

Financial Conflicts of Interest for Research Investigators

Effective Date Wednesday, February 6, 2013

Status Final

Last Revised Thursday, July 22, 2021

Policy Type [University](#)

Contact Office

[Vice President for Research \(Office of the\)](#)

Oversight Executive

[Vice President for Research](#)

Applies To

Academic Division The College at Wise

Table of Contents

[Policy Statement](#)

1. [Investigator's Disclosure Requirements](#)
2. [Institutional Official](#)
3. [Research Conflict of Interests Committee](#)
4. [State Conflict of Interest Act](#)
5. [Training](#)
6. [Research Carried Out Through Subcontracts](#)
7. [Enforcement](#)
8. [Responding to Public Requests for Information about PHS Funded Research](#)
9. [Record Retention](#)
10. [Dissemination of Policy](#)
11. [Compliance with Policy](#)

[Procedures](#)

Reason for Policy

This policy:

1. Informs investigators about their obligations concerning financial interests that could influence their research, and ensures a reasonable expectation that the design, conduct and reporting of research will be unbiased by any conflicting financial interest of the investigator in compliance with federal and state regulations which differ.
2. Intends to implement the following requirements:

- Federal Department of Health and Human Services (HHS) regulations on Promoting Objectivity in Research at 42 CFR Part 50, Subpart F, and 45 CFR Part 94. [For more detailed information and links to these regulations and federal policies on financial conflicts of interest related to human subject research, consult the NIH Office of Extramural Research, [Grants & Funding](#) and [Frequently Asked Questions](#).]
- National Science Foundation as specified in the Grant Policy Manual, Chapter V, Topic 510 Conflict of Interest Policies.

Investigators also must comply with the Virginia State and Local Government Conflict of Interests Act, at Section 2.2-3100 et seq. of the [Code of Virginia](#). Procedures for complying with the State Conflict of Interests Act are described below.

While this policy establishes a minimal standard for Conflict of Interest (COI) reporting, investigators must always review and comply with the requirement of agencies outside the governance of the Health and Human Service (HHS) and National Science Foundation (e.g., Department of Defense, Department of Education, etc.).

3. Provides University-wide requirements concerning financial conflicts of interest related to research. Individual Schools are not precluded from adopting additional, more stringent requirements that may be necessitated by circumstances specific to a School's mission. It is the responsibility of the School's Dean to notify the Research Conflict of Interests Committee of such additional measures.

Definition of Terms

A Note

The definitions used in this policy mirror those in the applicable federal or state regulations.

Family

Includes any spouse or dependent child.

Financial Conflict of Interest (FCOI)

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of the investigator's research.

Institutional Official

The Vice President for Research or their designee.

Institutional Responsibilities

An investigator's professional responsibilities on behalf of the University which may include, for example, activities such as research, research consultation, teaching, clinical or other professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator

The project director or principal investigator and any other person, regardless of title or position: (1) who is responsible for the design, conduct, or reporting of research or proposed research, which may include, for example, senior research staff, collaborators, or consultants; and (2) whose research is supported by extramural funding (not internal funds or gifts).

Management Plan

For this policy, an action plan 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 Awarding Component

The organizational unit of the Public Health service (PHS) within Health and Human Services (HHS) which funds the investigator's research.

Research

A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses both basic and applied research and includes all research meeting the definition of "research" in the Code of Federal Regulations, Section [45_CFR_46](#) and/or "clinical investigation" in the Code of Federal Regulations, Section [21_CFR_56](#). The term includes but is not limited to any such activity for which research funding is available from a Public Health Service (PHS) Awarding Component through a grant or cooperative agreement, whether authorized under the Public Health Services Act (42 U.S.C 6A) or other statutory authority, including but not limited to a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest

For this policy:

1. A financial interest consisting of one or more of the following interests of the investigator and those of the investigator's immediate family (spouse, dependent children), that reasonably appears to be related to: (a) the investigator's institutional responsibilities if the research will be PHS-funded, or (b) the study sponsor or an entity that would have an interest in the work and/or the outcome of the research project if the research will not be PHS-funded.
 - i. 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 combined with the value of any equity interest held 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.
 - ii. 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 when the investigator or his immediate family member holds any equity interest (e.g., stock, stock option, or other ownership interest).
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. The term *significant financial interest* also includes any reimbursed or sponsored travel related to their institutional responsibilities, including travel paid on behalf of the investigator and not reimbursed to the investigator (so that the exact monetary value may not be readily available); except for travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education located in the United States, as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with a United States institution of higher education as defined at [20 U.S.C. 1001\(a\)](#). The disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Institutional Official or designee will determine if further information is needed, including monetary value, in order to determine whether the travel constitutes a financial conflict of interest with sponsored research.
3. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by or on behalf of the University to the investigator, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights; 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; and, income from seminars, lectures, or teaching engagements sponsored by, or 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 affiliated with an institution of higher education.

