

Financial Conflict of Interest Policy

PURPOSE

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of Partners In Health (“PIH”) research and to comply with federal regulations.

This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F). This regulation was developed to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of research funded under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. An electronic version of the regulation is found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of financial conflict of interest. A complete list of official definitions can be found at 42 CFR 50.603.

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

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

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for, or receiving NIH research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy 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 or will be responsible for the design, conduct, or reporting of research funded by the NIH, 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.

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 NIH by the Institution under the regulation.

Significant Financial Interest (SFI)

(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:

(i) 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;

(ii) 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any 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; provided, however, that this disclosure requirement does not apply to travel that 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: 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; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

SUMMARY OF PROCESS

Significant Financial Interests (SFI), as defined above, shall be disclosed on the Significant Financial Interest Disclosure Form (Exhibit 1) by an Investigator requesting government-sponsored or company-sponsored funds for a research project or by an Investigator when a Significant Financial Interest arises during the course of research. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFI Disclosure Form annually.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects' approval.

The Significant Financial Interest Disclosure Form and supporting materials are forwarded to the PIH Grants Management & Compliance team at compliance@pih.org for review. The Grants Management & Compliance team will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

A SFI review must be completed before any expenses are incurred under an award.

Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the Grants Management & Compliance team at compliance@pih.org. Annual updates and newly acquired interests are reported using the Significant Financial Interest Disclosure Form.

TRAINING

FCOI training is required for all Principal Investigators and any other personnel involved with an NIH funded project that the Principal Investigator has determined should also be trained.

Training should be provided through the institution serving as the Prime Recipient of the NIH-funded research grant. Only in cases where this is not possible, an online training course is available at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Reasonable attempts must be made to first secure training through the Prime Recipient before the online course may be used.

Upon completion of the training, a certificate of completion must be sent to the Grants Management & Compliance team at compliance@pih.org. You should retain a copy for your records. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by PIH due to changes in the FCOI policy, non-compliance of an Investigator/Key Personnel or if the Principal Investigator or Investigator/Key Personnel are new to PIH. At a minimum, the FCOI training shall be taken every three (3) years.

PROCEDURES

A. Identification of Persons Required to Disclose a Significant Financial Interest - It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators or other Key Personnel who have a SFI requiring disclosure under this policy and to ensure that a SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

B. Submission and Review of Significant Financial Interest Disclosure Form - Every individual having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the Grants Management & Compliance team at compliance@pih.org. An initial review of the SFI Disclosure Form will be conducted by the Grants Management & Compliance team to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts.

All management plans are required to be signed by the Investigator and the Director of Grants Management & Compliance. Compliance of the management plan shall be monitored by the Grants Management & Compliance team.

C. Annual Reporting and After-Acquired Significant Financial Interests – All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the Grants Management & Compliance team at compliance@pih.org.

D. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the Director of Grants Management and Compliance shall make recommendations to the General Counsel regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, the Company shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its

own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

E. Record Keeping – Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Grants Management & Compliance team for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

G. Federal Reporting – The Grants Management & Compliance team is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

i. Initial report – prior to PIH’s expenditure of any funds under a NIH-funded research project, PIH must provide to the NIH, or the Prime Recipient in cases where PIH is a subrecipient, an FCOI report regarding any Investigator SFI found by PIH to be a financial conflict of interest in accordance with the regulation.

ii. During on-going NIH-funded research projects – PIH shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, PIH shall submit a FCOI report to the NIH, or the Prime Recipient in cases where PIH is a subrecipient, within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

iii. Annual FCOI report – For any FCOI previously reported to the NIH, or the Prime Recipient in cases where PIH is a subrecipient, PIH shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

Exhibit 1
Significant Financial Interest Disclosure Form

Name: Click or tap here to enter text. **Title:** Click or tap here to enter text.

Institution: Click or tap here to enter text.

Address: Click or tap here to enter text.

Phone: Click or tap here to enter text. **Email:** Click or tap here to enter text.

Grant Title: Click or tap here to enter text.

Prime Recipient of the Grant: Click or tap here to enter text.

Role on the Grant (i.e., PI, Co-PI, consultant, etc.): Click or tap here to enter text.

I am disclosing the following significant financial interests as defined in 42 CFR Part 50, Subpart F. I am attaching supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest:

- Salary or other payment for services (e.g., consulting fees or honoraria)
- Equity interests (e.g., stocks, stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)
- Travel that is sponsored or reimbursed by an outside entity
- Other significant financial interest of the investigator that possibly could affect or be perceived to affect the results of the research or educational activities funded or proposed for funding

Please explain: Click or tap here to enter text.

- I have no significant financial interests associated with this project

The Significant Financial Interest disclosed above is between the entity and:

- Myself
- A family member

What relationship, if any, is there between the business or activities of the organization and your current or planned areas of research or proposed sponsored activity?

Click or tap here to enter text.

Further I agree:

- That I have read and understood PIH's FCOI policy and will comply with all aspects of this policy.
- That I will be notified if disclosure information is requested or required by any outside entity, including, but not limited to government agencies, auditors, or funding agencies.
- To update this disclosure during the period of the award, either on an annual basis or as new reportable significant financial interests are obtained. In the case of travel, the disclosure will occur no more than 30 days after the date of travel.
- To cooperate in the development of a plan to resolve any conflicts of interest.
- To comply with any conditions or restrictions imposed by PIH to manage, reduce, or eliminate actual or potential conflicts of interests or to forfeit the award.

I certify that the disclosures made are accurate and truthful to the best of my knowledge.

Signed: _____ Date: _____
Investigator