



Document Title : **Financial Conflict of Interest in Research Activities Funded through US Public Health Service**

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Approval Statement : *Electronic signatures and signature dates of those individuals who prepared and approved this document are maintained in the FHI 360 Enterprise Document Management System database.*

Title	Financial Conflict of Interest in Research Activities Funded through US Public Health Service	Policy:	POL 06017
		Effective Date:	2019-08-31
		Version:	6

PURPOSE:

To define the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of FHI 360 research activities funded through the US Public Health Service (PHS).

SCOPE:

This policy applies to FHI 360 staff, collaborators, and sub-recipients receiving funding from, planning to apply for funding from, or having a salary funded by a grant or contract from any US PHS agency (Sponsor). FHI 360 staff, collaborators, and sub-recipients funded through the National Institute of Allergy and Infectious Disease Division of Acquired Immunodeficiency Syndrome (NIAID DAIDS) clinical research networks, such as HIV Prevention Trials Network, the International Maternal-Pediatric-Adolescent AIDS Clinical Trials Network, Microbicide Trials Network, (this list is not exhaustive), are deemed to comply with this policy as long as they complete the requirements through the NIAID DAIDS central network management as described in the document entitled “NIH HIV/AIDS Clinical Trials Networks, Financial Disclosure and Conflict of Interest Guidelines, Standard Operating Procedure” (see References).

DEFINITIONS:

1. *Financial Conflict of Interest (FCOI)* – A significant financial interest of each individual who may directly and significantly affect the design, conduct, or reporting of PHS-funded research.
2. *Public Health Service (PHS), hereinafter referred to as Sponsor* – The operating division of the US Health and Human Services Department (HHS) responsible for promoting the protection and advancement of the American population’s physical and mental well-being. PHS includes the following agencies and offices: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substance and Disease Registry (ATSDR), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Office of Global Affairs (OGA), Office of the Assistant Secretary for Preparedness and Response (OASPR), Office of the Assistant Secretary for Health (ASH), and Substance Abuse and Mental Health Services Administration (SAMSHA).
3. *PHS-Funded Investigator* – The Project Director (Project Leader), Principal Investigator, any other person identified by FHI 360 as senior/key personnel, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research supported through PHS funds.
4. *Research* – 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 and product development. 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.

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5. *Significant Financial Interest (SFI)* – 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 related to the investigator’s institutional responsibilities:
- For any publicly traded entity, a SFI 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;
 - Regarding any non-publicly traded entity, a SFI 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,
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

SFI does not include: (1) salary, royalties or other remuneration from FHI 360; (2) salary, royalties, or other payments from any source other than FHI 360 that, when aggregated for the investigator, spouse and dependent children in the 12 months preceding disclosure, are not expected to exceed \$5,000; (3) income from seminars, lectures, or teaching engagements, service on advisory committees or review panels sponsored by federal, state, or local government agencies, 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; (4) income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not control such fund’s or account’s investment decisions.

6. *Sub-recipient* – Any party that has entered into an agreement with FHI 360 as a sub-grantee, sub-contractor, collaborator, contractor, or consultant.

POLICY:

1. FHI 360 requires that PHS-funded investigators that receive funding from, plan to apply for funding from, or have a salary supported by US PHS funds comply with the PHS rules on training, disclosure, and establishment of financial conflict of interest (FCOI) in research. The following requirements apply in fulfillment of PHS FCOI in research activities:
 - 1.1 Training Requirements
 - PHS-funded investigators will complete a PHS-compliant FCOI training program prior to engaging in a PHS research project and thereafter, every four years (as long as they continue to be engaged in PHS supported research), or immediately if the FCOI policy or the training

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requirements are modified, or the investigator is found not to be in compliance with this policy or FCOI management plan.

