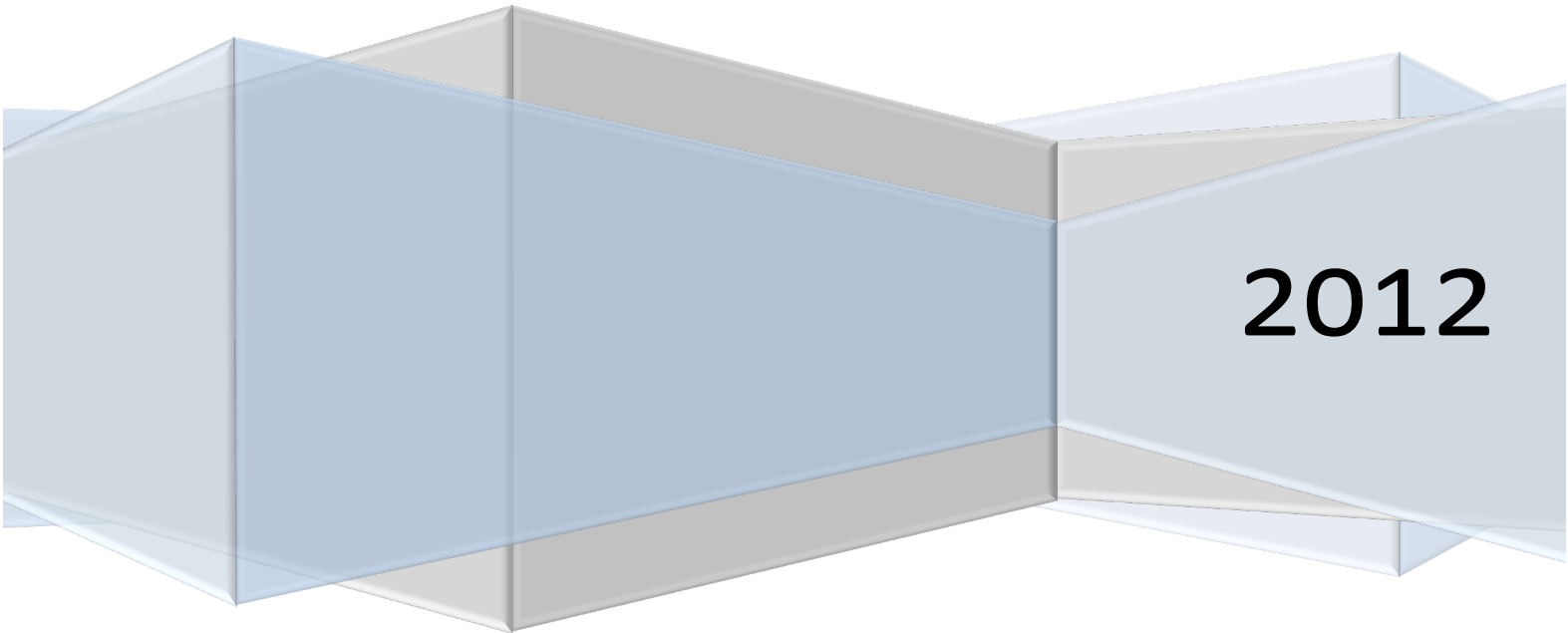


**University of Michigan**

**Policy for Identification and Management of  
Financial Conflicts of Interest**

**Office for the Vice President of Research**

**08/24/12**



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## I. Policy Statement

The University of Michigan will exercise care in accepting or entering into sponsored agreements or technology transfer agreements or human subject's research in which the Investigators involved (or their Family Members) have Significant Financial Interests or Management Interests that create conflicts. Such agreements will not be accepted if the conflicts:

- a. can be expected with reasonable certainty to compromise the integrity or objectivity of those investigations or undermine the employees' obligations to the University, sponsor, research subjects or students, and
- b. cannot be satisfactorily managed with appropriate administrative oversight.

