



Financial Conflict Of Interest Policy

Disclosure of Financial Interests Related to PHS-Sponsored Projects for Promoting Objectivity in Research

A. Introduction

This policy is consistent with the Public Health Service (PHS) Financial Conflict of Interest (FCOI) regulations, “Promoting Objectivity in Research,” 42 CFR Part 50 Subpart F and 45 CFR Part 94. These regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

B. Purpose

VMRF has established standards to prevent Investigators from using their decision making authority for purposes that are, or give the appearance of being, motivated by a desire for private financial gain while performing VMRF-administered research.

C. Applicability

This policy is applicable to VMRF and each Investigator (see definitions) who is planning to participate in, or is applying for, receives, or participates in PHS research funding by means of a grant or cooperative agreement. This policy applies to prime awards and subawards (subrecipient agreements) administered by VMRF. This policy applies to all grants and cooperative agreements awarded by the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) as they are agencies of PHS. This policy also applies to funding from other sources who have adopted the PHS FCOI regulations.

The regulation does apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) applications. In the event that IRC and/or VA Office of General Counsel (OGC) Ethics review results in differences between NIH’s guidelines on STTR and STTR grants, the more stringent of IRC and/or OGC Ethics determination over FCOI will govern.

VMRF follows the previously established rules and procedures under the VA San Diego Healthcare System (VASDHS) SOP titled “Independent Review Committee (IRC) for the VASDHS and VMRF”. Additional rules apply to PHS funded research. Additional or separate policies apply to individuals involved in Board governance, and VMRF key employees.

D. Definitions

1. **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 research funded by a PHS agency or proposed for such funding, which may include, for example, collaborators or consultants.
2. **Senior/Key Personnel** - Project Director/Principal Investigator (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 agency by the Institution under these regulations. NIH guidelines define key personnel as any individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.
3. **Disclosure** - A complete listing of financial and employment relationships between the principal investigator, co-investigator, other key personnel, their immediate families (spouse and dependent children), and (1) the sponsor of a project or (2) a profit or not-for-profit entity with a potential financial interest in the conduct or outcome of the research. Key personnel are required to submit a disclosure form specific to each project.
4. **Institutional Official** – The VMRF Executive Director/Chief Executive Officer (ED/CEO) (or designee)
5. **Institutional Responsibilities** - An Investigator's professional responsibilities on behalf of VMRF, in the conduct of VMRF administered projects funded under a PHS mechanism, e.g. NIH funded research.
6. **Financial Conflict of Interest** - A Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS funded research.
7. **Significant Financial Interest (SFI)**
 - a) 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 options (valued on best estimate on the day of submission of Financial Conflict of Interest form available from VMRF

Contracts & Grants Department), 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 options (valued on best estimate on the day of submission of Financial Conflict of Interest form available from VMRF Contracts & Grants Department), 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.
- b) 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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, is excluded from the disclosure requirement. Income from seminars, lectures, teaching engagements and service on advisory or review panels 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 is also excluded from disclosure.

E. Responsibilities

1. Investigators

- a. For the Principal Investigator (PI) of a PHS-funded study, it is the responsibility of the PI to submit the Disclosure forms for all project investigators, in sufficient time to allow for the IRC review of projects in which an investigator has disclosed a significant financial interest.
- b. Investigators must disclose, in writing, all SFIs which must include:
 - i. Any financial arrangement between the investigator and sponsor in which the value of the compensation to the investigator could be influenced by the outcome of the study. Investigators do not have to disclose past, current, or planned Cooperative Research and Development Agreements (CRADAs).
 - ii. Any significant payment of other sorts from the sponsor of the study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria.

- iii. Any proprietary interest in the tested product held by any investigator involved in a study. Royalties received through the VA or the respective affiliated University are excluded. All other interests, even if related to same material or product, must be disclosed.
- iv. Any significant financial interest in the sponsor of the study held by any investigator involved in a study.
- v. Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments. If an investigator develops a potentially patentable invention, the inventor must report the invention to the VA Technology Transfer Office through Research Service.

2. Independent Review Committee (IRC)

- a. The IRC functions as the review committee for Financial Conflict of Interest for the VASDHS, VA Southern Nevada Healthcare System, and VMRF. Its Policies and Procedures are documented in the IRC SOP. VMRF follows and implements, as appropriate, the results of the reviews and evaluations of the IRC.
- b. The VMRF Institutional Official for FCOI must serve on the IRC as an ex officio member.
- c. As part of the ex officio membership in the IRC, the VMRF Institutional Official will review all financial disclosures by Investigators and determine whether any additional Significant Financial Interest is related to PHS-funded research and a Financial Conflict of Interest exists by making a reasonable determination that the Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research.

