



The University of Vermont

Policy V. 6.3.4

Responsible Official: Vice President
for Research

Effective Date: January 22, 2013

Financial Conflict of Interest in Sponsored Research

Policy Statement

Investigators participating in externally funded research at the University of Vermont will report all significant financial interests held by themselves, their spouses, and their dependent children related to their institutional responsibilities when funded research is proposed, annually thereafter, and when new significant financial interests arise. Further, all those investigators will comply with conditions the University imposes to minimize the risk that those interests may compromise scientific objectivity.

Reason for the Policy

This policy promotes objectivity in research through full disclosure of financial interests and compliance with standards intended to ensure that the design, conduct, financial management, and reporting of research will not be biased by any related significant financial interest.

Its implementation also ensures compliance with certain federal and other funding agency requirements regarding the review and management of financial conflicts of interest in research, most notably the Public Health Service (PHS) policy [42 CFR Part 50, Subpart F, 45 C.F.R. Part 94] and National Science Foundation (NSF) policy [Federal Register: July 11, 1995 (vol. 60, no. 132)].

Applicability of the Policy

This policy applies to all investigators participating in externally funded research at the University of Vermont, including awards for research, career development, center grants and program projects, individual research fellowships, institutional research training grants, research resource awards, and awards for conferences. Investigators on Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) grants are excluded.

Policy Elaboration

None

Definitions

Designated Institutional Official: means the individual the University has designated to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, funded research.

Financial Conflict of Interest (FCOI): means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of funded research.

Institutional Responsibilities: means an Investigator's professional responsibilities on behalf of the University, or on behalf of the University and the University of Vermont Medical Center for Investigators with dual appointments, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, or service on panels such as institutional review boards or data and safety monitoring boards.

Investigator: means the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research or research proposed for sponsored funding. For the purpose of this policy, "investigator" includes principal investigators, co-investigators, key personnel, post-doctoral associates, statistical analysts, and others with independent responsibility for these tasks.

Research: means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Senior/key personnel: means the Project Director or Principal Investigator and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the sponsor by the institution.

Significant Financial Interest (SFI) means:

A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and 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), and 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 if 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 those rights and interests, if that income in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.
- (d) **For PHS funded research only**, any travel expenses reimbursed directly to an investigator or paid directly on the investigator's behalf, regardless of amount or value, related to his/her institutional responsibilities, excluding travel that is reimbursed or paid by a federal, state, or local government agency, an institution of higher education (including the University of Vermont), an academic teaching hospital (including the University of Vermont Medical Center), a medical center, or a research institute that is affiliated with an institution of higher education.

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

- (a) salary, royalties, or other remuneration paid by the University (and by the University of Vermont Medical Center for investigators with dual appointments) to the investigator if the investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to those rights;
- (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 education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- (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

Training:

Each investigator will complete the University's on-line conflict of interest training initially before making a disclosure under this policy, then at least once every four years thereafter, or at other times when required by the Designated Institutional Official (for example, when this policy

has changed or an investigator has demonstrated a lack of understanding of the policy's requirements).

Disclosure Responsibility:

Each investigator covered by this policy will annually report whether or not they have financial interests that are both significant and related to their institutional responsibilities according to the following schedule:

1. at the time of application for sponsored funding,
2. at least annually thereafter during the period of research activity, and
3. at any time during the research within thirty days of the discovery or acquisition of a new reportable financial interest.

In addition, investigators whose work is funded by the Public Health Service (PHS) will disclose, within thirty days of travel, the occurrence of any travel expenses reimbursed directly to them (not through the University or the University of Vermont Medical Center) or paid directly on their behalf, related to their institutional responsibilities. This disclosure 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.

