

STANDARD PRACTICE GUIDE

SECTION:

Human Resources

Number:

201.65-1

SUBJECT:

Conflicts of Interest and Conflicts of Commitment

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APPLIES TO:

All Faculty and Staff Members

ISSUED BY:

Office of the President and Office of the Provost and Executive Vice President for

Academic Affairs

T. **Policy**

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.

Given that the University of Michigan allows and encourages outside activities and relationships that enhance the mission of the University, potential conflicts of interest and commitment are inevitable. Outside activities should not, however, interfere with an individual's University obligations. Faculty and staff must ot use their official University positions or influence to further gain or advancement for themselves, parents, siblings, spouse or partner, children, dependent relatives, or other personal associates, at the expense of the University.

Faculty members and staff members with 50% or more appointments owe their primary professional commitment to the University of Michigan. Accordingly, a commensurate commitment of time and intellectual energy should be used to support and enhance the mission of the University. Other part-time faculty members and staff members owe time and effort commitments to the University commensurate with their appointments.

All actual and potential conflicts of interest or commitment must be disclosed to a designated University official; evaluated; and, if found to be significant, eliminated or managed as described in section III. Regulations below.

This policy is consistent with and is in addition to relevant federal and state law and University policies, as well as with unit policies and with other relevant University policies not listed here. See procedures. Academic or administrative units may require further disclosure and conflict management than mandated by this SPG as may be deemed appropriate by the unit and its supervising administrator.



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II. Definitions

A. Conflict of Interest

A potential conflict of interest exists whenever personal, professional, commercial, or financial interests or activities outside of the University have the possibility (either in actuality or in appearance) of (1) compromising a faculty or staff member's judgment; (2) biasing the nature or direction of scholarly research; (3) influencing a faculty or staff member's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, interactions with human subjects, or other matters of interest to the University; or (4) resulting in a personal or family member's gain or advancement at the expense of the University. For purposes of subsection (4), family members include spouse, domestic partners and dependents.

B. Conflict of Commitment

A **potential conflict of commitment** exists when a faculty or staff member's external relationships or activities have the possibility (either in actuality or in appearance) of interfering or competing with the University's educational, research, or service missions, or with that individual's ability or willingness to perform the full range of responsibilities associated with his or her position.

III. Regulations

Faculty, staff, and administrators in the schools, colleges, academic departments/programs, other administrative units, and central administration share the institution's obligation to implement University policies and practices related to conflict of interest and conflict of commitment. In meeting this obligation, each of these groups has specific roles and responsibilities, as described below.

A. Rights and Responsibilities of Faculty Members and Staff Members

- 1. *Right to Outside Interests*: Faculty members and staff members have the right to acquire and retain outside interests of a professional, personal, or economic nature that do not conflict with University interests or with the individual employee's commitment to the University, to the University's students, sponsors, patients, or to other parties to whom the University has a duty.
- 2. *Professional Commitments:* Faculty members and staff members must meet the specific responsibilities and professional activities that constitute their appropriate commitments to their respective schools, colleges, academic departments/programs, and other administrative units.
- 3. Requirement to Disclose: All faculty members and staff members must disclose all actual or potential conflicts of interest or conflicts of commitment to his or her appropriate dean, director, or supervisor (or his or her designate) as potential conflicts arise or are identified. A staff member must disclose all actual or potential conflicts of interest or conflicts of commitment to his or her supervisor or to the designated conflict of interest officer in his or her unit. In addition, when sponsored research or technology transfer is involved, a faculty member must disclose actual or potential conflicts of interest or conflicts of commitment to the appropriate conflict of interest committee. A faculty or staff member must also provide additional relevant information concerning disclosed or undisclosed matters as may be requested by his or her supervising authority for the purpose of evaluating actual or potential conflicts of commitment or interest. All disclosures must be made promptly.



