

Financial Conflict of Interest: Policies and Procedures

Policy Title

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Policy Text

Definitions

"Exclusions" The term significant financial interest does not include the following types of financial interests:

- a. 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;
- b. 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;
- c. Income from seminars, lectures, or teaching engagements sponsored by 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;
- d. 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; or
- e. Travel that is reimbursed or sponsored by 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.

"Financial Conflict of Interest" means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research. A financial conflict of interest exists when the Vice President for Finance, or his or her designated representative, reasonably determines that a significant financial interest related to research could directly and significantly affect the design, conduct, or reporting of the research or educational activities.

A significant financial interest **"directly affects"** the project when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest, or when the organization is a proposed subcontractor or participant in the project.

A project **"significantly affects"** the financial interest of an organization when it materially affects the value of the organization, its earnings, or the sales of its products, or the organization is a proposed subcontractor or participant in the project.

"Financial Interest" means anything of monetary value, whether or not the value is readily ascertainable. **"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.

"Investigator" means the project director (PD), principal investigator (PI), co-principal investigator (co-PI), and any other person who is responsible for the design, conduct, or reporting of research funded by the sponsor or proposed for such funding, which may include, for example, collaborators or consultants. In addition to Harding University faculty members, this definition may apply to staff, postdoctoral fellows, or others with independent responsibility for portions of the design, conduct, or reporting of research of an Investigator's proposed or funded project.

Each PI/PD is responsible for determining all project personnel who meet the above definition of Investigator and, therefore, who must be trained, disclose financial interests to the University, and report when the status of any financial interest changes or new interests are acquired. In making such determinations, the PI/PD should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

“Institution” means Harding University.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards.

“Significant Financial Interest” means 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:

- 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);
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- d. 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.

“Significant financial interests related to the research.” The Investigator must disclose all financial interests that reasonably appear to be related to the Investigator’s institutional responsibilities. Then, the University must determine whether an Investigator’s significant financial interest is related to the research. An Investigator’s significant financial interest is related to the research when the Vice President for Finance, or his or her designated representative, reasonably determines that the significant financial interest: could be affected by the research; or is in an entity whose financial interest could be affected by the research.

Procedure

1. Disclosure of Significant Financial Interests

Investigators must disclose to the Office of Sponsored Programs all significant financial interests before (within one year at most) the time a proposal is submitted to any external sponsor, and prior to engaging in any research.

In addition, Investigators must update those financial disclosures as follows:

- a. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new significant financial interest; and
- b. Annually within the period of the award, beginning with the anniversary date of the original disclosure.

Investigators must also disclose the purpose of any reimbursed or sponsored trip, the identity of the sponsor/organizer, the destination, and the duration. The Vice President for Finance, or his or her designee, will determine if further information is needed and if the travel constitutes a financial conflict of interest.

Investigators must disclose the significant financial interests using the Significant Financial Interest Disclosure Form and submit it to the Office of Sponsored Programs.

Disclosure of significant financial interest during the project period. Whenever, in the course of an ongoing research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the Office of Sponsored Programs and the Vice President for Finance shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to the research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the Vice President for Finance may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date of disclosure and the completion of the Institution's review.

2. Financial Conflict of Interest Policy Training

All Investigators who submit a proposal to an external sponsor are required to complete training in the University's financial conflict of interest policy and make the required financial disclosures within at most one year prior to submission of their proposal.

Re-training. All Investigators funded by an external sponsor must repeat financial conflict of interest training:

Every four years;

- a. When the University finds that an Investigator is not in compliance with this policy;
- b. When the Investigator is new to the Institution; and
- c. On any occasion when the University revises its financial conflict of interest policies and procedures in any manner that affects the Investigators' requirements. When such revisions occur, re-training must occur within forty-five (45) days of the issue date of the revised policy.

