

VERMONT STATE COLLEGES SYSTEM

CHANCELLOR'S PROCEDURES FOR IMPLEMENTING POLICY 435: *FINANCIAL CONFLICT OF INTEREST IN RESEARCH*

I. PURPOSE

The following procedures are adopted pursuant to Vermont State Colleges Policy 435, *Externally Funded Research*, and outline the steps for identifying and responding to a financial conflict of interest in externally funded research. These procedures are to be read to comply with all federal and state legal requirements, VSC Policy 408 and other applicable VSC policies.

These procedures apply to all VSC faculty and staff involved in applying for or carrying out externally funded research. The procedures are meant to comply with the requirements of the Department of Health and Human Services regulation [42 CFR Part 50, Subpart F, "Promoting Objectivity in Research."](#) Following federal regulations, the procedures do **not** apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs. The procedures do apply, however, to Phase II SBIR/STTR programs.

II. DEFINITIONS

As established by 42 CFR § 50.605, the following definitions are used in this policy:

"Designated Institutional Official" means the person(s) that the VSC institution 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 VSC system.

"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 investigator's professional responsibilities on behalf of their VSC 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) in excess of \$5,000, upon receipt of income related to such rights and interests;
- D. **For PHS-funded investigators only:** any travel expenses in excess of \$5,000 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 sponsored by a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education. This requirement only applies to investigators using PHS funding.
- E. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure.

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 located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S 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.

III. PROCEDURES

A. Training

Each institution's Office of Sponsored Programs, or its equivalent office, shall inform each principal investigator (PI) of the VSC's policy on financial conflicts of interest and the PI's responsibilities regarding disclosure of significant financial interests.

The VSC shall require all investigators conducting research to complete training on this policy prior to engaging in research and at least every four years after that. The Office of Sponsored Programs, or equivalent office, at each institution will track the training renewal dates and notify the PIs. The VSC shall also require investigators to complete the training if the VSC materially revises its financial conflict of interest policies or procedures, if a PI is new to a VSC institution, or if the institution finds that a PI is not in compliance with the financial conflict of interest policy or a management plan implemented to mitigate a conflict.

B. Disclosures

Investigators submitting a proposal to conduct research are required to submit *Form D: Conflict of Interest Disclosure* indicating if they, or their spouse, partner, or dependent children, have a significant financial interest in the proposed research that would reasonably appear to be affected by the research for which funding is sought. The disclosure form shall be submitted no later than at the time the proposal is submitted.

In addition, investigators are required to submit disclosures at the following times:

- 1) Annually during the period of award;
- 2) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest;
- 3) When a new investigator joins an ongoing research project; or
- 4) If the VSC institution finds that an investigator is not in compliance with the financial conflict of interest policy or management plan.

If a known significant financial interest in the research is identified on Form D, the investigator is required to fill out *Form E: Significant Financial Interests Disclosure*.

C. Travel Disclosures

For PHS-funded investigators only: Investigators conducting research with PHS funds are also required to disclose any travel expenses reimbursed directly to them (not through the VSC), or paid directly on their behalf, related to their institutional responsibilities. The disclosure shall be submitted to each institution's Office of Sponsored Programs, or equivalent, office, within 30 days of travel and include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. This requirement does not apply to travel that is reimbursed or paid by a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

D. Review and Determination

The Office of Sponsored Programs, or equivalent office, will forward *Form E: Significant Financial Interests Disclosure* to each institution's appropriate designated institutional official, who will review the disclosure.

A financial conflict of interest exists when the designated official reasonably determines that the investigator's significant financial interest is related to an externally funded project (i.e., the significant financial interest could be affected by the research, or the significant financial interest is an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of research. Any financial conflicts of interest will require a plan to eliminate, reduce, or manage the conflict.

E. Management of Financial Conflict of Interests

The investigator, after consulting with the designated institutional official, shall write and submit a management plan that specifies the actions to be taken to manage the financial conflict of interest.

Management plans may include but are not limited to the following:

- 1) Public disclosure of financial conflicts of interest to research personnel working on the study and, if applicable, to the Institutional Review Board and Institutional Animal Care and Use Committee, and when presenting or publishing the research;
- 2) For research involving human subjects, disclosure of financial conflicts of interest directly to participants;
- 3) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- 4) Modification of the research plan;

- 5) Change of personnel or personnel responsibilities, or disqualification from participation in all or a portion of the research;
- 6) Reduction or elimination of the financial interests (e.g., sale of an equity interest);
or
- 7) Severance of relationships that create financial conflicts.

The management plan shall include how the plan will be monitored for compliance on an ongoing basis until the completion of the research project. It shall also include confirmation of the investigator's agreement to the plan and the designated institutional official's approval.

