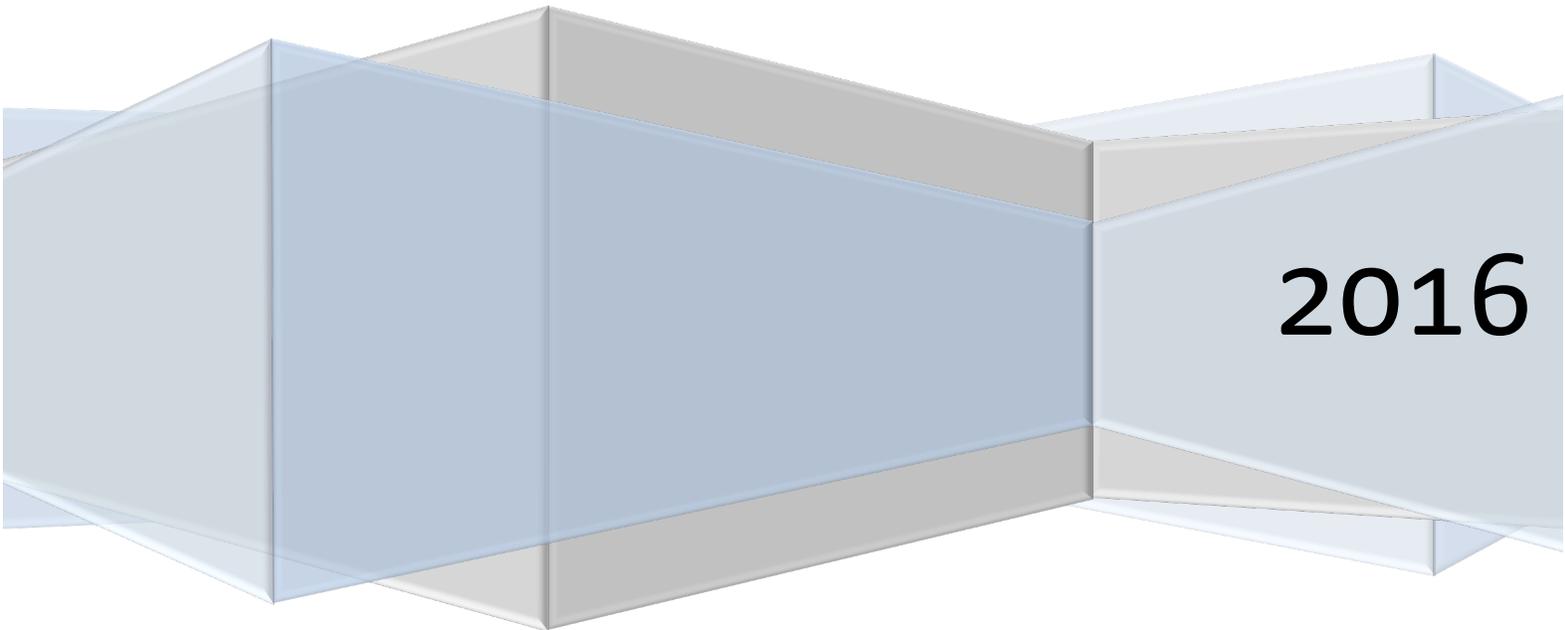


University of Michigan

**Policy for Identification and Management of
Conflicts of Interest in Research and
Technology Transfer**

Office of the Vice President for Research

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I. Policy Statement

The University of Michigan allows and encourages entrepreneurship and cooperative activities with companies and organizations external to the University, as well as other outside interests that enhance the missions of the University. This includes management and financial interests acquired and retained by University faculty and staff, provided that those obligations and commitments do not interfere with their duties or improperly distort the judgments expected of them. To this end, where conflicts exist, individuals are required to provide appropriate disclosure and to assure the fair treatment of all involved in the effort. When conflicts are effectively managed, the interests of all are protected.

The University will exercise care in accepting or entering into sponsored agreements, technology transfer agreements, and human subjects research in which the investigators involved (or their family members) have financial or management interests that create conflicts. Such agreements will not be accepted if the conflicts:

- a. can be expected, with reasonable certainty, to create the opportunity 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. Definitions

A **conflict of interest (COI) in sponsored research** exists when the University determines that a financial or management interest could directly and significantly affect, or be affected by, the design, conduct, or reporting of the research.

A **COI in a technology transfer agreement** exists when a University employee (also referred to as an “individual” for purposes of this policy) has an ownership interest or a management interest in an entity proposing to option, license, or be assigned University intellectual property (IP).

