

# University of Michigan

## Policy for Institutional Conflicts of Interest in Research

### Office of the President

#### 1. POLICY PURPOSE AND SUMMARY

This policy establishes and promotes principles and procedures designed to ensure high ethical standards when research is conducted at the University of Michigan (the “University”) that may be affected, or may appear to be affected by, the financial interests of the institution. The University encourages its faculty, staff, students, and trainees to participate in the development of new technologies and treatments that advance scientific knowledge and contribute to the public good. When licensing new University technologies, the University may take an equity position, or have other financial interests, in the company licensing the technology. The University desires to mitigate institutional conflicts of interest and to avoid the creation of other personal conflicts with regard to the University’s financial or business interests. This policy concerns institutional conflict of interest other than personal conflict of interest that may arise when a faculty member or other employee stands to benefit financially from the results of his/her own research. Personal conflicts of interest are covered by the [Policy for Identification and Management of Conflicts of Interest in Research and Technology Transfer](#). An institutional conflict of interest may occur when a financial interest of the University (e.g., investments held by the University in a company) or a Covered Official has the potential to bias research conducted by its employees or students. Policy principles include:

- A. The University desires to maintain the highest possible standards in research; to adhere to all applicable federal and state regulations; to maintain the primacy of the University’s educational mission; and to protect the reputation and credibility of the University, its faculty, staff, students, and trainees.
- B. Financial interests of the University must be identified, disclosed, and reviewed to prevent potential institutional conflicts of interest in research that may affect (or reasonably appear to affect) institutional processes for the design, conduct, reporting, review, or oversight of research.
- C. Institutional financial interests can be created by gifts, payments, royalty income, equity, and other financial benefits from or interests in for-profit entities.

#### 2. POLICY COMPLEMENTS

This policy represents one aspect of the University’s commitment to address and manage conflicts of interest. Other University policies that address conflicts of interest include:

- A. The Michigan Contracts of Public Servants with Public Entities statute ([Public Act 317 of 1968](#)) addresses, among other things, conflicts of interest in situations where the University enters into a contract with a private entity in which the University employee or officer has an interest.
- B. The University's [Standard Practice Guide 201.65-1](#) addresses the University-wide implementation of policies for academic or administrative units regarding conflicts of interest and conflicts of commitment for University faculty and staff.
- C. The University's [Policy for Identification and Management of Conflicts of Interest in Research and Technology Transfer](#) addresses conflicts of interest that arise from individual financial interests related to research and technology transfer.
- D. [Regents' Bylaw 1.14](#), [Supplemental Procedure to Bylaw 1.14](#), and the Michigan Members of the Legislature and State Officer Conflict of Interest Statute ([Public Act 318 of 1968](#)) address conflicts of interest related to regents of the University.
- E. [Regents' Bylaw 1.14](#) and the University's [Policy for Executive Officers and Presidential Direct Reports on Conflicts of Interest and Conflicts of Commitment](#) address conflicts of interest and conflicts of commitment related to executive officers and presidential direct reports.
- F. The Office of the Provost and Executive Vice President for Academic Affairs [Policy for Deans and Directors on Conflicts of Interest and Conflicts of Commitment](#) addresses conflicts of interest and conflicts of commitment related to deans and directors.
- G. University-approved [conflict of interest and conflict of commitment academic and administrative unit policies](#) address individual conflicts of interest with respect to outside financial interests, employment, conflict of commitment, and personal conflict of interest, and establish disclosure requirements for University employees to prevent personal or outside interests to interfere with University duties and responsibilities.

