Policy 01-04-003, Exhibit B

CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT PROCEDURES

Overview, Disclosure, Review, and Appeal

Overview

The purpose of the UMHS COI-COC Policy, 01-04-003, is to ensure against the formation of inappropriate relationships with the biomedical industry, e.g., "pharma", or other hospital vendors and suppliers.

This policy requires <u>all workforce</u> members to disclose job-related relationships (and those of their immediate family members) that may be in conflict with federal and state law, as well as UM SPGs and UMHS policies.

Under <u>UMHS Policy 01-04-003 Outside Interest and Conflicts of Interest</u>, managers, department chairs, etc. are responsible for managing conflicts of interest for their staff or others for whom he or she has oversight.

What this means is that the manager is charged with knowing and managing, as appropriate:

- When individuals over whom the manager has oversight is engage in a job-related interest, activity, or relationship with industry, e.g., "pharma" or other hospital vendors and suppliers that creates an actual (or perceived) conflict of interest or conflict of commitment, and for
- Developing conflict management strategies to reduce or eliminate the identified conflict of interest or conflict of commitment for those individual. Mangers should work with the conflicted employee and with human resources to develop and document conflict management strategies.

Example of conflicts of interest and conflicts of commitment:

Self-Benefit: Using your position within UMHS to promote your own interests or those of an immediate family member, including use of confidential or privileged information acquired in the course of your employment at UMHS.

Representing Industry: Presenting, speaking, or educating on behalf of industry or participating 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; or engaging in relationships where information is directly or indirectly shared with hedge fund managers or other financial representatives (insider trading).

University Resources: Use of University space, resources, data (patient, research or business information), etc., for personal gain or for use in furtherance of personal contracts.

Excessive Payment: Honorarium or travel expenses being disproportionate to the value of the services performed.

Business relationships and dealings: Approving grants, contracts, or other agreements related to purchasing decisions in which you or an immediate family member has a financial or other interest or relationship. For example:

 Being an employee, manager, consultant, partner, director or officer to an outside organization (for-profit or non-profit) in which you participate in decisions at UMHS related to this organization. Using your position at UMHS to influence major decisions through the review, negotiation, and approval of grants or contracts for your own personal gain or that of an immediate family member.

Stock ownership: Owning stock, stock options or other interests in a company that sponsors research at UMHS in which you participate. Exception: stocks held in 403(b) retirement account.

Personal Gifts: Soliciting or accepting a gift from any UMHS vendor and/or supplier (present or future).

Expert Witness: Acting as an expert witness in legal proceedings where UMHS is a potential party.

Political Activities: Using UMHS resources or speaking on behalf of UMHS while engaging in individual electoral politics or lobbying activities.

If a conflict of interest is determined to exist, then a conflict management plan is required to reduce or eliminate the conflict of interest or conflict of commitment for the individual (and for UMHS).

Management techniques may include:

- Require transparency disclosure of the interest/activity to patients, co-workers, committees, as applicable.
- Recusal from purchasing discussions and/or final decisions making.
- Stepping away from the activity altogether.

Contact COI-OID-Questions@med.umich.edu for assistance.

The individual under management should be given a copy of the signed conflict management plan and a copy of the signed plan should be kept with the employee's personnel file.

Please see the following information sources for additional assistance:

- Contact <u>COI-OID-Questions@med.umich.edu</u> for assistance.
- Outside interest disclosure process or the M-Inform system, http://www.med.umich.edu/u/coi/
- UMHS Policy 01-04-003 Outside Interests and Conflicts of Interests at http://www.med.umich.edu/i/policies/umh/01-04-003.html
- Other UM policies regarding conflict of interest are available at http://spg.umich.edy/pdf/201.65-1.pdf and http://orsp.umich.edu/policies/um/coi

1. Disclosures

A. UMHS Leadership, Fellows, House Officers, UMMS Faculty:

(For Adjunct Faculty, see Section 1(C) below; For Visiting Faculty, see Section 1(E) below)

- 1. Annually and as needed, UMHS Leadership, Fellows, House Officers and UMMS Faculty must disclose the Outside Interests, Conflicts of Interests or Conflicts of Commitments of themselves or their immediate family members in the University's online disclosure system, 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. Guidance and procedures related to Outside Interests, Conflicts of Interest and Conflicts of Commitment, which may be amended from time to time, are located at Compliance Topic: Conflict of Interest.
- 2. The department head or appropriate supervisor will evaluate the Outside Interest, Conflict of Interest and/or Conflict of Commitment. The department head or appropriate supervisor may approve or disapprove of the Outside Interest. The department head or appropriate supervisor also will reduce, manage or eliminate any conflicts as appropriate. Department heads and supervisors can receive advice and support related to these disclosures and conflict management from the UMHS Compliance Website located at: http://www.med.umich.edu/u/compliance/area/coi/Reviewer.htm. Depending upon the circumstances, review and approval by the COI Board also may be needed.
- 3. If the department chair or appropriate supervisor disapproves an Outside Interest disclosure, the individual is not permitted to engage in the Outside Interest absent an appeal.

