



OFFICE OF COMPLIANCE SERVICES
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POLICY

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Title: Financial Conflict of Interest in Sponsored Research

Policy Statement

The University of Vermont recognizes its obligation to identify and manage situations in which both real and perceived financial conflicts of interests could compromise objectivity or integrity relative to research. As such, Investigators must disclose to the University whether or not they, their spouse, and/or their dependent children hold any Significant Financial Interest that reasonably relates to the Investigator's institutional responsibilities.

Reason for the Policy

UVM recognizes the importance of allowing Investigators the ability to collaborate with outside entities. These collaborations stimulate UVM's research programs and are vital when translating academic research into knowledge and discoveries that can have significant public benefit. However, some outside activities may have an appearance, or could have the potential, to compromise the objectivity of the research being conducted. The challenge is to balance and manage these outside interests without compromising the integrity of the research.

This policy implements 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) and related components such as National Institutes for Health (NIH), and National Science Foundation (NSF) policy.

Applicability of the Policy

This policy applies to all Investigators defined as the Principal Investigator (PI), Project Director (PD) or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research proposed to, or funded by, external sponsors, under grants, contracts, cooperative agreements, or other awards for research.

In accordance with the federal regulations, this policy does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs; however, this policy does apply to Phase II SBIR/STTR programs.

Definitions

Designated Institutional Official: means the individual the University has designated to solicit and review disclosures of Significant Financial Interests (SFI) from each Investigator who is planning to participate in, or is currently participating in, externally funded research. The day to day procedural work may be delegated to staff.

Financial Conflict of Interest Committee: means a committee containing, at a minimum, three faculty members representing a cross section of academic disciplines. All members of the committee are appointed by the Vice President for Research. From time to time, the Designated Institutional Official may include an additional ad hoc member to the committee. At the request of the Designated Institutional Official, the Conflict of Interest Committee shall determine whether a disclosed Significant Financial Interest (SFI) represents or could reasonably appear to represent a Financial Conflict of Interest (FCOI).

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

Institutional Responsibilities: means an Investigator's professional responsibilities on behalf of the University, or, for Investigators with dual appointments, on behalf of the University and the University of Vermont Medical Center. Examples of institutional responsibilities include 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.

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 (PD) or Principal Investigator (PI) and any other person identified as senior/key personnel (i) by the institution in the grant application, or (ii) otherwise specified by sponsor regulations or funding document.

Significant Financial Interest (SFI): means a financial interest consisting of one or more of the following interests of the Investigator, the Investigator's spouse and/or the Investigator's 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 (and/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,
- (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 their 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 (including intellectual property rights assigned to the University and agreements to share in royalties related to those rights), 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;
- (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

Disclosures:

To promote the objectivity and integrity of research being conducted at the University of Vermont, Investigators shall disclose to the University any Significant Financial Interest (including the interests of the Investigator's spouse and dependent children), or absence thereof, at the following times:

- (1) No later than at time of a proposal submission for externally sponsored research;
- (2) At least annually thereafter during the period of research activity;
- (3) During the research within thirty days of the discovery or acquisition of a new reportable financial interest; and
- (4) At the time of award for Investigators whose work is funded by a sponsor that follows the Public Health Service (PHS) or the National Science Foundation FCOI Policies.

In addition, Investigators whose work is funded by the Public Health Service (PHS) will disclose, within thirty (30) 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. The disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. 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.

Investigators shall use the University's electronic research and compliance system found at Research Administration and Integrity website: <https://www.uvm.edu/ovpr/uvmclick-coi/coc/fcoi>.

Review of Disclosures:

The Designated Institutional Official or designee will monitor the receipt of disclosures and review such disclosures of significant financial interests from each Investigator. Reviews of an Investigator's initial disclosure will occur prior to the release of the awarded funds for research expenditures.

Determination:

Where the Designated Institutional Official or their designee, reasonably determines that a significant financial interest is related to the funded research, the disclosure is submitted to the University Financial Conflict of Interest Committee which will determine if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the funded research.

