

## **American Geriatrics Society**

### **Policy on Investigator's Conflicts of Interest for PHS-Funded Projects**

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#### **I. Purpose**

This Policy applies to all research funded or proposed for funding by the Public Health Service of the U.S. Department of Health and Human Services ("PHS"), including the National Institutes of Health ("NIH"). The purpose of this policy is to implement the requirements of the federal regulations set forth in 42 CFR Part 50 (Subpart F), 45 CFR Part 94, and any additional regulations that may be in effect from time to time, governing investigators' responsibilities for promoting objectivity in PHS-Funded Research. This policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

#### **II. Covered Parties**

This Policy applies to all persons responsible for designing, conducting or reporting PHS-Funded Research under the auspices of the American Geriatrics Society ("AGS").

#### **III. Defined Terms**

A. "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.

B. "Designated Official" means an institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official shall be the AGS Chief Executive Officer (CEO) and/or such other individual(s) as the Institution may designate in writing. All references herein to the CEO shall be deemed to refer to such other Designated Official(s) as appropriate.

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

D. "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 PHS-Funded Research. This may include, for example, graduate students, post-doctoral fellows, technicians, collaborators or consultants if they have such responsibilities.

E. "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.

F. "PHS-Funded Research" means Research funded by or proposed to be funded by the PHS, including without limitation NIH awards. The term includes any Research for which 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.

For purposes of this Policy, the term shall not include Phase 1 Small Business Innovative Research ("SBIR") or Small Business Technology Transfer ("STTR") applications or awards.

G. "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).

H. "Senior/key personnel" means the project director or principal investigator and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to the PHS for PHS-Funded Research.

I. "Significant Financial Interest" ("SFI") means:

1. A financial interest consisting of one or more of the following interests of an Investigator, or the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities:
  - a. With regard to a publicly traded entity, a significant financial interest exists if the value of any remuneration from the entity in the 12 months preceding the disclosure of the SFI and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship fees). 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.
  - b. With regard to a nonpublicly traded entity, a significant financial interest exists if the value of any remuneration, as described above, received from the entity in the 12 months preceding the disclosure of the SFI, when aggregated, exceeds \$5000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests).
  - c. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of royalties or other income related to such rights and interests that exceed \$5000.
  - d. Reimbursed or sponsored travel (sponsored travel being 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) related to an Investigator's Institutional Responsibilities.
2. Exceptions: "Significant Financial Interest" does not include:
  - a. Salary, royalties, or other remuneration paid by AGS to the Investigator, if the investigator is currently employed or otherwise currently holding an appointment at such institution;
  - b. Intellectual property rights assigned to AGS and agreements to share in royalties related to such rights (e.g., an Investigator's royalties received under the relevant Patent Policy.)
  - c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; and
  - d. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20

- i. U.S.C. 1001(a), an academic teaching hospital, a medical center, a research institute that is affiliated with an institution of higher education.

## IV. Policy

### A. Investigator Responsibilities

This Policy requires Investigators to (i) disclose Significant Financial Interests (including financial interests of the Investigator's spouse and dependent children), (ii) comply with the Review Process, and (iii) complete training with respect to PHS-Funded Research. (Training is dealt with in section F below.)

1. Disclosure. Every Investigator must disclose all of his or her Significant Financial Interests ("SFIs"), and those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's Institutional Responsibilities. The Investigator is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the PHS-Funded Research. That determination is made by a Designated Official as is further described below. Investigator disclosures are required as follows:
  - a. Upon Application. Each Investigator who is planning to participate in PHS-Funded Research must disclose SFIs to the AGS no later than the time of application or submission of a formal proposal for the PHS-Funded Research. With respect to SFIs of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
  - b. Annually. Each Investigator who is participating in PHS-Funded Research must submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph "a" above, or in any subsequent disclosure of SFIs, and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
  - c. New SFI. Each Investigator who is participating in PHS-Funded Research must submit a disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.

### B. Process for Reviewing Investigator Significant Financial Interests

1. **Initial Review and Action.** Before AGS disburses any funds for a PHS-Funded Research project, the Designated Official will do the following directly or acting through the Review Committee (the latter described in more detail in B(3), below):
  - a. Solicit and review Investigator Significant Financial Interest ("SFI") disclosures and any other information deemed relevant (e.g. research proposal summary, IRB application, etc.). In connection with this review, the Designated Official may require the Investigator to provide additional information;
  - b. Using Institutional guidelines, determine (1) whether an Investigator's SFI is related to PHS-Funded Research, and if it is, (2) whether the SFI is a Financial Conflict of Interest ("FCOI"); and
  - c. Take such actions as necessary to Manage the FCOI, including development and implementation of a management plan.
2. **Financial Conflict of Interest.** An Investigator's SFI is related to PHS-Funded Research when the Institution, through its Designated Official, reasonably determines that the SFI could be affected by the PHS-Funded Research or is in an entity whose financial interests could be affected by the PHS-Funded Research. A Financial Conflict of Interest exists when the

Institution, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research.

