



Interdisciplinary Leaders in  
Substance Use Education,  
Research, Care and Policy

AMERSA, Inc  
Financial Conflict of Interest (FCOI) Policy  
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## Purpose

This Financial Conflict of Interest (FCOI) Policy provides guidelines for identifying, disclosing and managing significant financial conflicts of interest related to AMERSA projects funded by Public Health Service (PHS) to comply with the National Institutes of Health (NIH) 2011 Revised Financial Conflict of Interest Regulation 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought”.

This policy applies to each Investigator, as defined by the regulation, who is planning to participate in or is participating in PHS funded AMERSA activities.

AMERSA’s Signing Official (SO) for PHS-supported research serves as the Institutional Official for this policy and is responsible for ensuring implementation of this policy. This policy operates in addition to AMERSA’s Conflict of Interest policy for its Board of Directors and key employees.

## Definitions

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

*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.

*Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

*Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution 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.

*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).

*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 the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution 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:

(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), 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 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. The Institution'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 the Institution's FCOI policy, the institutional official(s) 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 with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

## Training

The Institutional Official will provide each new Investigator with a copy of this FCOI policy and inform them of the federal regulation and their disclosure responsibilities.

Each Investigator will be required to complete FCOI training: 1) prior to engaging in research related to any PHS-funded grant, 2) at least every 4 years, and 3) immediately, if AMERSA revises this policy, if an Investigator is new to AMERSA or if an Investigator is not in compliance with the policy or management plan.

## Disclosure, Review and Monitoring

The Institutional Official will solicit disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities: 1) no later than at the time of application for PHS-funded research, 2) at least annually during the period of the award, and 3) within 30 days of discovering or acquiring a new SFI.

The Institutional Official or his/her designee will review all Investigator SFI disclosures and determine: (1) whether an Investigator's SFI is related to PHS-funded research; and (2) if so related, whether the SFI is an FCOI (i.e., a SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

If the Institutional Official determines the FCOI can be managed, the Institutional Official will develop and implement a written management plan, intended to reduce or eliminate the conflict, as appropriate, within 60 days. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before participating or continuing participation in any related PHS-sponsored research. The Institutional Official will monitor Investigator compliance with the management plan until completion of the project.

If the Institutional Official determines the FCOI cannot be managed, the Institutional Official will move forward with suspension of the Investigator's association with the planned or actual PHS-supported project. The Institutional Official will provide the Investigator with a written explanation of this determination.

The above procedure also applies to cases where an Investigator discloses a new SFI or the Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.

## Reporting

The Institutional Official or his/her designee will submit initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH as required by the regulation:

- (1) Prior to the expenditure of funds,
- (2) Within 60 days of identification for an Investigator who is newly participating in the project,
- (3) Within 60 days for new, or newly identified, FCOIs for existing Investigators,
- (4) At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report or at time of extension) to provide the status of any FCOIs and any changes to the management plan, if applicable, until the completion of the project.
- (5) Following a retrospective review to update a previously submitted report, if appropriate.

The Institutional Official will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded activities and will submit a Mitigation Report in accordance with reporting elements required under 42 CFR 50.605(a)(3)(iii).

The Institutional Official will also notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded activity.

## Maintenance of Records

The Institutional Official will maintain all FCOI-related records for at least 3 years from the date the final expenditures report is submitted to the PHS (NIH) and from other dates specified in 45 CFR 75.361, where applicable.

## Enforcement Mechanisms and Remedies and Noncompliance

If a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI or to materially comply with a management plan for a FCOI, the Institutional Official shall complete, within 120 days of this determination, a retrospective review. The Institutional Official will update any previously submitted report to the PHS and if bias is found, will submit a Mitigation Report in accordance with 42 CFR 50.605(b)(3), that will address the impact of the bias on the research project and the plan of action to mitigate its effect.

If an Investigator fails to comply with AMERSA's FCOI Policy they will be suspended from all relevant activities until the matter is resolved. In cases of extreme bias, the Investigator may be removed from the project.

## Subrecipient Requirements

AMERSA has no subrecipient Investigators.

## Public Accessibility

The Institutional Official or his/her designee will ensure that this policy is posted on the AMERSA website. In addition, the Institutional Official or his/her designee will make information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. This information will be kept up to date, will include the minimum elements as provided in regulation 42 CFR 50.605(a)(5)(i)-(iv), will be made available within 5 calendar days of a written request and will remain available for three years from the date the information was most recently updated.