UMHS Policy 01-04-003
Outside Interests, Conflicts of Interest, and Conflicts of Commitment

I. POLICY STATEMENT, PURPOSE AND SCOPE

It is the policy of the University of Michigan Health System ("UMHS") to address potential or actual conflicts of interest or conflicts of commitment promptly and fairly in order to ensure that they are reduced, managed, or eliminated as appropriate. All UMHS/UMMS employees, including UMMS faculty and UMHS leadership, staff, fellows, and house officers (collectively, "disclosing employees") are required to disclose outside interests, activities, and/or relationships related to their work or position at UMHS and to their University research.

A primary responsibility of all UMHS/UMMS employees is to support the missions of the UMHS and the University. No agreement, contract, or outside interest may interfere with or compromise the University's missions of clinical care, education, and research. University Contracts or grants may not result in any personal tangible benefit or financial gain/interest to a UMHS/UMMS workforce member or their family members beyond the terms of the agreement between the University and the sponsor.

The purpose of this policy is to enable UMHS to identify, minimize, manage, or eliminate, as appropriate, employee conflicts of interest or conflicts of commitment.

Conflict of Interest/Conflict of Commitment protocols for non-health system workforce members are governed according to the conflict of interest policy set forth by the University of Michigan Board of Regents in Regent Bylaw 1.14.

II. DEFINITIONS

Adjunct Faculty - Instructional faculty members in any rank whose primary employment responsibilities lie outside the University or in another capacity within the University. Appointments as adjunct instructional faculty are part-time, on an annual or shorter basis, and are not tenured appointments (Bylaw 5.22). The term includes professional practitioners in the community who hold a "Courtesy Staff" designation for purposes of the Hospitals and Health Centers ("HHC") Bylaws.

Annual Disclosure - The requirement of all disclosing employees to update their disclosures at least once yearly, even if the disclosure is to indicate "no outside interests".

Clinical and Educational Conflict of Interest Committee ("CECOI") - The governing body that reviews and manages UMMS faculty conflicts of interest related to clinical education as delegated by the UMMS Dean and potentially other matters designated by UMHS.

Compliance Committee - The applicable compliance committee for HHC, University of Michigan Health System ("UMHS"), and the University of Michigan Medical School ("UMMS").

Compliance Officer - Either collectively all or singularly the applicable Compliance Officer for HHC, UMHS, and UMMS.

Conflict of Commitment ("COC") - When a disclosing employee's external relationships or activities have the possibility (either in actuality or in appearance) of interfering or competing with:

- The University's missions of clinical care, education, and/or research; or
- An individual's ability or willingness to perform the full range of responsibilities associated with his or her position.

Examples of potential COCs are provided in Exhibit A, which may be amended from time to time.

Conflict of Interest ("COI") - Whenever personal, professional, commercial, or financial interests or activities outside of the University or UMHS have the possibility (either in actuality or in appearance) of:

- Compromising judgment in performing University obligations;
- Biassing the nature or direction of scholarly research;
- Unduly influencing decisions or behaviors with respect to teaching and student affairs, appointments and promotions, uses of University or UMHS resources, interactions with patients or human subjects, or other matters of interest to the University and UMHS; or
- Resulting in personal gain or advancement for the disclosing employee or for their family member(s) at the expense of the University or UMHS

Examples of potential COIs are provided in Exhibit A attached to this Policy, which may be amended from time to time.

**Faculty** - An individual with a primary, secondary, or dry (unfunded) appointment, including active emeritus at UMMS. It excludes visiting faculty and adjunct faculty.

**Family Members** - The disclosing employee's spouse, domestic partner, and dependents.

**UMMS Research Fellow** - A post-doctoral employee who is in a recognized training program and whose normal duties may be in a laboratory or other bench science setting, or may be those of a house officer.

**House Officer** - A physician or dentist who is in a recognized training program and whose normal duties, under the direction of an attending, courtesy, or honorary staff member, are to admit patients to the hospital, diagnose or treat patients, and assume all other functions and responsibilities of the house officer staff.

**Institutional Responsibilities** - An individual's professional responsibilities on behalf of the University, such as research, teaching, professional practice, and service on institutional committees.

**Management Staff** - Those UMHS staff whose job titles are in the managerial or executive job roles in the University Human Resources Classification System.

**Medical School Conflict of Interest Board** ("MEDCOI") - The governing body that reviews and manages conflicts of interest related to research or technology transfer as delegated by the University of Michigan Office of Research ("UMOR") and other matters designated by UMHS.

