

VERMONT STATE COLLEGES SYSTEM

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 _____ policy on 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 _____ 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 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;

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e)

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- 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-

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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