Policy Statement

A financial conflict of interest exists under this policy when an investigator or member of his or her immediate family has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. Such a conflict must be disclosed, appropriately managed and, if required, reported to the sponsor.

The specifics of financial interests and their relation to the proposed research activity may vary considerably. Therefore, it is not possible to guarantee that research may proceed under a management plan in any and all cases of financial conflict of interest. In extreme situations, such as the involvement of investigators with significant financial interests in experiments with human participants, there will be a rebuttable presumption that such activities may not proceed.

1. Investigator's Disclosure Requirements:

(1) An investigator who is planning to participate in research must disclose to his or her School's designated official(s) (through the [University's On-Line Disclosure System](#)) the investigator's significant financial interests as defined above, no later than the time of application for external research funding or prior to initiating research, whichever occurs first. Each School's designated official will be responsible for forwarding the disclosures to the Institutional Official for review.

(2) Investigators participating in any sponsored research must submit an updated disclosure of significant financial interests annually, in accordance with the University's annual request for such disclosure. Such disclosure shall include any information that was not disclosed previously and shall include updated information regarding any previously disclosed significant financial interest.

(3) An investigator who is participating in any sponsored research must submit an updated disclosure to his or her School's designated official(s) (through the [University's On-Line Disclosure System](#)), within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

2. Institutional Official:

The Institutional Official shall receive investigators' disclosures of significant financial interests from the Schools' designated officials, and review them to determine if they are related to the investigator's research, i.e., could be affected by the research or is in an entity whose financial interest could be affected by the research. The Institutional Official shall forward those financial interests determined to be related to the Research Conflict of Interests Committee for action as described below.

3. Research Conflict of Interests Committee:

The University shall maintain a [Research Conflict of Interests Committee](#), which shall:

- a. Receive and review disclosures of significant financial interests that the Institutional Official has determined are related to the investigator's research, to determine whether they could directly and significantly affect the design, conduct, or reporting of the research, creating a financial conflict of interest.
- b. Recommend to the Institutional Official management plans for significant financial interests related to research that create financial conflicts of interests.
- c. Through the Institutional Official, implement and monitor compliance with management plans approved by the Institutional Official, and when required make reports of financial conflicts of interests to the research sponsor.

The [Research Conflict of Interests Committee](#) shall cooperate with the Institutional Official to implement policies and procedures for investigators' disclosure and review of significant financial interests, management of financial conflicts of interests, reporting of interests to research sponsors when required, and record maintenance.

4. State Conflict of Interest Act:

The *State Conflict of Interests Act* bars University employees from having "personal interests" in a company (including ownership of more than 3% of the equity or anticipated annual compensation from the company of more than \$5,000) if the company enters into a contract with the University, unless an exception within the Act applies. **This prohibition applies even if the personal interest is unrelated to the contract (e.g., if an investigator has equity in or receives income from a company negotiating a contract with the University that is unrelated to the investigator's research).**

Investigators must disclose “personal interests” under the Act to the Institutional Official prior to negotiation of the contract. The Institutional Official will assist the investigator in determining whether an exception under the Act is available, and in applying for the approvals needed to qualify for an available exception. In addition, under the Act these investigators may be required to complete a state financial disclosure form prior to approval of the exception and during the contract period and to complete state COI training as required by the state.

Please note that the usual exception for research and development contracts is found at Section 2.2-3106 of the Code of Virginia; there are separate and distinct exceptions for other contracts (e.g., purchasing agreements; contracts for goods and services). If you currently have or anticipate that in the future you may have a conflict due to equity or equity/income ownership in a firm contracting or subcontracting with the University, you must submit a disclosure notice to the President through Procurement & Supplier Diversity Services.

Violations of Virginia’s Conflicts of Interest Act, Section 2.2-3102 et. seq., can result in imposition of both civil and criminal penalties and may constitute malfeasance in office or employment. See Section 2.2-3120, Section 2.2-3122 and Section 2.1-3124. Section 2.2-3121 (A) and (B) of the Act provide that state officials or employees shall not be prosecuted for knowing violations of the Act if they resulted from good faith reliance on a written opinion of the Attorney General made in response to the official or employee’s written request for such an opinion and such opinion was issued after a full disclosure of the facts.

