

University of Incarnate Word Financial Conflict of Interest in Research Policy

I. Policy

This policy governs the disclosure of individual Significant Financial Interests and the management and reporting of an Individual Financial Conflict of Interest in sponsored research performed at the University of the Incarnate Word. This policy is intended to comply with federal regulations implemented by the Public Health Service (PHS) of the US Department of Health and Human Services (DHHS) and the National Science Foundation (NSF). This policy promotes objectivity in research by establishing procedures to identify and address actual and apparent financial conflicts of interest.

II. Rationale

All employees of the University of the Incarnate Word are held to the highest standards of ethical conduct. Consistent with Section 7.2 of the University of the Incarnate Word Employee Handbook, UIW employees may not have a financial conflict of interest, direct or indirect, in any contract with UIW. Furthermore, federal regulations require investigators engaged in PHS and NSF funded research to disclose the existence of certain financial interests and require the institution to review those disclosures, determine whether any potential conflicts of interest may exist, and establish mechanisms to manage, reduce, or eliminate such conflicts of interest.

III. Definitions

Conflict of Interest Committee (COI Committee) means the university's committee or individual that advises the Institutional Official on Financial Conflict of Interest matters.

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and independent children) receives remuneration or in which any person has an ownership or equity interest.

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

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that the institution reasonably determines could directly and significantly affect the design, conduct or reporting of a PHS, NSF or other applicable agency-funded project.

Institutional Official means the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interest related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is the Associate Provost for Research and Graduate Education or his or her designee.

Investigator means the principal investigator, co-principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for funding by the NSF, PHS, or other applicable agencies. This definition may include postdoctoral associates, senior scientists, graduate students, collaborators, or consultants as appropriate. The Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

Investigator's Institutional Responsibilities means the investigator's professional responsibilities on behalf of the institution, which may include but are not limited to research, research consultation, teaching, committee service, administration, clinical activities, or professional practice.

Significant financial interest (SFI) means:

1. With regards to **Publicly-Traded Entities**, Payments or value exceeding \$5,000 (when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children) from a single entity during the prior 12 months. This includes any salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest).

2. With regards to **Privately Held Entities**, Payments or value exceeding \$5,000 (when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children) from a single entity during the prior 12 months or when the Investigator and the investigator's spouse/domestic partner and dependent children hold **any** equity interest (stock, stock option, or other ownership interest).

3. With regards to **Intellectual Property**, Intellectual property rights and interests (patents, copyrights) **upon receipt of income** related to such rights and interests.

4. With regards to **Travel Reimbursements**, Any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months (with the exception of 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).

The term "Significant Financial Interest" **does not include**: salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts; 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 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.

IV. Scope

This policy applies to all individuals engaged in PHS and NSF funded research who are responsible for the design, conduct, or reporting of the funded research, including, but not limited to principal investigators, co-investigators, and project directors. In addition, this policy applies to other funding agencies who require UIW investigators to disclose any financial conflicts of interest. If a specific federal law, regulation, policy, or contract of a sponsor or prime awardee includes different requirements than this policy, the more stringent requirement applies.

V. Process

a. When to Disclose a Financial Conflict of Interest

- i. *Time of Application:* Each investigator who is planning to participate in PHS- or NSF or other applicable agency-funded research must complete and submit to the Office of Research and Sponsored Projects Operations (ORSPO) a Significant Financial Interests Disclosure Form no later than the time of proposal submission. The Significant Financial Interest Disclosure Form is posted on the ORSPO website at <http://www.uiw.edu/orgs/research/compliance/fcoi.html>.
- ii. *During Award Period:* Each investigator who is participating in PHS- or NSF-funded research must submit an updated Significant Financial Interests Disclosure Form at least annually (two months prior to the annual progress report due date), during the period of the award. Such disclosure shall include any information that was not disclosed initially or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS- or NSF- funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant interest (e.g., the updated value of a previously disclosed equity interest). Furthermore, each investigator who is participating in PHS- or NSF- funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring a new significant financial interest.
- iii. For all other funding agencies that require disclosure of Significant Financial Interests, disclosure shall be in accordance with sponsor requirements.

b. Review, Determination and Management of Financial Conflict of Interest

- i. *Review and Determination:* If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official for a determination of whether it constitutes a Financial Conflict of Interest. The Institutional Official may appoint a COI Committee for consultation and guidance in specific or complex cases, or the application of the policy to a particular situation.