3. VMRF-Administration

- 1. VMRF is responsible to complete all necessary initial and annual reports to the funding agency.
- 2. VMRF will, whenever possible in collaboration with the IRC, conduct a review in any cases of non-compliance with the regulation. VMRF will notify the PHS awarding agency promptly and submit a report to the PHS awarding agency only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.
- 3. VMRF will implement and maintain training requirements as required per PHS regulations. To the degree possible, VMRF will seek efficiencies and collaborations with its affiliated VA and University entities..

4. VMRF will implement and maintain procedures to adequately communicate and monitor adherence to regulatory FCOI requirements in its collaboration and participation with its subrecipient(s) on PHS funded research.

F. Disclosure of Financial Interests

Investigators and VMRF are under a continuing obligation to disclose any potential conflict of interest as soon as it is known or reasonably should be known.

1. A Financial Disclosure Form OGE Form 450 Alt and Public Health Service (PHS) Regulation Compliance Addendum to OGE Form 450 Alt is required from all key personnel for every proposed PHS-funded project, at the time of submission. The IRC will review projects for actual, potential, or apparent COI to determine if outside activities or interest may conflict with the investigator's responsibilities to the research project.
2. An updated disclosure of SFI is required at least annually during the period of the award.
3. Within thirty days of discovering or acquiring (*e.g., through* purchase, marriage, or inheritance) a new SFI, submission of an updated disclosure is required.

G. Management, Reduction or Elimination of Conflicts of Interest

Under certain circumstances, the IRC may conclude that a conflict or potential conflict could directly affect the design, conduct, or reporting of the project, and the project will be placed on hold from any activity, until the IRC can recommend a management plan acceptable to the respective Medical Center Director, VMRF ED/CEO, the PI, and (if applicable) the sponsor. VMRF will report to any PHS awarding agency the existence of a conflicting interest (but not the nature of the interest or other details) that is found. VMRF will also assure the awarding agency that the interest has been managed, reduced or eliminated.

H. FCOI Compliance Failures

If an Investigator fails to comply with the VMRF Financial Conflict of Interest policy or the management plan, VMRF will, in collaboration with the IRC, and within 120 days:

1. Complete a retrospective review of the Investigator's activities and the PHS funded research project to determine any bias in the design, conduct, or reporting of research;
2. Document the retrospective review consistent with the regulation; and
3. Document VMRF's determination as to whether any PHS-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with VMRF's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased or might appear to be biased in the design, conduct, or reporting of such research. VMRF ED/CEO will submit such evaluation request to the VA/VMRF IRC for further action as necessary.

If bias is found, the Institution shall notify the PHS Funding agency promptly and submit a mitigation report that shall address the impact of the bias on the research project, and VMRF's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, VMRF will submit FCOI reports annually, in accordance with the regulation.

FOR PHS FUNDED CLINICAL RESEARCH PROJECTS whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, that has been designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by VMRF, VMRF shall require the Investigator 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.

I. Investigator Training

1. Each Investigator must complete training prior to engaging in research related to any PHS-funded VMRF administered research or contract and immediately following the circumstances identified below:
 - a. Institutional FCOI policies change in a manner that affects Investigator requirements
 - b. An Investigator is new to an Institution
 - c. An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

Subsequent to the initial training, training has to be renewed at least every four (4) years.

2. The training scope includes:
 - a. Regulation
 - b. Institution's Policy on FCOI
 - c. Investigator's responsibilities regarding disclosure of SFIs

VMRF will accept documentation of the completion of the respective University's FCOI training to fulfill investigators' training requirement. VMRF requires that investigator who completed the respective University's training to forward the respective University's training certification as proof of completion to VMRF.

VMRF will make it a priority to ensure Investigators understand and comply with the requirements of the regulation and VMRF's Financial COI policy.

VMRF will reinforce the FCOI training requirements. Investigator non-compliance is serious and may result, at the decision of the VMRF ED/CEO, freezing of all investigator funds.

J. Subrecipient Requirements

1. VMRF incorporates in its subrecipient agreements whether the FCOI policy of the VMRF or that of the subrecipient will apply to subrecipient investigators. VMRF's subrecipient agreements include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements.

2. Subrecipient institutions who rely on their FCOI policy must report identified FCOIs to VMRF in sufficient time to allow VMRF to report the FCOI to the PHS/NIH awarding agency to meet FCOI reporting obligations.

K. Public Accessibility of FCOI Policy

VMRF will ensure that this policy is publicly accessible on the VMRF website, www/vmrf.org as required by 42CFR50.604. VMRF is unlikely to accept PHS funding when an investigator on the grant discloses an ongoing significant financial interest related to the research that cannot be managed by the IRC, unless approved by the OGC. If such funding were to be accepted VMRF would provide certain information in response to a written request within five business days of a request as required by 42CFR50.605.

Approved by the VMRF Board of Directors: June 7, 2019