

**University of the Pacific**  
**Addendum to Conflict of Interest (COI) Policy**

**Policy for Compliance with NIH Financial Conflict of Interest Regulations**

**I. Introduction.**

The National Institutes of Health (NIH) financial conflict of interest regulations, effective August 24, 2012 have unique reporting and conflict management requirements. This Addendum is for the purpose of ensuring compliance with these regulations (hereinafter the Addendum will be referred to as the FCOI Policy)

All Investigators applying for funds from the NIH or other Public Health Service (PHS) agencies are obliged to comply with the requirements of the FCOI Policy. The purpose of the FCOI Policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of research personnel.

Specifically, all United States PHS agencies (includes National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ)) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors."

The FCOI Policy shall apply to disclosures of financial interests that involve PHS funded activities or activities funded by entities that require adherence to the FCOI Regulations.

Disclosure to the University is required of ALL "Significant Financial Interests" (SFI) in excess of \$5,000 that reasonably appear related to the Investigator(s) institutional responsibilities. See Section III for a list of financial interests that qualify as conflicts of interest.

**II. Mandatory Training**

The Office of Sponsored Programs (OSP) shall be responsible for ensuring that each Investigator is informed about (i) this Addendum to the COI Policy, (ii) the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and (iii) the FCOI Policy. OSP, through the designated institutional official, shall require each Investigator to complete training prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies:

- (1) This Addendum, the PHS FCOI Disclosure Statement (Disclosure), or procedures are revised in any manner that affects the requirements of the Investigators;
- (2) An Investigator is newly appointed at the University and transfers their PHS funding to Pacific; or
- (3) The University finds that an Investigator is not in compliance with this Policy or their management plan. "Immediately" shall mean the training is provided or made accessible and

the Investigators participate in the training within 5 business days following the event that triggers the training requirement.

### III. Disclosure of FCOI

The Investigator will submit a Disclosure of Significant Financial Interests prior to the time of submission of, the application to the PHS. "Investigator" means the principal investigator stated in the application and any other personnel who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, which may include, for example, consultants and unpaid collaborators. The lead principal investigator on a proposed PHS application for funding is responsible for obtaining a Disclosure for all participating Investigators.

The Disclosure shall ask the Investigator to list all of the Investigator's Significant Financial Interests (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. "Significant Financial Interest" means:

- (i) Publicly Traded-Entities - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- (ii) Privately Held Entities - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or domestic partner and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) at \$0 de minimis.
- (iii) Intellectual Property - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (iv) Travel Reimbursements - Investigators also must disclose the occurrence of any (\$0 de minimis) reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities in the twelve months preceding the disclosure.

The term "Significant Financial Interest" does not include:

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The Investigator shall update the disclosure of Significant Financial Interest during the period of the award, at least annually, in accordance with the specific time period prescribed by the OSP. With respect to transfers, disclosure shall be made to the University promptly to support acceptance of the appointment or employment to the University. In addition, an Investigator participating in PHS- funded research shall submit an updated Disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

An Investigator who is new to participating in PHS-funded activities shall submit a Disclosure at the time the Investigator is identified as a possible participant in a PHS-funded research project, such that training can be completed and timely reporting of a FCOI (if any) can be made to the respective funding agency.

All disclosures are required to be reviewed by the designated institutional official(s) in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the significant financial interest can be made, a management plan can be developed and all the necessary reviews and approvals can be secured, such that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that a FCOI exists. The Investigator's timely cooperation with the efforts of the designated institutional official(s) is needed to ensure timely reporting. Upon a failure to make timely reporting to the PHS funding agency of a FCOI, the University is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project.

#### **IV. Management of Financial Conflicts of Interests**

The designated institutional officials will review all Disclosures and determine whether an Investigator's Significant Financial Interest is related to PHS- funded research and, if so related, whether the Significant Financial Interest is a financial conflict of interest (FCOI). An Investigator's Significant Financial Interest is related to PHS-funded research when the designated institutional official(s) reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.

