

 <p><b>Category:</b> Administrative</p> <p><b>Policy applicable for:</b> Faculty/Staff</p>	<p><i>Policy Title:</i> <b>Conflict of Interest on Federally Sponsored Projects</b></p> <p><b>Effective Date:</b> 04/14/09</p> <p><b>Prior Effective Date:</b> mm/dd/yyyy</p> <p><b>Enabling Acts:</b> University Rules Ohio Revised Code, Government Publications, etc.</p>	<p><i>Policy Number:</i> <b>1.3.2</b></p> <p><b>Policy Owner:</b> VP for Research</p> <p><b>Responsible Office(s):</b> Sponsored Research Services General Counsel</p>
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**Applicable Regulatory Provisions and Agency Policies:**

42 CFR 50 Subpart F

45 CFR Part 94

NSF 09-01 Proposal and Award Policies and Procedure Guide

**I. Purpose and Scope**

This policy implements federal requirements pertaining to "Objectivity in Research" promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 Subpart F and 45 CFR Part 94. This policy also implements federal requirements contained in the National Science Foundation's (NSF) Award and Administrative Guide Chapter IV Grantee Standards. These agencies require the university to maintain an appropriate written policy on conflict of interest disclosure as a condition for receiving federal grants. The federal requirements, embodied in this policy, are applicable to all proposals and subsequent awards submitted to and accepted by these federal agencies.

**II. Definitions**

For purposes of this policy, the following definitions shall apply:

*"Conflict of interest"* is defined as a circumstance in which it is reasonably determined that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of NSF or NIH funded research or educational activities.

*"Immediate family"* means a spouse, dependent child or domestic partner.

*"Significant Financial Interest"* means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); loans, and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- (i) Salary, royalties or other remuneration from the applicant institution;
- (ii) Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- (iv) Income from service on advisory committees or review panels for public or nonprofit entities;
- (v) An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, *and* does not represent more than a 5% ownership interest in any single entity; or salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

*"Investigator"* is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH or NSF funded research, or proposed for such funding, *including* subgrantees, contractors, or collaborators.

*"OAR form"* shall refer to the electronic Outside Activity Reporting form that is required to be submitted at least annually by university employees.

### **III. Policy**

Applicable regulations and this policy require that Investigators disclose all Significant Financial Interests (and those of his/her immediate family) (i) that would reasonably appear to affect or be affected by the research for which PHS or NSF funding is sought, and (ii) in entities whose financial interests would reasonably appear to affect or be affected by the research.

#### **A. Disclosure Process**

Investigators who are faculty or staff of the university are required to disclose to the Vice President for Research or his/her designee all Significant Financial Interests as part of the required disclosures on their OAR form. The OAR form must be updated to reflect all current activities prior to submitting any application for funding to the Office of Sponsored Research Services for review. The OAR form must also be updated during the life of any award from PHS or NSF to allow the Office of Sponsored Research Services to report any subsequently identified conflicts of interest within 60 days as required by federal regulations.

Subgrantees, collaborators, or contractors (“subgrantees”) shall be required to disclose Significant Financial Interests to the university prior to the expending of any funds under subaward agreements from PHS and prior to the submittal of the proposal for NSF grants. The university shall notify NSF of any conflicts of interest that subgrantees are unable to manage, reduce, or eliminate, using the NSF Fastlane system. The subaward agreement shall include assurances that the subgrantee will comply with the applicable federal conflict of interest regulations. In the absence of a subaward agreement, Investigators will be required to comply with university policy.

The appropriate organizational unit head shall review OAR forms. The organizational unit head shall consider all factors relevant to the situation, including, but not limited to, the nature and time commitment of the activity disclosed, the amount of any financial interest, and the design of the research project and advise the employee in writing whether the activity or relationship may be undertaken. The Vice President for Research or his/her designee shall also review disclosure statement forms when a disclosure is made that relates to a sponsored proposal or award.

#### B. Resolution of Conflicts

In situations in which an Investigator has a Significant Financial Interest that would reasonably appear to present a Conflict of Interest, the organizational unit head or the Vice President for Research shall refer the situation to the Standing Conflict of Interest Committee, an independent oversight committee, to make recommendations to manage, reduce or eliminate the conflict. Examples of conditions or restrictions that might be considered include, but are not limited to:

- (i) Public disclosure of Significant Financial Interests;
- (ii) Monitoring of research by independent reviewers;
- (iii) Modification of the research plan;
- (iv) Disqualification from participation in all or a portion of the federally-funded research;
- (v) Divestiture of Significant Financial Interests;
- (vi) Severance of relationships that create actual or potential conflicts; or,
- (vii) Any other action deemed necessary by the Standing Committee to manage, reduce, or eliminate the conflict of interest.

The solution shall be set forth in a written conflict management plan. A copy of all such management plans shall be provided to the Vice President for Research, the Investigator and the Investigator’s organizational unit head.

### C. Reporting and Monitoring

The Office of the Vice President for Research shall report any conflict of interest to the appropriate federal grants manager as required by federal regulations. Additionally this office will include language in all of its subaward agreements that requires all subgrantees to certify compliance with the respective federal policy on financial conflicts of interest and to disclose Significant Financial Interests to the university.

Any conflict of interest disclosed after the initial report shall be subject to review as set forth in this policy. The university shall complete its review and report the existence of the conflict of interest and the measures taken to reduce, manage, or eliminate it within sixty (60) days of disclosure.

The appropriate organizational unit head or designee is responsible for overseeing the implementation of the disclosure, the review process and for monitoring compliance with any conflict management plan. These persons or their designees will address all breaches of this policy including:

- (i) Failure to comply with the disclosure requirement, whether by virtue of an employee's refusal to respond or by his/her responding with incomplete or inaccurate information;
- (ii) Failure to remedy conflicts; and
- (iii) Failure to comply with conditions in a prescribed conflict management plan.

### IV. **Failure to Comply**

Failure to comply with this policy may result in disciplinary actions. Procedures and sanctions are set forth in applicable collective bargaining agreements and university rules. When an Investigator's failure to comply with this policy biases the design, conduct, or reporting of the research, the Vice President for Research shall promptly report the corrective action taken to the appropriate funding agency

### V. **Maintenance of Records**

The Office of the Vice President of Research and the organizational unit will maintain records of all financial disclosures covered by this policy and of all actions taken to resolve conflicts of interest for at least three years beyond the submission of a final expenditures report or as otherwise provided under 45 CFR 74.53(b).

### VI. **Additional Resources:**

***Resources on conflicts of interest (Web links in red)***

**Bioethics resources on the Web**

## Objectivity in Research

NIH GUIDE, Volume 24, Number 25, July 14, 1995. Provides regulations establishing standards and procedures to be followed by institutions that apply for research to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.

## NIH Policy on Financial conflict of Interest

NIH Guide - Financial Conflicts of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards, June 5, 2000

## Office of Research Integrity Responsible Conduct of Research Resources

## Office of Extramural Research Financial Conflict of Interest Tutorial (faculty)

## Office of Research Integrity Financial Conflict of Interest (administrators)

### Phone Contacts:

Vice President for Research	(513) 558-0026
Associate Vice President for Research	(513) 556-5054
General Counsel	(513) 556-3483
Sponsored Research Services	(513) 558-2870