

## 1.45 – Financial Disclosures and Conflicts related to Public Health Service (PHS) Funded Research

General Counsel  
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All GEGR sites

### I. Overview

The purpose of this Procedure is to set forth the GE Global Research (GEGR) process for addressing significant financial conflicts of interest for Public Health Service (PHS) funded research. This Procedure supplements other Company conflict of interest policies and all GEGR personnel subject to this Procedure also remain subject to the Company's Spirit & Letter policies.

In view of the stated commitment by the U.S. Department of Health and Human Services (HHS) to preserving the public trust in the objectivity of research, HHS has issued regulations (42 CFR Part 50, Subpart F; hereinafter referred to as "the HHS Regulations") with the stated intent of promoting the conduct of research in accordance with the highest scientific and ethical standards.

According to the HHS Regulations, all recipients of U.S. Public Health Service (PHS) grants must maintain and enforce an appropriate written policy on financial conflicts of interest with respect to PHS-funded research. This GEGR Procedure implements the PHS requirements for assessment of financial conflicts of interest as required by the HHS regulations, and requires, amongst other things, that certain individuals involved with PHS-funded research disclose to GEGR any financial interests that are related to the respective individuals' GEGR duties.

### II. Definitions

**A. "Covered Family Member"** means the spouse and dependent children of an Investigator or other person required to report financial interests as set forth herein.

**B. "Disclosure of Significant Financial Interest"** means an Investigator's presentation to GEGR of information pertaining to significant financial interests (as defined herein).

**C. "Exempt Financial Interest"** means an Investigator's financial interest the value of which is excluded when determining whether the aggregate value of a financial interest exceeds the SFI Threshold Value.

Exempt Financial Interests include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by GE (or its affiliates that may pay or fund the Investigator) to the Investigator or Covered Family Members if the Investigator is currently employed or otherwise appointed by GEGR;

(ii) any equity ownership interest in GE held by the Investigator or Covered Family Members;

(iii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or Covered Family Members does not directly control the investment decisions made in these vehicles;

(iv) 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; and

(v) 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.

**D. “Financial Conflict of Interest” (FCOI)** means a Significant Financial Interest (as further outlined in the section below), that could directly and materially affect the design, conduct, or reporting of PHS-funded research.

**E. “FCOI Report”** means an Institution’s report of a financial conflict of interest to a PHS Awarding Component.

**F. “Financial Interest”** means anything of monetary value, whether or not the value is readily ascertainable.

**G. “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.

**H. “HHS Regulations”** means 42 CFR Part 50, Subpart F.

**I. “Institution”** means the GE business component known as “GE Global Research,” including the global entities associated with GE Global Research.

**J. “Institutional Responsibilities”** means an Investigator’s professional responsibilities for work performed for, or on behalf of the GEGR. Examples of “Institutional Responsibilities” include, but are not limited to, performance of research on behalf of GEGR, research consultation, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**K. "Investigator"** means the principal investigator (PI), all technologists assigned (or, in the case of proposal activity, reasonably expected to be assigned) to perform research funded by the PHS, and any other technologist, regardless of title or position, who is identified by the PI as being responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

**L. "Reportable FCOI"** means any FCOI that is identified by GEGR and will not be eliminated prior to the expenditure of PHS-awarded funds, and will therefore be reported to the PHS Awarding Component via an FCOI Report.

**M. "Senior/Key Personnel"** means the PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

**N. "Significant Financial Interest" (SFI)** means a financial interest of an Investigator (including those financial interests of the Investigator's spouse and dependent children), other than an Exempt Financial Interest, that meets the following criteria:

- (1) the financial interest is in an entity or undertaking that is reasonably related to the Investigator's Institutional Responsibilities; and
- (2) the value of the financial interest meets one or more of the Significant Financial Interest Threshold Values as defined herein below.

**O. "Significant Financial Interest Threshold Value"** is the threshold value above which an Investigator's financial interest can constitute an SFI, which threshold value will depend on the nature of the interest, as described below.

### **1. Publicly Traded Entity**

With regard to any **publicly** traded entity, the Significant Financial Interest Threshold Value is \$5,000 for the aggregate of a) the value of any remuneration received by the Investigator or Covered Family Members from the entity in the twelve months preceding the disclosure and b) the value of any equity interest in the entity as of the date of disclosure.