## II. Background

The overarching University policy on Conflicts of Interest and Conflicts of Commitment ([SPG 201.65-1](#)) states:

The University is committed to basic values of transparency, integrity of scholarship, and independence as it pursues its mission to create, preserve, and disseminate knowledge through teaching, research, and public service. Accordingly, the University of Michigan allows and encourages faculty and staff to engage in outside activities and relationships that enhance the mission of the University. All faculty and staff members are to act with honesty, integrity, and in the best interest of the University when performing their duties, and to abide by the highest standards of research, educational, professional, and fiscal conduct.

The University allows and encourages outside activities and relationships that enhance the missions of the University. In addition, University faculty and staff have the right to acquire and retain personal financial interests (including personal income from the transfer of technology) providing that those obligations and commitments do not interfere with their duties or improperly distort the judgments expected of them.

To be eligible to receive grants, contracts, or cooperative agreements from the Public Health Service (including NIH, see [PHS policy](#)) or grants or cooperative agreements from the National Science Foundation (see [NSF policy](#)) or grants from entities explicitly requiring compliance with the PHS FCOI regulations the University of Michigan is required to have policies for the disclosure of certain Significant Financial Interests held by Investigators (or their Family Members); procedures for the institutional review of the relevance of such personal outside interests for the design, conduct or reporting of the research; procedures for the management or elimination of those interests deemed to constitute Financial Conflicts of Interest; policies and procedures for reporting Financial Conflicts of Interest to the agency; and, in the case of PHS-funded research and research funded by entities following PHS FCOI regulations, policies

and procedures for making information about managed Financial Conflicts of Interest available to the public.

### **III. Relationship of Requirements to Source of Sponsorship**

The University has special requirements for research projects proposed for or receiving funding from the Public Health Service and entities explicitly requiring compliance with PHS FCOI regulations.

The University applies a common set of procedural requirements for all other sponsored research, technology transfer agreements, or human subject projects.

The University, in addition, abides by the [State of Michigan Conflict of Interest Law](#) that requires explicit approval of the Board of Regents before entering into a research or technology transfer agreement with University employees or enterprises in which they hold a stipulated interest.

This Policy operates in conjunction with other University policies related to conflict of interest and conflict of commitment, including unit-based policies on conflict of interest and conflict of commitment mandated by [SPG 201.65-1](#).

### **IV. Definitions**

**Disclosure Form** refers to a University on-line form used to report information about certain outside financial and management interests and activities related to their University responsibilities. The information requested includes but may go beyond “significant financial interests” as defined in PHS regulation.

**PAF (Proposal Approval Form) Disclosure** refers to a question asked of the Principal Investigator on any research proposal to be submitted to an outside sponsor.

A **Financial Conflict of Interest in Sponsored Research** exists when the University determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.

A **Conflict of Interest in a Technology Transfer Agreement** exists when a University employee has an ownership interest or a significant management interest in a proposed optionee, licensee, or assignee of University intellectual property.

**Family Member** means the Investigator's spouse, domestic partner, and dependents.

**Institutional Responsibilities** means an investigator's professional responsibilities on behalf of the University, such as research, teaching, conduct of sponsored projects, professional practice, and service on institutional committees.

An **Investigator** means the Principal Investigator or Project Director (PI/PD), Participating Investigators, and Senior/Key Personnel identified as such by the institution in a proposal or report to the sponsor, and any other investigator who is identified by the PI/PD as responsible for (i.e., not simply working on or engaged in) the design, conduct, or reporting of a sponsored research project.

**Management or Manage** means taking action to address a financial or management conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias. Examples include, but are not limited to:

- Public disclosure of Significant Financial Interests,
- Monitoring of the research or research management by independent reviewers,
- Assignment of ombudspersons for students,
- Modification of the research plan,
- Disqualification from participation in all or in a portion of the research,
- Divestiture of Significant Financial Interests, or
- Severance of the relationship that creates the Conflict of Interest.

A **Management Interest** in an outside organization means holding a position (such as officer, trustee, or director) that carries a fiduciary obligation, that is, a legal or ethical obligation to act in the best interest of the outside organization

A **Principal Investigator**, for the purposes of this policy, is the person designated on the sponsored project Proposal Approval Form (PAF), the Proposal Award Notice (PAN), or the investigator similarly designated on the IRB or UCUCA approval notice as the investigator having the background and training in scientific and administrative oversight necessary to conduct and manage the research or sponsored project.