### 3. DEFINITIONS

- A. ***Covered Official***: means an executive officer, dean, or [institute or center] director with day-to-day responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the University.
- B. ***Institutional Conflict of Interest***: means a situation in which the financial interests of the University, or of a Covered Official who has authority to act on behalf of the University, might affect, or reasonably appear to affect, research conducted by, or on behalf of, the University.
- C. ***Institutional Financial Interests***: mean the following financial or business interests of the University:

1. *Interests under Tech Transfer Licensing Agreements*: Payments, including royalty payments, milestone payments and other licensing fees, resulting from technology transfer licensing, that, for each arrangement, exceed \$100,000 in the twelve-month period immediately preceding the definitive agreement covering the research in question.
  2. *Non-publicly traded equity*: Except for equity managed by the University's Investment Office, University held equity interests (including equity held by Michigan Invests in New Technology Startups, "MINTS") in a non-publicly traded company resulting from the transfer of University technology or a University direct equity investment where such company is: (a) the sponsor of research at the University, or (b) the manufacturer, marketer, or license holder of University technology to be studied or tested at or under the auspices of the University.
  3. *Publicly-traded equity*: Except for equity managed by the University's Investment Office, University held ownership interests exceeding \$100,000 in value, in a publicly-traded company resulting from the transfer of University technology where such company is: (a) the sponsor of research at the University, or (b) the manufacturer, marketer, or license holder of University technology to be studied or tested at or under the auspices of the University.
  4. *Gifts from sponsors*: Gifts (including gifts in kind) to the University exceeding \$1,000,000 in value (cumulatively in the three-year period immediately preceding the gift) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or a philanthropic unit or an individual affiliated with these companies.
  5. *Covered Official relationships*: Executive officers, deans, and [institute and center] directors with day-to-day responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the University (and not simply broad or general University research oversight) who receive payments, honoraria, royalties (even from the University), equity, options and warrants, board of directorships and management positions, and gifts.
- D. **Research**: Research is defined as any organized program of scientific inquiry that involves a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral, and social-sciences research or other scholarly activity, that is performed at, or under the auspices of the University.

#### 4. ESTABLISHMENT AND AUTHORITY OF ICOI COMMITTEE

- A. In order to review and manage institutional conflicts of interest, the University establishes a committee that includes members of the University community in addition to independent members. The Institutional Conflict of Interest Committee (the "ICOI Committee") will be advisory to the President, who holds final authority regarding questions of institutional conflicts of interest. The ICOI Committee shall be composed of the following members, each appointed to a renewable three-year staggered term:

1. At least five University faculty members;
  2. One member from another educational institution with institutional conflict of interest experience (who is not also employed by the University);
  3. One community member (who is not employed by the University);
  4. The chair of Michigan Medicine's Medical School Conflict of Interest Board ("MEDCOI"), or a MEDCOI member designated by the chair, ex officio;
  5. The chair of the University of Michigan Office of Research Conflict of Interest Review Committee ("UMOR COI Review Committee"), or a UMOR COI Review Committee member designated by the chair, ex officio;
  6. Other individuals appointed at the discretion of the President, who may be University administrators, individuals unaffiliated with the University, etc.;
  7. Ex officio non-voting representatives designated from:
    - a. The Office of the President;
    - b. The Office of Research and Sponsored Projects;
    - c. The Office of Technology Transfer;
    - d. The UMOR Research Ethics and Compliance Office;
    - e. The UMOR COI Review Committee and the MEDCOI Board;
    - f. The Office of the Vice President and General Counsel;
    - g. The Office of University Development;
    - h. The Office of the Vice President for Communications;
    - i. The Michigan Medicine Corporate Compliance Office; and
    - j. Other University offices, as needed.
- B. The President of the University shall make voting committee member appointments.
- C. The President shall appoint a chair from the voting membership of the ICOI Committee for a renewable two (2) year term.
- D. Records of requests brought to the ICOI Committee and recommendations made by the ICOI Committee shall be maintained and stored by the UMOR COI Office. Final determinations and recommendations will be part of the record.

