlying PHS regulations, are Phase I SBIR awards and Phase I STTR awards.

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.

Significant Financial Interest (SFI): Significant financial interests consist of one or more of the following interests of the Investigator, the Investigator's spouse/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, excluding payments from intellectual property owned by the UC Regents.
- (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 excluding: federal, state or local governments, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes that are affiliated with an institution of higher education. Investigators should also exclude the travel reimbursements or sponsorships of their spouses, registered domestic partners and dependent children.

D. 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 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 Institutional Official.

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.

E. Policy

Investigators applying for PHS research funding or receiving PHS research support are required to disclose SFIs related to their Institutional Responsibilities at least annually by submitting and updating their Annual Disclosure.

Per the PHS regulations, Investigators are also responsible for adding their new SFIs to their Annual Disclosure within 30 days of acquiring or discovering the new SFI.

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 their sponsored or reimbursed travel within thirty (30) days of the occurrence of the travel event by providing the necessary information in the PHS Travel Log.

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 (Non-UCI Personnel)

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.

Non-UCI Investigators following UCI's PHS COI policy and procedures are required to complete the COI disclosure forms at least annually for each active PHS project and UCI's COI Training prior to engaging in the research and at least every four years thereafter as long as they are involved in an active PHS project.

F. Overview of Disclosure Review Process

All PHS Investigators are required to complete their Annual Disclosure at least annually while listed as an Investigator on an active PHS award or prior to submitting a PHS proposal. At notice of award or just-in-time, Investigators with SFIs will receive an email requesting the completion of the Annual Form 810 to provide more details about their SFIs for the relatedness review if a current Annual Form 810 is not already on file with the COI Office. The Annual Disclosure and the Annual Form 810 are valid for 12 months after the date of disclosure.

If the COI staff or COIOC member determines a SFI is related to the project, the Investigator will receive an email request for the last PHS disclosure form for the COIOC review.

Investigators from Other Institutions (Non-UCI Personnel)

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

The COIOC will review the provided documents 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.

G. 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.

H. Prospective 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.

I. 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 after the end of the calendar year in which the expiration/termination of the sponsored agreement occurs, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

J. Sanctions

Failure to complete the Annual Disclosure or the disclosures forms 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.