3. Review of Financial Disclosures

Determination of financial conflict of interest. The Office of Sponsored Programs shall collect and review each Significant Financial Interest Disclosure Form and preliminarily determine whether the disclosed significant financial interest relates to the research. If the significant financial interest reasonably appears to be related to the research, the Vice President for Finance will review the significant financial interest, decide if it relates to the research, determine whether a financial conflict of interest exists and identify what conditions or restrictions, if any, should be imposed by the Institution to manage, reduce, or eliminate the financial conflict of interest. The Vice President for Finance may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an ad hoc review committee to assist in the review, and they (or the Vice President for Finance) may request additional information from the Investigator who disclosed the significant financial interest.

Management of financial conflict of interest. If the Vice President for Finance determines that a significant financial interest constitutes a financial conflict of interest, he or she shall determine the conditions or restrictions to be imposed and implemented to manage or eliminate the conflict. The management plan may include, but is not limited to, the following elements:

Monitoring of research by independent reviews;

- a. Modification of the research plan;
- b. Disqualification from participation in the portion of the externally-sponsored research that would be affected by significant financial interests;
- c. Divestiture of significant financial interests;
- d. Severance of relationships that create conflicts; or
- e. Public disclosure of any financial conflicts of interest (e.g., when presenting or publishing the research).

If the Vice President for Finance determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interest of scientific progress, technology transfer, or the public health and welfare, then the Vice President for Finance may allow the research to go forward without imposing such conditions or restrictions.

The Office of Sponsored Programs shall communicate the financial conflict of interest determination and the means identified for eliminating or managing the financial conflict of interest to the individual Investigator, the relevant PI/PD (if applicable), the appropriate department chair, and as necessary, the awarding agency.

No expenditures of sponsor funds will be permitted until the Investigator has complied with the disclosure and training requirements of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the financial conflict of interest.

When a financial conflict of interest management plan is put in place, the University shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project.

Extenuating conditions for NSF-funded research projects. If the Vice President for Finance determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the NSF-funded research to go forward without imposing such conditions or restrictions.

4. Retrospective Review and Mitigation Report for PHS-funded Research

If the financial conflict of interest is not identified or managed in a timely manner due to the failure of the Investigator to disclose a significant financial interest that is determined to be a financial conflict of interest; the failure of the University to review or manage a financial conflict of interest; or failure by the Investigator to comply with the management plan, the Vice President of Finance shall, within 120 days of the determination of noncompliance, complete a retrospective review. The retrospective review will determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If bias is found during the retrospective review, the PHS agency will be notified promptly and a mitigation report will be submitted to the PHS agency. Based on the results of the retrospective review, previously submitted financial conflict of interest reports will be updated as necessary to specify the actions that will be taken to manage the financial conflict of interest going forward. Thereafter, the Institution will submit financial conflict of interest reports annually.

Documentation of the retrospective review will include, but not necessarily be limited to, all of the following key elements: project number; project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; reason(s) for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of

the review panel, documents reviewed); findings of the retrospective review; and conclusions of the retrospective review.

The mitigation report will include, at a minimum, key elements documented in the retrospective review and a description of the impact of the bias on the research project and University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

5. Subawardee, Subcontractor, or Subrecipient

When the University is a subawardee, subcontractor, or subrecipient of another institution, the University's financial conflict of interest policy will apply, unless the terms of the subaward or subcontract expressly prohibit it. Conversely, the University requires its subawardees, subcontractors, and subrecipients to develop and manage their own federally compliant financial conflict of interest policies as appropriate for each sponsor or abide by Harding's financial conflict of interest policy.

6. Record Keeping

The Office of Sponsored Programs shall maintain records of all financial disclosures and of all actions taken to resolve financial conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate or until the resolution of any federal action involving those records, whichever is longer.

7. Reporting.

Reporting for NSF-funded projects. The Office of Sponsored Programs shall report to the NSF Office of the General Counsel if the University is unable to satisfactorily manage an Investigator's financial conflict of interest.

