



Partners In Health Financial Conflicts of Interest Policy

In accordance with the requirements set forth by the Public Health Service (PHS), , Partners In Health (PIH) has established a Financial Conflict of Interest (FCOI) policy guided by federal regulations elaborated in 42 CFR Part 50 Subpart F (for grants and cooperative agreements) and 42 CFR Part 94 (for contracts). The Public Health Service informs the policy of several United States federal granting agencies such as the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC). Grants, Cooperative Agreements and Contracts awarded by these agencies, as well as any subcontracts originating from these agencies require compliance to the PHS FCOI requirements. These requirements are in addition to the rules set forth in the PIH Conflicts of Interest (COI) Policy and apply to all “investigators,” as defined below, in a research project for which an application for funding has been made through and/or granted to PIH.

I. Definitions.

A. Designated Officials. The Designated Officials will be the Chief Program Officer or the Chief Operating Officer.

B. Financial Conflict of Interest (FCOI). A Significant Financial Interest (SFI – please see below) or Travel that could directly and significantly affect the design, conduct, or reporting of Research.

C. Investigator. The project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research supported by a grant awarded to PIH.

D. PHS. The Public Health Service, including the various agencies that are designated as components through which research grants are issued. The PHS, through its funding agencies, implements and enforces the Department of Health and Human Services’ (HHS) Rule entitled “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors” and codified at 42 C.F.R. Parts 50 and 94.

E. Research. Any sponsored program falling under the purview of the PIH Financial Conflict of Interest policy.

F. Reviewable Interest. Any Significant Financial Interest (SFI) belonging to an Investigator or an investigator’s family, and any Travel reimbursement, to the extent either relates to the Investigators’ Institutional Responsibilities.

G. Significant Financial Interest (SFI). A financial interest consisting of one or more of the following interests:

1. With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measure of fair

market value) in the entity as of the date of the disclosure exceeds \$5,000.

2. With respect to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000, or any equity in the entity; or
3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

Exclusions: The term Significant Financial Interest does not include the following types of financial interests: 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.

- H. **Travel.** Any Travel that is reimbursed (i.e., the Investigator is made whole for the financial outlay required) or sponsored (i.e., the costs are paid on behalf of the Investigator such that the exact monetary value may not be readily available) other than by PIH, 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.

Protocols for Disclosure

- II. **Investigator Disclosure to PIH.** All PIH Investigators conducting Research must disclose the information required herein and by the PIH FCOI policy on an annual basis. At a minimum and no later than the time of application Investigators planning to participate in PHS-funded Research are required to disclose all Reviewable Interests (namely, (i) any Significant Financial Interests (SFIs) belonging to the Investigator or the Investigator's family, and (ii) any Travel that is reimbursed by a qualifying entity as described below). Investigators must update their disclosures annually during the period of the PHS award, as well as within 30 days of discovering or acquiring a new Reviewable Interest.

A. *Travel Disclosures:* Only PHS-funded Investigators are required to disclose Travel. The following information must be provided in connection with any Travel disclosure provided in the context of PHS-funded Research:

1. The purpose of the trip;
2. The identity of the sponsor/organizer of the trip;
3. The destination of the trip; and

4. The duration of the trip.

B. *Additional Information Requested by PIH:* Investigators must provide in a timely manner any information related to their disclosed Reviewable Interests that PIH, in its discretion, deems relevant to its review and FCOI assessment.

III. **Review by PIH.** Prior to expenditure of any funds under a Sponsored Research award, the Designated Official must reasonably determine whether any Reviewable Interest disclosed by any Investigator is related to the Research; if so, whether it can reasonably be determined that the Reviewable Interest constitutes a Financial Conflict of Interest (FCOI); and if an FCOI is determined to exist, how the FCOI will be managed. The determinations of the Designated Official will be informed by the recommendations of the PIH Audit Committee.

A. *Relatedness Standard:* An investigator's Reviewable Interest is related to Research when PIH reasonably determines that the Reviewable Interest could be affected by the Research; or is in an entity whose financial interest could be affected by the Research. PIH will be informed by the relevant Investigator in the determination of whether a Reviewable Interest is related to the Research.

B. *FCOI Standard:* An FCOI exists if PIH reasonably determines that the Reviewable Interest related to the Research could directly and significantly affect the design, conduct or reporting of the Research.

IV. **Management of Identified FCOIs.**

A. *Management Techniques:* For any identified FCOI, PIH, through its Designated Official and with the advice and counsel of the Audit Committee of PIH, will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan.