For purposes of this definition:

- (a) "remuneration" includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and
- (b) "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.

## 2. Non-Publicly Traded Entity

With regard to any **non-publicly** traded entity, the Significant Financial Interest Threshold Value is met by:

- (a) any equity interest in the entity; or
- (b) any remuneration received by the Investigator or Covered Family Members from the entity in the twelve months preceding the disclosure in an amount, in the aggregate, of \$5,000.

## 3. Intellectual Property Rights

The Significant Financial Interest Threshold Value is met by any income related to intellectual property rights not held by GE or its affiliates.

## 4. Travel

The Significant Financial Interest Threshold Value is met by any sponsored or reimbursed travel other than GE sponsored or reimbursed travel related to the Investigator's 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 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.

## III. Details

In order to comply with HHS regulations pertaining to PHS funded research, all GEGR Investigators (as defined herein) on proposals for PHS funded research, or on PHS funded research projects awarded to GEGR must complete a questionnaire (hereinafter referred to as an "SFI Questionnaire;" see attachment A) that identifies any SFIs (as defined above). SFI Questionnaires must be submitted as required by NIH regulation (e.g., at the time of bid submission and periodically thereafter).

Questions about the necessity of submitting an SFI report, or whether a matter should be reported on an SFI, should be promptly reviewed with GEGR Global Compliance Leader or Legal Counsel.

This Procedure supplements, but does not supplant, GE's Spirit & Letter policies regarding conflicts of interest. Thus, all members of the GEGR community are expected to comply with GE's Conflict of Interest Policy and all GEGR implementing procedures, which require employees to disclose all outside activities, financial interests, or relationships that may present possible conflicts of interest with respect to his/her GE duties.

### A. Identifying Financial Conflicts of Interest

The process for identifying FCOIs is outlined below.

1. The PI shall identify those persons who will be considered "Investigators" (as defined above) on the project being bid or executed. The PI and each person identified as an Investigator shall prepare an SFI Questionnaire and submit it to the SFI Lead Reviewer. In order to protect the privacy of the information on the SFI Questionnaire, the completed forms should be treated as GE Restricted data and should not be provided to the PI, the BD team, or the Contracts team.

2. Promptly upon receipt of the SFI Questionnaire, the SFI Lead Reviewer shall:

(a) review all Investigator disclosures of SFIs;

(b) preliminarily determine whether any SFIs relate to PHS-funded research;

(c) make a preliminary determination if there is the potential for an FCOI based on the following factors:

(i) the nexus of research to the SFI; and

(ii) whether the SFI has the potential to significantly bias the Investigator's design, conduct, or reporting of the PHS funded research. In making this determination, consideration should be given as to whether the conduct or findings of the PHS funded research has the potential to significantly affect the valuation of the SFI (including any valuation on non-GE intellectual property that constitutes the SFI).

(d) In the event of a preliminary determination of the potential for an FCOI, the SFI Lead Reviewer will convene the GEGR FCOI Review Board ("the Board") to make a final determination based on the above criteria.

The Board shall be comprised of, at a minimum, at least one GEGR employee from the following groups: (i) Finance (to be designated by the Manager, Finance Operations); (ii) Legal Operation (to be designated by the General Counsel); (iii) relevant Technical Organization (for the PHS-funded work to be performed) designated by the Technical Leader; and (iv) the SFI Lead Reviewer. Additional members appropriate for adjudication of a given SFI disclosure may be identified by the SFI Lead Reviewer. The Board will make a final determination as to the existence of an FCOI based on the above criteria.

## **B. Management of Financial Conflicts of Interest**

In the event of a determination of an FCOI:

1. the SFI Lead Reviewer will develop and, with the approval of the Board, implement a management plan that shall specify the actions that have been, and shall be, taken to manage the FCOI. Examples of conditions or restrictions that might be imposed to manage a conflict include, but are not limited to:

(a) public disclosure of the FCOI (*e.g.*, when presenting or publishing the research);

(b) for research projects involving human subjects research, disclosure of the FCOI directly to participants and persons considering participation;

(c) appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

(d) modification of the research plan;

(e) changing of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(f) reduction or elimination of the financial interest (*e.g.*, sale of an equity interest); and

(g) severance of relationships that create financial conflict.

2. Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or an existing Investigator discloses a new SFI to the Institution, or where GEGR did not previously review an existing SFI during an ongoing PHS-funded research project, GEGR shall, within sixty days:

(a) evaluate the SFI according to the process specified above (see section III (A)); and

(b) if an FCOI exists, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, GEGR may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date of disclosure and the completion of the Institution's review.

3. In addition, whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is subsequently determined by GEGR to constitute an FCOI; failure by GEGR to review or manage such an FCOI; or failure by the Investigator to comply with

an FCOI management plan, such situation shall constitute a Reportable FCOI and GEGR shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

(a) Where GEGR is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following elements:

(i) project number;

(ii) project title;

(iii) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(iv) name of the Investigator with the FCOI;

(v) name of the entity with which the Investigator has an FCOI;

(vi) reason(s) for the retrospective review;

(vii) detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(viii) findings of the review; and

(ix) conclusions of the review.

(b) Based on the results of the retrospective review, if appropriate, GEGR shall update previously submitted FCOI Report(s), specifying the actions that will be taken to manage the FCOI going forward. If bias is found, GEGR will to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and GEGR's plan of action or actions taken 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, GEGR will submit FCOI Reports annually with respect to that project. Depending on the nature of the FCOI, GEGR may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the dates that the FCOI or the

Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

4. Whenever GEGR implements a management plan pursuant to the HHS Regulations, GEGR (via the SFI Lead Reviewer) shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

5. Prior to the GEGR's expenditure of any funds on a given PHS funded research project, GEGR shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request, of information concerning any Reportable FCOIs pertaining to the given PHS funded research project.

6. The information that GEGR makes available via a publicly accessible website or written response to any requestor within five business days of a request, shall include, at a minimum, the following:

(a) Investigator's name;

(b) Investigator's title and role with respect to the research project;

(c) name of the entity in which the SFI is held;

(d) nature of the SFI; and

(e) approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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.

7. In the event GEGR uses a publicly accessible website for the purposes of this subsection, the information required by this Procedure to be posted on that site shall be updated at least annually. In addition, GEGR shall update the website within sixty days of receipt or identification of information concerning any additional SFI of the Senior/Key Personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of an SFI of Senior/Key Personnel new to the PHS-funded research project, if GEGR determines that the SFI is related to the PHS-funded research and is an FCOI. The website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within sixty days of GEGR's identification of a new FCOI. If GEGR responds to written requests for the purposes of this subsection, it will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an



annual basis and within sixty days of GEGR's identification of a new FCOI, which should be requested subsequently by the requestor.

8. Information concerning the SFIs of an individual subject shall remain available, for responses to written requests or for posting via GEGR's publicly accessible website for at least three years from the date that the information was most recently updated.

9. In addition to the types of FCOI that must be managed, GEGR may require the management of other FCOI in its policy on FCOI, as GEGR deems appropriate. Matters addressed under internal Company Integrity policies are not subject to the public reporting obligations herein.

### **C. Reporting of Financial Conflicts of Interest**

Prior to expenditures of any funds under a PHS funded research project, GEGR shall provide to the PHS Awarding Component an FCOI Report regarding any FCOI that is identified by GEGR and will not be eliminated prior to the expenditure of PHS-awarded funds ("Reportable FCOI"). For non-reportable FCOIs (that is, matters in which the potential FCOI has been or will be eliminated prior to the expenditure of PHS-awarded funds), GEGR is not required to submit an FCOI Report to the PHS Awarding Component.

1. Any FCOI Report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of GEGR's management plan. Elements of the FCOI Report shall include, but are not necessarily limited to, the following:

- (i) project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) name of the Investigator with the FCOI;
- (iv) name of the entity with which the Investigator has an FCOI;
- (v) nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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;
- (vii) a description of how the financial interest relates to the PHS funded

research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) a description of the key elements of the Institution's management plan, including:

(a) role and principal duties of the conflicted Investigator in the research Project;

(b) conditions of the management plan;

(c) how the management plan is designed to safeguard objectivity in the research project;

(d) confirmation of the Investigator's agreement to the management plan;

(e) how the management plan will be monitored to ensure Investigator compliance; and

(f) other information as needed.