An outside interest, activity, or relationship is **Related** to an investigator's institutional responsibilities when it relies upon the same expertise that an investigator uses to carry out his or her institutional responsibilities or when it has the potential to influence the duties that the University considers part of the work it pays or otherwise engages the investigator to do.

An entity **Related to a** sponsored research agreement includes any supplier of equipment, materials, or services, a business commercializing a product that the research is intended to evaluate or further develop, or a party whose financial interests would reasonably appear to be affected by the research or technology transfer agreement.

A **Significant Financial Interest** exists when a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's Family Members) reasonably appears to be related to the investigator's institutional responsibilities:

- Remuneration received from any publicly traded entity in the previous 12 months and the value of any equity interest in the entity, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to the University).
- Remuneration received from any non-publicly traded entity in the previous 12 months, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to the University).
- Any equity interest in a non-publicly traded entity.
- Any income received from intellectual property (IP) rights and interests not held by the University (e.g., patents, copyrights, and royalties from such rights).

Certain reimbursed or sponsored travel paid to or on behalf of the investigator, except that paid for by a federal, state, or local government agency, a domestic nonprofit institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education may constitute a Significant Financial Interest.

## **V. The Disclosure Process and Referral**

### **A. Research proposals to and awards from the Public Health Service and entities explicitly requiring compliance with the PHS FCOI regulations**

All investigators proposing or receiving grants, contracts, or cooperative agreements from the Public Health Service or entities explicitly requiring compliance with PHS policy must disclose at least annually their outside interests related to any of their University responsibilities as requested on the Annual Disclosure Form. Investigators must have completed this disclosure prior to submitting a grant proposal to the above entities, and must submit updates to their Annual Disclosure Form within 30 days of acquiring new disclosable interests. The Annual Disclosure Form must be submitted even if the investigator has no interests or activities to disclose.

At the time a research proposal is submitted to PHS or the entity requiring compliance with PHS FCOI regulations, the University will confirm that the proposed investigators have submitted Annual Disclosure Forms.

Proposals to PHS or the entity requiring compliance with PHS policy where one or more investigator has disclosed an outside interest on the Annual Disclosure form will be referred to one of the Conflict of Interest Review Committees.

## **B. Research proposals to other research sponsors**

The Principal Investigator on a proposed sponsored agreement to NSF or other Research Sponsors will determine if a Financial Conflict of Interest disclosure is required at the time a Proposal Approval Form (PAF) is first submitted and will make a declaration to that effect on the PAF. The PAF Disclosure requests information about certain Financial or Management Interests in outside Related Entities held by the Investigator and any other investigators who are responsible for the design, conduct, or reporting of the proposed research (and by their Family Members).

If the Principal Investigator discloses a significant financial or management interest that might be a Conflict of Interest in Sponsored Research, or if the project representative from the Office of Research and Sponsored Projects (ORSP) is aware of a Management Interest or Significant Financial Interest, the ORSP representative will refer the proposed project to the Office of Vice President for Research Conflict of Interest Review Committee (OVPR COI) or the Medical School Conflict of Interest Board (MEDCOI), as appropriate.

## **C. Proposed Technology Transfer Agreements**

The Office of Technology Transfer (OTT) will refer proposed agreements involving a Conflict of Interest in a Technology Transfer Agreement to either the OVPR COI or the MEDCOI, as appropriate (see Section VI.A, below).

## **D. IRB applications**

IRB applications ask investigators engaged in the proposed research involving human subjects, irrespective of outside sponsorship or support, certain trigger questions about financial, management, or other interests that might create conflicts of interest for investigators engaged in the proposed research. Reviews of those interests and management, as appropriate, are handled collaboratively between a COI committee and the IRB.

Committees pay special attention to proposed human subjects research in which the PI or senior/key personnel have significant financial interests that might be judged to be conflicts.

