

		<h1 style="margin: 0;">INVESTIGATOR FINANCIAL CONFLICT OF INTEREST</h1> <h2 style="margin: 0;">Standard Operating Practice</h2>	
Original Effective Date	16 APR 2010	Revised Effective Date	01 JUN 2018

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 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. It is Geneva's responsibility to:
 - 2.1.1 Maintain an appropriate written and enforced policy;
 - 2.1.2 Inform each Investigator of the Institution's FCOI policy, the Investigator's responsibilities regarding disclosure of significant financial interests, Public Health Service (PHS) regulations, and other applicable regulations;
 - 2.1.3 Require each Investigator to complete FCOI training or provide proof of institutional FCOI training prior to engaging in research related to any federally-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - a. The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;
 - b. An Investigator is new to an Institution;
 - c. An Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
 - 2.1.4 Require limited and targeted financial disclosure;
 - 2.1.5 Ensure subrecipient or contractor compliance for federally-funded projects by requesting a disclosure statement that indicates compliance with their institutional policies;
 - 2.1.6 Establish and describe adequate enforcement mechanisms and provide for sanctions where appropriate;
 - 2.1.7 Provide guidelines to identify financial conflicts of interest and take such actions as necessary to ensure that such conflicting financial interests will be managed, reduced, or eliminated;

- 2.1.8 Maintain records of Investigator financial disclosures and of actions taken to manage financial conflicts of interest;
 - 2.1.9 Certify in each proposal for funding that Geneva maintains a written and enforced process to address financial conflicts of interest;
 - 2.1.10 Designate one or more persons to review investigator financial disclosure statements to determine whether a FCOI exists, and determine what conditions or restrictions, if any, should be imposed by Geneva to manage, reduce or eliminate such FCOI and resolve actual or potential problems revealed;
 - 2.1.11 Require updated financial disclosures annually during the period of the award and as new reportable Significant Financial Interests are obtained;
 - 2.1.12 Provide initial and annual (i.e., ongoing) FCOI reports to the NIH through the eRA Commons FCOI Module, as required;
 - 2.1.13 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.
- 2.2 Not all Conflicts of Interest (COI) are financial. Such COI are outside the scope of this policy and should be disclosed to the Human Resources Director for management upon discovery. Other examples of COI that could apply to Investigators include:
- 2.2.1 Outside Activity/Outside Compensation: A conflict of Outside Activity/Outside Compensation may occur when a Geneva employee has secondary employment with an outside entity or institution which directly or significantly interferes with the employee's fulfillment of Geneva responsibilities.
 - 2.2.2 Nepotism and Relationships in the Workplace: Geneva permits hiring of individuals within the same family or those who have personal relationships. To avoid COI or an appearance of COI, no Geneva employee may initiate or participate in, directly or indirectly, decisions regarding direct benefit, e.g., initial hire or rehire, promotion, salary, performance appraisals, work assignments or other working conditions to those related by blood or marriage, membership in the same household, including domestic partners, or persons with whom employees have an intimate relationship.
 - 2.2.3 Institutional Conflict of Interest: An Institutional COI in research may occur when the financial interests of the institution, or of an institutional individual official who has authority to act on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the design, conduct, reporting, review or oversight of research.
- 2.3 If an Investigator has duties and responsibilities to another entity or institution that conflict with the Geneva Investigator Conflict of Interest policy, the most restrictive of the conflicting policies shall prevail.
- 2.4 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.

- 2.5 It is Geneva's responsibility to 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. 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 will be notified electronically.

3.0 References

- 3.1 GCD-F-018 Financial Conflict of Interest Resolution Plan Form
- 3.2 GCD-F-017 Significant Financial Interests Disclosure Form
- 3.3 GCD-F-003 Subrecipient Questionnaire
- 3.4 GEN-S-027 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 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.
- 4.2 Authorized Official (AO): An individual who is designated to give assurances, make commitments and execute legal documents on behalf of Geneva.
- 4.3 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).
- 4.4 Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.
- 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 HHS: The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- 4.7 Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency).
- 4.8 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.