2. For any FCOI previously submitted with regard to an ongoing PHS-funded research project, GEGR shall provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI Report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. GEGR shall provide annual FCOI Reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

#### **D. Remedies**

In the event of the failure of an Investigator to comply with this Procedure so as to have resulted in bias of the design, conduct, or reporting of the PHS-funded research, GEGR (through the GEGR Global Compliance Leader) shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken by GEGR. GEGR (through the GEGR Global Compliance Leader) shall further respond to any direction that the PHS Awarding Component provides in response to such submission.

1. As the PHS Awarding Component and/or HHS may inquire at any time (before, during, or after award) into GEGR's compliance with the FCOI regulations (including, for example, an Investigator's disclosure of financial interests and GEGR's review of, and response to, such disclosure, regardless of whether or not the disclosure resulted in GEGR's determination of a financial conflict of interest), GEGR is required to make available to the

Awarding Component records pertinent to compliance with the applicable regulations.

2. In any case in which the 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 GEGR as required by 45 CFR Part 50 Subpart F, GEGR shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### **IV. Responsibilities**

##### **A. Investigator**

The Principal Investigator shall identify those other persons engaged, or expected to be engaged on the research project, who shall be considered "Investigators" (as defined above); the PI and all persons identified by the PI as investigators shall be subject to the SFI reporting obligations set forth herein.

All GEGR Investigators working on PHS research bids or PHS-funded projects must be alert to report SFIs (as described herein), on behalf of oneself and Covered Family Members in a timely fashion. In particular, such submissions must be made:

- (a) prior to the time the bid for the PHS-funded research is submitted to NIH;
- (b) prior to commencing work on PHS-funded research projects;
- (c) periodically (at least annually) at time intervals to be established to enable GEGR to meet regulatory filing requirements;
- (d) within 30 days of a potential reportable SFI arising during the course of work on a PHS funded research project (*e.g.*, through purchase, marriage, or inheritance); and
- (e) at such other times as may be determined by GEGR Compliance Counsel.

The PI shall submit, and require Investigators to submit, SFI Questionnaires annually to the SFI Lead Reviewer. Such annual SFI Questionnaires should include any information that was not previously disclosed to GEGR (*e.g.*, any FCOI identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed SFI (*e.g.*, the updated value of a previously disclosed equity interest).

##### **B. SFI Lead Reviewer**

The SFI Lead Reviewer(s) will be designated by GEGR General Counsel (for backup or other process purposes, more than one individual may be charged with the responsibilities of the SFI Lead Reviewer).

The SFI Lead Reviewer shall review all disclosures of SFIs and, using the standards set forth in this procedure, determine whether there is a reasonable potential for the existence of an FCOI, as defined in this procedure. In the event the SFI Lead Reviewer assesses an SFI disclosure as presenting such a reasonable potential for an FCOI, the SFI Lead Reviewer will refer that disclosure to the FCOI Review Board for adjudication.

For those SFI disclosures that the SFI Lead Reviewer determines do not present a reasonable potential for the existence of an FCOI, the review process is complete and the SFI Lead Reviewer shall advise the cognizant Business Development Manager (BDM) of such fact.

Following the identification of an FCOI by the FCOI Review Board, the SFI Lead Reviewer will develop (subject to approval by the FCOI Review Board) and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI (see Section III(B)(3)).

At any time the SFI Lead Reviewer may consult with GEGR technologists, Legal, Compliance, and/or Finance, to obtain information with which to make the assessment of an SFI disclosure. Given the personal nature of the information involved, such consultations should be conducted on a confidential basis and only with those who have a legitimate business need to know of such information.

### **C. GEGR FCOI Review Board**

The responsibility of the Board will be to review any SFI disclosures referred by the SFI Lead Reviewer to assess whether an FCOI exists. Any member of the Board who does not concur in the assessment of the Board may present his or her concerns to the GEGR General Counsel.

In the case of an identified FCOI, the Board shall review and approve an FCOI management plan that shall specify the actions that have been, and shall be, taken by GEGR to manage such FCOI (see Management of Financial Conflicts of Interest, Section III(B)(1)).