3. **Review Committee on Research Conflicts of Interest (“Review Committee”).** The Review Committee will be composed of the Executive Committee of the AGS Board of Directors. Designated counsel of AGS will be involved on an as-needed basis but will not be a member of the Review Committee. Only members on the Review Committee hold the right to vote. A majority of the committee members must be present to constitute a quorum. The Committee is empowered to act by majority vote of the members present at a meeting at which a quorum is present, or by written or electronic consent of a majority of all members. The Review Committee will review the facts and on a case-by-case basis determine (1) whether the Investigator’s Significant Financial Interest is related to PHS-Funded Research and, if it is, (2) whether the SFI is a Financial Conflict of Interest, confirming the initial review conducted by the designated official. Investigators may be required to provide additional information. The Review Committee will prepare a report for the CEO detailing a recommended management plan, including any proposed conditions or restrictions to manage the FCOI.
4. **Decision by CEO.** If the Review Committee determines that a Financial Conflict of Interest exists, it will submit a report of its determination and recommended management plan to the CEO. The CEO may return the report to the Review Committee for clarification or supplementation, and will accept, reject or modify the Review Committee’s determination and recommendation. The CEO will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to manage the Financial Conflict of Interest. The CEO will provide copies of the final decision to the Investigator, and the responsible Institutional Review Board (if human subjects research is involved). On occasion, normally with respect to existing management plans, the CEO may provide for administrative handling, consisting of a letter that provides appropriate guidance and, if warranted, states that no additional safeguards or conditions are needed. Upon receipt of the decision, the Investigator must either acknowledge it or submit an appeal. Funding will be held until the Investigator agrees to comply with the management plan.
5. **Investigator Appeals.** The Investigator has 10 days from receipt of the CEO’s final decision to submit an appeal in writing to the Society President as applicable. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful to the President in making a final determination. This decision shall be final and not further appealable.
6. **Submission of the Research Application.** The Institution will certify in the application to the Institution’s effective, implemented policy and full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k) (1)-(5).
7. **Institutional Remedies.**
  - a. Investigators are required to comply with the final decision of the CEO or Society President. If an Investigator fails to comply, the CEO, with the aid of the Review Committee, will develop a corrective action plan for final review and approval by the Society President
  - b. The Institution may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to professional bodies or journals, or the public.
  - c. If an Investigator fails to comply with this Policy or a management plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, the Institution shall promptly notify the PHS awarding component of the corrective

action taken or to be taken (e.g., a mitigation report for the PHS-Funded Research, as further described below), and implement corrective action.

### C. Management of Financial Conflict of Interests

1. **Management Plans.** Each management plan shall specify the actions that have been, and shall be, taken to Manage the Financial Conflict of Interest (“FCOI”).
2. **Conditions or Restrictions.** Examples of conditions or restrictions that might be imposed to Manage an FCOI include, AGS are not limited to:
  - a. Public disclosure of the FCOI (e.g., when presenting or publishing the research);
  - b. For PHS-Funded Research projects involving human subjects research, disclosure of the FCOI directly to the human subjects as approved by the Institutional Review Board;
  - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-Funded Research against bias resulting from the FCOI;
  - d. Modification of the research plan;
  - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;
  - f. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
  - g. Severance of relationships that create the Financial Conflict of Interest.
3. **Clinical Research.** The existence of a Financial Conflict of Interest (“FCOI”) related to a clinical research project creates a rebuttable presumption that stringent management of the FCOI is appropriate. In any case in which the U.S. Department of Health and Human Services (“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 the Institution as required, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an Policy to previously published presentations.
4. **Monitoring Compliance with the Management Plan.** The AGS will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-Funded Research.

### D. New SFIs during ongoing PHS-Funded Research

Whenever, in the course of ongoing PHS-Funded Research, an Investigator who is new to participating in the PHS-Funded Research discloses an SFI or an existing Investigator discloses a new SFI, the Designated Official will do the following, acting directly or in conjunction with the Review Committee, within sixty (60) days:

- review the Significant Financial Interest;
- determine whether it is related to PHS-Funded Research;
- determine whether a Financial Conflict of Interest exists, and, if so;
- implement a management plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest.

