



The
UNIVERSITY
of **VERMONT**

Policy V. 3.2.3.1

Responsible Official: Vice President for
Research and Dean of Graduate Studies

Effective Date: May 4th, 2006

Related Significant Financial Interest In Research and Scholarly Activity

Policy Statement

All Investigators participating in externally funded research at the University of Vermont will annually report all financial interests held by themselves, their spouses, and their dependent children that are both significant and related to their externally funded research. Further, all such investigators will comply with conditions the University may impose to minimize the risk that such interests may compromise scientific objectivity. This policy supersedes the University's Conflict of Interest in Research and Scholarly Activity Policy developed in September 1995 by the University in response to specific funding agency requirements.

Reason for the Policy

This policy seeks to promote objectivity in research through full disclosure of related 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, Section 50.604.(c) (1)] and National Science Foundation (NSF) policy [Federal Register: July 11, 1995 (vol.60 number 132)].

Strategic Direction

This policy supports the following goal in the [University's Strategic Plan](#):

- Strengthening research while fostering our stated values, including integrity and a commitment to rigorous intellectual inquiry and critical thinking.

Applicability of the Policy

This policy applies to all Investigators participating in externally funded research at the University of Vermont.

Definitions

Investigator - Any person at the University who is responsible for the design, conduct, or reporting of extramurally funded research. Typically this will include the Principal Investigator and co-investigators. For the purposes of this disclosure requirement, the term "Investigator" includes the investigator's spouse and dependent children.

Related Financial Interest -- a financial interest that would, to a reasonable objective observer familiar with such issues, appear to actually or potentially affect or be affected by the research being undertaken. Some examples of related financial interests include these situations:

1. The Investigator is carrying out research and the results of that research would be relevant to the development, manufacturing, or improvement of the products or services of the entity in which there is a significant financial interest,
2. The Investigator has a significant financial interest in an entity that might manufacture or commercialize a drug, device, procedure, or any other product used in the sponsored project,
3. The Investigator has an intellectual property interest on a patent, patent application, or copyright of software assigned or licensed to an outside party and the results of the research could affect the value of the patent or copyright,
4. The Investigator is conducting research the results of which could affect the amount of royalty income the Investigator would receive through the licensing of intellectual property developed by the investigator,
5. The Investigator's financial interest is in the sponsor of the research,
6. The entity in which the Investigator has a financial interest is serving as a sub-awardee, subcontractor, or consortium member for the project.

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

Significant Financial Interest - Anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights), and other proprietary or financial interests in products, materials, or processes being studied or evaluated (e.g., the right to receive royalties directly or through the employing institution from the sale or use of such product, materials, or processes).

This definition specifically excludes:

1. Salary or other remuneration from the University except royalty income paid by the University through its patent/intellectual property policy;
2. Income from seminars, lectures, and teaching sponsored by public or nonprofit entities;

3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. An equity or ownership interest that (when aggregated for the Investigator and the Investigator's spouse and dependent children) meets both the following tests: does not exceed \$10,000 in value and does not represent more than a five percent ownership interest in any single entity;
5. Salary, royalty, or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months are not expected to exceed \$10,000; and
6. A management position, such as board member, director, officer, partner, or trustee, held in any business entity by the Investigator that does not result in compensation or ownership in excess of the thresholds described in 4 and 5 above.

Procedures

Disclosure Responsibility: Each Investigator covered by this policy will annually report all financial interests that are both significant and related held by themselves, their spouses, or their dependent children at the following times:

1. When submitting the research as part of an application for outside funding,
2. At least annually thereafter during the period of the research activity,
3. At any time during the research when a new related significant financial interest is obtained.

The existence of a related significant financial interest will be indicated when proposals are being submitted, and full disclosures of such interests will be made by use of the Investigator's Statement of Related Significant Financial Interest for Sponsored Projects and sent to the Associate Vice President for Research Administration.

Review and Disposition: Positive disclosures will be reviewed by a University Independent Financial Interest Review Committee (IFIRC). The IFIRC is composed minimally of the Associate Vice President for Research Administration, the Vice President for Research and Dean of Graduate Studies or designee, a faculty member appointed by the Dean of the College of Medicine, a faculty member appointed by the Vice President for Research and Dean of Graduate Education, a faculty member from the University Research, Scholarship and Graduate Education Committee, and a faculty member from the Committee on Human Research in the Medical Sciences. Others may be appointed to the IFIRC by the University Vice President for Research and Dean of Graduate Studies to provide appropriate expertise. Ad hoc reviewers may be consulted on a case-by-case basis.

In those cases in which, in consultation with the faculty member involved, the IFIRC determines that a real or apparent conflict may reasonably be expected to arise from related significant financial interests, it will take one of the following actions:

1. Accept the sponsored project;
2. Not accept the sponsored project; or
3. Accept the sponsored project subject to certain conditions designed to manage any

potential conflicts that may result from related significant financial interests, e.g.: monitoring of research by independent reviewers; public disclosure of significant financial interests; modification of the research plan; Investigator disqualification from participation in all or part of the sponsored project; divestiture of significant financial interest; severance of relationships that create actual or potential conflicts.

A report of the IFIRC's actions will be forwarded to the Investigator and the Vice President for Research and Graduate Education. If the Vice President determines that further action is required to implement conditions designed to manage the conflict, the report will be sent to the Investigator's department chair and dean as appropriate for implementation. A report summarizing relevant actions will also be submitted to the University's reviewing Institutional Review Board (IRB) for clinical studies or other projects involving human subjects so that the IRB can determine if additional actions may be required to protect human subjects.

The Investigator shall report on the implementation of the IFIRC's conditions with future annual disclosures.

Appeal of the decision may be made to the Senior Vice President and Provost, who will consult with the Investigator and the IFIRC before making a final determination, within thirty days of the appeal, as to the action to be taken. In all cases, resolution of the actual or apparent conflict of interest will be achieved before the University accepts a sponsored project.

Compliance: Alleged violations of this policy will be reviewed by means of an inquiry conducted by the appropriate Department Chair or Dean. Instances of 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 will be evaluated by an ad hoc faculty committee appointed by the University Senior Vice President and Provost. This committee will recommend to the Senior Vice President and Provost the 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 and/or seek IRB approval and/or supervise graduate students; non-renewal of appointment; or dismissal.

Records: The Disclosure Form and records of all actions related to disclosure will be maintained in the Office of Sponsored Programs for three years following termination of the relevant award, or any subsequent action relating to that award. All disclosures and related documentation are considered confidential, and only those persons involved in the implementation of this policy will have access to those records.

Notification to Funding Agencies: If required by funding agency policy the University will report the existence of related significant financial interest to the funding agency. PHS and funding agencies that have adopted the PHS requirement, require the reporting of the existence of a conflict of interest that is being managed prior to the expenditure of funds awarded. The NSF Conflict of Interest Policy requires the reporting of the existence of a conflict of interest that the University unable to be resolved prior to the expenditure of funds awarded.

Forms

[Investigator's Statement of Related Significant Financial Interest for Sponsored Projects](#)

Contacts

Questions related to the daily operational interpretation of this policy should be directed to:

Assoc. VP for Research Administration
656-3360

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

Related Documents / Policies

[University Conflict of Interest Policy](#)

[Institutional Review Board \(IRB\) Policy Regarding Investigator Financial Interest](#)

[Contract Approval & Signatory Authority Policy](#)

Effective Date

Approved by the President on May 4, 2006