

Policy

Disclosure of Significant Financial Interests (SFI) Related to Sponsored Projects

I. Introduction

A. Purpose

This policy aims to promote transparency, integrity, and compliance in research and programmatic activities conducted at Pacific Lutheran University (PLU). It establishes guidelines and procedures for disclosing, reviewing, managing, and mitigating Financial Conflicts of Interest (FCOI) in accordance with [42 CFR Part 50 Subpart F](#).

B. Scope and Applicability

This policy applies to all PLU investigators, including faculty, staff, and students, who are engaged in the design, conduct, or reporting of research and programmatic activities funded by the United States Public Health Service (PHS), the National Science Foundation (NSF), or any other funding agency that requires compliance with 42 CFR Part 50 Subpart F as indicated in the written conditions of award.

This policy also applies to investigators at subaward recipient institutions when it is determined, via contractual agreement, that PLU's policy and procedures will be followed. In cases where the subaward institution's policy and procedures will be followed, the institution must certify in the agreement that their policy complies with 42 CFR Part 50 Subpart F and that they agree to submit any required disclosures to PLU for the duration of the funding period so that PLU is able to meet reporting requirements of the funding agency.

II. Definitions

A. Investigator

An *investigator* is any individual responsible for the design, conduct, or reporting of research activities funded by an PHS, NSF, or an agency requiring compliance with 42 CFR Part 50 Subpart F.

B. Significant Financial Interest (SFI)

A *significant financial interest (SFI)* is anything of monetary value held by an investigator (and/or their spouse, domestic partner, and dependent children) related to the investigator's institutional responsibilities.

A significant financial interest includes but is not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria) in the previous 12 months that exceeds \$5,000;
- equity interests (e.g., stocks, stock options, or other ownership interests) exceeding \$5,000;
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and
- Travel paid for or reimbursed by someone or entity other than a government agency, college or university, or academic medical institution.

A significant financial interest does not include:

- Salary, royalties, or other remuneration from Pacific Lutheran University, including intellectual property rights assigned to PLU and agreements to share royalties related to such rights.
- Income from investment vehicles (mutual funds or retirement accounts that are not managed directly by the individual).
- Income from seminars, lectures, or teaching engagements sponsored by a US federal, state, or local government agency, a U.S. Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.
- Income from service on advisory committees or review panels for a US federal, state, or local government agency, a U.S. institution of higher education as defined by 20 U.S.C. 1001(a). (e.g., NIH review panel).
- Travel that is reimbursed or sponsored by a US federal, state, or local government agency, a U.S. institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

C. Financial Conflict of Interest (FCOI)

A *financial conflict of interest (FCOI)* is a significant financial interest (SFI) held by an investigator that could directly and significantly affect the design, conduct, or reporting of research.

III. Investigator disclosure requirements

A. Initial disclosure

Prior to beginning the funded research, all investigators must disclose their significant financial interests using the designated disclosure form. The disclosure should include the nature and value of the interest, as well as any potential conflicts that may arise. If an investigator does not have a significant financial interest, they must still complete the form and certify that there are no interests to disclose.

B. Annual disclosure

Investigators must submit an updated disclosure form annually, even if there have been no changes since the initial disclosure. Annual disclosures will be required for the duration of the funded project period.

C. Updates

If there is a change in the reported information during the year, Investigators must submit an updated disclosure form within 30 days of discovering or acquiring a new significant financial interest.

IV. Investigator Training Requirements

A. Initial training

Prior to beginning the funded research, Investigators must complete the following activities to increase their understanding of financial conflict of interest regulations and their obligations as an investigator in the funded project.

1. Participate in web-based financial conflict of interest training and pass the quiz. The training can be accessed at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. Completion certificates must be submitted to the office of sponsored programs.
2. Review PLU's policy and procedures for disclosing significant financial interests.

B. Follow up training

Every four years Investigators must review PLU's policy, complete the FCOI training, pass the quiz, and re-send their certification of completion to the sponsored programs office.

C. Immediate training, when applicable

Investigators must immediately complete the required training when any of the following circumstances apply:

- PLU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- An investigator is new to PLU; or
- PLU determines that an investigator is not in compliance with PLU's financial conflict of interest policy or management plan.

