

FINANCIAL CONFLICT OF INTEREST - OBJECTIVITY IN RESEARCH

[Definitions](#) | [Disclosure and Review](#) | [Conflict of Interest Management](#) | [Additional Requirements for PHS Awards](#)

The purpose of this policy is to promote objectivity in research by establishing standards that create a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from conflicting financial interests of investigators.

A conflict of interest (actual or perceived) occurs when any financial or other arrangement, situation, or action affects or could be perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

A researcher is required to disclose a significant financial interest when he or she, any of his or her family, or any associated entity possesses a significant financial interest in a research activity that is related to his or her responsibilities as a member of the Veterans Education and Research Association of Michigan (VERAM) conducting research at VA Ann Arbor Healthcare System (VAAAHS).

VERAM members are also subject to the conflict of interest policies of the federal government and institutions such as VAAAHS and the University of Michigan (UM) with whom they may have an affiliation or appointment, and have a responsibility to disclose financial interests in research according to the policies of those institutions.

This policy covers all VERAM administered research projects or programs and closely adheres to the policy as promulgated in the 2011 revised Department of Health and Human Services (DHHS) Financial Conflict of Interest (FCOI) regulation. Research supported by U.S. Public Health Service (PHS) funding has additional requirements addressed in the section for Additional Requirements for PHS Awards and in definitions noted below.

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.

[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.

[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. Institutional Responsibilities on behalf of VERAM include research and service by the Executive Director and VERAM Board of Directors.

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. 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). 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.

[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.

DISCLOSURE AND REVIEW

For all research projects, Investigators must disclose financial interests prior to review and approval by the Research & Development (R&D) Committee.

For VERAM Board members, each Director must disclose annually for Board review or prior to any vote that may have a potential conflict of interest.

For Investigators under the PHS policy, disclosure is additionally required at the time of application and at least annually thereafter as delineated in the Financial Conflict of Interest Guidelines for PHS Awards. Disclosure should include the relationship of the financial interest to their institutional duties.

Investigators are responsible for disclosing new or changed financial relationships as they occur but no later than within 30 days. These will be reviewed in the same manner as original disclosures.

Retrospective reviews will be required for significant financial interests not disclosed in a timely manner.

RETROSPECTIVE REVIEWS (Refer to [NIH FCOI FAQ I.1](#)).

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
v2/4.2023

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by VERAM or VAAHS to constitute a Financial Conflict of Interest;
- Failure by VERAM or VAAHS to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

The Institution shall, within 120 days of the Institution’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. (Refer to [NIH Responsibility of Applicants for Promoting Objectivity in Research \(2011 Revised Regulations\) FAQ I.1](#))

KEY ELEMENTS FOR DOCUMENTING THE RETROSPECTIVE REVIEW (Refer to [NIH FCOI FAQ I.2](#)).

The Institution shall document the retrospective review which must include at least the following key elements:

- A. Project number;
- B. Project title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has a financial conflict of interest
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- H. Findings of the review; and
- I. Conclusions of the review.

IF BIAS IS FOUND (Refer to [NIH FCOI FAQ I.3](#)).

If bias is found, the Institution must notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a “Revised FCOI Report.” (see FAQ H.2.). The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

NIH FOLLOW UP REQUIREMENTS POST-RESTROSPECTIVE REVIEW (Refer to [NIH FCOI FAQ I.4](#)).

When bias is not found following the completion of a Retrospective Review, VERAM does not submit a “Revised” FCOI report to notify NIH that either the Retrospective Review has been completed or that bias is not found. NIH guidelines for the submission of a “Revised” FCOI report following the completion of a Retrospective Review is outlined within [NIH FCOI FAQ H.22](#)).

CONFLICT OF INTEREST SUBCOMMITTEE

VERAM reviews potential conflicts of interest for research through the Conflict of Interest Subcommittee, in which VAAAHS and UM are also represented. This subcommittee of the VAAAHS R&D Committee reviews proposed research and makes recommendations regarding management of conflicts of interest. Whenever there is a significant financial interest, disclosures must be submitted by Investigators to VERAM. VERAM will refer significant financial interests related to institutional duties to the Conflict of Interest Subcommittee for review.

The Conflict of Interest Subcommittee consists of four voting and one non-voting member:

- A representative of the management of VERAM;
- A representative of the UM's Office of the Vice President for Research;
- Two experienced clinical or biomedical research scientists not currently serving on the R&D Committee; and
- The Associate Chief of Staff for R&D is an ex officio/non-voting member.

For VA investigators, the subcommittee relies on, among other rules, federal guidelines contained in 5 CFR Part 2635 and 18 USC§208.

The subcommittee meets on an ad hoc basis. Its membership is reviewed and authorized on a federal fiscal year basis. The subcommittee reports to the R&D Committee and VERAM management in the form of meeting minutes. These minutes include recommendations regarding management of the real or potential conflicts of interest disclosed by Investigators. Persons appointed to the subcommittee are required to disclose their own potential conflicts of interest to the subcommittee and recuse themselves from reviewing and voting on any matter in which they may have an interest.

In addition to VERAM and PHS policy, as noted above, specific conflict of interest rules and ethics standards apply to VA investigators and are considered in the review.