## **E. Disclosure updates**

If the outside interests of an Investigator change so as to introduce a new, heretofore, undisclosed Financial Interest or Management Interest in a sponsored research project or technology transfer agreement, the investigator must either revise the Annual Disclosure Form or revise a disclosure already submitted to the OVPR COI or the MEDCOI within 30 days of acquiring the new interest.

## VI. Committee Review

### A. Committees

The Vice President for Research is the designated Institutional Official responsible for Conflict of Interest policy for sponsored projects and technology transfer agreements. The Office of the Vice President for Research (OVPR) has authorized two conflict of interest committees to receive disclosures referred from the Office of Research and Sponsored Projects (ORSP) or OTT and review and manage the risks associated with the disclosed interests.

1. The OVPR Conflict of Interest Review Committee (OVPR COI)

OVPR COI has eight members representing the diverse interests of the Colleges and Schools. Committee members are named by the Vice President for overlapping 3-year terms.

2. Medical School Conflict of Interest Board (MEDCOI)

MEDCOI has the authority and responsibility to review and manage the risks associated with interests in sponsored projects falling within its jurisdiction, as described below. The committee has 16 members, including one or more members with faculty appointments outside the Medical School. Members are appointed by the Dean of the Medical School for overlapping 3-year terms. Membership rosters are reported to the Vice President for Research, or designee, annually.

3. Jurisdiction

As a general rule, the OVPR COI reviews sponsored projects involving faculty and staff with primary appointments outside the Medical School.

The MEDCOI reviews and manages sponsored projects for which the PI or Co-PI or Participating Investigator has a primary appointment in the Medical School. The MEDCOI also reviews and manages sponsored projects with a proposed technology transfer agreement involving conflicted Investigators with an appointment in the Medical School. The review of other conflict of interest situations, or categories of situations, may be delegated in whole or in part by the Vice President for Research upon the recommendation of the OVPR COI and the MEDCOI. Specific proposals or awards may be assigned to a particular committee with the agreement of the chairs of the OVPR COI and the MEDCOI.

Both the OVPR and Medical School COI committees reserve the right to request additional information from faculty or staff on disclosures including travel paid to or on behalf of the investigator.



## **B. Determinations**

When a sponsored project, human subjects project, or technology transfer agreement comes to the attention of the committee, the committee will review the financial and management interests it deems related to the project or agreement and determine whether one or more investigators have a Financial Conflict of Interest or a Management Conflict of Interest, that is, whether their interests could directly and significantly affect the design, conduct, or reporting of the research. If a Financial or Management Conflict of Interest exists, the committee may:

1. Require some specific type of administrative oversight or Management, or
2. Recommend the withdrawal of the proposal or suspension of the technology transfer arrangement.

ORSP or OTT will make an initial determination whether any situation recommended to move forward triggers the State Conflict of Interest law, thereby requiring approval by the Board of Regents. Those situations, along with information on the proposed Management, will be forwarded to the Vice President for Research for approval, and, if approved, sent to the Board of Regents.

Each review committee will have the assistance of administrative staff in handling the flow of paperwork, correspondence, record keeping, and the oversight and implementation of Management decisions made by the committee.

Each committee will review sponsored projects under conflict of interest Management at least annually. If an investigator acquires and discloses a new interest that may be a Financial Conflict of Interest, the committee will review the interest if appropriate, within 60 days.

## **VII. Sub Recipient Requirements**

When the University carries out PHS or NSF funded grants or cooperative agreements through sub grantees, contracts, or collaborators, the University standard agreements require that Investigators comply with a policy at their institution that complies with PHS or NSF COI regulations, as appropriate. In limited circumstances, the University may offer assistance to the sub awardee in meeting its obligations.

## **VIII. Appeal**

A decision by a committee not to approve the acceptance of a sponsored project, to suspend negotiations on a technology transfer agreement, or to require administrative Management objectionable to an interested party may be appealed to the Vice President for Research within 30 days of the date the committee notifies the investigator of the committee's decision. Within 14 days of receipt of a written appeal, the Vice President for Research will decide either to

endorse the committee's decision or to reverse the decision. The Vice President may impose conditions on the arrangement before approval. (If the Vice President for Research has a Financial Conflict of Interest himself or herself the decision will be made by the Provost or another Executive Officer without such a conflict.)

