

# Policy for the Identification and Management of Conflicts of Interest in Research, Sponsored Projects, and Technology Transfer

## 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 and relationships that enhance the missions of the University ([Regents Bylaw 5.12](#) and [U-M Faculty Handbook section 9.E](#)). This includes, among other things, financial interests/investments and management positions acquired and retained by University employees, provided that those external obligations and commitments do not interfere with the University employees' respective duties or adversely affect their judgment in carrying out University responsibilities. The overarching University policy on Conflicts of Interest (COIs) and Conflicts of Commitment (COCs) is the [SPG 201.65-1](#) (noted in [U-M Faculty Handbook section 9.G](#)), which requires employees to provide appropriate disclosure of their outside activities, relationships, and interests. This policy assures the fair treatment of all involved in the process to identify and manage COIs in research, sponsored projects, and technology transfer.

The Vice President for Research (VPR) is the designated Institutional Official responsible for the COI policy for research, sponsored projects, and technology transfer agreements. The VPR has established the following policy and [website of procedures](#) for the oversight of research, sponsored agreements, and for the protection of University intellectual property, which includes:

1. Requiring disclosure of outside activities, relationships, interests, and investments held by employees or their spouse, domestic partner, and/or dependent children.
2. Institutional review of any opportunity for such outside activities, relationships, and interests to:
  - a. compromise the integrity or objectivity of research, sponsored projects, or technology transfer agreements;
  - b. bias the design, conduct, or reporting of the research; or
  - c. undermine the employees' obligation to the University, sponsor, research subjects, junior faculty, trainees, or students.
3. Management or elimination of those activities, relationships, and interests deemed to constitute COIs.

If the outside activity creates a conflict that cannot be satisfactorily managed with appropriate administrative oversight, the research, sponsored project, or technology transfer agreement will not be accepted.

The University is required to follow sponsor-specific regulations and guidance for proposed or funded projects (e.g., the Public Health Service (PHS) and other funding organizations that explicitly require compliance with [PHS Financial Conflict of Interest \(FCOI\) regulations](#)). The University also applies standard COI review requirements to all other research, sponsored agreements, and technology transfer agreements.

Further, [state law](#) requires approval by the Board of Regents before the University may enter into a contract (e.g., research, subcontract, sponsored agreement, technology transfer agreement, purchase agreement, etc.) with an individual who has a University appointment or with an external enterprise in which a University employee has certain relationships and interests.

## II. Disclosure and Review

### A. Disclosure Requirements

This policy requires the following employees to disclose outside activities, relationships, and interests in the M-Inform disclosure system:

1. all investigators listed on proposal approval forms (PAF) or awards (AWD) for any sponsored projects (effective July 1, 2020);
2. investigators on unfunded agreements and human subjects applications that have a [related](#) outside activity, relationship, or interest;
3. inventors of optioned or licensed U-M intellectual property; and
4. employees upon the request of a COI committee.

If an investigator has an active **National Institutes of Health** (NIH) award (direct or prime funding) **or** has submitted or plans to submit a proposal for NIH funding for their U-M research during the current fiscal year, as part of the disclosure of any outside activity with a foreign entity, the investigator must submit the original and English translation of all contracts, grants, appointment/acknowledgement letters, statements of work, and any other agreements with the foreign entity.

Disclosure is required at least annually and within 30 days of a change to an existing outside activity, relationship, or interest **or** engagement in new reportable outside activities, relationships, or interests (see [disclosure process](#)).

### B. Review

The VPR has authorized two COI committees to review and manage the risks associated with disclosed outside activities, relationships, and interests, perceived or actual COIs, or other research-related situations referred by the Office of Research and Sponsored Projects (ORSP), Office of Technology Transfer (OTT), schools/colleges/departments, Procurement, Real Estate Office, or others (see [initial review process](#)).

1. The [UMOR COI Review Committee](#) has the authority and responsibility to review and manage perceived or actual conflicts of interest of University employees engaged in research with primary appointments outside of Michigan Medicine. UMOR COI membership represents the diverse interests of the Colleges and Schools.
2. The [Medical School Conflict of Interest Board](#) (MEDCOI) has the authority and responsibility to review and manage perceived or actual conflicts of interest of University employees with primary appointments in Michigan Medicine.

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

### C. Determinations

When potential conflicts of interest involving research, sponsored agreements, technology transfer agreements, individual disclosures, etc., come to the attention of the COI committees, the committees may require additional information, as necessary, in order to determine whether the outside activity, relationship, or interest could directly and significantly affect the design, conduct, or reporting of the research, or the oversight of/commitment to students, trainees, and junior faculty (see [committee determination process](#)).

If a COI exists, the committee may (among other options) require:

- 1) Management of the COI with conditions such as:
  - a) Public disclosure of the COI;
  - b) Monitoring of the research or research management by independent reviewers;
  - c) Restriction of the role or responsibility in the conduct of research;
  - d) Assignment of ombudspersons for students/trainees/junior faculty;
  - e) Requirement of additional contractual agreements; and/or
  - f) Modification of the research plan.
- 2) Elimination of the conflict by:
  - a) Disqualification from participation in all or a portion of the research;
  - b) Divestiture of the interest;
  - c) Severance of the relationship that creates the COI;
  - d) Withdrawal of the proposal; and/or
  - e) Suspension of the technology transfer arrangement.

### D. Appeal

An individual may appeal a COI committee decision in writing to the VPR within 30 days of the date of the committee's notification of that decision. Within 30 days of receipt of a written appeal, the VPR (or the VPR's designee) will decide the appeal. The VPR may impose conditions on the arrangement before approval of the appeal. If the VPR has a COI themselves, the Provost or another Executive Officer without such a conflict will decide the appeal.

The VPR (or the VPR's designee) will respond in writing to an appeal and notify the relevant committee of his or her decision and the reasons for it.

### **III. Training**

The University provides training for the disclosure of outside activities, relationships, and interests through the M-Inform disclosure system.

### **IV. Noncompliance**

The COI committees will work cooperatively with University employees and others to resolve any minor noncompliance.

Flagrant or repeated noncompliance (after notice) will be handled through University disciplinary procedures. In the event that the University determines that an employee's undisclosed outside activity, relationship, or interest has resulted in bias to the design, conduct, or reporting of research, the University will promptly report the noncompliance to research sponsors and/or funding agencies, as required.

False, fictitious, or fraudulent statements or claims (including intentional omissions) in violation of this policy may result in criminal, civil, administrative, or University penalties.

### **V. Governance**

This policy is owned and maintained by the VPR. It will be reviewed and updated, as necessary, on a regular basis. The VPR will approve the final policy and revisions.

### **VI. Resources and Contact Information/Public Accessibility**

This policy and procedures are available on the Research Ethics and Compliance COI website at: <http://research-compliance.umich.edu/conflict-interest-coi>

[COI Policy](#)

[Disclosure Procedures](#)

[Review Procedures](#)

[Committee Determination Procedures](#)

Definitions and frequently asked questions are available at:

<https://research-compliance.umich.edu/m-inform-glossary-faq>

Specific questions can be directed to: [COI.Support@umich.edu](mailto:COI.Support@umich.edu)

Public/external requests for PHS FCOI information must be sent to: [PHSCOIRequest@umich.edu](mailto:PHSCOIRequest@umich.edu)