Managing Financial Conflicts of Interests:

Where the Financial Conflict of Interest Committee determines a financial conflict of interest exists, a management plan shall be developed and implemented that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

If, during an SFI's review, it is determined that the SFI constitutes a Financial Conflict of Interest (FCOI), the Designated Institutional Official is responsible for the development and monitoring of a management plan. All those named in the management plan are responsible for following and complying with the management plan. Specific procedures will depend in part on the requirements imposed by the external sponsor of the research.

Management Plans conditions may include, but are not limited to, any and all of the following actions:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
2. For research projects involving human subjects research, 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 FCOI;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

Management Plans will include the following key elements:

1. The role and principal duties of the conflicted Investigator in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the Investigator's agreement to the management plan;
5. How the management plan will be monitored to ensure Investigator compliance; and
6. Other information the University judges to be relevant.

Compliance:

Alleged violations of this policy should be reported to the Designated Institutional Official who will inform the appropriate Department Chair, Dean, the Director of Compliance Services, and the Vice President of Research. At their discretion, the appropriate Department Chair or Dean will determine the manner in which the alleged violation will be investigated.

In the event that the investigation reveals there was a deliberate breach of the policy, including, but not limited to, (i) failure to file; (ii) knowingly filing incomplete, erroneous or misleading disclosure forms; or (iii) failure to comply with procedures prescribed in fulfillment of this policy, the Dean will consult with the Vice President for Research on the appropriate sanction, if any, to be imposed.

Possible sanctions include (i) formal admonition; (ii) letter to the Investigator's personnel file; (iii) suspension of privileges to apply for external funds or seek IRB approval or supervise graduate students; (iv) non-renewal of appointment; or (v) dismissal.

The Dean will act accordingly, taking all appropriate actions. Sanctions are subject to otherwise applicable grievance rights.

Retrospective Review:

Whenever (i) an Investigator fails to disclose a Significant Financial Interest that is determined by the institution to constitute a Financial Conflict of Interest, (ii) the University fails to review or manage such a Financial Conflict of Interest, (iii) an Investigator fails to comply with a Financial Conflict of Interest management plan, or (iv) in some other manner, a Financial Conflict of Interest is not identified or managed in a timely manner, the Designated Institutional Official will notify the Director of Compliance Services. A retrospective review may be required under specific agency regulations or, in consultation with the Director of Compliance Services, the University may itself determine that a retrospective review is warranted. If so, the Designated Institutional Official shall conduct a retrospective review to determine whether any funded research, or portion thereof, conducted during the time period of the non-compliance, 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.

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.

Requests for public accessibility should also follow UVM's [Records and Documents Request Policy](#).

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.

Additional procedures related to the implementation of this policy can be found at the [Research and Integrity website](#).

Contacts

Questions concerning the daily operational interpretation of this policy should be directed to the following (in accordance with the policy elaboration and procedures):	
Title(s)/Department(s):	Contact Information:
Office of Research Administration & Integrity	conflict@uvm.edu (802) 656.7863

Forms/Flowcharts/Diagrams

- None

Related Documents/Policies

- [Conflict of Interest and Conflict of Commitment Policy](#)
- [Contract Approval and Signatory Authority Policy](#)
- [Records and Document Requests Policy](#)

Regulatory References/Citations

- [42 CFR Part 50.604\(a\)](#)
- [NSF: Award and Administration Guide: Chapter IV-Grantee Standards](#)

Training/Education

Training/education related to this policy is as follows:

Training Topic:	Financial Conflict of Interest in Sponsored Research		
Training Audience:	All Investigators	Delivered By:	Research Integrity
Method of Delivery:	On-Line	Frequency:	No later than prior to engaging in sponsored research, and at least once every four years thereafter; and when required by the Designated Institutional Official (for example, when this policy has changed in a manner that affects the requirements of the Investigators or when an Investigator has demonstrated a lack of understanding of the policy's requirements).

About This Policy

Responsible Official:	Vice President for Research	Approval Authority:	President
Policy Number:	V.6.3.5	Effective Date:	January 29, 2019
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