

American Society for Bone and Mineral Research Policy on Investigator's Conflicts of Interest for PHS-Funded Projects

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.

Purpose of Federal Regulation 42 CFR Part 50 Subpart F

The purpose of this regulation is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants and cooperative agreements will be biased by any conflicting financial interest of an Investigator.

Application of Policy

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

Training Requirements

Every Investigator will complete training on Investigator policy responsibilities at the following times: Prior to engaging in PHS-Funded Research and at least once every four years thereafter;

1. When this policy is revised in any manner that affects the requirements of Investigators;
2. When an Investigator is new to ASBMR, even if the PHS-Funded Research has already begun;
3. When an Investigator is not in compliance with this policy or a management plan, as determined by the Ethics Advisory Committee.

Please see FCOI required training at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Financial Conflict of Interest (FCOI)

An FCOI exists when ASBMR, through its Ethics Advisory Committee, reasonably determines that an Investigator (including their spouse and dependent children) has a Significant Financial Interest (SFI) related to a NIH-funded research project that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Significant Financial Interest (SFI)

Investigators are required to disclose to ASBMR a listing of SFIs (and those of his/her spouse and dependent children) that: 1) would reasonably appear to be affected by the research for which funding is sought, and 2) includes those entities whose financial interests would reasonably appear to be affected by the research.

PHS FCOI regulation defines a "Significant Financial Interest" as follows:

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:

- a. 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 etc.); 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 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
 - c. 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) related to their 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 by 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. ASBMR's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with ASBMR's FCOI policy, the Ethics Advisory Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI regarding the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests:
- a. Salary, royalties, or other remuneration paid by ASBMR to the Investigator, if the Investigator is currently employed or otherwise appointed by ASBMR;
 - b. Ownership interests in ASBMR, if ASBMR is an applicant under the SBIR and STTR programs;
 - c. Intellectual property rights assigned to ASBMR and agreements to share in royalties related to such rights;
 - d. Any ownership interest held by the Investigator, if the Institution is a commercial or for-profit organization;
 - e. 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;

- f. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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;
- g. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined by 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.

Disclosure of a SFI

An Investigator is under a continuing obligation to disclose any SFI (and those of his/her spouse and dependent children), or the appearance of a financial conflict, as soon as it is known, or reasonably should have been known.

Each Investigator who is planning to participate in PHS-Funded Research must disclose SFIs to ASBMR at the following intervals:

1. At the time of application or submission of a formal proposal for the PHS-Funded Research.
2. Within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.
3. On an annual basis during the period of the award. Such disclosure shall include any information that was not disclosed initially 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).

Procedures for Review of an Actual or Potential FCOI

When there is reason to believe that an actual or potential FCOI exists, or the appearance of an FCOI exists, between the interests of ASBMR and that of an Investigator, the Ethics Advisory Committee shall ultimately be responsible for determining the appropriate response. This shall include, but not necessarily be limited to, invoking the procedures described below with respect to a specific proposed action.

Where the appearance of a SFI or an actual or potential SFI involves an Investigator, the Ethics Advisory Committee shall review the matter and determine whether an Investigator's SFI is related to PHS-funded research and if so related, whether the SFI is an FCOI. The Committee will take appropriate action but may discuss their suggestions for management of the conflict with the ASBMR Executive Committee. The Executive Committee consists of the President, Past-President, President-Elect and Secretary-Treasurer. The Executive Committee in conjunction with the Ethics Advisory Committee shall determine if any further Council review or action is required.

In addition, the Ethics Advisory Committee will present a report of all FCOI cases to Council annually.

Procedures for Addressing an FCOI

Where an actual or potential FCOI exists or the appearance of an FCOI exists, the following procedures

will apply:

1. An Investigator who has an actual or potential FCOI or the appearance of an FCOI shall not participate in, or be present during, the deliberations and decision-making with respect to this action unless requested by the Ethics Advisory Committee, and then will be present only to answer questions, provide information about the alleged FCOI, or respond to proposed ASBMR actions.
2. If a finding of an FCOI, or a decision about an FCOI, is to be determined by the Ethics Advisory Committee, the meeting minutes shall reflect that the FCOI was discussed and the nature of the committee's decision.
3. Members of the Ethics Advisory Committee must recuse themselves from any discussion and vote on issues in which they have an FCOI or appear to have an FCOI.

