The Gerontological Society of America
Research Financial Conflict of Interest Policy

Purpose:

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest in compliance with Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Promoting Objectivity in Research. This policy does not apply to SBIR Program Phase I applications.

Scope:

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH).

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by The Gerontological Society of America (GSA) to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

Definitions:

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

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of GSA, including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

Investigator means the project director or principal Investigator and any other person, 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. This may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS means 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 National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means 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 PHS by GSA.

Significant financial interest 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) With regard to any publicly traded entity, 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, exceeds $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) With regard to any non-publicly traded entity, 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 $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), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available),

(3) The term *significant financial interest* does not include the following types of financial interests:

a. Salary or consulting fees paid by GSA to the Investigator if the Investigator is currentlyemployed or otherwise appointed by GSA.

b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, orlocal government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Small Business Innovation Research **(SBIR)** Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Policy

Prior to initiating a PHS funded application and each year thereafter, any investigator who conducts research on any GSA project must disclose via a significant financial interest disclosure form (SFIDF) any significant financial interests (SFIs) that are relevant to an investigator's institutional research responsibilities or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has

been eliminated.

Investigators are required to complete the annual disclosure form even if they have no financial interest to report. Transactional disclosure by the PI is also required at the time a research proposal is submitted to GSA's Grants Signing Official (SO)in order to ensure compliance with Federal disclosure and management requirements.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects approval.

The SFIDF and supporting materials are forwarded to the SO for review. The SO will be responsible for, in consultation with the Authorized Organization Representative (AOR), evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the AOR is required prior to engaging in government-sponsored research. An SFI review must be completed before any expenses are incurred under an award. The AOR provides approval as signatory of the research agreement, simple agreement, or engagement contract, or provides written approval for a GSA signatory to sign in their stead.

Training

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants and key personnel engaged in NIH-funded research or its compliance on behalf of GSA.

The course is accessible at **http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm**. Upon completion of the training, a certificate of completion must be turned into the SO. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by GSA due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or new to the GSA. At a minimum, the FCOI training shall be taken every four (4) years.

Procedures

1. **Identification of Persons Required to Disclose a Significant Financial Interest**

   It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that a SFIDF is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed. To assist PIs with this responsibility, the SO will send out reporting reminders, SFIDF forms, and receive completed SFIDFs and provide to the AOR for review, these will occur yearly and just prior to application submissions. PIs are responsible for reporting SFIs that occur between these reporting timelines.

2. **Submission and Review of SFIDF**

   Every individual having a SFI requiring disclosure under this policy shall prepare a fully completed SFIDF that shall be submitted to the SO. An initial review of the SFIDF will be conducted by the SO to determine whether a potential for conflict of interest exists. The SO will utilize the Review of Conflicts Form (RCF) to consider if a potential financial conflict of interest exists. This form compares the focus, contractual involvements, and research goals of the research project against the SFIDF provided by the researcher. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFIDF. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to these actions) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

   - Public disclosure of significant financial interests;
   - Review of research protocols by independent reviewers;
   - Monitoring of research by independent reviewers;
   - Modification of research plan;
   - Disqualification from participation in all or a portion of the research funded;
   - Divesture of significant financial interests;
   - Severance of relationships that create actual or potential conflicts.

   All management plans are required to be signed by the Investigator and the AOR. Compliance of the management plan shall be monitored and implemented within 60 days of identified FCOI.

3. **Annual Reporting and After-Acquired Significant Financial Interests**

   All Investigators shall provide annual SFIDFs or more frequently if required by the management plan or acquired interests. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFIDF within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research

project submits the required SFIDF to the SO. The SO must report to NIH any FCOIs within 60 days of notification of new SFIs identified by the PI on either notification report, or annual report, and immediately upon review and determination of any bias found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation, and including the following NIH FCOI reporting items:

- The name of the Investigator with the FCOI
- The name of the entity with which the Investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the GSA's management plan, including other required information

4. **Violations of Conflict of Interest Policy**

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the SO shall make recommendations to the AOR regarding the impositions of sanctions or disciplinary proceedings against the violating individual. The SO and AOR will review together with the employee or Investigator the specific behaviors and consequences that are determined relevant based upon review, and any other administrative actions to assure Investigator compliance, including but not limited to supervised research activities. The SO and AOR must conduct retrospective reviews within 120 days of the Institution determining noncompliance for SFIs not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

In addition, GSA shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved. In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluation 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 compliantly managed or reported, the

Investigator involved will be required to: (i) disclose the FCOI in each public presentation of the results of the research, and (ii) request an addendum to previously published presentations of the same. Investigator will provide evidence of these disclosures to GSA.

5. **Record Keeping**

Records of Investigator SFIDFs, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the SO for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

6. **Sub-recipient Requirements**

Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. Prior to Notification of Award, GSA and sub-awards will establish in written agreement which FCOI policy will be followed by which Investigator, and if applicable, certification that the sub-award policy complies with the regulations, requirement to report identified FCOIs in a timeframe that permits GSA to report identified FCOIs to NIH as required by regulation, or that GSA will solicit and review subrecipient Investigator disclosures to enable identification, management and reporting of FCOIs as required by NIH. If an SFI is identified by the sub- award recipient, they are required to notify the SO of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

7. **Federal Reporting**

The SO is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH:

i. Initial report – prior to GSA's expenditure of any funds under a NIH-funded research project, the GSA must provide to the NIH an FCOI report regarding any Investigator SFI found by GSA to be a financial conflict of interest in accordance with the regulation.

ii. During on-going NIH-funded research projects – GSA shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, GSA shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

iii. Annual FCOI report – For any FCOI previously reported to the NIH, GSA shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.

8. Public Accessibility Requirements

GSA will provide public access to this policy on publicly accessible page of www.geron.org. The SO will ensure that any updated versions of this policy are provided for updated posting immediately upon implementation. In addition, and FCOI determined to exist for any Investigator or Senior Key Personnel will be posted to this same webpage in compliance with regulation, including the date of posting and (i) the minimum elements as provided in the regulation; (ii) posting within 5 days of a written request; (iii) annual updates, unless written requests are made which should continue to be available; (iv) any updates within 60 days of newly identified FCOI; and remain available for three years from the date the information was most recently updated.