Disclosure means the reporting of an outside interest, activity, or relationship related to an individual’s University responsibilities. The information disclosed includes, but is not limited to, “significant financial interests” as defined in the [Public Health Service \(PHS\) Financial Conflict of Interest \(FCOI\) Regulation](#).

Family member means the investigator's spouse, domestic partner, and dependents.

Institutional Conflict of Interest (ICOI) means investments and relationships developed by U-M leadership or administrative units. These situations are considered in cases that are reviewed by the COI Review Committees and incorporated into management conditions as needed.

Institutional responsibilities mean an individual'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 (PI), participating investigators, co-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 as responsible for (i.e., not simply working on) the design, conduct, or reporting of a sponsored research project.

Management or manage means taking action on financial or management activities to address an actual, potential, or perceived COI, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias and that the academic success of trainees and junior faculty is maximized. Examples of management strategies include, but are not limited to:

- Public disclosure of the COI
- Monitoring of the research or research management by independent reviewers
- Assignment of ombudspersons for students/trainees/junior faculty
- Modification of the research plan
- Disqualification from participation in all or in a portion of the research
- Divestiture of the interest
- Severance of the relationship that creates the COI

A **management interest** means holding a position (e.g., officer, trustee, director) in an outside organization that carries a fiduciary (e.g., legal or ethical) obligation to act in the best interest of the outside organization.

Organizational conflict of interest (OCI), as defined by the Intelligence Advanced Research Project Activity's (IARPA), means that because of [outside interests], activities, or relationships with other [individuals] or [outside] organizations, [an individual] is unable or potentially unable to render impartial assistance or advice to the government, or the [individual's] objectivity in performing the contract work is or might be otherwise impaired, or [an individual] has an unfair competitive advantage. OCI includes consulting for or service to a federal funding agency or federal committee. An OCI does not include participation on National Institute of Health (NIH), National Science Foundation (NSF), or other federal agency study sections or proposal review committees.

An **outside interest, activity or relationship** (referred to as an "outside interest" for purposes of this policy) with an outside organization that relates to an individual's institutional responsibilities, and that applies to the individual and his or her family members, may consist of:

- Paid or unpaid activities for, and relationships with, an outside organization for which the individual utilizes the same skills and knowledge as for his or her institutional responsibilities
 - Membership in professional societies does not constitute a relationship in this context; however, leadership, paid travel, and paid activity on behalf of the society do represent an outside interest
- Ownership in a company or business, including equity, stock, or stock options (exclusive of 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)
- Intellectual property rights or interests, including license and option agreements made through the Office of Technology Transfer (OTT) for technology developed at U-M, and non-UM patents, copyrights, and royalties
- Compensation, loans (other than student loans), other payment(s), or items of value received from an outside organization for an activity related to the individual's institutional responsibilities
- Travel expenses that are reimbursed to an individual or paid directly by an outside organization (disclosure required by either PHS regulations or the individual's unit COI policy)

A **principal investigator (PI)**, for the purposes of this policy, is the person so designated on the records including, but not limited to, a sponsored project PAF, a Proposal Award Notice (PAN), an unfunded agreement (UFA), a human subjects proposal (HUM), a subcontract agreement (SUBK), the Institutional Animal Care and Use Committee (IACUC) approval notice, an internally sponsored project proposal, etc., as the investigator having the responsibility, including the necessary background and training in scientific and administrative oversight, to conduct and manage the research or sponsored project.

An outside interest is **related** to an individual's institutional responsibilities when it relies upon the same expertise that an individual 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 individual to do.

An entity is **related** to a sponsored research agreement or technology transfer agreement if:

- the entity is sponsoring the research
- the entity is the supplier of equipment, materials, or services for the project or agreement
- the entity is a business commercializing a product that the research is intended to evaluate or further develop
- the entity's financial interests would reasonably appear to be affected by the research or technology transfer agreement

A **significant financial interest (SFI)** 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 that, when aggregated, exceeds \$5,000 (lesser amounts must still be reported to the University)
- Remuneration received from any non-publicly traded entity (including non-profit organizations) in the previous 12 months that, 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 (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

Exceptions include:

- 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
- Income from service on advisory committees or review panels, and/or income from seminars, lectures, or teaching engagements sponsored by:
 - a Federal, state, or local government agency
 - an institution of higher education
 - an academic teaching hospital
 - a medical center
 - a research institute that is affiliated with an institution of higher education
- Income from sponsored projects or agreements processed through and paid by the University

III. Overview

The overarching University policy on COIs and Conflicts of Commitment (COCs) ([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 interests that enhance the missions of the University. This includes management and financial interests acquired and retained by University faculty and staff, provided that those obligations and commitments do not interfere with their duties or improperly distort the judgments expected of them.