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- 4. Requirement to Abide by Plans to Resolve Conflicts: When a faculty member or staff member has disclosed a potential conflict of interest or conflict of commitment, and the appropriate dean, director, supervisor, or conflict of interest committee has determined that a conflict exists, the appropriately designated University official or body will also determine whether further management or elimination of the conflict is required. If required, that official or body will develop a plan in consultation with the faculty or staff member, and the faculty member or staff member must abide by the terms of the plan.
- 5. Prohibition Against Using Position or Influence for Personal Gain or Advancement: It is not acceptable for any University employee to use his or her official position or influence to further his or her personal gain or advancement, or that of family members or personal associates, at the expense of the University and against University policy.
- 6. Use of University Resources: Except as authorized by the appropriate University official, faculty members and staff members may make only incidental use of University resources for purposes unrelated to the education, research, scholarship, and public service missions of the University. Such resources include but are not limited to facilities, personnel, students, equipment, and confidential information.
- 7. *Knowledge of Policies and Procedures:* Faculty and staff must know and abide by applicable University and unit policies and procedures.

B. Responsibilities of Executive Officers and Chancellors

Consistent with this policy and all other relevant University policies, each Executive Officer and Chancellor will:

- 1. Ensure the development of implementation policies for conflicts of interest and conflicts of commitment for all faculty and staff members who hold appointments in his or her area of responsibility; and
- 2. Approve and monitor the relevant implementation policies.

C. Rights and Responsibilities of Schools, Colleges, and Administrative Units

Consistent with this policy and all other relevant University policies, the dean of each school or college, in consultation with the faculty as set forth in procedures developed in conjunction with this SPG, and the director of each administrative unit (or his or her designate) must articulate and disseminate implementation policies that apply to faculty and/or staff within that unit, including:

- 1. Procedures that faculty members and staff members in the academic unit or administrative unit must follow to disclose potential or actual conflicts of interest and conflicts of commitment that arise in their units. At a minimum, all faculty members and staff members must promptly disclose matters as they arise or are identified. The procedures shall also require further additional relevant disclosures when the evaluator at the academic or administrative unit determines that such information is required for disclosed or undisclosed matters that may be actual or potential conflicts. Schools, colleges, and administrative units may add additional disclosure requirements and procedures, as appropriate to their circumstances;
- 2. A conflict of interest and conflict of commitment implementation policy at the unit level (i.e., school, college, or administrative unit) that addresses the expectations and responsibilities that the



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school, college, or administrative unit associates with professional appointments and other job classifications within the unit;

- 3. Procedures for evaluating disclosures and managing conflicts of interest and conflicts of commitment;
- 4. Standards and procedures for governing employees' actions with regard to soliciting and accepting gifts;
- 5. Procedures for responding to alleged violations of this policy (see section IV. *Violations* below); and
- 6. Procedures to follow when a faculty or staff member wishes to dispute or appeal any action or decision related to a conflict of interest or conflict of commitment. See section V. *Disputes and Appeals* below.

IV. Violations

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

Violations include but are not limited to situations in which:

- 1. A faculty member or staff member knows of a situation that places him or her in a potential or actual conflict of interest or conflict of commitment but fails to disclose it fully, according to the policies of his or her unit; and
- 2. A faculty member or staff member discloses a potential or actual conflict of interest or commitment but fails to abide fully by the required plan for avoiding or managing the conflict.

V. Disputes and Appeals

When a faculty or staff member disputes any action or decision related to a potential conflict of interest or conflict of commitment, existing University policies for disputes of faculty and staff will be used. Disputes with decisions or actions taken by an established conflict of interest committee for those projects for which the committee is responsible must be through the processes established by the applicable committee. If a school, college or administrative unit develops additional procedures for handling disputes or appeals regarding any action or decision taken with respect to a faculty or staff member's conflict of interest or conflict of commitment, the additional procedures must coordinate with and may not substitute for existing University policies for handling disputes.