**M-Inform** - The University's web-based disclosure system for Outside Interests.

**Outside Interest** - An external activity, relationship, or interest (paid or unpaid) of the disclosing employee or of their family member that is related to the disclosing employee's work or position at UMHS. An interest is related when the activity, relationship, or interest is associated with or relies upon the disclosing employee's scientific, medical, or other expertise required to fulfill his or her UMHS responsibilities.

**Procedures** - The conflict of interest and conflict of commitment procedures attached as Exhibit B to this policy, which may be amended from time to time.

**Related** - When an outside interest, activity, or relationship relies upon the same expertise that an individual's ability to carry out his or her institutional responsibilities relies upon. Also, any interest, activity, or relationship that has the potential to influence the duties that the University considers part of the work it pays or otherwise engages an individual to do.

**Staff** - All UMHS staff excluding management staff.

**UMHS** - The University of Michigan Health System, including the University of Michigan Hospitals and Health Centers (UMHHC), the University of Michigan Medical School (UMMS), and the Michigan Health Corporation (MHC).

**Visiting Faculty** - Those appointments with UMMS for professorships for individuals with employment responsibilities with another institution of higher education consistent with the UMMS Faculty Handbook. "Visiting Faculty" also includes faculty that hold a "Visiting Staff" designation for purpose of the HHC Bylaws.

### III. POLICY STANDARDS
A. Outside Interest Disclosure Requirements
<table>
<thead>
<tr>
<th>Who Discloses</th>
<th>When to Disclose</th>
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<tr>
<td>UMHS Leadership (managers and executives)</td>
<td>Annually and within 30 days of any change</td>
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<td>Fellows, House Officers</td>
<td>Annually and within 30 days of any change</td>
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<td>Physician Assistants</td>
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<td>Advanced Practice Registered Nurses</td>
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<td>• Certified Nurse Midwives (CNM)</td>
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<td>• Nurse Practitioners (NP)</td>
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<tr>
<td>• Certified Registered Nurse Anesthetists (CRNA)</td>
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<tr>
<td>UMMS Faculty</td>
<td>Annually and within 30 days of any change</td>
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<tr>
<td>UMHS Staff</td>
<td>When engaged in a job-related outside interest, activity or relationship and annually thereafter until the interest, activity, or relationship has ended and it is documented as ended in M-Inform.</td>
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<tr>
<td>Individuals Engaged in Research</td>
<td>Individuals with effort on federally-funded research projects (or other entities following PHS rules) must disclose annually and within 30 days of any change</td>
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All job-related outside interests, activities, and relationships must be disclosed in M-Inform, the University’s online disclosure system.

Disclosure Guidance

1. **UMHS Leadership, Fellows, House Officers, UMMS Faculty**

   UMHS Leadership, Fellows, House Officers, and UMMS Faculty must prospectively and promptly disclose any job-related outside interests of themselves or their family member(s) in M-Inform, as well as disclose potential or actual conflicts of interest or conflicts of commitment directly to their chair, supervisor, or principal investigator, as appropriate. Outside Interest disclosures must be made at least annually and must be updated within 30 days when circumstances change or when a new outside interest arises. UMMS employees must also disclose travel within 30 days of its occurrence. M-Inform disclosures will be reviewed by Department Chairs or Supervisors or their designees for any potential conflict of interest or conflict of commitment, and assessed both for the appropriateness of the activity as well as level of compensation to ensure it is commensurate with their effort and UMMS policies. Disclosures are subject to review by an institutional official (Compliance Office, Office of Regulatory Affairs, MECOI Board, or CECOI, as appropriate), and when a conflict is found to exist, it will be reduced, managed, or eliminated as appropriate and as provided in the procedures at Exhibit B, Faculty House Officers or Management Staff.

2. **Staff**
Staff must promptly disclose job-related outside interests, activities, or other relationships pertaining to themselves or their family member(s) in M-Inform and to their supervisor (or designee). M-Inform disclosures will be reviewed by the staff member’s supervisor (or designee) for any potential conflicts of interest or conflicts of commitment and reviewed for the appropriateness of the activity, as well as conduct a review of the level of compensation to ensure it is reasonably commensurate with the effort. The supervisor (or designee) determines if the staff member’s conflict is manageable, i.e., if the conflict can be reduced or eliminated as provided in the procedures at Exhibit B, Staff. If not manageable, the activity, interest, or relationship may not be approved. Disclosures are subject to review by an institutional official, as appropriate.

3. Individuals Engaged in Research

Anyone with a research-related outside interest must inform their supervisor and disclose in M-Inform. Individuals who are required to accept their role on the eResearch Regulatory Management Application (IRB Application) must also indicate their related interests in that application. The Principal Investigator on an IRB application or proposal application form (PAF) is responsible for assuring that conflicts of interests for all members involved in the research are disclosed regardless of whether or not they are listed on the IRB Application or the PAF.