- FHI 360 PHS-funded investigators shall comply with these training requirements by completing the NIH FCOI training module. The course is named “Financial Conflict of Interest (FCOI)” and can be found at the link below:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

1.2 Disclosure, Review and Monitoring Requirements

- PHS-funded investigators will complete a US PHS Significant Financial Conflict of Interest Disclosure Form (APX 06017_01) disclosing SFI that could reasonably appear to be related to their institutional responsibilities at the time of the PHS funding application. Further, PHS-funded investigators will provide an updated US PHS Significant Financial Conflict of Interest Disclosure Form, annually or within 30 days of a change in financial status (whichever comes first).
- FHI 360’s Director, Clinical Regulatory and Compliance (CRC), is the designated official to review SFI disclosures and determines whether disclosed SFI constitute a FCOI.
- In instances when a FCOI is identified, the Director, CRC, will notify the respective Operating Unit (Business Unit [BU] or Regional Office [RO] Director) and the Office of General Counsel (OGC), who, in collaboration with the PHS-funded investigator, will develop an FCOI management plan prior to the expenditure of funds and in conformance with PHS standards and other applicable federal and sponsor requirements.
- The Operating Unit (BU, RO) Director or designee shall monitor PHS-funded investigator compliance with established management plans

1.3 Reporting Requirements

- FHI 360 OGC or designee shall provide FCOI reports to Sponsors regarding disclosed and identified FCOI in conformance with applicable Sponsor requirements and prior to the expenditure of funds.
- FHI 360 OGC or designee shall submit an FCOI report prior to the expenditure of funds, within 60 days after its determination that a new FCOI exists. If an FCOI is not disclosed in a timely manner, FHI 360 shall submit an FCOI report to the Sponsor within 60 days of the discovery, as well as complete a retrospective review of the PHS-funded investigator SFIs within 120 days of discovery of noncompliance.
- FHI 360 OGC shall provide annual FCOI reports to the Sponsor addressing the status of the FCOI and any changes to its related management plan.

1.4 Sub-recipient Requirements

- Sub-recipients shall provide a certification that their FCOI policy complies with the US PHS FCOI regulation and that their portion of the research project (as detailed in their sub-award agreement) is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, the entity shall notify the Director, CRC, of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with US PHS FCOI regulations.
- Sub-recipients that do not have their own FCOI policy may agree to follow and comply with the requirements of this policy. FHI 360 will not finalize any sub-award agreement requiring compliance with US PHS FCOI disclosure until the sub-recipient either certifies it has an FCOI policy which it will follow, or in the absence of an internal policy, will comply with the requirements of this FHI 360 FCOI policy.

1.5 Public Accessibility Requirements

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- In accordance with the applicable regulations this policy is posted on the FHI360.org external website.
- Information concerning an identified FCOI will be available via written request to the Director, CRC at FHI360. The information will be made available within five business days of such a request and will include the following information:
 - The PHS-funded investigator’s name;
 - The title and role of the PHS-funded investigators with respect to the research project;
 - The name of the entity in which the SFI is held;
 - The nature of the SFI; and
 - The approximate dollar value of the SFI 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.

1.6 Compliance Requirements

- PHS-funded investigator(s) working on clinical research projects to evaluate the safety and efficacy of a drug, medical device, or treatment who fail to disclose an FCOI, or where an FCOI is not managed in accordance with this policy, shall disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.
- FHI 360 shall follow Sponsor regulations regarding the notification of the sponsoring agency in the event a PHS-funded investigator has failed to comply with this policy.
- Failure to comply with this policy may result in disciplinary action, up to and including termination of employment at FHI 360.