### **D. Manager, External Affairs & Technology Programs (or designee Business Development Manager)**

With regard to participation in PHS-funded research, the Manager, External Affairs & Technology Programs (or designee) shall perform the tasks listed below.

1. At Bid/No Bid Meetings ("Tollgate 1"), the BDM having responsibility for the proposed bid will discuss requirements of this Procedure with the PI and Key Personnel.

2. By the time of the Final Cost Volume E-review ("Tollgate 6"), the BDM shall ensure, pursuant to GEGR Procedure 1.06, that each Investigator has submitted a completed SFI Questionnaire identifying his/her known SFIs. (An example document for this process is included as Attachment A.

#### **E. Legal Counsel**

With regard to participation in PHS-funded research:

1. GEGR Legal Counsel (or designee) shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with the HHS Regulations; and
2. GEGR General Counsel (or designee) shall designate the SFI Lead Reviewer(s).

#### **F. GEGR Global Compliance Leader**

The GEGR Global Compliance Leader (or designee) shall:

1. make a copy of this Procedure publicly-available as required by HHS regulations;
2. communicate as appropriate with the PHS Awarding Component regarding any reportable FCOI matters and otherwise take actions as may be required under HHS regulations, including reporting conflicts to designated PHS entities, to ensure that identified conflicting interests are managed, reduced, or eliminated;
3. manage review and adjudication of SFI Questionnaires made pursuant to this Procedure to assure compliance with applicable regulations;
4. provide guidance, upon request, to Investigators regarding the requirements of this Procedure, the Investigator's responsibilities regarding disclosure of SFIs, and the HHS Regulations;
5. ensure appropriate training materials are available outlining the requirements of this Procedure and the HHS Regulations and deliver training to each Investigator regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
  - (a) GEGR revises this Procedure in any manner that affects the requirements of Investigators;
  - (b) an Investigator is new to GEGR; or

(c) GEGR finds that an Investigator is not in compliance with this Procedure or a management plan initiated hereunder; and

6. maintain records of SFI Questionnaires and GEGR's review of, and response to, disclosures and necessary follow-up actions for at least three years from the submission date of the final expenditure report or longer as may be required under other U.S. regulations or GEGR's Document Management Procedure.

## **G. Finance – Manager, Contract Services**

With regard to participation in PHS-funded research, the Manager, Contracts Department (or designee) shall:

1. require each Investigator to have submitted to the SFI Lead Reviewer a completed SFI Questionnaire identifying his/her known SFIs.

(a) At Kickoff Meetings ("Tollgate 2"), the Contracts Administrator (CA) will brief technical personnel potentially subject to the requirements of this Procedure on the requirements of this Procedure and provide the SFI Questionnaires for completion by the affected individuals (i.e., the PI and persons to be designated as Investigators on the project).

(b) At award and through contract negotiation, the CA shall re-issue requests for verification to PI/Key Personnel and subcontractors.

(c) At the start of the program, the CA shall re-issue requests for verification to PI/Key Personnel and subcontractors

2. CA will also be responsible for managing potential subcontractors in accordance with the requirements of the HHS Regulations by:

(a) inquiring whether the subcontractor has an existing policy consistent with the HHS Regulations;

(b) incorporating as part of a written agreement with the subcontractor terms that establish whether the FCOI policy of GEGR or that of the subcontractor will apply to the subcontractor's Investigators;

(i) if the subcontractor's Investigators must comply with the subcontractor's FCOI policy, requiring the subcontractor to certify as part of the agreement referenced above that its policy complies with the HHS Regulations, and if the subcontractor cannot provide such certification, the agreement shall state that subcontractor Investigators are subject to the terms of this Procedure;

- (ii) if the subcontractor's Investigators must comply with the subcontractor's FCOI policy, the agreement referenced above shall specify time period(s) for the subcontractor to report all identified FCOI to GEGR, with such time period(s) being sufficient to enable GEGR to provide timely FCOI Reports, as required;
  - (iii) if the subcontractor's Investigators must comply with this Procedure, the agreement referenced above shall specify time period(s) for the subcontractor to submit all Investigator disclosures of SFIs to GEGR, with such time period(s) being sufficient to enable GEGR to comply timely with its review, management, and reporting obligations;
- (c) including in subcontracts the necessary flow down clauses as required by the GEGR prime contract and by this Procedure and applicable regulations; and
- (d) establishing a subcontractor SFI reporting process consistent with this Procedure.

