Investigator Financial Conflict of Interest

STANDARD OPERATING PRACTICE

ORIGINAL EFFECTIVE DATE	16 APR 2010	REVISED EFFECTIVE DATE	01 AUG 2020

POLICY: The Geneva Foundation (Geneva) promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of funded research will be biased by any financial conflicting interest of an Investigator.

1.0 PURPOSE AND BACKGROUND

1.1 The purpose of this Standard Operating Practice (SOP) is to to define a financial conflict of interest (FCOI) and outline the procedures for determining and managing FCOI on all federally funded research programs.

2.0 SCOPE AND RESPONSIBILITIES

2.1 This scope applies to anyone responsible for the design, conduct, or reporting of research, regardless of the person's title or role on the project or the receipt of funding ("Investigator").

2.2 It is Geneva's responsibility to:

2.2.1 Inform Investigators of Geneva's FCOI policy and its responsibilities regarding disclosure of significant financial interests in accordance with Public Health Service (PHS) and other applicable regulations;

2.3.1 Provide initial and annual (i.e., ongoing) FCOI reports to the National Institute of Health (NIH) through the eRA Commons FCOI Module, as required;

2.4.1 Notify The National Science Foundation's (NSF) Office of the General Counsel (OGC) if it determines that it is unable to manage a significant financial interest related to a NSF-funded project satisfactorily.

a. If Geneva determines a financial conflict with NSF research to be unmanageable (i.e. imposing conditions or restrictions would be either ineffective or inequitable, and the potential negative impacts that may arise from a significant financial interest are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare), the NSF Office of General Counsel is notified electronically.

2.5.1 Ensure subrecipient or contractor compliance for federally-funded projects by requesting a disclosure statement that indicates compliance with their institutional policies or intent to rely on Geneva policy;

2.6.1 Provide guidelines Provide guidelines to identify FCOI and take such actions necessary to ensure that such conflicting financial interests be managed, reduced, or eliminated;

2.7.1 Maintain records of Investigator financial disclosures and of actions taken to manage financial conflicts of interest;

2.8.1 Agree to make financial conflict of interest information available, upon request, to HHS and promptly notify the PHS awarding component of the corrective action taken or to be taken.

2.3 It is the Investigator's responsibility to:

2.1.1 Complete FCOI training or provide appropriate proof of FCOI training prior to engaging in research related to any federally-funded grant no less than every four years or immediately when any of the following circumstances apply:

a. Geneva revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;

b. An Investigator is new to Geneva;

c. Geneva finds that an Investigator is not in compliance with its FCOI policy or the Investigator's management plan.

2.2.1 Provide initial and updated financial disclosures annually during the period of the award and as any new reportable Significant Financial Interests are obtained.

2.4 If an Investigator has duties and responsibilities to another Entity that conflicts with this policy, the most restrictive of the conflicting policies shall prevail.

2.5 This policy does not apply to Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Phase I grant applications. The Phase II grants are for larger amounts therefore, PHS requires compliance with PHS regulations.

2.6 Non-financial COI are outside the scope of this policy and should be disclosed to Human Resources for management upon discovery, as detailed in GEN-S-014 Organizational Conflict of Interest.

3.0 REFERENCES

3.1 GEN-F-037 Agreement Questionnaire

3.2 GEN-F-049 Significant Financial Interest Disclosure

3.3 GEN-F-050 Financial Conflict of Interest Resolution Plan

3.4 GEN-S-004 Retention of Corporate Records

3.5 42 CFR 50, Subpart F, Sections 50.601 to 50.607

3.6 45 CFR Part 94, Sections 94.1 to 94.6

4.0 DEFINITIONS

4.1 Authorized Official (AO): An individual who is designated to give assurances, make commitments and execute legal documents on behalf of Geneva.

4.2 Entity: Any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

4.3 Family Member: Family Member: Group of relations, includes a person's parents, siblings, spouses, children, or an individual related by blood whose close

association is an equivalent of a family relationship. It can contain others connected by birth, adoption, marriage, civil partnership, or cohabitation, such as grandparents, great-grandparents, grandchildren, great-grandchildren, aunts, uncles, siblings-in-law, half-siblings, cousins, adopted children and step-parents/step-children, and cohabiting partner.

4.4 Federal Agency: Any federal sponsor agency that provides funding for extramural research through grants, contracts, or cooperative agreements in support of research (e.g. DoD, NIH, CDC).

4.5 Financial Conflict of Interest (FCOI): A FCOI exists when Geneva reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of Federal sponsored projects.

4.6 Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

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

4.8 Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

4.9 Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including, but not limited to, 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.