Procedures: http://www.umich.edu/~hraa/procedures/spg201-65-1.htm

Policy and Procedures for Dealing with Financial and Outside Management Conflicts of Interest in Sponsored Projects and Technology Transfer

Policy Statement

The University of Michigan will exercise care in accepting or entering into sponsored agreements and technology transfer agreements 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 conflict:

- 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.

The University of Michigan exercises special care in accepting or entering into sponsored research agreements involving human subjects including using drugs, devices or other clinical treatments licensed to third parties.

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) so long as those obligations and commitments do not interfere with their duties or improperly distort the judgments expected of them.

To be eligible to receive grants or cooperative agreements for research from the Public Health Service (including NIH, see <u>PHS policy</u>) or the National Science Foundation (see <u>NSF policy</u>), the University of Michigan is required to have a policy for the disclosure of Significant Financial Interests held by Investigators (or their Family Members) related to proposed research and to have procedures for the institutional review of the relevance of such personal outside interests to the integrity of the research.

The University applies a single policy and procedure for review and approval of all sponsored research and technology transfer agreements, incorporating, to the extent feasible, the federal definitions of "Investigator," and "Significant Financial Interest," and the concept of "relatedness" of a Significant Financial Interest to proposed research.

This Policy, in addition, abides by the <u>State of Michigan Conflict of Interest Law</u> 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 <u>SPG 201.65-1</u>.

When the University carries out PHS- or NSF-funded grants or cooperative agreements through subgrantees, contracts, or collaborators, the University standard agreements require that Investigators comply with this Policy or with a policy at their institution that complies with PHS and NSF COI regulations.

Definitions

A Conflict of Interest may take many forms and exists whenever personal, professional, commercial, or financial interests or activities outside of the University have the possibility of (1) compromising a faculty or staff member's judgment; (2) biasing the nature or direction of scholarly research; (3) influencing a faculty or staff member's decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, interactions with human subjects, or other matters of interest to the University; or (4) resulting in a personal or Family Member's gain or advancement at the expense of the University.

A Conflict of Interest in Sponsored Research exists when the University determines that a Significant Financial Interest or Management Interest in an outside entity could reasonably appear to be affected by the research.

A Conflict of Interest in a Technology Transfer Agreement exists when a University faculty or staff member has an ownership or management interest in a proposed licensee or assignee of University intellectual property.

Disclosure Form means the University's form for disclosure of significant financial or management interests in a sponsored project and/or technology transfer agreement at the University of Michigan. (See http://www.research.umich.edu/policies/um/coi/forms.html)

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

An **Investigator** means the Principal Investigator, Co-Investigators, study team members and any other person at the University or elsewhere who are responsible for the design, conduct, or reporting of a sponsored research project.

Management or Manage means the conditions or restrictions that might be imposed to manage, reduce or eliminate a Conflict of Interest. 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 a Related Entity involved in a technology transfer agreement or to a sponsored project means holding a position of officer, trustee, director, or scientific advisory board member.

A **Principal Investigator**, for the purposes of this policy, is the person designated on the sponsored project Proposal Approval Form (PAF) as the individual responsible for the administrative and programmatic aspects of the proposed project.

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

A **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 interests (e.g., stock, stock options or other ownership interests); and intellectual property rights not held by the University (e.g., patents, copyrights and royalties from such rights). It does not include:

- Salary, royalties or other remuneration received from the University;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;

- An equity interest in a publicly traded enterprise that when aggregated for the Investigator and the Investigator's Family Members does not exceed \$10,000 in value and does not represent more than 1% ownership interest (42 CFR 50.602 revised for Michigan COI Law); and
- Salary, royalties, or other payments that when aggregated for the Investigator or the Investigator's Family Members over the next twelve months, are not reasonably expected to exceed \$10,000.

Although PHS and NSF policies exclude Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs from consideration, the University requires Investigators to disclose involvement in these programs.

