

U.S. Public Health Service Grants and Financial Conflict of Interest Policy

Purpose

AMSEA shall design, conduct, and report on research funded under Public Health Service (PHS) grants or cooperative agreements in a manner that is free from bias resulting from Investigator financial conflicts of interest, as required under 42 CFR Part 50, Subpart F.

Definitions

AMSEA means the Alaska Marine Safety Education Association and designated staff and officers

Chairman means the Chairman of the AMSEA Board of Directors

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Executive Director means the AMSEA Executive Director

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.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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

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

Institutional responsibilities means an Investigator's professional responsibilities on behalf of AMSEA, and as defined by AMSEA in its policy on financial conflicts of interest, which may include for example: 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.

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, which 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 under this subpart.

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. 201et 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). As used in this subpart, 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 AMSEA in the grant application, progress report, or any other report submitted to the PHS by AMSEA under this subpart.

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:
 - 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); 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. 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; except for travel that is reimbursed or sponsored by a Federal, state, or local government agency, 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.

3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by AMSEA to the Investigator if the Investigator is currently employed or otherwise appointed by AMSEA, including intellectual property rights assigned to AMSEA and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, 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; or income from service on advisory committees or review panels for a Federal, state, or local government agency, 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.

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. The term, *SBIR Program*, also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Treasurer means the Treasurer of the AMSEA Board of Directors

Institutional Responsibilities

AMSEA shall maintain a written policy regarding financial conflicts of interest in research funded by the Public Health Service, consistent with the requirements of 42 CFR Part 50, Subpart F. The Treasurer will ensure that the FCOI policy will be published on the AMSEA website prior to the expenditure of PHS funds. Methods and instructions for implementation of this policy are contained in the AMSEA Financial Conflict of Interest Procedures document.

AMSEA requires that Investigators understand AMSEA's FCOI policy and receive FCOI training. Any subrecipients of PHS funding must maintain an FCOI policy that complies with 42 CFR Part 50, Subpart F or adhere to AMSEA's FCOI policy prior to the expenditure of PHS funds.

AMSEA requires Investigators to disclose significant financial interests (and those of the Investigator's spouse and dependent children), prior to applying for PHS-funded research. Investigators shall update their disclosure of their significant financial interests (and those of their spouse and dependent children), annually or when a new significant financial interest is acquired.

AMSEA will review significant financial interests for FCOIs and determine if a FCOI exists. If an FCOI exists, AMSEA will develop and implement a FCOI management plan designed to eliminate or mitigate the FCOI. The management plan that will specify the actions that have been, and will be, taken to manage such financial conflict of interest. AMSEA may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the AMSEA's review. AMSEA will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

AMSEA will publish any information concerning existing FCOIs on the AMSEA website. Information regarding FCOIs will be updated annually or within 60 days of the determination of additional FCOIs. Information regarding FCOIs published on the AMSEA website will be maintained for three years after the last update.

Non-Compliance

If AMSEA identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Treasurer during an ongoing PHS-funded research project, AMSEA will determine if an FCOI exists and implement a management plan if required.

If an FCOI exists, AMSEA will conduct a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If bias is found, AMSEA will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Thereafter, the Treasurer will submit FCOI reports annually, for the duration of the PHS-funded research project.

Based on the results of the retrospective review, if appropriate, the Treasurer will update any previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. AMSEA will review all incidents of non-compliance by an investigator for consideration of disciplinary action.