V. Review and management of financial conflicts of Interest

A. Review process

The Office of Sponsored Programs will conduct an initial review of all submitted disclosure forms. Those without significant financial interests noted will be confidentially retained for three years beyond the termination of the funded project and referenced for required reporting purposes.

Those disclosures with significant financial interests present will be sent to the Office of Institutional Effectiveness for further review. The goal of this review is to determine whether the significant financial interest is related, and if so, determine whether or not it represents a financial conflict of interest.

B. Determination of relation to project

To determine whether the SFI is related to the project, the designated official will answer the following questions.

1. Could the significant financial interest be affected by the project?
2. Is the significant financial interest in an entity whose financial interests could be affected by the project?

If the answer to either question is "yes," the significant financial interest is related and it must be further evaluated to determine if a financial conflict of interest is present. If the answer to both questions is "no," the review is complete and the determination can be filed in the Office of Sponsored Programs for required reporting purposes.

C. Determination of a Financial Conflict of Interest

If the significant financial interest is related, the designated official must determine if it presents a financial conflict of interest by answering the following question:

Could the significant financial interest directly and significantly affect the design, conduct, or reporting of the project?

If yes, it is a financial conflict of interest and additional steps must be taken to manage or mitigate the conflict. If “no,” the review is complete and the determination can be filed in the Office of Sponsored Programs for required reporting purposes.

D. Development of Management Plans

When a financial conflict of interest is identified, a management plan will be developed to ensure that the research is conducted objectively and without bias. The designated official within the Office of Institutional Effectiveness will work with the investigator to develop a plan to either manage, reduce, or eliminate the financial conflict of interest as well as a plan for monitoring. This may include actions such as oversight, modification of the investigator’s role on the project, protocols, and/or divestment of financial interests.

E. Monitoring and Enforcement

The Office of Sponsored Programs will work with Investigators to determine whether this policy applies to an externally funded project. If it is applicable, a designee within this office will ensure all project Investigators have met the required training and disclosures 1) prior to expending project funds and 2) annually, near the anniversary of project start date.

Additional monitoring may be applicable given the circumstances of the project. These may include:

- Changes in project personnel,
- Changes in research plan,
- Changes to an existing disclosure, and/or
- To meet monitoring requirements of an established management plan.

Retrospective review, when applicable

If it is determined that an investigator is non-compliant or a reporting deadline was missed, PLU will complete and document a retrospective review to determine the impact of the initiating event. If bias is found, PLU will develop and submit a mitigation report to the sponsoring agency.

F. Record Retention

All disclosure forms, determinations of financial conflict of interest, relevant management plans, and actions taken under this policy will be confidentially retained by the office of sponsored programs for at least three years beyond the termination date of the funded project. These records will be referenced to meet relevant reporting requirements.

VI. Reporting and Transparency

A. Reporting

PLU will comply with all reporting requirements stipulated by 42 CFR Part 50 Subpart F as well as the requirements of the funding agency.

B. Public Accessibility

This policy will be accessible to the public through PLU’s website.

Additionally, summary information on identified financial conflicts of interest, while safeguarding confidential and proprietary information, will also be made publicly accessible through PLU’s website. This will include:

- Investigators name, title and role related to the research project,

- Name of entity in which SFI is held,
- Nature of the SFI (consulting fees, travel, equity interest, etc), and
- Approximate dollar value of the SFI.

VII. Non-compliance and consequences

A. Non-compliance with disclosure requirements

Failure to comply with the disclosure requirements outlined in this policy may result in disciplinary actions, including but not limited to suspension of privileges, modification or termination of funded projects, withdrawal of funding, or other appropriate measures.

B. Non-compliance with financial conflict of interest management plan

Failure to comply with an established financial conflict of interest management plan may result in disciplinary actions, including but not limited to suspension of privileges, modification or termination of funded projects, withdrawal of funding, or other appropriate measures.

VIII. Policy review and updates

This policy will be reviewed every three years and updated as necessary to remain in compliance with 42 CFR Part 50 Subpart F and any related federal regulations and guidelines.

Policy was approved by PLU's Executive Council on March 19, 2024

Next review date: March 2027