

PUBLIC HEALTH SERVICES AWARDS FINANCIAL CONFLICTS OF INTEREST POLICY

1. INTRODUCTION

In this Financial Conflict of Interest Policy (**Policy**), references to The George Institute are to The George Institute for Global Health, together with its subsidiary and associated companies worldwide (**The George Institute** or **TGI**).

The George Institute aims to conduct its operations with integrity and credibility and consistently with international standards which promote objectivity in research. This Policy applies to TGI and to investigators undertaking any research-related work in any capacity for, or on behalf of, TGI on projects funded by the US Public Health Service (**PHS**). This may include permanent or temporary employees, students, consultants, contractors, secondees, volunteers, and any other associates undertaking work if they fall within the definition of Investigator below (i.e. they are responsible for the design, conduct, or reporting of research funded by the PHS).

The PHS has adopted regulations (42CFR Part 50 Subpart F) (the **Regulations**) on *Promoting Objectivity in Research*. The Regulations establish standards for institutions and investigators in order to provide a reasonable expectation that the design, conduct and reporting of research funded under PHS grants will be free from bias resulting from investigator financial conflicts of interest. The Regulations apply to The George Institute and to its investigators who apply for or receive PHS research funding by a prime grant and to subawards where the originating sponsor is PHS.

The Regulations require investigators to disclose significant financial interests related to their institutional responsibilities before submitting applications for funding to PHS (e.g. funding from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control), or to a PHS Grantee¹.

2. DEFINITIONS

Conflict of interest Committee or **COIC** means The George Institute's committee to consider and manage conflicts of interest.

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of TGI and as defined in this Policy, which may include for example: activities such as

¹This policy may also be used for subawards under a non-PHS sponsor which adopts the PHS *Promoting Objectivity in Research* regulations

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 who is responsible for the design, conduct, or reporting of PHS-funded research, or who applies for such funding, which may include, for example, collaborators or consultants.

PD/PI means a project director or Principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator.

PHS Awarding Component means the organizational unit of the PHS that funds the research.

PHS Grantee is the organisation that receives a prime award directly from the PHS and under that prime award, issues a subaward to a subrecipient.

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report TGI submits to the PHS.

Significant Financial Interest or SFI means:

- (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) publicly traded entities: 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 for the Investigator, Investigator's spouse and dependent children, exceeds US\$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) non-publicly traded entities: 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 US\$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): a significant financial interest exists if the Investigator receives income greater than US\$5,000 related to such rights and interests.
- (2) **Third party reimbursed or sponsored travel** paid on behalf of the Investigator and/or the Investigator's spouse/dependent children of greater than US\$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed by Investigators to TGI. This

disclosure must include, the purpose of the trip, the identity of the sponsor/organiser, the destination, and the duration. Travel paid for by The George Institute is excluded¹

- (3) The term significant financial interest does not include the following types of financial interests:
- (i) Salary, royalties, or other remuneration paid by TGI to the Investigator if the Investigator is currently employed or otherwise appointed by TGI including intellectual property rights assigned to TGI and agreements to share in royalties related to such rights;
 - (ii) 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;
 - (iii) Income from seminars, lectures, or teaching engagements sponsored by a U.S. 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 centre, or a research institute that is affiliated with an Institution of higher education; or
 - (iv) Income from service on advisory committees or review panels for a U.S. 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 centre, or a research institute that is affiliated with an Institution of higher education.

3. SUBRECIPIENTS AND SUBAWARDS

If The George Institute carries out PHS-funded research through a subrecipient (e.g. subcontractors or consortium members, but excluding vendors providing routine goods and services), then The George Institute must enter into formal, written agreements with each subrecipient to ensure that the subrecipient complies with the Regulations by:

- (1) Incorporating in a written agreement (the **Agreement**) with the subrecipient terms that establish whether The George Institute's financial conflicts of interest policy or the subrecipient's policy will apply to the subrecipient's Investigators.
- (i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy:
 - a. Either, the subrecipient must certify in the Agreement that its policy complies with the Regulations or the Agreement must require subrecipient Investigators to comply with The George Institute's financial conflicts of interest policy.
 - b. The Agreement must include time period(s) for the subrecipient to report all identified financial conflicts of interest to The George Institute in a timeframe that allows The George Institute to report identified FCOIs as required by the Regulations.

¹ The following are also excluded: travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. 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

- (ii) Alternatively, if the subrecipient's Investigators must comply with The George Institute's financial conflicts of interest policy, the Agreement must require

The George Institute to solicit and review subrecipient Investigator disclosures that enable The George Institute to identify, manage and report identified FCOIs as required by the Regulations.

- (2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with the Regulations, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI

4. DISCLOSURES

The Conflict of Interest Committee will solicit and review disclosures of SFIs from Investigators planning to participate in PHS funded research or who are currently participating in PHS funded research.

Each Investigator planning to participate in PHS-funded research (whether under a prime award or a subaward) must disclose to the COIC an up-to-date listing of their SFIs (and those of their spouse and dependent children), no later than at the time of application. Investigators who are new to a research project, must disclose their SFIs to the COIC promptly and prior to participation in the project.

While the COIC will solicit and review disclosures of SFIs, typically, TGI's designated official will be the Investigator's manager (the **Designated Manager**).

Investigators must submit an updated disclosure of SFI at least annually, during the period of the award. The disclosure must include any information that the Investigator did not disclose initially, or in a subsequent SFI disclosure (e.g. a Financial Conflict of Interest on a PHSfunded project that was transferred from another Institution), and must include updated information regarding previously disclosed SFIs (e.g. the updated value of a previously disclosed equity interest).

