



Financial Conflict of Interest in Research Policy

Updated as of: March 4, 2026

PURPOSE

A conflict of interest exists when financial or other interests create bias, or give the appearance of bias, that affects the truth, objectivity, reliability, or integrity of a research study. The purpose of this policy is to address conflicts of interest that may affect One PIH research studies and to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest when they occur. Research is a core element of Partners In Health's (PIH's) Strategic Plan. PIH coordination, care delivery, and university sites strive to conduct research that meets the highest ethical and scientific standards, for the benefit of our patients and the larger global health community. This policy complies with United States federal regulations regarding conflicts of interest in research, specifically [the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research \(42 CFR part 50 subpart F\)](#).

SCOPE and APPLICABILITY

This policy applies to Investigators (as defined under "Key Definitions" below) who are involved in the design, conduct, or reporting of Research (as defined under "Key Definitions" below) that is funded by the US Public Health Services (PHS) (as defined under "Key Definitions" below) to PIH. This policy also applies to any Investigator involved in Research funded by a donor to PIH who has adopted the PHS rules regarding Financial Conflicts of Interest.

STATEMENT OF POLICY

PIH requires Investigators to disclose all Significant Financial Interests (SFIs) and Sponsored Travel:

- a) Annually,
- b) In connection with any Research proposal submission to the Restricted Funding Forum, and
- c) Within 30 days of obtaining any new or increased SFI or Sponsored Travel.

Investigators must submit a Disclosure Form annually and at the time a new PHS proposal is submitted, regardless of whether an SFI or Sponsored Travel exists. Instructions and a template for submitting these disclosures are set forth below. The Conflicts of Interest Committee must approve all SFIs or Sponsored Travel for all Investigators under an award before PIH can incur any expenses under the award. Investigators should note that they must disclose SFIs and Sponsored Travel as defined below, even if the SFI or travel does not appear to relate specifically to any PHS-funded research.

PIH requires Investigators to complete regular FCOI training every 4 years. PIH Compliance will provide access to the online training module. It is the responsibility of the Investigator to ensure that their training is up to date, and to submit their updated certificate to PIH Compliance by emailing a copy to

compliance@pih.org. PIH also requires Investigators to review the PIH Research Financial Conflicts of Interest Policy and the Summary Training attached to this policy as Annex 2, annually.

KEY DEFINITIONS

Definitions in this Policy have the same meaning as those included in 42 CFR 50.603. The following definitions are summarized and provided as a reference, a complete list of definitions can be found at 42 CFR 50.603.

Investigator means any person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of Research funded by the PHS to PIH or proposed for such funding. Investigators include all senior/key personnel named under a Research proposal or award, and may include, for example, the project director or clinical lead, principal investigator, collaborators, or consultants. If there is any question about whether an individual is an Investigator for purposes of this policy, please contact PIH Compliance at compliance@pih.org.

Research means a systematic investigation, study or experiment designed to develop or 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). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

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 involved may be delegated, including the National Institutes of Health (NIH), Centers for Disease Control (CDC), Food and Drug Administration (FDA) Indian Health Services (IHS), Health Resources and Services Administration (HRSA), and Substance Abuse and Mental Health Services (SAMHSA). For the purposes of this policy PHS shall also refer to donors who have adopted the PHS FCOI rules.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of PIH, regardless of whether the Investigator is a PIH staff member, which may include for example: activities such as Research, Research consultation, teaching, professional practice, including medicine, nursing, and healthcare, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable, such as intellectual property, patents, stocks, bonds, or shares in a company.

Significant Financial Interest (SFI) means a Financial Interest (as defined immediately above) 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) An Interest with any publicly traded entity, consisting of remuneration (such as salary, payment for services, consulting fees, honoraria, paid authorship, or certain travel expenses) received from

the entity in the twelve months preceding the disclosure and/or the value of any equity interest (including any stock, stock option, or other ownership interest) in the entity as of the date of disclosure, which, when aggregated, exceeds \$5,000.