Management of an FCOI

If the Ethics Advisory Committee determines that an FCOI exists or has the potential to exist, they shall determine what conditions or restrictions, if any, should be imposed by ASBMR to manage these actual or potential conflicts. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

1. Public disclosure of the FCOI (e.g., when presenting or publishing the research);
2. 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;
3. 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;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;
6. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
7. Severance of relationships that create the Financial Conflict of Interest.

If the Ethics Advisory Committee does impose conditions or restrictions upon an Investigator with respect to managing an FCOI, a management plan shall be prepared that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or regarding their relationship with ASBMR. The management plan shall be signed by the Investigator and the chair of the Ethics Advisory Committee. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated, and/or they will be disclosed to the sponsoring agency for action.

If the Ethics Advisory Committee determines that imposing the above-referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Ethics Advisory Committee may determine that the research should go forward without imposing such conditions or restrictions, although an Investigator would still need to disclose the nature of the conflict on a yearly basis.

Compliance monitoring of the SFI will occur through a yearly review of the management plan by the Ethics Advisory Committee. Based on Investigator compliance, the Committee may decide to maintain,

reduce, or eliminate the ongoing compliance monitoring plan or impose additional conditions or restrictions upon an Investigator, as outlined above. In addition, the Committee may discuss the outcome of the review with the ASBMR Executive Committee and determine if further Council review or action is required.

Reporting Requirements to NIH

1. Prior to the Institution's expenditure of any funds under PHS-Funded Research, the ASBMR 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, ASBMR 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, ASBMR 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, ASBMR 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 ASBMR 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.

Subrecipient Investigator Requirements

ASBMR will incorporate language, as part of a written agreement with the subrecipient, that the FCOI Policy of the subrecipient will apply to the subrecipient's Investigator. The subrecipient must provide ASBMR with certification that the subrecipient Investigator is in compliance with 42 CFR Part 50 Subpart F and must submit all Investigator reported SFIs to ASBMR within 30 days of discovering or acquiring a new SFI or, at the very least, in sufficient time for ASBMR to meet its FCOI reporting obligations. If a subrecipient does not have an FCOI Policy that complies with 42 CFR Part 50 Subpart F, a subrecipient Investigator must follow the ASBMR FCOI Policy in all aspects.

Maintenance of Records

All FCOI-related records will be retained for at least 3 years from the date the final expenditure report is submitted to PHS. Documents will also be retained from the dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Public Accessibility

This Policy and all related forms shall be made publicly available on the ASBMR website

(www.asbmr.org). Upon written request to ASBMR, 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 ASBMR and meeting the following criteria:

1. The SFI was disclosed and is still held by the Senior/Key Personnel;
2. ASBMR has determined that the SFI is related to the PHS-Funded Research; and
3. ASBMR 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 ASBMR receives the request.

Key Definitions

Financial Conflict of Interest (“FCOI”) - a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

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

Investigator - 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.

PHS-Funded Research - 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.

Senior/key personnel - 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.

Significant Financial Interest (SFI) - one or more of Investigator Financial Interests (and those of the Investigator’s spouse and dependent children) that reasonably appears related to the Investigator’s institutional responsibilities, and where the value of such Investigator Financial Interest exceeds \$5,000, existing at the date of SFI disclosure and going back 12 months. SFI does not include: (1) salary, royalties, or other remuneration from ASBMR, (2) salary, royalties, or other payments from any source other than ASBMR that, when aggregated for the Investigator and spouse and dependent children in the 12 months preceding disclosure, are not expected to exceed \$5,000, (3) income from seminars, lectures, or teaching engagements, service on advisory committees or review panels sponsored by federal, state or local government agencies, 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 as defined at 20 U.S.C. 1001(a), (4) an equity interest that, when aggregated for the Investigator/Project Director and spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or (5) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not control such fund’s or account’s investment decisions.