3. CA will notify Investigators annually of the requirement to submit annual SFI Questionnaires to the SFI Lead Reviewer.

#### **H. GEGR Technical Leaders (TLs)**

GEGR Technical Leaders (TLs) are responsible for ensuring that all personnel in their respective technical organizations who are subject to the provisions of this Procedure (*i.e.*, soliciting or performing PHS-funded research) are aware of the requirement to be trained in the requirements of the HHS Regulations and this Procedure at least every four years, and immediately when any of the following circumstances apply:

- (1) GEGR revises this Procedure in any manner that affects the requirements of Investigators;
- (2) an Investigator is new to GEGR; or
- (3) GEGR finds that an Investigator is not in compliance with this Procedure or a management plan initiated hereunder.

For his/her respective technical organization, each TL shall ensure that new PI's to ongoing PHS-funded research projects are aware of the requirements under the HHS Regulations and this Procedure.

TLs are responsible for assuring compliance with this Procedure on the part of all affected personnel in their respective technical organizations, including compliance with the requirements regarding the submission of annual SFI Questionnaires.

## I. Business Program Managers (BPMs)

BPMs, or their respective designees, shall confirm with the GEGR Global Compliance Leader and the appropriate CA and, as appropriate, certify, in each application for funding to which the HHS Regulations apply, that GEGR:

(1) has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS;

(2) shall promote and enforce Investigator compliance with the requirements of the HHS Regulations;

(3) shall manage FCOI and provide initial and ongoing FCOI Reports to the PHS Awarding Component consistent with the HHS Regulations; and

(4) agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of SFI and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.

## IV. Related Information

The following sources provide further information on approval and signature requirements and limitations for specific transactions.

- GEGR Procedure 1.06 – Proposals and Contracts
- GEGR Procedure 1.37 – Misconduct in Science
- 2 CFR part 376—Nonprocurement debarment and suspension (HHS)
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations
- 45 CFR part 79—Program fraud civil remedies
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments



## V. Revision History

Date	Description	Author
May 2016	Inserted Training and Summary details. Modified SFI Questionnaire	Dafniotis
January 2015	Corrected location for submitting completed SFI questionnaires	Don Brovich
July 2012	New procedure created	Emery, Dafniotis, Ingraham

## GEGR HHS FCOI Training Summary & SFI Questionnaire

### What's the Purpose & Scope of the Regulations?

- **Promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator and his/her covered family members' financial conflicts of interest (FCOIs)**
- Covers each institution that applies for or receives PHS grants or cooperative agreements for research (e.g. GEGR) – see last section below for historical PHS funding sources
- Covers Investigators planning to participate in or participating in research
- Note: Investigators are still required to adhere to GE's general Conflict of Interest policy & procedure

### What's Different about the Revised Regulations?

- Expanded definition of "Investigator"
- Modified definition of "Significant Financial Interest (SFI)"
- Extent of Investigators' SFI disclosure per project to GEGR
- GEGR's management of resulting "Financial Conflicts of Interest (FCOIs)"
- Information reported to the PHS funding component
- Information potentially disclosed to the public

### Key Terms

- **Investigator:** the Principal Investigator (PI) and any other technologist, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants; **for GEGR, this is the PI plus all technologists staffed on the project**
- **Covered family members:** each Investigator's spouse & dependent children
- **Institutional responsibilities:** an Investigator's professional responsibilities **on behalf of GEGR**, which includes activities 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
- **Significant Financial Interest (SFI) Lead Reviewer:** GEGR US Compliance Leader
- **Financial Conflict of Interest (FCOI):** see next page
- **FCOI Review Board:** SFI Lead Reviewer, Finance rep, Legal rep, Technology rep

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### When & to Whom do Investigators Need to Disclose their SFIs?