- 4.9 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.
- 4.10 Investigator: Any person, regardless of title or position, who is responsible for the design, conduct or reporting of research.
- 4.11 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.
- 4.12 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.
- 4.13 PHS Awarding Component: The organizational unit of the PHS that funds the research that is subject to PHS regulations.
- 4.14 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.
- 4.15 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.
- 4.16 Significant Financial Interest: 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:
 - 4.16.1 Compensation totaling more than \$5,000 received in the preceding 12-month period (e.g. salary, consulting, fees, honoraria or other payments);
 - 4.16.2 Any equity in a non-publicly traded entity as of the date of disclosure;
 - 4.16.3 Equity in a publicly traded entity valued in excess of \$5,000;
 - 4.16.4 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;
 - 4.16.5 Intellectual property (IP) rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - 4.16.6 Reimbursed travel or sponsored travel
- 4.17 The term significant financial interest does not include the following types of financial interests:
 - 4.17.1 Compensation received from Geneva;
 - 4.17.2 Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:
 - a. Geneva

- b. An Institution of higher education
 - c. A research institute affiliated with an institution of higher education
 - d. An academic teaching hospital
 - e. A medical center
 - f. A Federal, state or local government agency
- 4.17.3 Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g. mutual funds, retirement accounts)
- 4.17.4 IP rights from which an Investigator has not received income;
- 4.17.5 IP assigned to Geneva;
- 4.17.6 Travel for which expenses are paid for or reimbursed by:
- a. Geneva
 - b. An Institution of higher education
 - c. A research institute affiliated with an institution of higher education
 - d. An academic teaching hospital
 - e. A medical center
 - f. A Federal, state or local government agency

5.0 Practices and Procedures

5.1 FCOI Disclosure

- 5.1.1 Prior to engaging in federal research, each Investigator is required to complete a Significant Financial Interest Disclosure Form (GCD-F-017) with the required supporting documentation. The completed form is submitted to the Geneva team 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.
- 5.1.2 All significant financial interests are disclosed prior to the time a prime proposal is submitted to the National Institute of Health (NIH). The Geneva team will review the electronic repository for an active Significant Financial Interests Disclosure Form (GCD-F-017) for all Geneva Investigators. If no financial disclosure is on file or the financial disclosure has expired for the Investigator, the Geneva team will obtain a new or updated form at the time a proposal is submitted.
- a. Any subrecipient to Geneva on a NIH funded proposal will provide certification of a pre-existing policy and/or GCD-F-017 forms at the time a proposal is submitted. Subrecipient certifications will be housed in the pre-award electronic repository.

- 5.1.3 Significant Financial Interests Disclosure Forms will be maintained in the electronic repository.
- 5.2 FCOI Training
 - 5.2.1 Prior to engaging in research activities, GCD personnel confirm that all Investigators have completed an approved FCOI training within the last four years.
 - 5.2.2 GCD personnel send notifications out to key personnel when annual financial disclosures are due. Prior to sending the notification, GCD personnel verify that the FCOI training is up to date. If the FCOI training was completed more than four years ago, GCD personnel notify 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 SOP and/or an existing FCOI Resolution Plan, GCD personnel notify 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 will be maintained in the electronic repository.
- 5.3 Prior to the execution of a subrecipient agreement, subrecipients will provide GCD personnel with GCD-F-003 Subrecipient Questionnaire. In doing so, subrecipients certify that senior/key personnel at that site will comply with 42 CFR 50, Subpart F, Sections 50.601 to 50.607.
- 5.4 As part of a written agreement with the subrecipient, GCD personnel will include applicable terms that establish whether Geneva's FCOI SOP or that of the subrecipient will apply to sub-recipient Investigators and include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements.
 - 5.4.1 Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to Geneva in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.
 - 5.4.2 The PHS requires awardees to obtain a certification from each subrecipient, including commercial firms, stating that it complies with Federal policies regarding Investigator financial interest disclosure and that its portion of the project is in compliance with company policies. Subrecipients from commercial firms must provide such certification when the prime award is from the PHS.
- 5.5 Initial Review: If a potential FCOI is discovered during an initial review, defined by this document as commencing at least sixty (60) days prior to the award, the following actions are to be taken:
 - 5.5.1 The Authorized Official (AO) informs Geneva's President for determination of an apparent or perceived FCOI;
 - 5.5.2 The AO or President advises the Investigator of the decision of the preliminary review. The Investigator prepares a proposed Financial Conflict of Interest (FCOI) Resolution Plan (GCD-F-018) detailing the

proposed steps that will be taken to manage, reduce, or eliminate any FCOI. The draft FCOI Resolution Plan addresses such conditions or restrictions that may be imposed to manage the FCOI.

