



Policy on PHS/NIH Conflict of Interest in Research

Pepperdine University | Office of Research and Sponsored Programs

INTRODUCTION

The Department of Health and Human Services amended its regulations related to financial disclosure on 8/25/2011. All institutions applying for U.S. Public Health Service (PHS) funding for research are required to have a policy that complies with these amended regulations; this Policy on PHS/NIH Conflict of Interest in Research is designed to comply with the federal regulations and hereby incorporates by reference 42 CFR chapter I, subchapter D, part 50.

These guidelines define general Pepperdine University (Pepperdine) policy and procedures regarding conflicts of interest in relationship to research and sponsored programs funded by PHS (including NIH). Their purpose is to protect the credibility and integrity of the Pepperdine's faculty and staff so that public trust and confidence in Pepperdine's PHS-funded sponsored activities is ensured.

This policy applies to all Investigators (as defined by the policy) who are involved with PHS-funded research. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Pepperdine policy.

DEFINITIONS

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse or partner.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching

- hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) if income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Institution means Pepperdine University, or any school within.

Institutional Official means the individual within the Institution who has been designated to solicit and review disclosures from Investigators (and their families) of significant financial interests related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official will be the Vice Provost for Research and Strategic Initiatives.

Institutional Responsibilities means the Investigator's responsibilities on behalf of Pepperdine, which are defined by Pepperdine as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards (e.g., IACUC and IRB).

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS-funded research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or 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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health and the Centers for Disease Control.

Research means a systematic investigation, study, or experiment designed to 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).

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty and staff about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and Pepperdine to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator must become familiar with, and abide by, the provisions of this policy. If a situation arises which raises questions of conflict of interest, an Investigator should discuss the situation with the Pepperdine University Office of Research and Sponsored Programs.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests to Pepperdine on an annual and on an ad hoc basis, as described below, using the Financial Interest Disclosure Form. Forms are available upon request from the Office of Research and Sponsored Programs. The Office of Research and Sponsored Programs is responsible for the receipt, processing, review, and retention of disclosure forms.

Regardless of the minimum disclosure requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Investigators provide the following information for all Significant Financial Interests: name of the entity, nature of the financial interest, the monetary value of the financial

interest or its approximate value, and any supporting documentation needed to make a determination of whether a FCOI exists.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests to Pepperdine, through the Institutional Official or designee, at least annually during the grant period in conjunction with filing the required annual report.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure.

New Hires: All Investigators involved with PHS-funded research must disclose their Significant Financial Interests to Pepperdine, through the Office of Research and Sponsored Programs, within 30 days of being appointed or employed.

New grant proposal or subaward: Before submitting grant proposals for PHS funding or entering into subaward agreements for PHS-funded research, each Investigator must submit to the Office of Research and Sponsored Programs an ad hoc updated disclosure of his or her Significant Financial Interests. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

New Significant Financial Interest: All Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Conflict of Interest, the Investigator will ask the Department Chair or Designee to promptly review whether it constitutes a Financial Conflict of Interest. This should occur prior to submission of the Financial Interest Disclosure Form to the Office of Research and Sponsored Programs. The

Department Chairperson or designee will then be required to certify that they have reviewed the form and have determined either:

- A conflict of interest exists and the department cannot recommend approval of this activity.
- A conflict of interest exists but it is minimal and the department does NOT recommend management, reduction, or oversight.
- A conflict of interest exists but it can be reduced, eliminated, or managed.

If appropriate, the Department Chairperson will then be expected to recommend action to eliminate, reduce, or manage the conflict.

Upon submission to the Office of Research and Sponsored Programs, the Institutional Official will then review the Financial Interest Disclosure Form and Department Chairperson's recommendations as to whether the activity cannot be approved, exists but is minimal and does not require management, reduction or oversight, or exists but can be reduced, eliminated, or managed. The Institutional Official will then make a formal decision on behalf of the University as to whether the plan, as recommended, will be formally adopted or modified.

Examples of conditions or restrictions that might be imposed to manage conflicts of interest 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, Pepperdine is required to monitor Investigator compliance with the management plan on an on-going basis until the completion of the PHS- funded research project.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor how the activity is conducted (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

3) REPORTING TO PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional Official will report in accordance with PHS regulations. If the funding for the Research is a subaward from a prime PHS-awardee, reports shall be made to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Before expending any funds under a PHS funded grant, cooperative agreement or contract, or subaward where the prime award is funded by a PHS entity, Pepperdine must report to the applicable PHS funding agency (or to the prime awardee) the existence of any FCOI (as defined above) and assure that Pepperdine has implemented a management plan in accordance with the FCOI Regulations.

If Pepperdine identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, Pepperdine is not required to submit a FCOI report to the respective agency.

4) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator and, where applicable, the IRB or IACUC, and will notify the individual of the right to appeal the decision.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, within 120 days, the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will promptly update any report previously submitted to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

When bias is not found following the completion of a retrospective review, Pepperdine should not submit a "Revised" FCOI report to notify NIH that either the retrospective review has been completed or that bias is not found.

5) TRAINING

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators are required to complete NIH's Financial Conflict of Interest Training Module, available at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. Investigators are required to confirm that they have completed the training via email to rspinfo@pepperdine.edu.

Investigators must also complete training immediately, if: this Policy is substantively amended in a manner that affects the requirements of Investigators; an Investigator is new to Pepperdine University; or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

6) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

7) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding an Investigator's research, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity that made the funding available to the Institution, if requested or required. If the Institution provides disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8) SUBRECIPIENT INVESTIGATORS

If Pepperdine carries out the PHS-funded research through a subrecipient, the agreement between Pepperdine and the subrecipient will articulate whether subrecipient Investigators will comply with the Financial Conflict of Interest Policies of the subrecipient institution or whether they will be subject to Pepperdine's policy. If subrecipient Investigators are subject to the policies of the subrecipient institution then the subaward agreement shall include a certification that the subrecipient Investigators will comply with the PHS regulations governing financial conflicts of interest and shall specify a time period for the subrecipient to report all identified conflicts of interest to Pepperdine. If the subrecipient Investigators are subject to Pepperdine's policy, the subaward agreement shall specify time period(s) for the subrecipient to submit all Investigator FCOI disclosures to Pepperdine, so that Pepperdine has sufficient time to provide timely reports, as necessary, to PHS.

9) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution will ensure public accessibility of information about any FCOI, via response to requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy.

10) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.