SFIs must always be disclosed per project **only to the SFI Lead Reviewer**:

- **At Bid/No-Bid Meeting:** the PI will identify those to be deemed as Investigators, including sub recipient Investigators if applicable, who will then be required to disclose SFIs.
- **Prior to Final Cost Volume E-Review:** each Investigator will disclose SFIs
- **Prior to Commencing Work on the Project:** each Investigator will disclose SFIs
- **Annually:** each PI & Investigator will submit an updated disclosure of SFIs annually during the period of the award.
- **Within 30 days: each Investigator** will submit an updated disclosure of SFIs within 30 days of **discovering or acquiring** (e.g. through purchase, marriage, or inheritance) **a new SFI**.
- **Within 30 days:** each **new Investigator** assigned to an ongoing project will submit a disclosure of SFIs within 30 days.

### What's the Difference between an SFI and a Financial Conflict of Interest (FCOI)?

An **"FCOI"** is an SFI that could directly and materially affect the design, conduct, or reporting of PHS-funded research. For example:

- A GEGR employee was paid \$7,500 in consulting fees by a university hospital 6 months ago. That employee has now been identified as a potential Investigator participating in a bid with the same hospital for an NIH grant.

### What will the "SFI Lead Reviewer" do with the SFI Disclosures?

*Note: The SFI Lead Reviewer will handle disclosures as "GE Restricted" data.*

- The SFI Lead Reviewer will review SFIs disclosed by each Investigator.
- The SFI Lead Reviewer will make an initial assessment as to whether an SFI is an FCOI.
- If an initial assessment of FCOI is made, the SFI Lead Reviewer will review with the FCOI Review Board, who will make the final determination.
- If determined to be an FCOI, the SFI Lead Reviewer will work with the FCOI Review Board, PI and Investigator to develop a management plan that specifies actions to take.
- If it's determined initially or otherwise there is no FCOI, the SFI Lead Reviewer will notify the project's Business Development Manager (BDM).

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### What are GEGR's Options for Managing FCOIs?

- Public disclosure of FCOI
- Modification of research plan
- Change of Investigator or Investigator responsibilities
- Reduction or elimination of the SFI (e.g. sale of equity interest)
- Severance of relationship creating FCOI

### What does a "Management Plan" consist of?

- Role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance
- Other information as needed

### Who Reports FCOIs, and When?

**For FCOIs that have not been eliminated prior to the expenditure of funds**, the SFI Lead Reviewer will provide initial & ongoing reports to PHS:

- Prior to the expenditure of funds
- During the period of the award (i.e. within 60 days of identifying a new FCOI)
- Annually report on the status of FCOIs & any changes in applicable management plans

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### What does "Public Disclosure of FCOIs" Mean?

Prior to expenditure of funds, the SFI Lead Reviewer will ensure information concerning FCOIs is provided via written response within 5 business days of a request by the public. GEGR must retain this information for 3 years:

- Investigator's name
  - Investigator's title & role with respect to the research project
  - Name of entity in which the SFI is held
  - Nature of the SFI
  - Dollar range of the SFI (\$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts > \$100K by increments of \$50K), or, a statement that the value cannot be readily determined
- Severance of relationship creating FCOI

### GEGR Historical PHS Funding Sources

- AHRQ – Agency for Healthcare Research and Quality
- ASPR (BARDA) – Assistant Secretary for Preparedness and Response
- CDC – Centers for Disease Control and Prevention
- CMS – Centers for Medicare & Medicaid Services
- FDA – Food and Drug Administration
- NIH – National Institutes of Health

## GEGR HHS FCOI Training Summary & SFI Questionnaire

PHS Proposal

PI Name: \_\_\_\_\_

Proposal Number: \_\_\_\_\_

Proposal Name: \_\_\_\_\_

**GE CONFIDENTIAL (when filled in)**

### GEGR Significant Financial Interests (SFI) Questionnaire for PHS-Funded Research

*NOTE – information requested below is required pursuant to Federal regulations governing PHS-funded research. GEGR shall treat all sensitive personal information below as Strictly Private/GE Restricted Information, to be handled only by designated persons for purposes of complying with applicable regulations and policies.*

*This form is to be completed by proposed Investigators for all PHS-funded grants and proposals including the NIH.*

*Note: Significant Financial Interest" (SFI) is defined below.*

**NOTE: THE INFORMATION PROVIDED IS TO BE FOR THE INVESTIGATOR AND ALSO FOR THE INVESTIGATOR'S SPOUSE AND DEPENDENT CHILDREN.**