### E. Review of Existing SFIs and Retrospective Review during ongoing PHS-Funded Research

The Designated Official, acting directly or in conjunction with the Review Committee, will take the following actions with respect to a Financial Conflict of Interest in ongoing PHS-Funded Research:

1. **Review of Existing SFIs.** Whenever AGS identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g. was not timely reviewed or reported by a subrecipient), the Designated Official will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth in Section IV. D, above.
2. **Retrospective Review.** Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI, failure by the Institution to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the Designated Official will, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such Research. The AGS will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1)-(9), for PHS-funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.
3. **Notification and Mitigation Report.** If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the AGS will notify the PHS awarding component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5(a)(3)(iii), described further in section H(3), below.
4. **Interim Measures.** At any time, the Designated Official may determine that interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research.

## F. Training

Every Investigator will complete training on Investigator policy responsibilities at the following times:

1. Prior to engaging in PHS-Funded Research and at least once every four years thereafter;
2. When this policy is revised in any manner that affects the requirements of Investigators;
3. When an Investigator is new to AGS, even if the PHS-Funded Research has already begun;
4. When an Investigator is not in compliance with this policy or a management plan, as determined by the Designated Official.

## G. Subrecipients

If AGS is the awardee and conducts PHS-Funded Research through a subrecipient (e.g. subcontractors or consortium members), the Designated Official will take reasonable steps to ensure that subrecipient Investigators comply with this Policy, as follows:

1. AGS's written agreement with the subrecipient will establish whether this Policy or the subrecipient's Financial Conflicts of Interest policy will apply to the subrecipient's Investigators. The written agreement will state either that:
  - a. The subrecipient certifies that its Financial Conflicts of Interest policy complies with the applicable federal regulations, and that the subrecipient's Investigators will comply with the subrecipient's policy or,
  - b. if the subrecipient cannot provide such certification, that subrecipient Investigators are subject to this Policy.

2. If the subrecipient's policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to AGS. The time period(s) will be sufficient to enable AGS to provide FCOI reports to the PHS prior to the expenditure of funds and within 60 days of finding any additional FCOI.
3. If AGS's policy, as awardee, applies, the subrecipient Investigators will disclose all Significant Financial Interests that are directly related to the subrecipient's work for AGS. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing AGS enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI reports to the PHS prior to the expenditure of funds, within 60 days of finding any additional FCOI and annually thereafter.

#### **H. Reporting of Financial Conflict of Interest**

1. Prior to the Institution's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to the PHS, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented. The report ("FCOI Report") to PHS will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable.
2. For newly acquired FCOIs during ongoing PHS-Funded Research, described in Section IV.D above, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, an FCOI Report ensuring that the Institution has implemented a management plan.
3. For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section IV.E above, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a)(3)(iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias.
4. After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI Reports that address the status of the Financial Conflict of Interest and any changes to the management plan for the duration of the PHS-Funded Research (including extensions with or without funds) in the time and manner specified by the PHS awarding component.
5. The AGS shall, upon request of the PHS, make information available to the PHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest.

#### **I. Maintenance of Records**

The AGS will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in an FCOI finding), and any other action under this policy, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b), relating to records retention.

## **J. Public Accessibility**

1. This Policy and all related forms shall be made publicly available on AGS' website (<http://americangeriatrics.org>)
2. Upon written request to the AGS, information will be provided including, at a minimum, that specified in 42 CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to AGS and meeting the following criteria:
  - a. The SFI was disclosed and is still held by the Senior/Key Personnel;
  - b. AGS has determined that the SFI is related to the PHS-Funded Research; and
  - c. AGS has determined that the SFI is an FCOI.

Information concerning the SFIs of Senior/Key Personnel shall remain available for responses to written requests for at least three years from the date that the information was most recently updated. When the PHS-Funded Research is conducted by a subrecipient Investigator, and under their written agreement the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

Responses will be returned within five (5) business days from when the AGS receives the request.

## **V. Responsible Parties**

The AGS is responsible for overseeing implementation of and ensuring compliance with this policy.

## **VI. Related Policies and References**

### A. Related AGS Policies

- a. [American Geriatrics Society Conflict of Interest Policy & Procedures](#)

## **VII. Policy History**

This Policy is effective starting October 11, 2013.