



## **FINANCIAL CONFLICT OF INTEREST POLICY 4.1.01**

### **PURPOSE:**

The Center for Veterans Research and Education (CVRE) is required, by federal law (C.F.R. Part 50 Subpart F), to comply with regulations pertaining to Financial Conflicts of Interest in government-funded research. As an institution that receives federal funding for research, CVRE is required to have a written and enforced policy on conflict of interest. The policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS), National Institute of Health (NIH), National Science Foundation (NSF) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The policy further provides a mechanism for all conflicts of interest for each award to be managed, reduced or eliminated prior to the expenditure of the award funds.

### **POLICY:**

By law, all Investigators applying for and working on Public Health Services (PHS), National Institutes of Health (NIH), or National Science Foundation (NSF) funded research must disclose significant financial interests (SFIs) that are related to the Investigator's institutional responsibilities. Investigators are ALL persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research proposed for funding by the PHS, NIH, or NSF, including collaborators or consultants. This policy provides the framework to identify, evaluate and correct or remove real, apparent and potential conflicts of interest.

### **PROCESS:**

At the time of application for PHS-sponsored research, a list of all SFI(s) must be disclosed using the CVRE disclosure form. Any disclosures will be reviewed at the time of submission to CVRE.

In addition to the project-specific disclosure, the following disclosures are also required:

Annually verify existing disclosures and update if necessary, both general and project specific.  
Disclose new or increased SFIs within 30 days of acquisition or discovery.

An investigator must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under the designated circumstances:

- ▶ Institutional financial conflict of interest policies changes in a manner that affects Investigator requirements
- ▶ An investigator is new to the organization
- ▶ If an investigator is found to be out of compliance with the FCOI Policy or a Conflict Management Plan

## **EXCEPTIONS:**

None

## **APPLIES TO:**

All investigators applying for and working on PHS-related research held by CVRE.

## **DEFINITIONS:**

*Disclosure of significant financial interests* – an Investigator's disclosure of significant financial interests to an Institution. *Financial conflict of interest (FCOI)* – a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

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

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

*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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

*Manage* – acting 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* – a project director or principal Investigator of a PHS-funded research project.

*PHS* – 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* – 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 policy, 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* – the PD/PI and any other person identified as senior/key personnel by The Center for Veterans Research and Education in the grant application, progress report, or any other report submitted to the PHS by CVRE.

*Significant financial interest* –

(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. Investigator recipients of sponsored travel are required, at minimum, to disclose to the Center for Veterans Research and Education the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Grants and Contract Manager or appropriate official within 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 to the Investigator if the Investigator is currently employed or otherwise appointed by CVRE, including intellectual property rights assigned to CVRE 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.

## **CONTACTS:**

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History: January 2020