

VERMONT STATE COLLEGES SYSTEM

CHANCELLOR'S PROCEDURAL ~~1.0.1~~ (P) Md - -0aF ~~1.1.1~~ MPS ~~1.1.1~~ SES

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;

- 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

- 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)

- 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:

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.