Each Investigator who is participating in PHS funded research must submit an updated SFI disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.

5. REPORTING FINANCIAL CONFLICTS OF INTEREST

The George Institute will provide initial and ongoing FCOI reports to the PHS as described in this section and in the associated Work Instruction GE-WI Managing Financial Conflict of Interest.

The initial FCOI report must be sent to the PHS Awarding Component (if The George Institute is the holder of the prime award) or PHS Grantee (if it is a subaward), prior to the expenditure of any PHS funds. The FCOI report must detail any Investigator's SFI found to be conflicting and TGI must implement a management plan. No report is required if the FCOI is eliminated before expenditure of PHS-awarded funds. For subawards, TGI cannot incur expenditure until it has received approval from the PHS Grantee. For prime awards held by TGI, no funds can be spent until the procedures in this paragraph have been completed.

While the PHS-funded research is ongoing (including any extensions with or without funds), TGI will provide to the PHS Awarding Component or PHS Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any SFI that is identified as conflicting subsequent to the initial FCOI report (e.g. a new Investigator on a research project, or a newly identified FCOI), TGI must provide within 60 days to the PHS Awarding Component or PHS Grantee, an FCOI report and ensure that the Designated Manager has implemented a management plan and the Investigator has agreed to the relevant management plan.

If an SFI that was not disclosed timely, is identified during an ongoing PHS-funded research project (e.g. it was not disclosed by the Investigator or not reviewed by TGI for whatever reason), the Designated Manager must within 60 days:

- Review the SFI
- Determine if it is related to PHS-funded research
- Determine if a FCOI exists, and if so:
 - Implement a management plan specifying the actions to manage the FCOI going forward;
 - Complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine if any PHS-funded research conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research.

More details of the contents of the retrospective review are contained in Work Instruction GE-WI Managing Financial Conflict of Interest. Based on the results of the retrospective review, TGI must update the previous FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, TGI must notify the PHS Awarding Component promptly and submit a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and TGI's plan of action(s) to eliminate or mitigate the effect of the bias (e.g. impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, TGI will submit FCOI reports annually.

The report must include sufficient information to enable the PHS Awarding Component or the PHS Grantee to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan.

If an Investigator's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, TGI must promptly notify the PHS Awarding Component (or the PHS grantee for subawards) of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to TGI for further action, which may include directions on how to maintain appropriate objectivity in the PHS-funded research project.

The Regulations allow the PHS Awarding Component and/or HHS to inquire at any time before, during, or after award into any Investigator disclosure of financial interests and TGI

review (including a retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in TGI's determination of a Financial Conflict of Interest. TGI must submit, or permit on site review of, all relevant records pertinent to compliance with the Regulations. If the PHS Awarding Component decides that a particular Financial Conflict of Interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that TGI has not managed the Financial Conflict of Interest in accordance with the Regulations, then the PHS Awarding Component may impose specific award conditions or suspend funding take other enforcement action.

6. TRAINING

Each Investigator must complete training on this Policy prior to applying for or engaging in research related to any PHS-funded grant *and* at least every four years, *and* immediately if:

- TGI revises this Policy, or related procedures, in any manner that affects the requirements of Investigators (training must be completed within the timeframe specified in communications announcing those changes);
- An Investigator is new to TGI (training is to be completed prior to his/her participation in the research); or
- TGI finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the Designated Manager).

All Investigators must complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. All Investigators must print a certificate of completion at the end of training and retain it for audit purposes.

7. CLINICAL RESEARCH

If the US department of Health and Human Services (or the prime award holder in the case of a subaward) determines that a PHS-funded clinical research project 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 a Financial Conflict of Interest that was not managed or reported by TGI, the Investigator must disclose the Financial Conflict of Interest in each public presentation of the results of the research and must request an addendum to previously published presentations.

8. FAILURE TO COMPLY WITH THIS POLICY

No expenditure of funds for PHS-funded research (whether TGI holds the prime award or is a subaward holder) is permitted unless the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with a FCOI management plan.

Failure by TGI employees to adhere to this Policy may result in disciplinary action, including, in severe cases, termination, and termination of PHS funding or the subaward.

If TGI identifies an instance of a SFI which was not identified or managed in a timely manner, the Designated Manager will manage the SFI in consultation with the COIC and in accordance with GE-WI Managing Financial Conflict of Interest.

9. PUBLIC ACCESSIBILITY OF INFORMATION RELATED TO FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any PHS-sourced funds TGI, will ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- The SFI was disclosed and is still held by the Senior/Key Personnel. Senior/Key Personnel are the PD/PI and any other person identified as Senior/Key Personnel in the application to the PHS Awarding Component or the PHS Grantee, progress report or any other report;
- TGI' has determined that the SFI is related to the PHS-funded research; and
- TGI has determined that the SFI is a Financial Conflict of Interest.

10. REVISION HISTORY

Major changes in each new version should be documented in a table; minor typing or grammatical changes do not need to be listed.

Version number	Replaces	Reason/description of change
V3.0 (09062021)	V2.0	Updated as per 42CFR Part 50 Subpart F as at May 2021 and clarification of prime awards and subawards.
V2.0 (08072013)	V1.0	Updated
V1.0	NA	First version

10. APPROVAL

Title of Owner / Author Director of Centre for Operational and Research Excellence	
Approved by: COO	