However, to be eligible to receive grants, contracts, or cooperative agreements from external agencies and entities (e.g., federal sponsors, industry sponsors, etc.) that follow [PHS](#), [NSF](#), or other COI disclosure and review requirements, the University of Michigan has policies and procedures for:

- The disclosure of certain related outside interests held by individuals or their family members
- The institutional review of the relevance of such outside interests to the design, conduct or reporting of the research
- The management or elimination of those interests deemed to constitute COIs
- Reporting COIs to the sponsoring or gifting agency or entity
- Making information about managed COIs available to the public in the case of PHS-funded research and [research funded by entities following PHS FCOI regulations](#)

While the University has special requirements for research projects proposed for or receiving funding from the PHS and entities explicitly requiring compliance with PHS FCOI regulations, it applies a common set of procedural requirements to all other sponsored research, technology transfer agreements, or human subject projects.

Further, [state law](#) may require explicit approval by the Board of Regents before entering into a financial contract (e.g., research, technology transfer agreements, subcontracts, etc.) with University employees or enterprises in which they hold a direct or indirect interest in the contract.

This Policy operates in addition to other University policies related to COIs and COCs, including unit-based policies mandated by [SPG 201.65-1](#).

IV. The Disclosure Process and Referral

A. General Disclosure Requirements

Disclosures are required for completion of:

- Proposal Approval Form (PAF)

- M-Inform on-line disclosure system
- Institutional Review Board (IRB) HUM
- OTT IP and licensing discussions
- SUBK
- UFA (e.g., Material Transfer Agreement)
- Procurement Services, and
- As otherwise required

B. Research proposals to, and awards from, the PHS and entities explicitly requiring compliance with the PHS FCOI Regulations

All investigators proposing or receiving grants, contracts, or cooperative agreements from the PHS, or entities explicitly requiring compliance with the PHS FCOI Regulations, must disclose, at least annually, their outside interests related to any of their University responsibilities as requested on the M-Inform disclosure or the non-UM affiliate disclosure form. Investigators must have completed their disclosure prior to submitting a grant proposal to the above entities, and must submit updates to their disclosure within 30 days of any change. An annual disclosure must be submitted even if the investigator has no outside interests.

At the time a research proposal is submitted to PHS or an entity requiring compliance with PHS FCOI Regulations, the University will confirm that the proposed investigators have submitted disclosures.

Proposals to PHS, or an entity requiring compliance with PHS FCOI Regulations, where one or more investigators have disclosed an outside interest, will be referred to one of the COI Review Committees.

C. Research proposals to other research sponsors

The PI on a proposed sponsored agreement to any research sponsor will determine if COI disclosures are required at the time a PAF is first submitted and will make a declaration to that effect on the PAF. The declaration will pertain to any investigator responsible for the design, conduct, or reporting of the proposed research, and will include information about financial or management interests in related outside organizations held by those individuals and/or their family members.

If the PI discloses for him or herself, or on behalf of any investigator, an outside interest that might be a COI in sponsored research, or if the project representative from the Office of Research and Sponsored Projects (ORSP) is aware of an outside interest, the ORSP representative will refer the proposed project to the COI Review Committees.

D. Proposed Technology Transfer Agreements

The OTT will refer proposed agreements involving a COI in a technology transfer agreement to the COI Review Committees.

E. IRB applications

IRB applications ask investigators engaged in proposed research involving human subjects, irrespective of outside sponsorship or support, questions about related outside interests. Reviews of those outside interests and management, as appropriate, are handled collaboratively between the COI Review Committees and the IRB.

F. Disclosure updates

An investigator must report a new outside interest, or a change to a previously disclosed outside interest, within 30 days.

V. Committee Review

A. Committees

The Vice President for Research is the designated Institutional Official responsible for the COI policy for research and technology transfer agreements. The Vice President for Research has authorized two conflict of interest committees to receive certain individual disclosures and disclosures referred from ORSP, OTT, or others; and review and manage the risks associated with the disclosed interests.

1. UM Office of Research Conflict of Interest Review Committee (UMOR COI)

UMOR COI has the authority and responsibility to review and manage the risks associated with interests falling within its jurisdiction, as described below. UMOR COI membership represents the diverse interests of the Colleges and Schools. The Vice President for Research appoints committee members for overlapping three-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 falling within its jurisdiction, as described below. MEDCOI includes one or more members with faculty appointments outside the Medical School. The Medical School Dean or designee appoints members for overlapping three-year terms. Membership rosters are reported to the Vice President for Research, or designee, annually.

