

VERMONT STATE COLLEGES SYSTEM
Chancellor's Procedures for Implementation of Policy 435:
Financial Conflict of Interest in Research

PURPOSE

The following procedures are adopted pursuant to Vermont State Colleges System Policy 435, 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, VSCS Policy 435 and other applicable VSCS policies. Terms defined in Policy 435 carry the same definition in these procedures.

PROCEDURE

I. Training

The VSCS shall inform each principal investigator (PI) of the VSCS's policy on financial conflicts of interest and the PI's responsibilities regarding disclosure of significant financial interests.

The VSCS 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 VSCS shall also require investigators to complete the training if the VSCS materially revises its financial conflict of interest policies or procedures, if a PI is new to a VSCS Institution, or if the VSCS finds that a PI is not in compliance with the financial conflict of interest policy or a management plan implemented to mitigate a conflict.

II. Disclosures

Investigators submitting a proposal to conduct research are required to submit a disclosure form to the VSCS Office of Sponsored Projects that lists any known significant financial interests (and those of the investigator's spouse or partner and dependent children) 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:

- a) Annually during the period of award;
- b) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest;
- c) When a new investigator joins an ongoing research project; or

- d) If the VSCS finds that an investigator is not in compliance with the financial conflict of interest policy or management plan.

III. 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 VSCS), or paid directly on their behalf, related to their institutional responsibilities. The disclosure shall be submitted to the Office of Sponsored Projects 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, 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.

IV. Review and Determination

If the disclosure form indicates a significant financial interest, the Office of Sponsored Projects will forward the form to each Institution's appropriate designated institutional official, who will review the disclosure.

If the designated official reasonably determines that the investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of research, this shall constitute a financial conflict of interest. Any financial conflicts of interest will require a plan to eliminate, reduce, or manage the conflict.

V. 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:

- a) Public disclosure of financial conflicts of interest (e.g., such as when presenting or publishing the research);
- b) For research involving human subjects, disclosure of financial conflicts of interest directly to participants;
- c) 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;
- d) Modification of the research plan;

- e) Change of personnel or personnel responsibilities, or disqualification from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interests (e.g., sale of an equity interest); or
- g) 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.

VI. 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 VSCS and the employee under any collective bargaining agreement, or the VSC personnel handbook, will apply to any resulting disciplinary action or appeal.

VII. 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 VSCS shall follow the reporting requirements established by the funder.

For PHS-funded investigators only: Within 60 days of determining a financial conflict of interest exists for any PHS-funded project, the VSCS is required to report this conflict to the PHS awarding component providing the funding. This report shall be submitted before any further funds are expended for the project and shall include the following:

- a) 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;
- b) 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;

- c) 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;
- d) A description of how the financial interest relates to the PHS-funded research and the basis for the VSCS's determination that the financial interest conflicts with such research; and
- e) 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 VSCS shall do the following within 60 days:

- a) Review the disclosure of the significant financial interest;
- b) Determine whether it is related to the PHS-funded research; and
- c) 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 VSCS, the VSCS 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.

VIII. 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:

- a) An investigator fails to disclose a significant financial interest that is determined to be a financial conflict of interest;
- b) The VSCS fails to review or manage a reported financial conflict of interest;
or
- c) An investigator fails to comply with a financial management plan.

For PHS-funded investigators only: PHS regulations require the VSCS 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 VSCS's financial conflict of interest policy is found to have biased the research project, the VSCS is required to notify the PHS awarding component promptly and submit a mitigation report.

IX. Subrecipients

For PHS-funded research only: If a VSCS Institution conducts research by passing through funding to a subrecipient, the VSCS is required to take reasonable steps to ensure that any subrecipient investigator complies with federal regulations on financial conflicts of interest in research. The VSCS shall incorporate as part of its written agreement with the subrecipient terms that establish whether the VSCS 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 VSCS. Such time periods shall be sufficient to enable the VSCS to provide timely financial conflict of interest reports as necessary.

X. Record Retention

The VSCS shall maintain records relating to all investigator disclosures of financial interests and the VSCS'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*.)

XI. Public Accessibility

The VSCS 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.

Effective July 1, 2019

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

- a) The significant financial interest was disclosed and is still held by the investigator;
- b) The VSCS determines that the significant financial interest is related to the PHS-funded research; and
- c) The VSCS 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.

XII. 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 Office of Sponsored Projects and the VSCS member Institutions.

Adopted: July 1, 2019