F. Compliance

If an investigator fails to disclose a significant financial interest or to comply with the financial conflict of interest management plan, the designated institutional official shall consult with appropriate administrators at the investigator's Institution to determine what disciplinary action to take. This may include the suspension of the research project or other disciplinary sanctions, up to and including termination. The decision shall be documented in writing and shall include information about the right of the individual to appeal the decision. The procedures and mutual obligations of the VSC and the employee under any collective bargaining agreement, or the VSC personnel handbook, will apply to any resulting disciplinary action or appeal.

G. Reporting Financial Conflicts of Interest to the Sponsor

In the event that a financial conflict of interest is determined to exist for a research project funded by non-PHS sources, the VSC institution shall follow the reporting requirements established by the funder.

For PHS-funded investigators only: VSC institutions are required to report identified conflicts of interest to the PHS awarding component prior to the expenditure of funds under a new award and within 60 days of identifying a conflict during the period of award. This report shall be submitted before any funds are expended for a new award or further funds are expended for an existing project. The report shall include the following:

- 1) Sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict and assess the appropriateness of the management plan;
- 2) Project number, principal investigator, name of the investigator with a financial conflict of interest, name of the entity with which the investigator has a financial conflict of interest, and nature of the financial interest;

- 3) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- 4) A description of how the financial interest relates to the PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research; and
- 5) A description of the key elements of the management plan, including the role and principal duties of the conflicted investigator in the research project, the conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project, confirmation of the investigator's agreement to the management plan, and how the management plan will be monitored to ensure investigator compliance.

If, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest, the institution shall do the following within 60 days:

- 1) Review the disclosure of the significant financial interest;
- 2) Determine whether it is related to the PHS-funded research; and
- 3) Determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.

For any financial conflict of interest reported by the institution, the institution shall provide the PHS awarding component an annual financial conflict of interest report that addresses the status of the financial conflict and any changes to the management plan. The annual report, which shall be submitted for the duration of the PHS-funded research project, shall specify whether the financial conflict is still being managed or explain why it no longer exists.

H. Retrospective Review

In cases where a financial conflict of interest is not identified or managed in a timely manner, a retrospective review may be required to determine whether any funded research conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Examples of noncompliance include but are not limited to the following:

- 1) An investigator fails to disclose a significant financial interest that is determined to be a financial conflict of interest;
- 2) The VSC institution fails to review or manage a reported financial conflict of interest; or
- 3) An investigator fails to comply with a financial management plan.

For PHS-funded investigators only: PHS regulations require the VSC institution to complete a retrospective review of the investigator's activities within 120 days after noncompliance is determined. Documentation of the retrospective review shall include the project number, project title, principal investigator for the grant, the name of the investigator with the financial conflict of interest, name of the entity with which the investigator has the financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and the findings and conclusions of the review. If a failure of the investigator to comply with the VSC financial conflict of interest policy is found to have biased the research project, the institution is required to notify the PHS awarding component promptly and submit a mitigation report.

I. Subrecipients

For PHS-funded research only: If a VSC institution conducts research by passing through funding to a subrecipient, the institution is required to take reasonable steps to ensure that any subrecipient investigator complies with federal regulations on financial conflicts of interest in research. The institution shall incorporate as part of its written agreement with the subrecipient terms that establish whether the VSC policy or that of the subrecipient will apply to the subrecipient's investigators. The written agreement shall also specify time periods for the subrecipient to report all identified financial conflicts of interest to the institution. Such time periods shall be sufficient to enable the institution to provide timely financial conflict of interest reports as necessary.

J. Record Retention

The VSC institutions shall maintain records relating to all investigator disclosures of financial interests and the institution's review of, and response to, such disclosures for at least three years from the date the final expenditure report is submitted. (See Policy 209: *Records Retention*.)

K. Public Accessibility

The VSC institutions shall ensure public access to disclosed financial conflicts of interest by following the accessibility requirements outlined by external sponsors, which may vary depending on the funder.


For PHS-funded research only: Within five business days of receiving a request for information about financial conflicts of interest, the VSC institution shall provide a written response to the requestor if it meets the following criteria:

- 1) The significant financial interest was disclosed and is still held by the investigator;
- 2) The institution determines that the significant financial interest is related to the PHS-funded research; and
- 3) The institution determines that the significant financial interest is a financial conflict of interest.

The information provided shall include, at a minimum, the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest using dollar ranges, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

L. Updates

The Chancellor shall periodically update these procedures consistent with federal and state law and general industry practice. Such updates will generally be developed in consultation with the VSC member institutions.

Signed by: 
 Elizabeth Mauch, Chancellor

Date	Version	Revision	Approved By
August 17, 2023	1.0	Adopted	Chancellor
April 10, 2024	2.0	To comply with National Institutes of Health requirements	Chancellor