NOTE: The State Conflicts Act definition of a conflict-triggering financial interest differs from the federal definition. *Anticipated* income in the coming year can create a conflict. Also, the definition of immediate family includes a spouse and any dependents who reside in the same household as the investigator. Also, there is no exception specifically for income from federal, state, or local government agencies, institutions of higher education, academic teaching hospitals or medical centers or research institutes.

For details on the State Conflicts Act, see [Section 2.2-3100 et seq. of the Code of Virginia](#) and University Policy [FIN-054: Employee Obligation to Report Potential Conflicts of Interest](#).

5. Training:

Each Investigator is required to complete training regarding conflicts of interests prior to engaging in research and at least every four years, and immediately when any of the following apply:

- (1) The University revises its financial conflicts of interest policies or procedures in any manner that affects the requirements of investigators.
- (2) An investigator is new to the University.
- (3) The University finds that an investigator is not in compliance with the University’s financial conflict of interest policy or management plan.

6. Research Carried Out Through Subcontracts:

If research will be carried out through a sub-recipient (e.g., a subcontractor or consortium member) and is funded by PHS, NSF or a sponsor who has adopted PHS or NSF financial conflict of interest

requirements: (a) the sub-recipient shall certify in a written agreement that its research conflict of interests policy complies with the sponsor requirement, and that it will report any financial conflicts of interests of its investigators to the University by dates sufficient for timely reporting by the University to the sponsor; or (b) if it is unable to certify compliance, the sub-recipient shall enter into a written agreement requiring its investigators to report significant financial interests to the University and complete the University's financial conflict of interest training pursuant to this policy and associated procedures.

7. Enforcement:

Investigators who fail to comply with the requirements of this policy or with a [Research Conflict of Interests Committee](#) management plan shall be subject to appropriate disciplinary action, up to and including suspension or termination of employment as provided in applicable University policies. The Institutional Official shall conduct a retrospective review to determine if the non-compliance has resulted in any bias in the research and if so, shall implement a mitigation plan and do any required reporting.

Violations of Virginia's Conflicts of Interest Act, Section 2.2-3102 et. seq., can result in imposition of both civil and criminal penalties and may constitute malfeasance in office or employment.

8. Responding to Public Requests for Information about PHS-Funded Research:

The University shall respond in writing within five business days to requests from the public for information about financial conflicts of interest of senior/key personnel (the principal investigator or project director and any other person identified as senior/key in the PHS funding application or other reports to PHS) if such conflicts are related to PHS-funded research. The response will be made in writing, postmarked within five business days, and include the investigator's name, a description of the interest, and its dollar value range as required by the HHS regulations on Promoting Objectivity in Research.

The same approach will be taken when responding to public requests for information about research funded by sponsors who have adopted PHS financial conflict of interest requirements. Requests for information about research funded by other sponsors will be subject to standard University policies and procedures applicable to public requests for information.

9. Record Retention:

Records related to disclosures and management of financial conflicts of interest must be maintained for at least five years from completion of the research and in accordance with University policy [IRM-017: Records Management](#).

10. Dissemination of Policy:

The University shall make this policy publicly available on its website.

11. Compliance with Policy:

Failure to comply with the requirements of this policy may result in disciplinary action up to and including termination in accordance with relevant University policies.

Questions about this policy should be directed to the [Office of the Vice President for Research](#).

Procedures

[On-Line Disclosure System](#)

Related Information

[FIN-019: Acceptance of Gifts and Special Benefits from Vendors](#)

[FIN-054: Employee Obligation to Report Potential Conflicts of Interest](#)

[IRM-017: Records Management](#) [See [Records & Information Management](#) for requirements for the destruction of records.]

[Executive Order 18](#)

[Frequently Asked Questions](#)

Work Flow Process [link to be added]

[State and Local Government Conflicts of Interests Compliance](#)

Major Category [Research Administration](#)

Next Scheduled Review Thursday, August 24, 2023

Revision History

Edited *Significant Financial Interest* 4/2/24; Added Compliance section 7/22/21; Added Section 9 8/24/20; Updated Links 7/29/20; Updated 2/23/17, 12/2/14.

Applies To Text

Academic Division and the College at Wise.

Supersedes Policy Text

Objectivity in Research Policy; VIII.B.1, Resolution of Conflicts of Interest as They Relate to Research Contracts.

Last modified April 2, 2024 - 8:26am

Approved By Executive Vice President and Provost (as President's Designee)

Approved Date February 6, 2013 - 12:00pm