4. Visiting Faculty

Visiting Faculty must promptly disclose related outside interests or conflicts of commitments pertaining to themselves or their family member(s) to the sponsoring UMHS Department Chair or supervisor. Any identified conflicts will then be reported by the visiting faculty member in M-Inform and assessed and reduced, managed, or eliminated as appropriate.

B. Additional Policy Information

1. Accepting Paid and Unpaid Work Outside the Health System

a. Workforce members must exercise good judgment in accepting paid or unpaid work with industry or other hospital vendors and suppliers (present and future) to avoid actual (or perceived) conflicts of interest and conflicts of commitment.

b. Personal consulting arrangements may be entered into by workforce members, with manager approval, provided that they do not negatively impact the institution's interests and do not conflict with the workforce member's ability to carry out his or her job duties or other institutional responsibilities.

i. University space, resources, data (patient, research, or business information), etc., may not be used as part of any personal consulting arrangement without appropriate institutional approvals and without appropriate contractual agreement(s), signed by the Regents.

c. All arrangements must reflect industry-standard fair market value.

2. Speaking Engagements

a. While workforce members may accept industry fair-market-value support (travel and honorarium), with manager approval, to give presentations at national conferences or other departmentally approved venues, any such presentations must be based on the workforce member's own work product (professional experiences, research, or other scholarship).

b. Workforce members are to maintain editorial and content independence at all times to preserve academic freedom, e.g., develop their own content, and retain full editorial control over their content.

c. Workforce members may not represent the interests of industry or other hospital vendors/suppliers, e.g., present, speak, or educate on behalf of industry or participate in events where the purpose (predominate or implied) is to market/sell industry products and services or where the event is to illustrate the merits of any one product or service over another.
d. In any case, there should be presenter/audience freedom and opportunity for critical discussion contemporaneous with any presentation or other speaking engagement.

3. Personal Gifts or Loans from Outside Organizations

Personal gifts of any kind from vendors to faculty, fellows, House Officers, Management, or other staff or their family members are not permitted. For purposes of this policy, personal gifts include soliciting or accepting money, travel, credits, preferential discounts, gifts, raffles, lotteries, gratuities, entertainment, favors, or services. UMHS faculty, fellows, house officers, management, or other staff who accept loans for themselves or their family members from outside companies or organizations with which they interact on behalf of UMHS must promptly disclose this fact to their department chair or supervisor as discussed in Section III(A) above. Depending upon the circumstances, review and approval by the COI Board may be needed with respect to personal gifts or loans.

4. Vendor-Sponsored Site Visits and Training

It is not permitted for University employees to accept travel expenses from a vendor for site visits or training, unless the site visit or training is included in a negotiated contract through Procurement (see SPG 507.01 Procurement General Policies and Procedures).

5. Vendor Product Demonstrations

Vendors may be invited to demonstrate products at UMHHC. Vendors as well as faculty and staff must comply with UMHHC Policy 01-04-008 Vendor Visitation and Interaction.

6. Records and Sensitivity of Disclosures and Additional Information Provided

Outside Interests, Conflicts of Interest, and Conflicts of Commitment, and any additional information shall be treated as "Sensitive Data" under SPG 601.12 Institutional Data Resource Management Policy, and access to this information shall be permitted only with specific authorization and only to those University or UMHS departments or units that need this information to perform their University or UMHS obligations or to make decisions on behalf of the University or UMHS. These records will be maintained by the department chair, supervisor, COI Board, and/or the Outside Interest Disclosure Database as applicable. This information will be protected to the extent permitted by law. This information is subject to the Freedom of Information Act (FOIA).

7. Sponsored Research & Technology Transfer

The Medical School Conflict of Interest (MEDCOI) Committee will review and approve management for situations in which faculty, fellows, house officers, management, or other staff and their family members have an outside interest in or related to sponsored research or technology transfer as delegated by the University of Michigan Office of Research and other matters designated by UMHS. These matters will be reviewed in accordance with MEDCOI Operational Guidelines.

8. Management of Other Situations

If an outside interest, conflict of interest, or conflict of commitment is not related to sponsored research, technology transfer, or other matters designated for review and management by the MEDCOI, the review, approval, and management related to the outside interest will be handled by the appropriate department chair or supervisor as provided in the Procedures.

9. Interactions with Other University or UMHS Units

In some instances, the UMHS Compliance Office, department chairs, supervisors, MEDCOI, CECOI, and others involved in the evaluation of outside interests will need to consult with other University or UMHS units or the UMHS Compliance Office. These instances include but are not limited to:

- The Office of the Provost when there are conflicting policies between academic units.
- The Office of the General Counsel and/or UMHS Contracting Office where legal obligations or potential liability to the University or UMHS may be involved.
- University Procurement when the COI involves purchasing.

