

**Procedures for Complying with
Public Health Service (PHS) Regulations for
Promoting Objectivity in Research**

**California Polytechnic State University
San Luis Obispo**

I. Background

The U.S. Public Health Service (PHS) has issued regulations designed to ensure objectivity in the conduct of research funded by PHS, by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. These regulations can be found in the Code of Federal Regulations at [42 C.F.R. Part 50, Subpart F](#) (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought). The purpose of the procedures established in this document is to ensure compliance with these regulations which stipulate certain disclosures, reporting and management of financial conflicts of interest related to PHS-funded research. All Principal Investigators (PIs) and any other personnel who are or would be responsible for the design, conduct, or reporting of research funded or proposed for funding by the PHS, are obligated to comply with the subject regulations and these procedures. In addition, Principal Investigators and other key personnel must comply with Cal Poly's Policy on Conflict of Interest in Externally Funded Research (<http://rgp.calpoly.edu/policyCOI.html>).

For purposes of this document, all references to PHS refer to the specific PHS funding agency(ies) through which the Principal Investigator is seeking or has received funding. Eight agencies are designated components of the U.S. Public Health Service: 1) the Agency for Healthcare Research and Quality (AHRQ), 2) the Agency for Toxic Substances and Disease Registry (ATSDR), 3) the Centers for Disease Control and Prevention (CDC), 4) the Food and Drug Administration (FDA), 5) the Health Resources and Services Administration (HRSA), 6) the Indian Health Service (IHS), 7) the National Institutes of Health (NIH), and 8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

I. Definitions

As used in this document:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to Cal Poly.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means a report of a financial conflict of interest by Cal Poly to a PHS-Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means California Polytechnic State University or the Cal Poly Corporation insofar as they are applying for or receiving PHS research funding on behalf of faculty staff and students.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policies and procedures on financial conflicts of interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to the regulations indicated in Section I. of this document.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). For purposes of this document, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution in compliance with the regulations indicated in Section I. of this document.

Significant financial interest means:

1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities. Specifically:

a) 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;

b) 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 dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

c) Intellectual property rights and interests (e.g., patents, copyrights) may constitute a *significant financial interest* only upon receipt of income related to such rights and interests.

2) 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 Investigators' institutional responsibilities, must also be disclosed as a potential *significant financial interest*; unless the travel is reimbursed or 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.

3) The term *significant financial interest* does **not** include the following types of financial interests: salary, royalties, or other remuneration paid by Cal Poly to the Investigator if the Investigator is currently employed or otherwise appointed by Cal Poly, including intellectual property rights assigned to Cal Poly 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 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.

Financial Conflict of Interest means, for the purposes of this document, a significant financial interest that has been determined by the Institution, through its designated official(s), to be related to PHS-funded research, and potentially affected by the PHS-funded research or in an entity whose

financial interest could be affected by the research.

II. Institutional Responsibilities

To comply with the regulations that are the subject of this document Cal Poly will:

- A. Post and maintain this document on the Cal Poly website and provide links from associated pages, particularly those that will facilitate public access to the document.
- B. Inform each Investigator of the PHS regulations, the procedures contained herein, and the Investigator's responsibilities regarding disclosure of significant financial interests.
- C. Require each Investigator to complete training regarding the PHS regulations prior to engaging in research related to any PHS-funded grant and at least every four years, as well as immediately when any of the following circumstances apply:
 - 1) the Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - 2) an Investigator is seeking or receiving PHS funding for the first time at Cal Poly;
 - 3) the Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy, these procedures or a management plan that has been put in place.
- D. Require Investigators who are seeking or currently receiving PHS funding for research to disclose significant financial interests at the time of application and prior to expenditure of any PHS funds, with disclosure updates as required.
- E. Take reasonable steps to ensure that any subrecipient's Investigator(s) complies with the regulations and these procedures if the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members). The Institution will:
 - 1) incorporate as part of a written agreement with the subrecipient, terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators;
 - 2) require that the sub-recipient certify as part of the agreement referenced above that its policy complies with PHS regulations in cases where the sub-recipient's Investigators must comply with the sub-recipient's financial conflicts of interest policy.
 - 3) require the sub-recipient to disclose to Cal Poly significant financial interests that are directly related to the sub-recipient's work for Cal Poly in cases where the sub-recipient cannot provide the certification noted above, and to report all identified financial conflicts of interest to Cal Poly, in a timely way, to enable Cal Poly to comply with requirements to report financial conflicts of interest to the PHS;

4) require the sub-recipient's Investigators to follow Cal Poly's procedures contained herein in cases where the sub-recipient elects to comply with Cal Policy's policies and procedures on financial conflicts of interest and include in the written agreement with the sub-recipient specific time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Cal Poly such that Cal Poly is able to fulfill in a timely way its review, management, and reporting obligations under PHS regulations.

5) provide reports to the PHS Awarding Component regarding all financial conflicts of interest of all sub-recipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

- F. Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in PHS-funded research, and provide guidelines to these officials on how to 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.
- G. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a sub-recipient Investigator pursuant to paragraph D of this section. Management of an identified financial conflict of interest will include development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to PHS regulations.
- H. Provide initial and ongoing FCOI reports to the PHS as required.
- I. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in PHS regulations.
- J. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- K. Prior to the expenditure of funds, make certain that information concerning FCOIs held by senior/key personnel is publicly accessible via a web site or by a written response to any requester within five business days of a request or as required by law. This information will include: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (in pre-specified dollar ranges), or a statement that a value cannot be readily determined. This information will remain publicly accessible for at least three years from the date that it was most recently updated.
- L. Certify, in each application for funding to which these regulations apply, that the Institution:

- 1) has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
- 2) promotes and enforces Investigator compliance with PHS regulations and these procedures, including those pertaining to disclosure of significant financial interests;
- 3) shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;
- 4) agrees to make information available, promptly upon request, to Health and Human Services relating to any Investigator's disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
- 5) agrees to fully comply with the PHS regulations contained in [42 C.F.R. Part 50, Subpart E](#).

