



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

Title: Financial Conflict of Interest in Research

Policy Statement

The University of Vermont (the "University" or "UVM") recognizes its obligation to identify and manage situations in which both real and perceived financial conflicts of interest 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 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

This policy applies to all UVM and University of Vermont Health (UVM Health) 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, regardless of source of funding.

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



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

Assigned Committee: means the Committee to which the Investigator's potential conflict is assigned and reviewed. Financial Conflict of Interest (FCOI) Committee, typically reviews potentials conflicts cases unrelated to human subject research triggered by Sponsored Project Administration and the Clinical Research Conflict of Interest (RCOI) Committee, will typically review potentials conflicts cases associated with research involving human subjects triggered by the Research Protections Office/IRB.

Clinical Research Conflict of Interest Committee or CRCOI Committee: means a committee including, at a minimum, three members with expertise in research involving human subjects. All members of the committee are appointed by the Vice President for Research or designee. From time to time, the Designated Institutional Official may include an additional ad hoc member to the committee.

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 or FCOI Committee: means a committee including, at a minimum, three members representing a cross section of academic disciplines. All members of the committee are appointed by the Vice President for Research or designee. From time to time, the Designated Institutional Official may include an additional ad hoc member to the committee.

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

Related Entity: means an entity that an Investigator holds an SFI in.

Research: means a systematic investigation designed to develop or contribute to generalizable knowledge.

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:

1. 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

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

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;

2. 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
3. Intellectual property rights and interests (e.g., patents, copyrights), and/or technology that has been disclosed to UVM Innovations.
4. **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), an academic teaching hospital (including UVM Health), 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:

1. Salary, royalties, or other remuneration paid by the University (and, for Investigators with dual appointments, by UVM Health) to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
2. 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;
3. 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
4. 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.



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

Disclosures

To promote the objectivity and integrity of research being conducted at the University and UVM Health, 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, or the time of submission of research involving human subjects to the Institutional Review Board (IRB);
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 UVMHN) 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, [UVMClick](#), to fulfil their disclosure requirements.

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, or, as applicable, prior to the IRB approval of the research involving human subjects.

Determination

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

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

Managing Financial Conflicts of Interests

Where the Assigned 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 review, it is determined that the SFI constitutes a Financial Conflict of Interest (FCOI), the Designated Institutional Official is responsible for the development and administration 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.

In some cases, inventors or creators of intellectual property will not be allowed to serve as Principal Investigator, Co-Investigators, or study team personnel for research involving that intellectual property or if allowed, may not be allowed to conduct certain activities such as determining eligibility, data analysis or consenting and enrolling patients in the research.

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



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

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, the Vice President of Research, and, if applicable, the officials of UVM Health. At their discretion, the appropriate Department Chair or Dean, or if applicable, UVM Health officials will determine the manner in which the alleged violation will be investigated. When applicable, investigation for represented employees will occur in accordance with provisions of the applicable collective bargaining agreement.

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 students in a research capacity; (iv) non-renewal of appointment; or (v) dismissal.

When applicable, determination of discipline for represented employees will occur in accordance with provisions of the applicable collective bargaining agreement.

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, and, if applicable, the officials of the University of Vermont Health. 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.



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

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](#)
- [Research Integrity – Financial Conflict of Interest](#)



POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM’s Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

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 Research		
Training Audience:	All Investigators	Delivered By:	Research Integrity using CITI Program
Method of Delivery:	On-Line through CITI Program	Frequency:	No later than prior to engaging in 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
Revision History:	<ul style="list-style-type: none"> • V.3.2.3.1 Approved by the President on May 4, 2006 • V.3.2.3.2 Approved by the President on July 5, 2011 • V.3.2.3.3 Approved by the President on August 16, 2012 		



OFFICE OF COMPLIANCE SERVICES
UVM.EDU/POLICIES

POLICY

****FOR PRINTED USE ONLY****

Policies residing on UVM's Institutional Policy website are the most current versions available. If you are viewing a policy anywhere else including in printed form or embedded on other websites, it may not be the most current.

	<ul style="list-style-type: none">• V.6.3.4 Approved by the President on January 23, 2013• V. 6.3.5 Reaffirmed October 5, 2022
--	---

University of Vermont Policies and Operating Procedures are subject to amendment. For the official, approved, and most recent version, please visit UVM's [Institutional Policies Website](#).