*Questions? - More information is available in GEGR Compliance Procedure 1.45; also contact GEGR Compliance Counsel or the GEGR SFI Lead Reviewer (US Compliance Leader)*

Investigator's Name: \_\_\_\_\_ Date: \_\_\_\_\_

GEGR GTO or Non-GE Organization: \_\_\_\_\_

SSO ID No.: \_\_\_\_\_ Project Role: \_\_\_\_\_

**As an investigator (and for your spouse and dependent children), you must report all Significant Financial Interests, which are defined as follows:**

**"Significant Financial Interest" (SFI)** means a financial interest of an Investigator (including those financial interests of the Investigator's spouse and dependent children), other than an Exempt Financial Interest, that meets the following criteria:

- (1) the financial interest is in an entity or undertaking that is reasonably related to the Investigator's Institutional Responsibilities; and
- (2) the value of the financial interest meets one or more of the Significant Financial Interest Threshold Values as defined herein below.

## GEGR HHS FCOI Training Summary & SFI Questionnaire

To be reportable as an SFI, the financial interest must be in excess of the following “Significant Financial Interest Threshold Value”

### 1. Publicly Traded Entity

With regard to any **publicly** traded entity, the Significant Financial Interest Threshold Value is \$5,000 for the aggregate of a) the value of any remuneration received by the Investigator or Covered Family Members from the entity in the twelve months preceding the disclosure and b) the value of any equity interest in the entity as of the date of disclosure.

For purposes of this definition:

(a) “remuneration” includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and

(b) “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.

### 2. Non-Publicly Traded Entity

With regard to any **non-publicly** traded entity, the Significant Financial Interest Threshold Value is met by:

(a) any equity interest in the entity; or

(b) any remuneration received by the Investigator or Covered Family Members from the entity in the twelve months preceding the disclosure in an amount, in the aggregate, of \$5,000.

### 3. Intellectual Property Rights

The Significant Financial Interest Threshold Value is met by any income related to intellectual property rights not held by GE or its affiliates.

### 4. Travel

The Significant Financial Interest Threshold Value is met by any sponsored or reimbursed travel other than GE sponsored or reimbursed travel related to the Investigator’s 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 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.

## GEGR HHS FCOI Training Summary & SFI Questionnaire

**To be reportable, the SFI should reasonably relate to your (the Investigator's) Institutional Responsibilities, which are defined as:** an Investigator's professional responsibilities for work performed for, or on behalf of the GEGR. Examples of "Institutional Responsibilities " include, but are not limited to, performance of research on behalf of GEGR, research consultation, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**"Exempt Financial Interest"** means an Investigator's financial interest the value of which is excluded when determining whether the aggregate value of a financial interest exceeds the SFI Threshold Value. Exempt Financial Interests include the following types of financial interests:

- (1) salary, royalties, or other remuneration paid by GE (or its affiliates that may pay or fund the Investigator) to the Investigator or Covered Family Members if the Investigator is currently employed or otherwise appointed by GEGR;
- (2) any equity ownership interest in GE held by the Investigator or Covered Family Members;
- (3) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or Covered Family Members do not directly control the investment decisions made in these vehicles;
- (4) 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; and
- (5) 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.



## GEGR HHS FCOI Training Summary & SFI Questionnaire

Do you have any potential Significant Financial Interests (as defined above) to be reported?

NO

YES

Please indicate below the applicability of this SFI Questionnaire by selecting one of the following:

At Proposal \_\_\_\_\_

Prior to Commencing Work on the Project \_\_\_\_\_

Annually \_\_\_\_\_

Within 30 days of discovering or acquiring a new SFI \_\_\_\_\_

Within 30 days for each new Investigator \_\_\_\_\_

By signing below, you hereby certify that you have reviewed and understand the training materials accompanying this form and have, to the best of your knowledge, provided accurate and complete information in accordance with 42 CFR Part 50, Subpart F.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print name

WHEN COMPLETED, SUBMIT THIS FORM DIRECTLY TO:

GEGR SFI LEAD REVIEWER  
K-1 3A45A

**The SFI Lead Reviewer shall keep this Questionnaire on file for 3 years from the date of the final expenditure report.**