- b) An interest with any non-publicly traded entity, consisting of total remuneration received from the entity in the twelve months preceding the disclosure, that 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
- c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interests do **not** include: salary or other remuneration paid by PIH to the Investigator if the Investigator is currently employed or otherwise appointed by PIH, or 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. Please contact the PIH compliance group at compliance@pih.org with any questions about whether a financial interest constitutes an SFI.

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

Sponsored Travel means any travel (a) that is related to the Investigator's Institutional Responsibilities, and (b) the cost of which is either reimbursed to the Investigator or paid for directly on behalf of the Investigator; **except** that 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, is not treated as sponsored travel. As an example, air travel to or from an academic conference on a topic related to an Investigator's work for PIH, that is paid for by a private company, is sponsored travel that Investigators must disclose using the process described below.

DISCLOSURE PROCESS

This policy requires that each Investigator disclose **all** Significant Financial Interests and Sponsored Travel in the manner and at the times described below. A Conflicts of Interest Committee (also described below) will review all disclosed SFIs or Sponsored Travel and determine whether they could represent a Financial Conflict of Interest. The Conflicts of Interest Committee will notify Investigators if any follow-up action is required. Follow-up actions may include management plans, designed by the Committee, to mitigate risk of bias created by the SFI or Sponsored Travel, and disclosure of the potential conflict and related management plan to external sponsors and government agencies.

Annual Disclosure. Each Investigator must submit an updated Disclosure Form annually. The form can be accessed via the [PIH Research Compliance SharePoint site](#). Investigators must submit the form annually whether or not they have an SFI or Sponsored Travel to report. PIH will send Investigators an email reminder to submit the annual form. A sample form is also attached to this Policy as Annex 1.

Disclosure Upon Proposal Submission to Restricted Funding Forum (RFF). Any Investigator participating in the development of a proposal for PHS-funded Research on behalf of PIH must submit an updated Disclosure Form. This form may be accessed via the [PIH Research Compliance SharePoint site](#). Investigators must submit the form whether or not they have an SFI or Sponsored Travel to report.

New or Increased SFIs or Sponsored Travel. An Investigator who acquires any new or increased SFI or

Sponsored Travel must report it as soon as possible, and in any event **within 30 days** of obtaining it.

Disclosure Forms may be accessed via the [PIH Research Compliance SharePoint site](#).

TRAINING

PIH requires FCOI training for all PIH Investigators:

- a) Investigators must complete the online training, available on www.citiprogram.org every 4 years. Investigators must retain a copy of their certificate of completion for this training and send a copy to compliance@pih.org.
- b) Investigators must read the PIH FCOI Summary Training, attached to this policy as Annex 2, annually. Investigators will confirm they have reviewed this PIH FCOI Summary Training as part of their annual update to the Disclosure Form.

CONFLICTS OF INTEREST COMMITTEE

A Conflicts of Interest Committee comprises at least 3 PIH staff who will be members of Grant Compliance, Clinical, and Legal teams, and shall be responsible for reviewing conflict of interest disclosures, supporting the development of management plans, disclosing information regarding conflicts of interest as required by donors or applicable law, and addressing violations of this policy. Decisions regarding the management of any identified FCOI or violation of this policy may be elevated to relevant executive leadership as necessary and consistent with applicable conflict of interest policy.

MANAGEMENT PLANS

If the Conflicts of Interest Committee determines 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 mitigate the conflict. A management plan may require one or more of the following actions:

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

All management plans are required to be signed by the Investigator and the PIH Chief Financial Officer. Compliance of the management plan shall be monitored by the Grant Management & Compliance team.

VIOLATIONS, RECORD KEEPING AND REPORTING

- a) **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, a Conflicts of Interest Committee shall make recommendations to the PIH General Counsel and the PIH Chief of Human Resources, who will consult with relevant site leadership, regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, PIH will 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.

- b) **Record Keeping** – Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by PIH 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. Records relating to violations of this policy and actions taken to address them will be retained in accordance with PIH’s record retention policy.