10. Abiding by Conflict Management
If appropriate, the UMHS Compliance Office, department chair, supervisor, and/or MEDCOI or CECOI will develop and document a plan to manage, reduce, or eliminate any conflicts as provided in the Procedures. Faculty, Fellows, House Officers, Management, or other Staff are required to fully abide by any conflict management plan if a conflict is determined to exist. Any change in the circumstances of the conflict that could affect the current conflict management plan must be promptly disclosed to the individual's department chair, supervisor, and/or MEDCOI or CECOI as applicable. It is the responsibility of the human resources department, department chair, supervisor, and/or MEDCOI or CECOI to monitor an individual's compliance with the conflict management plan and report any non-compliance to the applicable Compliance Officer and/or to the MEDCOI or CECOI as applicable.

11. Education

Education related to this Policy will be included in the UMHS COI mandatory (accessible through MLearning), which is required training for all Faculty, Fellows, House Officers, Management, and Staff employed by or working in HHC locations. Research-related conflict of interest education is included in M-Inform and in the University's Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS).

12. General Responsibilities

Faculty, Fellows, House Officers, Management, and Staff are responsible for knowing and abiding by this Policy and other applicable University and UMHS policies and procedures. They also must promptly provide additional information related to an Outside Interest, Conflict of Interest, or Conflict of Commitment as requested.

13. Reporting

Any suspected violations or concerns related to this Policy should be reported to the Compliance Office at COI-support@umich.edu or COI Concerns or Questions. The Compliance Office or its designee will work with the reporter in order to investigate and resolve any suspected violations or concerns related to this Policy.

14. UMHS Committees and Committee Recommendations

Certain committees designated by UMHS will be responsible for identifying and managing as appropriate any potential or actual Conflicts of Interest of its members, consultants, and staff, etc. To the extent implemented, any conflict management must be appropriately documented and monitored by the Committee.

IV. PROCEDURE ACTIONS

Specific disclosure processes are set forth in Exhibit B, Procedures, based on an individual's role.

Upon disclosure of an Outside Interest, Conflict of Interest, or Conflict of Commitment, the department chair or supervisor may approve or disapprove the activity or interest and reduce, manage, or eliminate any conflicts as appropriate. If the disclosure is disapproved, the UMHS Faculty, Fellows, House Officer, or Staff is not permitted to engage in the activity or interest unless the matter is appealed, as provided in the Procedures.

V. EXHIBITS

Exhibit A: Examples of Conflict of Interest and Conflict of Commitment
Exhibit B: Conflict of Interest and Conflict of Commitment Procedures - Revised June 24, 2016

VI. REFERENCES AND RESOURCES
Regents' Bylaw 1.13 *Business Transactions*

Regents' Bylaw 1.14 *Regental and Executive/Senior Officer Conflict of Interest Policy*

Regents' Bylaw 2.16 *Gifts to Regents and University Employees*

Regents' Bylaw 3.10 *Ownership of Patents, Copyrights, Computer Software, Property Rights, and Other*

Regents' Bylaw 5.12 *Outside Employment*

Regents' Bylaw 5.13 *Governmental Activities*

SPG 201.23 *Appointment of Relatives or Others with Close Personal or External Business Relationships*

SPG 201.65-0 *Work Outside the University*

SPG 201-.65-1 *Conflict of Interest*

SPG 201.85 *Special Stipends*

SPG 303.01 *Implementation of Regents' Policy Concerning Research Grants, Contracts, and Agreements*

SPG 303.03 *Policy Statement on the Integrity of Scholarship and Investigating Allegations of Misconduct in the Pursuit of Scholarship and Research*

SPG 303.04 *Policy on Intellectual Properties: Including Their Disclosure, Commercialization, and Distribution of Revenues from Royalties and Sale of Equity Interest*

SPG 500.01 *Fiscal Responsibilities*

SPG 507.1 *General Policies and Procedures*

SPG 601.3-2 *Policy on Ownership of Copyrighted Works Created at or in Affiliation with the University of Michigan*

SPG 601.32 *Policy on External Entity Contracts for Central Administration Services or Resources*

SPG 602.02 *Gift Acceptance*

UMHHC Policy 01-04-008, Vendor Visitation and Interaction
Medical Staff Bylaws

UMMS Faculty Handbook

UMMS External Clinical Activity Policy

OVPR Policy for Identification and Management of Financial Conflicts of Interest

Policy on Institutional Conflict of Interest in Clinical Trials of Drugs, Devices, or Biologics Supported by University Start-up Companies

Guidance: Outside Interests and Conflicts of Interest

**Author:** UMHS Compliance Office