CONFLICT OF INTEREST MANAGEMENT

The subcommittee will consider all information obtained from the Investigator, VERAM, VA, and UM in deciding how best to address conflicts of interest. Options for managing conflict of interest include, but are not limited to:

- Disclosure of significant financial interests to the public, human subjects, researchers and other participants, publishers, and/or conference organizers;
- Requiring additional disclosures or actions with respect to IRB or IACUC applications or materials;
- Monitoring of research by disinterested co-researchers or independent reviewers or committees capable of taking measures to protect research from bias;
- Disqualification from participation in activity affecting or affected by a technology transfer transaction;
- Requiring that investigator participation in the recruitment or consent of subjects be prohibited or restricted;
- Requiring that the significant financial interest be divested, restructured, or placed in a blind trust;
- Modification or severance of relationships that create potential conflicts of interest;
- Changing terms of the grant agreement or CRADA relating to the research;
- Requiring non-participation in any business transactions between the parties to agreements involving the research in question.

Conditions imposed by the Conflict of Interest Subcommittee or the VAAHS R&D Committee must be met by the Investigator in order to receive approval to conduct a proposed research project. VERAM will not expend funds in support of a research project until any significant financial interest has been reviewed by the Conflict of Interest Subcommittee and any conflict of interest has been satisfactorily managed or eliminated.

VERAM will comply with sponsor requirements for ongoing reporting of FCOIs including management plans, retrospective reviews and mitigation reports. Any violation of this policy may require reporting to a sponsoring entity and affiliated institutions as appropriate.

RECORD RETENTION

VERAM maintains and retains all records related to Investigator disclosures of financial interests for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in [45 C.F.R. 75.361](#) (see [NIH FCOI FAQ A.11](#)) for different situations. These include:

- Investigator disclosures of financial interests
- VERAM's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest)
- All actions under the VERAM's policy or retrospective review

VERAM will retain records for each competitive segment as provided in the regulation and as expected by NIH.

VERAM's record retention policy complies with PHS regulations.

ADDITIONAL REQUIREMENTS FOR PHS AWARDS

Additional requirements for PHS awards are promulgated by the 2011 revised DHHS Financial Conflict of Interest (FCOI) regulation, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 C.F.R. Part 50, Subpart F](#)) and Responsible Prospective Contractors ([45 C.F.R. Part 94](#)). Compliance with these regulations is delineated under the Financial Conflict of Interest Guidelines for PHS Awards found on the VERAM website.

Investigators entering into consortium arrangements should be aware that VERAM will include a requirement that subrecipient institutions comply with the PHS policy on Financial Conflict of Interest.

The PHS policy requires travel disclosure and training as defined below.

Travel and training requirements do not extend to Investigators' immediate family members (spouses and dependent children).

SPECIAL REQUIREMENT FOR CLINICAL RESEARCH (Refer to [NIH FCOI FAQ A.8](#))

In any case in which the HHS determines that an NIH-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 a conflicting interest that was not managed or reported by the VERAM as required by the regulation, the Institution must require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public

presentation of the results of the research and to request an addendum to previously published presentations. Institution's Financial Conflict of Interest policy may have additional requirements.

Disclosure Under PHS Awards

Investigators must disclose all significant financial interests as defined above and in addition include 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. However, 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; an academic teaching hospital; a medical center; or a research institute that is affiliated with an Institution of higher education.

Disclosures are required: (1) at the time of application for PHS-funding; (2) at least annually during the period of award; (3) within 30 days of acquiring or learning of a newly acquired significant financial interest; (4) within 30 days of an Investigator newly participating in the project; and (5) within 30 days of travel.

Mandatory Training Requirements (Regulatory Citation [42 CFR 50.604\(b\)](#))

As part of mandatory training, this policy will be provided to each investigator engaged in PHS-funded research. The investigator's disclosure responsibilities of all foreign and domestic significant financial interests (SFI) as defined by [42 CFR 50.604\(b\)](#). Additional details regarding the SFI definition is supported by NIH's FAQs [E.9.](#) and [E.20.](#) Investigators are to review and comply with the **Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulations)** (See NIH's [FAQ L.1.](#), "FCOI Training" tutorial and other training resources on NIH's [FCOI Training website](#))

FCOI training for PHS-supported Investigators must be completed:

1. Prior to engaging in research related to any PHS/NIH-funded grant
2. At least every four (4) years
3. Immediately, if:
 - a. Institution revises its FCOI policy that affects requirement of Investigators
 - b. An Investigator is new to an Institution
 - c. An Investigator is not in compliance with the policy or management plan

Please refer to [NIH's FCOI Training webpage](#) and the [NIH's FAQs webpage](#) for more information. Also review the NIH Notice issued September 16, 2022, [NOT-OD-22-210](#) "Financial Conflict of Interest (FCOI) and Other Support: Reminders".

To complete the training requirement:

1. View the [NIH FCOI Tutorial](#);
2. Complete the quiz;
3. Print the certificate of completion; and
4. Email the certificate of completion to cgm@veram.org

Public Availability

In accordance with PHS policy, VERAM makes identified FCOIs held by Investigators available to requestors within five calendar days of the receipt date of a written request.