B. *Disclosed Interests That are Not FCOIs:* PIH reserves the right to impose any requirements it sees fit on any disclosed interest, even those that are not prohibited by the PIH FCOI policy, do not constitute Reviewable Interests and/or do not constitute an FCOI requiring management in accordance with this policy and/or applicable regulations.

C. *Compliance with Management Plans:* Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this policy. PIH will monitor Investigator compliance with an imposed management plan on an ongoing basis until the completion of the Research project.

V. **Reporting FCOIs to PHS.**

A. *Content of Report:* For all PHS awards, prior to expenditure of any funds under the award, PIH is required to report to the PHS awarding agency the existence of an FCOI and submit an FCOI report.

B. *Timing of Report:* PIH is responsible for submitting FCOI reports to PHS initially (prior to expenditure of funds), annually during the award period, and within 60 days of any subsequently identified FCOI.

VI. **Subrecipient.** When proposed PIH Research is to be funded by PHS and carried out through a subrecipient, PIH will incorporate as part of a written

agreement with the subrecipient terms that establish whether this policy, or that of the subrecipient will apply to the subrecipient's investigators, as well as the time frames within which the subrecipient must provide any information necessary to ensure that PIH is able to meet its reporting obligations to the PHS awarding agency.

- VII. **Public Accessibility.** For PHS-funded Research, PIH will ensure public accessibility of information concerning the FCOIs currently held by personnel subject to this policy.
- VIII. **New Interests that Arise During an On-Going Research Project.** To the extent a new Reviewable Interest is disclosed to PIH in the course of an on-going Research project (i.e., an Investigator who is new to participating in the research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), or PIH identifies a Reviewable Interest that was not previously reviewed in a timely manner by PIH in accordance with this policy, PIH will, within 60 days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the investigator's Research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with this policy. PIH may, depending on the circumstances of the SFI, conclude that additional interim measures are necessary with regard to the investigator's participation in the Research between the date of disclosure or identification and the completion of PIH's review (including, where warranted for PHS-funded Research, a retrospective review as discussed below).
- IX. **Retrospective Review, Identification of Bias and Mitigation Reporting of PHS-Funded Research.**
- A. *Retrospective Review.* For PHS-funded Research, in the event of failure to meet PHS regulations, including failure by the Investigator to disclose timely a Reviewable Interest that is determined to constitute an FCOI; PIH's failure to review or manage such an FCOI; or Investigator failure to comply with an FCOI management plan, PIH will, within 120 days of its determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine any bias in the design, conduct or reporting of research during the time period of the noncompliance. PIH will document the retrospective review in accordance with applicable PHS regulations.
- B. *Mitigation.* If bias is found during the retrospective review of PHS-funded Research, PIH will notify the PHS awarding agency promptly, if applicable, develop and implement a mitigation plan, and submit the PHS required mitigation report, which will include at least the elements documented in the retrospective review and a description of the impact of the bias on the Research and PIH's plan of action or actions taken to eliminate or mitigate the effect of the bias. Any FCOI report submitted to the PHS awarding agency with respect to such Research will be updated as necessary in light of the results of the retrospective review.
- C. *Disclosure for PHS-Funded Drug/Device Research:* In any case in which the Department of Health and Human Services (HHS) 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 an FCOI that was not managed or reported by PIH, the Investigator will be required to disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

- X. **Training.** For PHS-funded Research, investigators must complete all required conflicts of interest training prior to engaging in research at or under the auspices of PIH, and at least every four years following the initial training. Additionally, investigators will be required to receive training immediately in any of the following circumstances:
- PIH revises its policy or procedures governing FCOI in PHS-funded Research in any manner that affects the requirements applicable to Investigators;
 - An Investigator is new to PIH;
 - PIH finds that an Investigator is not in compliance with this policy or an imposed management plan.
- XI. **Record Retention.** PIH will retain documentation related to its FCOI review and management process to the extent required by law and any other applicable PIH record retention policies.
- XII. **Noncompliance and Sanctions.** In the event an Investigator fails to comply with this policy or an FCOI management plan imposed hereunder, the PIH Executive Leadership Committee may impose a wide variety of sanctions, including but not limited to restricting or conditioning the investigator's ability to apply for grants through PIH. Additionally, if the failure of an Investigator to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of PHS-funded Research, PIH shall promptly notify the PHS awarding agency of the corrective action taken or to be taken.