4.10 Intellectual Property: A work or invention that is the result of creativity, such as a manuscript or a design, to which one has rights and for which one may apply for a patent, copyright, trademark, etc.

4.11 Investigator: Any person, regardless of title or position, who is responsible for the design, conduct or reporting of research.

4.12 Manage: Addressing an FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting or research will be free from bias.

4.13 PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

4.14 PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to PHS regulations.

4.15 Portfolio Manager (PM): The role responsible for managing the technical and programmatic progress of the award on behalf of Geneva. The Portfolio Manager is not a specific position at Geneva but rather the function.

4.16 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 and 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.

4.17 Senior/Key Personnel: The PD/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 Federal Agency by the Institution.

4.18 Significant Financial Interest: Is a financial interest that meets any of the criteria for significance set forth below and is received or held:

2.1.1 By an Investigator; or

2.2.1 By an Investigator and members of their Family; or

2.3.1 Solely by members of the Investigator's Immediate Family, but only if the financial interest could reasonably appear to be related to the Investigator's Institutional Responsibilities.

A financial interest is deemed to be significant if:

a. Compensation totaling more than $5,000 received in the preceding 12-month period (e.g. salary, consulting, fees, honoraria or other payments);

b. Any equity in a non-publicly traded Entity as of the date of disclosure;

c. Equity in a publicly traded Entity valued in excess of $5,000;

d. Equity in a publicly traded Entity and compensation received from the same entity in the preceding 12 months equals a combined total value exceeding $5,000;

e. Intellectual property (IP) rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

f. Reimbursed travel or sponsored travel

Significant Financial Interest does NOT include:

a. Travel for which expenses are paid for or reimbursed by:

a.1 Geneva

a.2 An Institution of higher education

a.3 A research institute affiliated with an institution of higher education

a.4 An academic teaching hospital

a.5 A medical center

a.6 A Federal, state or local government agency

b. Compensation received from Geneva;

c. Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:

c.1 Geneva

c.2 An Institution of higher education

c.3 A research institute affiliated with an institution of higher education

c.4 An academic teaching hospital

c.5 A medical center

c.6 A Federal, state or local government agency

d. Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts);

e. IP rights from which an Investigator has not received income; and

f. IP assigned to Geneva

5.0 PRACTICES AND PROCEDURES

5.1 FCOI Disclosure

5.1.1 Prior to engaging in federal research, each Investigator is required to have a completed a Significant Financial Interest Disclosure (GEN-F-049). The Portfolio Manager (PM) confirms that all Investigators have completed a FCOI Disclosure within the last year.

5.1.2 If a FCOI Disclosure has not been completed within the last year or one is not on file for the Investigator, the completed form is requested by the Portfolio Manager (PM) and/or their designee and submitted to Geneva for evaluation. Each Investigator is required to disclose:

a. Any significant financial interest of the Investigator that reasonably appears to be affected by the research activities funded, or proposed for Federal funding; or

b. Any significant financial interest of the Investigator in an entity whose financial interest reasonably appears to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

5.1.3 All significant financial interests are disclosed prior to the time a prime proposal is submitted to the National Institute of Health (NIH). The Portfolio Manager (PM) and/or their designee reviews the electronic repository for an active FCOI Disclosure for all Geneva Investigators. If no FCOI Disclosure is on file or the FCOI Disclosure has expired for the Investigator, the Geneva team obtains a new or updated disclosure at the time a proposal is submitted.

a. Any subrecipient to Geneva on an NIH funded proposal provides certification of a pre-existing policy or an FCOI Disclosure at the time a proposal is submitted. Subrecipient certifications are retained in the pre-award electronic repository.

5.1.4 FCOI Disclosures are maintained in the electronic repository.

5.2 FCOI Training

5.2.1 Prior to engaging in research activities, the Portfolio Manager (PM) confirms that all Investigators have completed an approved FCOI training within the last four years.

5.2.2 The PM and/or their designee sends notifications out to Investigators when annual FCOI Disclosures are due. Prior to sending the notification, Geneva verifies that the FCOI training is up to date. If the FCOI training was completed more than four years ago, Geneva notifies the Investigator that the FCOI training must be updated.

5.2.3 If an Investigator is found not to be in compliance with Geneva's FCOI policy and/or an existing FCOI Resolution Plan, Geneva notifies the Investigator, the Principal Investigator(s), and the AO that the FCOI training must be taken again. The Investigator must stop work on any federally-sponsored studies until FCOI training requirements have been met.

5.2.4 FCOI training records are maintained in the electronic repository.

5.3 Prior to the execution of a subrecipient agreement, subrecipients provide Geneva with GEN-F-037 Agreement Questionnaire.