A Financial Conflict of Interest will exist when the Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of research funded by PHS, NSF, or other applicable agencies.

- ii. *Management:* If the Institutional Official determines that there is a Financial Conflict of Interest, he or she must require and approve a written management plan before any related research goes forward or any funds can be expended. The affected Investigator or the COI Committee, as appropriate, is responsible for developing and submitting a proposed management plan for approval by the Institutional Official.

A management plan may impose any condition and prescribe any action necessary to manage a Financial Conflict of Interest, including an action reducing or eliminating the Financial Conflict of Interest, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include, but are in no way limited to:

- public disclosure of the conflict of interest in presentations and publications;
- for human subjects research, direct disclosure of the conflict of interest to research participants;
- appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
- modification of the research plan;
- change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- divestiture or reduction of the financial interest; or
- severance of relationships that create an actual or potential Financial Conflict of Interest.

The management plan must be in the form of a written agreement and must provide that the Investigator acknowledges receipt of the approved plan and understands the requirements of this Policy and the required actions and other terms of the plan.

c. Reporting

Should any Financial Conflict of Interests or non-compliance require reporting to PHS, NSF, or other funding agencies which require such disclosure and reporting, the ORSPO, in consultation with the Institutional Official or the COI Committee, will report as required.

In general, PHS regulations require a Financial Conflict of Interests Report include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the management plan.

d. Non-Compliance

- i. *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 or the COI Committee, as applicable, and will notify the individual of the right to appeal the decision.

- ii. *Retrospective Review Required by PHS:* 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, the Institutional Official or the COI Committee, if designated by the Institutional Official, will complete a retrospective review of the Investigator's activities and the PHS funded project to determine whether the PHS funded project conducted during the period of non-compliance was biased in the design, conduct or reporting of such project.

The ORSPO, in consultation with the Institutional Official or the COI Committee, will report to PHS any Financial Conflict of Interests determined as a result of the retrospective review in accordance with PHS regulations. If bias is found through retrospective review, ORSPO, in consultation with the Institutional Official or the COI Committee, will notify PHS promptly and submit a mitigation report in accordance with PHS regulations.

e. Training Required by PHS

Each Investigator must complete training and provide proof of completion of training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, when an investigator

is new to the institution, or if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities.

Financial Conflict of Interests Training will be attained via the Collaborative Institutional Training Initiative's (CITI) Financial Conflict of Interest Module. Upon successful completion, Investigator, as defined herein, shall provide a completion certificate to the ORSPO.

The ORSPO, in consultation with the Institutional Official, is responsible for ensuring that each Investigator, as defined herein, completes training as required under this Policy.

f. Record Retention

The ORSPO 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 funding agency or to the prime awardee or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

g. 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 research of the faculty member, to a requestor of information concerning Financial Conflict of Interests related to PHS, NSF or other applicable agency funding, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

h. Public Accessibility

- i. *Public Accessibility Required by PHS:* Institution shall make this Policy available via a publically accessible website at <http://www.uiw.edu/orgs/research/compliance/fcoi.html>.
- ii. Prior to the expenditure of funds, Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interests held by PHS senior/key personnel that meets the following criteria:
 - The Significant Financial Interest was disclosed and is still held by the senior/key personnel;
 - A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
 - A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

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

- iii. *Public Accessibility Required by Other Agencies:* Should any other funding agency require public accessibility of Financial Conflict of Interests, the Institution shall provide such public access as required.

- i. Subrecipients

If a PHS funded project involves a subrecipient, the Institution will take reasonable steps to ensure that any subrecipient investigator complies with the PHS Financial Conflict of Interest policy by:

- confirming that the subrecipient is listed on the Federal Demonstration Project (FDP) FCOI Clearinghouse; or
- documenting that the subrecipient has a financial conflict of interest policy that complies with the regulation; or
- if the subrecipient cannot so document, requiring the subrecipient to follow the financial conflict of interest policy of the Institution.

The University, through the ORSPO, will report to the funding agency any financial conflicts of interest which are identified by any subgrantee, subcontractor, or collaborator to the University in the manner required under PHS regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified financial conflict of interest.

- VI. References

- a. 2 CFR 200.112, Conflict of Interest
- b. NSF Proposal & Award Polices & Procedures Guide, Part II: Award, Administration and Monitoring of Grants and Cooperative Agreements, Chapter IX: Grantee Standards, A. Conflict of Interest Policies
- c. Public Health Service (PHS): Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought, 42 CFR 50, Subpart F