Monitoring and Review of Disclosures:

The Designated Institution Official will monitor the receipt of disclosures of SFIs and manage their review. Procedures for the review of disclosures depend in part on the requirements imposed by the external sponsor of the research. For specific requirements refer to the appropriate section below:

Research supported by the National Science Foundation

http://www.uvm.edu/spa/COI/COI_NSF_funded_research_addendum.pdf

Research supported by the Public Health Service

http://www.uvm.edu/spa/COI/COI_PHS_funded_research_addendum.pdf

All other sponsored research

http://www.uvm.edu/spa/COI/COI_Other_funded_research_addendum.pdf

Managing Financial Conflicts of Interests:

If during an SFI's review it is determined that the SFI constitutes a Financial Conflict of Interest (FCOI) that may compromise scientific objectivity, a management plan to eliminate or minimize the risk will be developed, followed and monitored. The Designated Institution Official will manage the development of the plan and its monitoring. Specific procedures depend in part on the requirements imposed by the external sponsor of the research. For specific requirements refer to the appropriate section below:

Research supported by the National Science Foundation

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Research supported by the Public Health Service

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All other sponsored research

http://www.uvm.edu/spa/COI/COI_Other_funded_research_addendum.pdf

Compliance:

Alleged violations of this policy should be reported to the Designated Institutional Official who will inform the appropriate department chair, dean and Chief Compliance Officer. Alleged violations will be reviewed by means of an inquiry conducted by the appropriate department chair or dean, the manner to be determined at their discretion. If this review finds there was a deliberate breach of the policy, including failure to file; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed in fulfillment of this policy, the Dean will consult with the Vice President for Research on appropriate sanction, if any, to be imposed. Possible sanctions include: formal admonition; letter to the investigator's personnel file; suspension of privileges to apply for external funds or seek IRB approval or supervise graduate students; non-renewal of appointment; or dismissal. The Dean will act accordingly, taking all appropriate actions. Sanctions are subject to otherwise applicable grievance rights.

Retrospective Review:

Whenever:

- (1) an investigator fails to disclose a significant financial interest that is determined by the institution to constitute a financial conflict of interest;
- (2) the University fails to review or manage such a financial conflict of interest;
- (3) an investigator fails to comply with a financial conflict of interest management plan; or
- (4) in some other manner a financial conflict of interest is not identified or managed in a timely manner;

the University may conduct a retrospective review to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of the research. In all cases involving PHS-funded research, the University will conduct its review within 120 days of determining the non-compliance. This review will be conducted for all other sponsored research at the University's discretion. Procedures for retrospective review depend in part on the requirements imposed by the external sponsor of the research. For specific requirements refer to the appropriate section below:

Research supported by the National Science Foundation

http://www.uvm.edu/spa/COI/COI_NSF_funded_research_addendum.pdf

Research supported by the Public Health Service

http://www.uvm.edu/spa/COI/COI_PHS_funded_research_addendum.pdf

All other sponsored research

http://www.uvm.edu/spa/COI/COI_Other_funded_research_addendum.pdf

Reporting and Public Accessibility:

Requirements for reporting and public accessibility of disclosures depend in part on the requirements imposed by the external sponsor of the research. For specific requirements refer to the appropriate section below:

Research supported by the National Science Foundation

http://www.uvm.edu/spa/COI/COI_NSF_funded_research_addendum.pdf

Research supported by the Public Health Service

http://www.uvm.edu/spa/COI/COI_PHS_funded_research_addendum.pdf

All other sponsored research

http://www.uvm.edu/spa/COI/COI_Other_funded_research_addendum.pdf

Records:

The disclosure form and records of all actions related to disclosure will be maintained for three years following the submission of the final financial report for the related award(s) or other retention periods specified by law or regulation as applicable.

Forms

Disclosures are made using the University's on-line disclosure system at

https://spogi.uvm.edu/UVM_COI/

Contacts

Questions related to the daily operational interpretation of this policy should be directed to the Associate Vice President for Research Administration, who is the University's Designated Institutional Official for this policy.

(802)-656-3360

The Vice President for Research is the official responsible for the interpretation and administration of this policy.

Related Documents / Policies

Conflict of Interest and Conflict of Commitment Policy

http://www.uvm.edu/policies/general_html/conflictinterest.pdf

Contract Approval & Signatory Authority Policy

<http://www.uvm.edu/policies/procure/contract.pdf>

Effective Date

Approved by the President on January 23, 2013

V.3.2.3.3 Approved by the President on August 16, 2012

V.3.2.3.2 Approved by the President on July 5, 2011

V.3.2.3.1 Approved by the President on May 4, 2006