5.3.1 Geneva includes a certification within the subaward for all subrecipient Institutions who rely on their FCOI policy. The certification, at a minimum designates that the subrecipient complies with Federal policies regarding Investigator FCOI Disclosure and that its portion of the project is in compliance with Institution policies.

a. For any subrecipients that rely on Geneva's policy, Geneva provides the policy to the subrecipient and follows the procedures for collecting disclosures and documented FCOI training.

5.3.2 Subrecipients are required to disclose identified FCOIs, pertinent to Geneva-supported projects. In the case of PHS-funded projects, subrecipients must report this information, along with their management plan, in sufficient time to allow Geneva to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module).

5.4 FCOI Resolution Plan & Management

5.4.1 If a FCOI is disclosed, the following actions are taken within 60 days of the disclosure:

a. The Portfolio Manager (PM) informs the Authorized Official (AO) for determination of an apparent or perceived FCOI;

b. The AO advises the PM if a FCOI Resolution Plan (GEN-F-050) is required to detail the proposed steps taken to manage, reduce, or eliminate the FCOI.

b.1 If a Resolution Plan is not required, the AO provides authorization within the FCOI Disclosure.

c. The FCOI Disclosure and drafted Resolution Plan is forwarded to an Ad Hoc COI Committee for FCOI Review.

c.1 The Committee's members are appointed by the President and CEO and include Geneva's legal representative.

d. The COI Committee members review the materials provided and a meeting is scheduled at which the Investigator may discuss their financial interests and any deviations or required adjustments to the proposed FCOI Resolution Plan to manage any financial conflict.

d.1 The Committee may negotiate the terms, conditions, and restrictions, if any, that are required as part of the FCOI Resolution Plan on a case-by-case basis.

e. The Committee may consult with other members of the research team, as appropriate, when assessing a significant financial interest and the development of a proposed resolution plan.

f. Examples of conditions or restrictions that may be imposed to manage FCOI include, but are not limited to:

f.1 Monitoring of the research by independent reviewers;

f.2 Modification of the research plan;

f.3 Disqualification from participation in all or a portion of the research;

f.4 Divestiture of significant financial interests; or

f.5 Severance of relationships that create actual or potential conflicts.

g. After deliberations, the Committee approves or amends the conditions or restrictions of the plan and certifies its approval within the form.

h. The approved FCOI Resolution Plan is communicated in a letter of disposition with copies provided to relevant Department of Clinical Investigations (DCI) Chiefs, Department Chairs, AOs, and to other persons deemed appropriate.

i. Investigators may appeal the Committee's decision to Geneva's President.

5.5 Violation of or Deviation from FCOI Policy

5.5.1 If the Investigator does not make disclosure or it is reviewed after 60 days, Geneva's AO develops an interim management plan and within 120 days of the Institution's determination of noncompliance, completes a retrospective review of the Investigator's activities and the research project to determine whether any research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

a. Documentation of a Retrospective Review includes, as applicable, the following:

a.1 Project Number

a.2 Project Title

a.3 PD/PI or contact PD/PI if a multiple PD/PI model is used

a.4 Name of the Investigator with the FCOI

a.5 Name of the entity with which the Investigator has a FCOI

a.6 Reason(s) for the retrospective review

a.7 Detailed methodology used for the retrospective review (i.e. methodology of the review process, composition of the review panel, documents reviewed)

a.8 Findings and conclusions of the review

5.5.2 If noncompliance has biased the design, conduct, or reporting of PHS-funded research, Geneva promptly notifies the PHS Awarding Component

of the corrective action taken or to be taken.

5.5.3 If at any time a bias is found, Geneva notifies the sponsor promptly and submits a mitigation report to the sponsor including the following information:

a. Key elements documented in retrospective review

b. Description of the impact of the bias on the research project

c. Plan of action(s) to eliminate or mitigate the effect of the bias

5.5.4 If an Investigator violates this policy or the terms of the FCOI Resolution Plan, the Committee recommends an appropriate response. At a minimum, Geneva:

a. Communicates such actions to the institution at which the Investigator is employed; and

b. Follows Federal regulations regarding the notification of the sponsor if an Investigator fails to comply with the stated policy.

5.5.5 Geneva may take any other action it deems appropriate, including suspension of funding for an Investigator until the matter is resolved.

5.5.6 For non-compliance in clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, Geneva requires the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results and to request an addendum to previously published presentations.

5.6 Geneva retains all records of Investigator financial disclosures and of the actions taken to manage, reduce, or eliminate the actual or potential conflicts of interest as detailed in GEN-S-004 Retention of Corporate Records.

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