2. Responsibilities

- 2.1 Business Development & Diversification (BDD) is responsible for:
- Informing PHS-funded investigators of the requirement to submit a US PHS Significant FCOI Disclosure Form and evidence of completed FCOI training to the Director, CRC - prior to a PHS proposal submission.
- 2.2 PHS-funded investigators are responsible for:
- Ensuring that all PHS-funded investigators have completed the required PHS FCOI training and declaration requirements before a PHS proposal submission deadline, and for the duration of the project implementation (including extensions with or without funds), as required by US federal regulations; and
 - Facilitating disclosure of PHS-funded investigator and sub-recipient investigator FCOIs to the Director, CRC at FHI 360, for the duration of the project implementation (including extensions with or without funds).
- 2.3 The Director, CRC is responsible for:
- Reviewing US PHS Significant FCOI Disclosure Forms and making FCOI determinations;
 - Notifying Operating Unit Directors in cases when FCOIs have been identified and requesting development of FCOI management plans;
 - Notifying the OGC and Operating Unit Directors or their designees when PHS-funded investigators are found to be in violation of this policy for development of mitigation activities; and
 - Maintaining records of and related to financial interest disclosures and FCOI determinations for a minimum of three years from the date of submission of the final expenditures report.
- 2.4 Contract Management Services (CMS) is responsible for:
- Verifying completion of training and management plans (if applicable) prior to release of funds, and after the proposal has been awarded;

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- Obtaining certifications from sub-recipients that such sub-recipient has a PHS-compliant FCOI policy. If the sub-recipient does not have a PHS-compliant FCOI policy, FHI 360’s policies will be followed; and
 - Verifying that any new personnel who are identified by the Project Director or Principal Investigator as meeting the definition of PHS-funded investigator and who have been added to an award or proposal have the needed FCOI documentation.
- 2.5 The FHI 360 OGC is responsible for:
- Reporting FCOIs to sponsors according to established sponsor procedures;
 - Providing mitigation reports for non-compliance to sponsors; and
 - Maintaining the required public information on the FHI360.org external internet site.
- 2.6 CRC is responsible for providing technical assistance in the collaborative review of this policy and identifying training options for FHI 360 PHS-funded investigators.
3. This policy does not limit the impact of any foreign laws or regulations, local institutional policies or external sponsor requirements that may be applicable and may impose additional requirements.

For questions related to this policy, contact: Director, CRC.

RELATED DOCUMENTS:

1. Policies

- POL 02004: Conflicts of Interest

2. Standard Operating Procedures

- SOP 03017: Process for Financial Conflict of Interest Disclosure in Research Activities Funded through U.S. Public Health Service

3. Appendices

- APX 06017_01: US Public Health Service Significant Financial Conflict of Interest Disclosure Form
- APXS 03017_01: FHI 360 Guidance for identifying PHS-funded investigators

REFERENCES:

1. US Code of Federal Regulations, Title 42: Part 50 (Subpart F): Promoting Objectivity in Research
2. US Code of Federal Regulations, Title 45: Subpart 94: Responsible Prospective Contractors
3. “NIH HIV/AIDS Clinical Trials Networks, Financial Disclosure and Conflict of Interest Guidelines, Standard Operating Procedure” https://www.hanc.info/smetl/Documents/Cross-network%20FDCOI_SOP.pdf, Version 7.0, April 19, 2018
4. NIH PHS FCOI resources: <http://grants.nih.gov/grants/policy/coi/index.htm>
5. NIH Office of Extramural Research Financial Conflict of Interest Tutorial – https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

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POLICY REVISION HISTORY:

POL#	Date Reviewed (DD MMM YYYY)	Summary of Changes
125.00	--	New
POL 06017	16 APR 2013	New POL number for EDMS migration
POL 06017	20 APR 2015	Revised responsibilities section and requirements for sub-recipients that do not have their own FCOI policy
POL 06017	2 NOV 2015	Minor change to replace Business Planning and Proposals with Business Development & Diversification on clause 2.1 due to organizational restructuring
POL 06017	2 DEC 2016	Changed designated official to review SFI from Chief Compliance Officer to Director Clinical Regulatory and Compliance. Changed all places where Chief Compliance Officer noted to Director, CRC. Updated link for training information on FCOI. Added clarification regarding responsibilities for Contract Management Services (CMS).
POL 06017	14 JUN 2017	Minor administrative change to update the link to the FCOI training on clause 1.2.
POL 06017	07 JUL 2019	Clarify significant financial interest definition to include sponsored travel and update to training link.