The Vice President will respond in writing to an appeal and notify the relevant committee of his/her decision and the reasons for it.

## **IX. Training**

Investigators proposing or conducting PHS-supported research will complete University-provided training prior to engaging in any PHS funded award and at least every 4 years. Such training will cover the University's policy, the Investigator's disclosure responsibilities, and the applicable federal regulation.

Investigators proposing or conducting PHS-supported research must complete University-provided training immediately if the University revises its policy such that requirements for investigators are affected, when an investigator is new to the University, and when an investigator is determined not to be in compliance with the policy or applicable management plan.

## **X. Reporting Conflicts of Interest to the Public Health Service**

To the extent a Significant Financial Interest or Management Interest involves sponsored research covered by Public Health Service (PHS) regulation, the University will report, prior to the expenditure of any funds, the existence of a Financial Conflict of Interest (FCOI) and assure that the Conflict of Interest has been Managed in accordance with this Policy and to protect the research from bias. The FCOI report to the PHS agency will include:

1. Project (grant) number
2. PI/PD
3. Name of the Investigator with FCOI
4. Outside entity
5. Nature of the FCOI
6. Value of the FCOI
7. How financial interest is related to the PHS funded research
8. Why the financial interest constitutes an FCOI
9. Key elements, conditions and monitoring of the management plan
10. How the management plan safeguards objectivity
11. Investigator agreement to the management plan

For Significant Financial Interests or Management Interests identified subsequent to the initial PHS award or for an investigator who is newly participating in a PHS project, the University will report all elements of the Conflict of Interest noted above to the PHS agency and assure that the Conflict of Interest has been managed in accordance with this Policy within sixty days of identification. The University will make available within 5 days of a written request the identified Financial Conflicts of Interest in PHS awards held by senior/key investigator prior to the expenditure of funds. The information provided upon request will include, at a minimum, the following:

1. Investigator's name
2. Investigator's title and role with respect to the research project
3. Name of the entity in which the Significant Financial Interest is held
4. Nature of the Significant Financial Interest
5. Approximate dollar value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

## **XI. Record Retention**

Significant Financial Interest and Management Interest disclosures, and all actions taken by the University with respect to these interests, will be maintained for at least three years from the date of submission of the final expenditures report, unless other state or federal law or University policy requires a longer retention period.

## **XII. Noncompliance**

The OVPR COI, the MEDCOI, and the OVPR will work cooperatively with Investigators and others to resolve any minor noncompliance.

The University will conduct retrospective reviews within 120 days of a determination that Significant Financial Interests have not been disclosed in a timely manner or previously reviewed or when a Financial Conflict of Interest is not identified or managed in a timely manner to document the review.

Flagrant or repeated noncompliance with policy, procedures, or Management requirements after notice is handled through University disciplinary procedures.

Failure by an Investigator to comply with this Policy as determined by the University to have biased the design, conduct or reporting of PHS funded research will be promptly reported by the University to the PHS including the corrective action taken or to be taken.

In any case in which the PHS determines that PHS-funded clinical research that evaluates the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator who did not disclose, or have under management, a conflicted interest, the University will require the Investigator(s) to disclose the Conflict of Interest in each public presentation of the results and to request an addendum to previously published presentations.

### **XIII. Governance**

This policy will be reviewed and updated, as necessary, on an annual basis by a committee appointed by the Office of the Vice President of Research. The final policy and annual revisions will be approved by the Vice President for Research.

### **XIV. Contact Information/Public Accessibility**

This policy is posted on the following website:

<http://orsp.umich.edu/policies/um/coi/OVPRCOIPolicy.html>

Questions can be directed to the contacts listed on the following website:

<http://orsp.umich.edu/policies/um/coi/contact.html>

Requests for information must be sent to [PHSCOIRequest@umich.edu](mailto:PHSCOIRequest@umich.edu)