IV. Investigator Responsibilities

Investigators who wish to apply for and/or receive PHS funding for research through Cal Poly (including the Cal Poly Corporation) must comply with procedures in this document, including truthful and accurate disclosures to Cal Poly of significant financial interests as detailed and defined in this document; cooperation with any management or mitigation plans that the Institution may put in place, with FCOI reporting to PHS/HHS that may be required and with public disclosures of FCOIs that the Institution may be required to make; and completion of required training.

Disclosure.

Each Investigator who is applying for PHS research funding or planning to conduct PHS-funded research at Cal Poly must disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research. The lead Principal Investigator on a proposed PHS application for funding or a PHS-funded project is responsible for obtaining disclosures on the specified forms from other participating Investigators.

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of significant financial interests at least annually, on a date specified by the Institution and determined by the timeframe of the specific PHS application and award. Such disclosure shall include any information that was not disclosed initially to the Institution, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Cooperation with designated officials.

Each Investigator must cooperate with the designated officials by providing timely disclosures and updates and by participating as needed in the review of Investigator's significant financial interest to determine if it is related to the PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest.

Similarly each Investigator must cooperate as needed for the Institution to meet its obligations regarding FCOI reporting and public disclosures when these are required.

Required training.

Prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract, each Investigator is required to complete training regarding the PHS regulations on Financial Conflict of Interest. Cal Poly offers this training to Investigators through the CITI Program, a subscription service providing research ethics education (<https://www.citiprogram.org/>). The Grants Development Office will provide information to each Investigator on how to access and complete the CITI FCOI training.

Each Investigator is required to complete this training course at least every four (4) years if Investigator continues to be involved in PHS-funded research, and immediately when any of the following occurs: 1) Cal Poly's FCOI policies, procedures or disclosure forms are revised in any manner that affects the requirements of Investigators; 2) Investigators become involved for the first time in PHS-funded research proposals or projects at Cal Poly; or 3) if Cal Poly finds that an Investigator is not in compliance with the FCOI regulations or a management plan.

V. Review of Disclosures and Determination of FCOI

The Grants Development Office will be responsible for determining which individuals listed on PHS-funded projects/proposals meet the definition of *Investigator* in Section II of this document and will ensure that all those identified as Investigators complete the required disclosure forms. The Director of the Grants Development Office will review the disclosures to identify those that meet the definition of *significant financial interest* and will refer these to the Dean of Research and Graduate Programs. The Director of Grants Development will provide the disclosures of *significant financial interest* to the Dean of Research and Graduate Programs within 10 days of receipt. The Dean will review the disclosures to determine whether the *significant financial interest* might reasonably be construed to constitute a *financial conflict of interest* as defined in Section II. In making this determination the Dean may request additional information to better understand how the *significant financial interest* is related to the Investigator's PHS-funded research and/or institutional responsibilities. Those *significant financial interests* that appear to constitute a potential *financial conflict of interest* will be referred to the University's Conflict of Interest in Research Committee (CIRC) for further review.

Within 20 days of receipt from the Grants Developments Office, the Dean of Research and Graduate Programs will forward disclosures of *significant financial interest* that appear to constitute a potential *financial conflict of interest* to the CIRC for review. The CIRC will be convened in a timely manner to determine the existence of a *financial conflict of interest*. In cases in which a *financial conflict of interest* is identified, within sixty (60) days of that determination a management plan will be developed; the necessary reviews and approvals will be secured, and any required report to the applicable PHS funding agency will be submitted. In filing reports, Cal Poly will comply with the requirements outlined in [42 C.F.R. Part 50, Subpart F](#).

VI. Management of Financial Conflicts of Interest.

For all cases in which a *financial conflict of interest* is determined to exist, the Conflict of Interest in Research Committee will develop a management plan that will include conditions or restrictions designed to manage the *financial conflict of interest*. Such restrictions or conditions may include, but are not limited to: 1) public disclosure of significant financial interests; 2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the *financial conflict of interest*; 3) modification of the research plan; 4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; 5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or 6) severance of relationships that create financial conflicts.

For all management plans, Cal Poly will monitor Investigator compliance with the management plan on an on-going basis until the completion of the PHS-funded research.

VII. Enforcement.

All persons required to comply with the procedures described herein are expected to comply with them fully and promptly. Failure to do so will result in sanctions by the University and potential loss of PHS funding.

VIII. Record Retention

All PHS-related disclosures of *significant financial interest*, and all related records of actions taken by the University with respect to disclosures of *significant financial interest*, will be retained for a period of at least three years from the date of submission of the final expenditures report on the project to the PHS, and longer in particular situations to which other regulations apply.

IX. Full Compliance with [42 C.F.R. Part 50, Subpart F](#).

Cal Poly will fully comply with all requirements in [42 C.F.R. Part 50, Subpart F](#), whether or not explicitly stated in this procedural document.