
VERAM

Financial Conflict of Interest Policy & Training Overview

Purpose

Welcome to VERAM's Financial Conflict of Interest (FCOI) training.

The purpose of this training is to inform Public Health Service (PHS)-funded Investigators of:

- VERAM's revised FCOI policy effective April 25, 2023.
- The PHS 2011 revised FCOI regulation
- Their responsibilities regarding disclosure of Significant Financial Interests

Purpose

Q: Why did VERAM revise the policy?

A: In response to the NIH Notice issued September 16, 2022, [NOT-OD-22-210](#) “Financial Conflict of Interest (FCOI) and Other Support: Reminders”

Institutions receiving funding from PHS entities are required to be in compliance with all of the requirements as outlined within [42 CFR Part 50 Subpart F](#)

Investigators applying for funds from PHS entities have additional responsibilities for Significant Financial Interest disclosure.

Department of Health and Human Services
(DHHS)

Public Health Service (PHS)

Agency for
Healthcare
Research
and Quality
(AHRQ)

Centers for
Disease
Control and
Prevention
(CDC)

Food and Drug
Administration
(FDA)

Health
Resources and
Services
Administration
(HRSA)

Indian
Health
Service
(IHS)

National
Institutes
of Health
(NIH)

Office of Public
Health
and Science
(OPHS)

Substance
Abuse & Mental
Health Services
Administration
(SAMHSA)

Purpose

What is the purpose of VERAM's FCOI Policy?

- The purpose of the policy is to promote objectivity in research by establishing standards that ensure a reasonable expectation that the design, conduct, or reporting of research is not biased by any conflicting financial interest.

Who is affected by the PHS FCOI Policy?

- The PHS policy mainly affects personnel who are responsible for the design, conduct, or reporting of research.

2023 Policy Changes

VERAM's revised FCOI Policy includes several changes. Focusing, in particular, on these areas:

- Expanded definitions reflective of those within [Subpart F—Promoting Objectivity in Research](#)
- General definition of institution of higher education as defined within [20 U.S.C. 1001\(a\)](#)
- Disclosure and Review, Retrospective Reviews and Post-review NIH Notification procedure
- Record Retention
- Inclusion of NIH's [Frequently Asked Questions](#)
- NIH's [FCOI Training](#)
- **UPDATED:** Mandatory Investigator training
- Reminder for compliance with “Promoting Objectivity in Research” [42 CFR Part 50 Subpart F](#)
- Review of [NOT-OD-22-210](#) “Financial Conflict of Interest (FCOI) and Other Support: Reminders”

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.

Definitions (cont.)

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.

Definitions (cont.)

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) (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

Definitions (cont.)

- (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.

Definitions (cont.)

(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.

VERAM & the COI Subcommittee

- Determine if disclosed SFI are FCOI and establish a Conflict Management Plan to mitigate or eliminate the FCOI.
- Monitor Investigator compliance with Conflict Management Plans.
- Perform retrospective reviews within 120 days from the date of determining any non-compliance with the regulation.
- Make identified FCOIs available to requestors within five calendar days of the receipt date of a written request.
- Retain records for a minimum of three years from the date of submission of final reports to the sponsor.
- Provide initial and annual FCOI reports to PHS sponsors.
- Confirm subrecipient (subcontract) Investigators comply with the VERAM FCOI Policy, or another institution's FCOI policy that meets the PHS regulation's standards.

Institutional Responsibilities

- Determine if disclosed SFI are FCOI and establish a Conflict Management Plan to mitigate or eliminate the FCOI.
- Monitor Investigator compliance with Conflict Management Plans.
- Perform retrospective reviews within 120 days from the date of determining any non-compliance with the regulation.
- Make identified FCOIs available to requestors within five calendar days of the receipt date of a written request.
- Retain records for a minimum of three years from the date of submission of final reports to the sponsor.
- Provide initial and annual FCOI reports to PHS sponsors.
- Confirm subrecipient (subcontract) Investigators comply with the VERAM FCOI Policy, or another institution's FCOI policy that meets the PHS regulation's standards.

Investigator Responsibilities

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

A list of all SFI(s) must be disclosed using the VA FCOI ([via IRBNet](#)) or [VERAM disclosure form](#). Any disclosures will be reviewed at the Just-In-Time Stage.

NIH FCOI Training

VERAM requires that FCOI training be completed by viewing the [NIH Office of Extramural Research's FCOI Tutorial](#)

To complete the training requirement:

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

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".