Reporting for PHS-funded projects. As necessary, the University will provide initial, annual, and revised reports on financial conflicts of interest for PHS-funded projects as follows:

Prior to the expenditure of PHS agency funds;

- a. Within sixty days of identifying a financial conflict of interest for an Investigator who is newly participating in the PHS-funded project;
- b. Within sixty days for new, or newly identified, financial conflicts of interest for existing Investigators on PHS-funded projects;
- c. Annually, at the same time as when the grantee submits the annual progress report, including multi-year progress report or at time of extension to provide the status of the financial conflict of interest and any changes to the management plan, if applicable, until the completion of the PHS-funded project; and
- d. Following a retrospective review to update a previously submitted report, if appropriate.

The Office of Sponsored Programs shall notify the PHS agency promptly (at least within thirty days) if an Investigator fails to comply with Harding's financial conflict of interest policy, if bias is found with the design, conduct or reporting of PHS-funded research, or if a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.

8. Public Accessibility

The University financial conflict of interest policy shall be made publicly available on its website.

Public accessibility for PHS-funded projects. Prior to the expenditure of PHS agency funds, the Institution will ensure that information concerning identified significant financial interests held by senior/key

personnel is made available to any requestor within five business days of the request. The information to be made available shall be: 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; the date through which the information is known to be current; notice that the information is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor; and the approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. Information concerning the significant financial interests of an individual subject to public disclosure shall remain available for at least three years from the date that the information was most recently updated.

In any case in which the DHHS 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 has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Investigator involved shall be required to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

9. Enforcement

The Vice President for Finance shall establish appropriate mechanisms for enforcement of this policy, which shall provide for sanctions where appropriate. Disciplinary proceedings initiated in connection with this policy shall be conducted in accordance with the University's Faculty Handbook, the Staff Handbook, or the Student Handbook. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.

10. Disclosure Statements

All Investigators who are submitting proposals to any external funder must complete the attached disclosure form. The certification page of a research proposal cannot be signed until disclosure forms for all Investigators have been submitted to the Office of Sponsored Programs.

11. Examples of Circumstances Presenting a Potential Conflict of Interest

The following examples of activities by a University employee present potential conflicts of interest. The circumstances described in these examples would in most cases require disclosure and management under this policy. The management plan would likely prohibit such activities. The activities on the following list do not represent all possible conflict of interest. The determination of whether any actual circumstances create a conflict of interest and all decisions regarding management of conflicts shall be made by the relevant person according to the procedures described in this policy.

- a. Participating in University research involving a technology owned by or contractually obligated (by license, option, or otherwise) to a business in which the employee has a financial interest.
- b. Participating in University research that would validate or promote a product of a business in which the University employee has a financial interest.
- c. Disclosing, outside of normal academic publication and teaching, privileged or confidential information to a business in which the University employee has a financial interest.
- d. Providing consulting services as a private venture of the University employee using University facilities, equipment, personnel or other University resources.
- e. Use by a University employee of University students or staff to perform administrative duties in support of the University employee's external activities.
- f. Using University purchasing contracts or service relationships to purchase goods or services for an external business, private consulting project or other external activity.

- g. Receiving, through contract or grant, research support under University auspices (whether in dollars or in kind) for research from a business in which the University employee has a financial interest.
- h. Purchasing goods or services for the University from businesses in which the University employee has a Financial Interest.
- i. Engaging in any paid consulting work with any University donor or sponsor.

Rationale

The purpose of the Financial Conflict of Interest (FCOI) Policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.

The policies and procedures set forth here are intended to apply to any externally-funded project performed by Harding personnel or performed at Harding University. The policies and procedures are meant to satisfy the conflict of interest regulations of the Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS) set forth in 42 CFR Part 50 and 42 CFR Part 94 and the National Science Foundation (NSF) set forth in Section IV of the NSF Proposals and Award Policies and Procedures Guide.

Forms

[Significant Financial Interest Disclosure Form](#)

Governance

Authority: Federal

Responsible Office: Provost (Academics), Finance

Responsible Committee: Office of Sponsored Programs

Document History

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