3. Jurisdiction

As a general rule, the UMOR COI oversees the review and management of COIs involving faculty and staff with primary appointments outside of the Medical School and UM Health System.

The MEDCOI oversees the review and management of COIs involving faculty and staff with primary appointments in the Medical School and UM Health System.

Review and management of a specific research project or situation may be assigned to a particular committee with the agreement of the chairs of the UMOR COI and the MEDCOI.

B. Determinations

When a sponsored project, human subjects project, internally funded project, technology transfer agreement, outside interest disclosure, etc., comes to the attention of the COI Review Committees, they may require additional information (e.g., remuneration expected over the course the research) from individuals as part of their review of the outside interest to determine whether one or more investigators has a COI; that is, whether their outside interests could directly and significantly affect the design, conduct, or reporting of the research, or their oversight of trainees and junior faculty. If a COI exists, the committee may (among other options):

- Require some specific type of administrative oversight or management condition
- Recommend the withdrawal of the proposal or suspension of the technology transfer arrangement

Situations will be reviewed to determine if they invoke the State of Michigan statute “Contracts of Public Servants with Public Entities Act 317 of 1968”. 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 as required by the statute.

The COI Review Committees 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 committees.

The COI Review Committees, or administrative staff on behalf of the committee, will review new and updated outside interest disclosures of individuals within 60 days of submission, and sponsored projects under COI management at least annually.

VI. Sub Recipient Requirements

When the University carries out PHS or NSF funded grants or cooperative agreements through subawards, contracts, or collaborators, the standard University agreement requires that external investigators comply with a policy at their institution that complies with PHS or NSF COI Regulations, as appropriate. If their institution does not have a PHS FCOI compliant policy, they must follow the University policy. In limited circumstances, the University may offer assistance to the subawardee in meeting its regulatory obligations.

VII. Appeal

An individual may appeal a COI Review Committee decision in writing to the Vice President for Research within 30 days of the date of the committee's notification of that 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 for Research may impose conditions on the arrangement before approval of the appeal. (If the Vice President for Research has a COI himself or herself, the Provost or another Executive Officer without such a conflict will make the decision.)

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

VIII. Training

Investigators proposing or conducting research sponsored by an agency, organization, or other entity that follows the PHS FCOI regulations must complete University-provided training prior to engaging in any PHS funded award and at least every four (4) years thereafter. Such training will cover the University's policy, the investigator's disclosure responsibilities, and the applicable federal regulation. At any point, if the training is updated, investigators will be instructed to complete the new training.

IX. Reporting COIs to the PHS

To the extent a SFI or management interest involves sponsored research covered by the PHS FCOI Regulation, the University will report, as appropriate, prior to the expenditure of any funds, the existence of a FCOI and assure that the COI 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 organization
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 SFIs 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 COI noted above to the PHS agency and assure that the COI has been managed in accordance with this Policy within 60 days of identification.

X. Public Inquiries Regarding COIs Related to PHS Funded Research

The University will make available, within five (5) days of a written request, the identified FCOIs in PHS awards held by senior/key investigators in accordance with regulatory requirements. 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 SFI is held
4. Nature of the SFI
5. Approximate dollar value of the SFI 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

SFI 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 termination of the grant, contract, or agreement, unless other state or federal law or University policy requires a longer retention period.

XII. Noncompliance

The COI Review Committees will work cooperatively with investigators and others to resolve any minor noncompliance.

The University will conduct retrospective reviews for PHS funded projects within 120 days of a determination that SFIs have not been disclosed appropriately or when a FCOI is not identified or managed in a timely manner.

Flagrant or repeated noncompliance with policy, procedures, or management requirements after notice to an individual is handled through University disciplinary procedures. Failure by an investigator to comply with this policy for reporting a related outside interest which has been determined by the University to have biased the design, conduct, or reporting of PHS funded research will be promptly reported by the University to 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 to disclose the COI 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 a regular basis by a committee appointed by the Vice President for Research. The Vice President for Research will approve the final policy and revisions.

XIV. Contact Information/Public Accessibility

This policy is posted on the following website:

<http://research-compliance.umich.edu/files/fcoipolicyv13-finalversionpdf>

Questions can be directed to: COI.Support@umich.edu

More information about the UMOR COI Review Committee or MEDCOI Board is listed on the following website: <http://research-compliance.umich.edu/conflict-interest-coi>

Requests for PHS information must be sent to: PHSCOIRequest@umich.edu