The Disclosure Process and Referral

The Principal Investigator on a proposed sponsored agreement 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 Disclosure Form requests information about Management Interests or Significant Financial Interests in outside Related Entities held by the Investigator and any other individuals (and by their Family Members) who are responsible for the design, conduct, or reporting of the proposed research. A separate Disclosure Form will be submitted upon request to the relevant conflict of interest committee.

If the Principal Investigator discloses a Conflict of Interest in Sponsored Research, or if the project representative from the Division of Research Development and Administration (DRDA) is aware of a Management Interest or Significant Financial Interest, the DRDA representative will refer the proposed project to either the University Conflict of Interest Review Committee or the Medical School Conflict of Interest Board.

The Office of Technology Transfer (OTT) will refer proposed agreements involving a Conflict of Interest in a Technology Transfer Agreement to either the University Conflict of Interest Review Committee or the Medical School Conflict of Interest Board.

If the outside interests of an Investigator or employee change so as to introduce a new, heretofore undisclosed Significant Financial Interest or Management Interest in a sponsored research project or technology transfer agreement, the individual is honorbound to initiate a disclosure or to revise a disclosure already submitted.

Committee Review

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 established a conflict of interest committee to receive disclosures referred from DRDA or OTT and review and Manage the risks associated with the disclosed situation. The committee 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.

The Vice President for Research has delegated to the Medical School Conflict of Interest Board the authority and responsibility to review and Manage the risks associated with sponsored projects in which a conflicted Principal Investigator has a primary appointment in the Medical School, when the principal conflicted individual related to a proposed technology transfer agreement has an appointment in the Medical School, or when otherwise agreed to by the two committees.

Other situations or categories of situations may be delegated in whole or in part by the University Conflict of Interest Committee to the Medical School Conflict of Interest Board. The University Conflict of Interest Committee will not impose requirements on individuals with primary appointments in the Medical School, and the Medical School Conflict of Interest Board will not impose requirements on individuals with primary appointments outside the Medical School without consultation with the other committee.

The delegation from OVPR to the Medical School Conflict of Interest Board is conditioned upon the Board having at least one member unaffiliated with the Medical School and on the establishment, maintenance, and communication to OVPR and DRDA of sponsored project specific Management.

With regard to a disclosed situation, the conflict of interest committees will identify Conflict of Interest risks and evaluate their magnitude. The committee may:

- 1. Recommend that the proposal or agreement go forward without modification, or
- 2. Require some specific type of administrative oversight or Management, or
- 3. Recommend the withdrawal of the proposal or suspension of the technology transfer arrangement.

DRDA or OTT will make an initial determination whether any situation recommended to go 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.

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 Conflict of Interest (but not the nature of the interest or other details) and assure that the Conflict of Interest has been Managed in accordance with this Policy. For Significant Financial Interests or Management Interests identified subsequent to the initial PHS award, the University will notify the PHS of the Conflict of Interest and assure that the Conflict of Interest has been Managed in accordance with this Policy within sixty days of identification. Upon request, the University will make information available to the U.S. Department of Health and Human Services (HHS) regarding identified Conflicts of Interest and how those interests have been Managed to protect the research from bias.

Appeal

A decision by the University Conflict of Interest Review 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 individual 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.

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 requires a longer retention period.

Noncompliance

The University Conflict of Interest Review Committee, the Medical School Conflict of Interest Board, and the OVPR will work cooperatively with Investigators and others to resolve any minor noncompliance.

Flagrant or repeated noncompliance with policy, procedures, or Management requirements after notice is handled through University disciplinary procedures and/or in accordance with the Policy on Integrity in Scholarship.

Failure by an Investigator to comply with this Policy as determined by the University that has 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 HHS 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.

Contact Information

Questions about this Policy may be directed to the contact listed on the following web site: http://www.research.umich.edu/policies/um/coi/contact.html.

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