The following are examples of when an Investigator would be deemed to have a financial conflict of interest:

- (i) if the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or
- (ii) the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University which has resulted in license income and that technology is the subject of a proposed

PHS-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

All FCOIs shall have a management plan developed for them, which will be overseen by the designated institutional officials. The Office of Sponsored Programs will finalize the management plan and communicate it to the affected research personnel. Management measures may, as appropriate, include, but are not limited to:

- Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others;
- Research personnel's abstention from certain project segments or decisions;
- Modification of the external commitment or financial interest;
- Modification of the research plan (including the assignment of responsibilities);
- Monitoring of the potentially affected research activity by an independent individual or subcommittee;
- Divestiture or severance of an external commitment or financial interest;
- Independent review of student research progress;
- Discontinuation of advisee's or subordinate employee's participation in External Entity.

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at plan-determined intervals. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to OSP.

Additional Input on Management Plans: In making review and management decisions, Cabinet may consult with others on an as-needed basis, including campus administrative offices, University Counsel, as well as the Research Personnel and unit heads, particularly when the management plan will likely require unit-level implementation and/or monitoring.

Management Plan Notification: The Office of Sponsored Programs communicates the decision and management plan to the research personnel, unit head and those responsible for implementation of the management plan. In addition, the NIH will be notified of the existence of a managed conflict per their regulations.

Any failure by research personnel to adhere to an approved management plan will be cause for sanctions, at the discretion of the Associate Provost for Research. In addition, where such failure is not remedied, the non-compliance may be reported to the NIH. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable university policies and codes, including those set forth in the Faculty Handbook.

## **V. Reporting Financial Conflicts of Interests to PHS**

Prior to expending any funds under an PHS funded grant, cooperative agreement or contract, the University, through OSP, must report to the applicable PHS funding agency the existence of any FCOI and assure that the University has implemented a management plan. If the University identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the University is not required to submit a FCOI report to the respective agency.

For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the FCOI Regulations shall be made to the applicable funding agency by OSP for the duration of the research project in the time and manner specified by the applicable funding agency.

For any Significant Financial Interest that the University identifies as being a FCOI subsequent to the University's initial FCOI report under the award, the report will be made to PHS and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification.

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the University, through the OSP, shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning a Significant Financial Interest which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI.

#### **VI. Subrecipient Compliance and Reporting**

All proposed subrecipients under PHS-funded research of the University shall either have a financial conflicts of interest policy that conforms to the requirements of the PHS FCOI Regulations, or follow Pacific's policy. Pacific will check the FDP Clearinghouse to check if the institution has a policy that is compliant with regulations. If the institution is not listed, they will be asked within subrecipient commitment form to verify a compliant policy. If the subrecipient individual(s) have an identified FCOI, it should be revealed, by their employing institution, to Pacific's ORSP before proposal submission.

If the subrecipient individuals will be following Pacific's policy, they will be required to disclose directly to Pacific's OSP their Significant Financial Interests. If it is determined that there is an FCOI, they will be subject to the same requirements as are Pacific-employed investigators.

Pacific, through OSP, will report to the PHS funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the University in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

#### **VII. Remedies**

If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, the University, through OSP, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, OSP shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University to take further action to maintain the objectivity of the research.

For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an

Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the University, through OSP, must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

#### **VIII. Enforcement and Sanctions**

All persons subject to the Conflicts of Interest Policy and this Addendum are expected to comply with it fully and promptly. Whenever an Investigator has violated the Conflicts of Interest Policy and this Addendum, for example by a failure to disclose a Significant Financial Interest, OSP may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.

Violations of this Addendum and the PHS FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective University policy and procedures governing allegations of research misconduct.

In addition, with respect to conflicts of interest that are not properly disclosed and handled, State of California ethics laws may apply. Violations of the State ethics laws can lead to civil fines and criminal prosecution.

#### **IX. Records**

The University, through OSP, is required to maintain all Disclosures and all related records of actions taken by the University with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.