



Manual of Policy and Procedures

Title	Number	Page
FINANCIAL CONFLICT OF INTEREST IN RESEARCH	435	1 of 4
	Date	
	6/20/2019	

PURPOSE

The purpose of this policy is to promote objectivity in research by ensuring, to the extent possible, that the design, conduct, or reporting of research is not compromised by a researcher’s conflicting financial interests. The policy establishes the steps that the Vermont State Colleges System should take to mitigate real or perceived financial conflicts of interest associated with externally-funded research.

SCOPE

This policy applies to all VSCS faculty and staff involved in applying for or carrying out externally-funded research. This policy is meant to comply with the requirements of the Department of Health and Human Services regulation 42 CFR Part 50. Following federal regulations, the policy does **not** apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs. The policy does apply, however, to Phase II SBIR/STTR programs.

STATEMENT OF POLICY

Individuals at VSCS Institutions who conduct research are required to disclose whether they, their spouse or partner, and/or their dependent children hold any significant financial interests that might bias their research. Designated officials at each Institution shall review financial disclosure statements and determine whether a financial conflict of interest exists. If a financial conflict of interest is identified, the VSCS shall appropriately manage, reduce, or eliminate the conflict.

DEFINITIONS

As used in this policy:

“Designated Institutional Official” means the person(s) that the VSCS has designated to review disclosures of significant financial interests. Unless otherwise elsewhere stated, this term

shall mean the President, or designee, for each member Institution, and the Chancellor, or designee, for the VSCS.

“Financial Conflict of Interest” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research funded by non-Institutional sources.

“Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

“Institutional Responsibilities” means an investigators’ professional responsibilities on behalf of their VSCS Institution. Examples include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review 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.

“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, the primary division of the U.S. Department of Health and Human Services.

“PHS Awarding Component” means the organizational unit of the PHS that provides funding for research. The following agencies award PHS funds: National Institutes of Health (NIH), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Office of Global Affairs (OGA), Office of the Assistant Secretary for Preparedness and Response (OASPR), and Office of the Assistant Secretary for Health (ASH).

“PHS-Funded Investigator” refers to a researcher receiving funding from any federal agencies that award PHS funds.

“Principal Investigator” means the person in charge of a research grant.

“**Research**” means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. 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).

“**Significant Financial Interest**” means a financial interest consisting of one or more of the following interests of the investigator, the investigator’s spouse or partner, and/or dependent children that reasonably appears to be related to the investigator's institutional responsibilities:

- a) 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;
- b) 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
- c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- d) **For PHS-funded investigators only:** any travel expenses reimbursed directly to an investigator or paid directly on the investigator’s behalf, regardless of amount of value, that is related to the investigator’s institutional responsibilities, excluding travel that is reimbursed or paid 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. This requirement only applies to investigators using PHS funding.

The term *Significant Financial Interest* does not include the following types of financial interests:

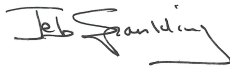
- a) Salary, royalties (including intellectual property rights and agreements to share in royalties related to those rights), or other remuneration paid by the VSCS to the investigator if the investigator is currently employed or appointed by the VSC;
- b) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;

- c) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, a domestic institution of higher, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- d) Income from service on advisory committees or review panels for 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.

PROCEDURES

The Chancellor shall establish and periodically update the procedures for identifying, managing and excluding financial conflicts of interest in externally funded research at all VSCS Institutions. Such procedures shall be consistent with federal legal requirements and any collective bargaining agreements governing the rights and responsibilities of the VSCS, its member Institutions and employees.

The procedures established by the Chancellor may be modified as necessary to comply with federal and state law and to ensure compliance with research funding requirements, as applicable.

Signed by: 
_____ Jeb Spaulding, Chancellor

Date	Version	Revision	Approved By
6/20/2019	1.0	Adopted	VSCS Board of Trustees