

## PUBLIC HEALTH SERVICES AWARDS FINANCIAL CONFLICTS OF INTEREST POLICY

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### 1. INTRODUCTION

In this Financial Conflicts 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**).

The George Institute aims to conduct its operations with integrity and credibility and consistently with international standards which promote objectivity in research.

The PHS regulations (42CFR Part 50 Subpart F) (the **Regulations**) on *Promoting Objectivity in Research* establish standards for institutions and Investigators 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. This Policy and the Regulations apply to The George Institute and Investigators who apply for or receive a prime grant or subaward of PHS funding.

The Regulations require investigators to disclose significant financial interests related to their institutional responsibilities before submitting applications for funding to PHS or to a PHS Grantee<sup>1</sup>. PHS funding includes funding from the National Institutes of Health, the Food and Drug Administration, the Centres for Disease Control and other organisations.

### 2. SCOPE

This Policy applies to The George Institute and to The George Institute Investigators undertaking research on projects funded by the Public Health Service of the U.S. Department of Health and Human Services (**PHS**). This Policy applies to permanent or temporary employees, students, consultants, contractors, secondees, volunteers, and any other associates undertaking work if they fall within the definition of Investigator below.

### 3. 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 The George Institute and as defined in this Policy, which may include for example: activities

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

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 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.

**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 The George Institute 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 The George Institute. 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 excluded<sup>2</sup>

- (3) **significant financial interest** does not include:
- (i) Salary, royalties, or other remuneration The George Institute pays to the Investigator if the Investigator is currently employed or otherwise appointed by The George Institute including intellectual property rights assigned to The George Institute 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.

#### 4. 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 this 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 this policy, and
    - b. The Agreement must include time period(s) for the subrecipient to report all identified FCOIs to The George Institute's COI Committee in a timeframe that allows for the reporting of identified FCOIs as required by the Regulations.
  - (ii) Alternatively, if the subrecipient's Investigators must comply with this 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.

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<sup>2</sup> 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

- (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

## 5. DISCLOSURES

All Investigators planning to participate in PHS funded research or who are currently participating in PHS funded research must disclose SFIs to The George Institute's Conflict of Interest Committee.

The disclosure must be made before the application date. Investigators who are new to a research project, must disclose their SFIs to the COIC promptly and before participation in the project.

While the COIC will review disclosures of SFIs, typically, The George Institute's designated official responsible for soliciting and reviewing SFI disclosures will be the Investigator's manager (the **Designated Manager**).

## 6. 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-09 Managing Financial Conflict of Interest.

## 7. TRAINING

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

- The George Institute revises this Policy, or related procedures, in a 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 The George Institute (training must be completed prior to his/her participation in the research); or
- The George Institute finds that an Investigator has breached this Policy or a management plan under this Policy (training must 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>, and
- print a certificate of completion and retain it for audit purposes.

## 7. PRESENTATIONS AND PUBLICATIONS

If the HHS (or the prime award holder for subawards) 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 FCOI that was not managed or reported by The George Institute, the Investigator must disclose the FCOI 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 The George Institute 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 The George Institute 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 The George Institute identifies an 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 The George Institute, will ensure public accessibility, via written response to any requestor within 5 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.
- The George Institute has determined that the SFI is related to the PHS-funded research; and
- The George Institute has determined that the SFI is an FCOI.

## 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
V4.0	V3.0	Minor typographical errors, reviewed as per schedule including separation of procedures from policy.
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**

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