- c) **Federal Reporting** – PIH must report the 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 FCOI in accordance with the regulation.
- ii. **During on-going NIH-funded research projects** – PIH shall submit an FCOI report to the NIH, or the Prime Recipient in cases where PIH is a subrecipient, within 60 days after its determination that a new FCOI exists. If an FCOI was not disclosed timely, PIH shall submit an FCOI report within 60 days of PIH’s discovery of the FCOI. In such a case, PIH will also complete a retrospective review of the FCOI and submit this retrospective review within 120 days of discovery of the FCOI.
- 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.

Version	Date		Revision Notes
0.2	March 4, 2026	Revised	Clarified reporting requirements and added links to new online materials

Annex 1
Financial Conflict of Interest Disclosure Form

Name:

Email:

Award Title(s):

Prime Recipient of the Award(s):

Role on the Award(s) (i.e., PI, Co-PI, consultant, etc.):

Award Title	Is PIH the Prime Recipient of the Award	Are you the PI or Co-PI on the Award?

1. Significant Financial Interests

I have no Significant Financial Interests as defined in the PIH Financial Conflict of Interest in Research Policy

I am disclosing the following Significant Financial Interests. (The Conflicts of Interest Committee will follow up for more information):

- 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)
- 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:

2. Sponsored Travel

I have no Sponsored Travel as defined in the PIH Financial Conflict of Interest in Research Policy.

I am disclosing the following Sponsored Travel (for each trip, please specify the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration):

Further I agree:

- That I have read and understood PIH’s Financial Conflict of Interest in Research Policy, including the PIH FCOI Summary Training attached to the policy as Annex 2, and will comply with all aspects of this policy.
- To update this disclosure during the period of the award, either on an annual basis or as new Significant Financial Interests or Sponsored Travel are obtained. In the case of new SFIs or travel, the disclosure will occur no more than 30 days after the date of travel.

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

Signed: _____ Date: _____
Investigator

Annex 2

PIH Research Financial Conflicts of Interest Summary Training

In order to ensure the objectivity and reliability of its research activities, PIH requires key personnel participating in research that is funded (directly or through one or more subawards or subcontracts) to PIH by the US Public Health Service (a collection of US government agencies that includes the NIH and CDC), to undergo regular training regarding financial conflicts of interest and to disclose certain financial interests. Key research personnel should note that they must disclose to PIH all “significant financial interests” and all “sponsored travel” (in each case as defined in the policy) that could reasonably appear to relate to their professional responsibilities at PIH, regardless of whether those interests or travel relate specifically to work performed in connection with USG-funded research. For full details, please review the PIH Financial Conflicts of Interest in Research Policy. This summary training is intended to give general guidance for complying with that policy.

The individuals subject to the financial conflicts of interest (FCOI) disclosure and training requirements are referred to in the policy as “Investigators.” “Investigator” for this purpose includes all senior/key personnel named under a proposal or award for Research funded by the PHS. If you have any question about whether you or any other individual is an Investigator for purposes of the policy, please contact PIH Compliance at compliance@pih.org.

Investigators are required to complete FCOI training in order to comply with PIH policy. Investigators can complete the required training online using the CITI training program: [www.citiprogram.org]. Please note that the FCOI training is separate from IRB or other modules within the CITI suite of research trainings. This training is specific to FCOI and must be updated every four years. Please be sure to retain a copy of your certificate and send a copy to compliance@pih.org.

Investigators are required to disclose any Significant Financial Interests and Sponsored Travel, as defined in the policy:

- a) Annually,
- b) In connection with any proposal for PHS-funded research, and
- c) Within 30 days of obtaining any new or increased Significant Financial Interest or Sponsored Travel.

Disclosures can be made via the [PIH Research Compliance SharePoint site](#), or by using the form attached to the policy as Annex 1. Investigators must submit a Disclosure Form annually and at the time a new PHS proposal is submitted, **regardless of whether a Significant Financial Interest or Sponsored Travel exists.**

Individuals who do not comply with this policy risk imposition by PIH of sanctions and/or disciplinary proceedings.