## 5. REVIEW PROCESS AND PROCEDURES

- A. ***Review of Institutional Financial Interest:*** The University shall aim to manage potential institutional conflicts of interest prior to entering into any definitive agreement governing such research. At the earliest stage of the technology licensing and development process, the Office of Technology Transfer will refer investigators to the appropriate resources to advise and inform on the ethics and value of avoiding conflicts of interest in evaluating, validating, or testing University-owned intellectual property.
- B. ***ICOI Committee Disclosure:*** In order to manage potential institutional conflicts of interest, the Office of Technology Transfer, any University investment fund (including MINTS, but excluding investment funds managed by the University Investment Office) authorized to make direct investments, the Office of University Development, the Office of the President, and the Office of the Provost will each notify the ICOI Committee promptly after the following:
1. ***Office of Technology Transfer:*** when the Office of Technology Transfer acquires University equity in a third party or has received \$100,000 in payments/fees from a third party under the terms of a Tech Transfer Licensing Agreement.
  2. ***Individuals responsible for University investment funds authorized to make direct investments:*** when the University investment fund enters into an agreement to acquire equity in a third party;
  3. ***Office of University Development:*** when a third party commits to a gift that exceeds \$1,000,000 in value (cumulatively in the three-year period immediately preceding the gift) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or a philanthropic unit or an individual affiliated with such company;
  4. ***Office of the President:*** when an executive officer with day-to-day responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the University (and not simply broad or general University research oversight) discloses the receipt of any payments, honoraria, royalties, equity, board of directorship or management position, and gifts from a potential commercial sponsor of research; and
  5. ***Office of the Provost:*** when a dean or [institute or center] director with day-to-day responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the University (and not simply broad or general University research oversight) discloses the receipt of any payments, honoraria, royalties, equity, board of directorship or management position, and gifts from a potential commercial sponsor of research.

- C. ***Process of Tracking Financial Interest:*** Institutional conflicts of interest will be tracked and monitored in M-Inform, the University's disclosure and conflict of interest management system. Upon receipt by the ICOI Committee of the disclosures in Section 5.B of this policy, the ICOI Committee representative at the MEDCOI or UMOR COI Offices shall flag the corresponding company in M-Inform for a potential institutional conflict of interest.
- D. ***ICOI Committee Notice:*** In connection with entering into an agreement for research with a company that has been flagged by the ICOI Committee in M-Inform, the University unit authorized to approve the research agreement will notify the ICOI Committee of the potential research agreement that may lead to an institutional conflict of interest.
- E. ***ICOI Committee Determination:*** The ICOI Committee shall evaluate whether the institutional financial interest could inappropriately affect or reasonably appear to inappropriately affect University research. The ICOI Committee will determine whether an institutional conflict of interest is manageable or if it should be reduced or eliminated.

The ICOI Committee's determination should also take into consideration any personal conflicts of interest of individual investigators and whether the institutional financial interests disclosed as outlined above have the potential to, or appear to, affect any of the following:

1. Safety of human research subjects and use of research animals, and responsible conduct of research involving hazards;
  2. Integrity of research;
  3. Appropriate allocation of resources;
  4. The dissemination of research results in accordance with the highest scientific, professional, and ethical standards;
  5. Objectivity and independence of educational activities, including non-exploitation of students or trainees;
  6. Objectivity and independence in managing and licensing intellectual property resulting from research activities; and
  7. Independence of professional practice judgment.
- F. ***ICOI Management:*** The ICOI Committee's determination to address a potential institutional conflict of interest may include:
1. Prohibiting the research from taking place at the University;
  2. Permitting the research to proceed, subject to a plan for managing the institutional conflict of interest and any personal conflicts of interest; or

3. Permitting the research to proceed coupled with divestiture of financial interests of the University and individual investigators.

G. ***ICOI Advisory Role:*** The ICOI Committee will be available to provide advice regarding difficult conflict of interest issues that address risks previously unaddressed. The ICOI Committee will provide a high-level recommendation for these situations.

## **6. FINAL DECISION AUTHORITY**

The ICOI Committee will recommend disposition of cases brought to its attention to the President. The President, or his/her designee, shall make the final institutional decision.

## **7. NON-COMPLIANCE / FAILURE TO DISCLOSE**

Noncompliance with this policy on the part of a faculty or staff member as determined by the appropriate dean, director, supervisor, or conflict of interest committee may be subject to institutional sanctions up to and including termination of appointment in accordance with applicable disciplinary procedures.