- 5.5.3 The disclosure material reviewed by the President and the draft FCOI Resolution Plan is forwarded to an Ad Hoc Committee for Investigator FCOI Review. The Committee's members are appointed by the President and include Geneva's legal representative. The Committee members review the financial disclosure material and the draft FCOI Resolution Plan. A meeting of the Committee is scheduled at which the Investigator may discuss his/her financial interests and proposed plan to manage any financial conflict. A FCOI exists when the Committee reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of federally sponsored research.
- 5.5.4 The Committee determines the terms, conditions, and restrictions, if any, that are required as part of the FCOI Resolution Plan on a case-by-case basis. The Committee consults with the Investigator and other members of the research team as appropriate when assessing a significant financial interest and developing a plan. Examples of conditions or restrictions that may be imposed to manage FCOI include, but are not limited to:
 - a. Public disclosure of the interest;
 - b. Monitoring of the research by independent reviewers;
 - c. Modification of the research plan;
 - d. Disqualification from participation in all or a portion of the research;
 - e. Divestiture of significant financial interests; or
 - f. Severance of relationships that create actual or potential conflicts.
- 5.5.5 After reviewing the material and discussing it with the Investigator, the Committee approves or amends the conditions or restrictions of the draft FCOI Resolution Plan, finalizes, and approves the Plan.
- 5.5.6 Investigators may appeal the Committee's decision to Geneva's President.
- 5.5.7 The approved FCOI Resolution Plan is incorporated into an agreement between Geneva and the Investigator which details the conditions and restrictions imposed on the investigator in the conduct of the research.
- 5.5.8 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.
- 5.6 For financial interests acquired or discovered during the award period, Geneva reviews and determines whether there is a FCOI within 60 days of disclosure by the Investigator. If a FCOI is acquired or discovered:
 - 5.6.1 Geneva will implement a plan to manage, reduce, or eliminate the FCOI and submit a FCOI report to the sponsor within this same 60-day period.
 - 5.6.2 If the Investigator does not make disclosure or it is reviewed after 60 days for whatever reason, 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 will include, 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
 - b. If bias is found, the Institution notifies the sponsor promptly and submits a mitigation report to the sponsor. A Mitigation Report includes:
 - b.1 Key elements documented in retrospective review
 - b.2 Description of the impact of the bias on the research project
 - b.3 Plan of action(s) to eliminate or mitigate the effect of the bias
- 5.7 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 the Retention of Corporate Records SOP (GEN-S-027).
- 5.8 If an Investigator violates this SOP or the terms of the Investigator Agreement, the committee recommends sanctions, which could include actions ranging from a public letter of reprimand to a restriction from applying for funds through Geneva for a period of years depending on the seriousness of the violation.
- 5.8.1 Such actions are communicated to the institution at which the Investigator is employed.
 - 5.8.2 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.
 - 5.8.3 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.
 - 5.8.4 Geneva follows the Federal regulations regarding the notification of the sponsor if an Investigator fails to comply with the stated policy. Geneva

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

5.9 FCOI Reporting

5.9.1 Geneva provides initial and ongoing FCOI reports to applicable federal sponsors:

- a. Prior to the expenditure of funds;
- b. During the period of award (within 60 days of identifying a new FCOI);
- c. Annually, report on the status of FCOI and any changes in management plan

5.9.2 All NIH-related FCOI reports are submitted to NIH through the eRA Commons FCOI Module, as required.

Approved By

Kathlyn Huson, Regional Grants Director
Kelly Lehner, Regional Grants and Contracts Director