B. Adjunct Faculty Conflict of Interest and Conflict of Commitment Disclosures:

- 1. Adjunct Faculty must promptly disclose any Conflicts of Interest or Conflicts of Commitment of themselves and their immediate family members to their department chair or the appropriate dean.
- 2. The department chair or appropriate dean will evaluate the Conflict of Interest and/or Conflict of Commitment disclosed by the Adjunct Faculty. The department chair or dean may approve or disapprove of the activity or interest associated with the Conflict of Interest or Conflict of Commitment. The department chair or dean also will assess and reduce, manage or eliminate any conflicts as appropriate. Department chairs and deans can receive advice and support related to these disclosures and conflict management from the UMHS Compliance Website located at:
 http://www.med.umich.edu/u/compliance/area/coi/Home.htm. Advice is available from their Compliance Officer or the COI Board. Depending upon the circumstances, review and approval by the COI Board also may be needed.

- 3. If the department chair or appropriate dean disapproves a Conflict of Interest or Conflict of Commitment, the Adjunct Faculty is not permitted to engage in the activity or interest that generates the conflict absent an appeal.
- 4. When there is no department chair or dean to whom the Adjunct Faculty should disclose potential conflicts, the disclosure shall be made to the Compliance Officer. It will be the responsibility of the Compliance Officer to ensure that the disclosures are provided where legally relevant for any University Hospital System process or committee. There are only two positions that currently meet this criteria: the Executive Vice President for Medical Affairs and the University President as Chair of the Hospital & Health Centers Executive Board.

C. Staff Conflict of Interest and Conflict of Commitment Disclosures:

- 1. Staff must disclose the Outside Interests, Conflicts of Interests or Conflicts of Commitments of themselves or their immediate family members as they arise in the University's online disclosure system, 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. Guidance and procedures related to Outside Interests, Conflicts of Interest and Conflicts of Commitment, which may be amended from time to time, are located at Compliance Topic: Conflict of Interest.
- 2. The department head or appropriate supervisor will evaluate the Outside Interest, Conflict of Interest and/or Conflict of Commitment. The department head or appropriate supervisor may approve or disapprove of the Outside Interest. The department chair or appropriate supervisor also will reduce, manage or eliminate any conflicts as appropriate. Department chairs or deans can receive advice and support related to these disclosures and conflict management from the UMHS Compliance Website located at: http://www.med.umich.edu/u/compliance/area/coi/Reviewer.htm. Advice is available from their Compliance Officer or the COI Board. Depending upon the circumstances, review and approval by the COI Board also may be needed.
- 3. If the department head or appropriate supervisor disapproves a Conflict of Interest or Conflict of Commitment, the individual is not permitted to engage in the activity or interest that generates the conflict absent an appeal.

D. Visiting Faculty Conflict of Interest Disclosures:

- 1. Visiting Faculty must promptly disclose any Conflicts of Interest of themselves and their Family Members to their department chair.
- 2. The department chair or appropriate dean will evaluate the Conflict of Interest and/or Conflict of Commitment disclosed by the Visiting Faculty. The department chair or dean may approve or disapprove of the activity or interest associated with the Conflict of Interest or Conflict of Commitment. The department chair or dean also will assess and reduce, manage or eliminate any conflicts as appropriate. Department chairs and deans can receive advice and support related to these disclosures and conflict

management from the <u>UMHS Compliance Website</u> located at http://www.med.umich.edu/u/compliance/area/coi/Home.htm. Advice also is available from their Compliance Officer or the COI Board. Depending upon the circumstances, review and approval by the COI Board also may be needed.

- 3. If the department chair or appropriate dean disapproves a Conflict of Interest or Conflict of Commitment, the Visiting Faculty is not permitted to engage in the activity or interest that generates the conflict.
- E. <u>Disclosures Related to Research</u>: In addition to the procedures above, UMHS faculty and staff must disclose potential or actual Conflicts of Interest related to research activities by completing the form in the University's online disclosure system, M-Inform and attestation in the eResearch applications.

2. Appeals

- A. Faculty Conflict of Interest Appeals Process. If Faculty, Adjunct Faculty and Visiting Faculty disagree with their department chair's decision, then the disapproval by the department may then be appeal within 30 days of the denial by the department chair. The appeal will be resolved according to the COI Board procedures related to appeals, which can be found at http://www.med.umich.edu/u/coi/process_board_appeal.htm. These COI Board procedures related to appeals also will comply with the appeals process as set forth by the Office of the Vice President for Research.
- B. <u>Staff Conflict of Interest Appeals Process</u>. If Management Staff or Staff disagree with the supervisor's decision, then the denial by the supervisor may then be appealed to the applicable Compliance Officer in writing within 30 days of the denial by the supervisor.
 - 1) At their option, the applicable Compliance Officer may either:
 - i. Accept, modify or reject the supervisor's decision, which will be set forth in writing to the aggrieved Management Staff or Staff within 14 business days of their decision. If rendered, the Compliance Officer's decision will be final and binding absent a written appeal by the aggrieved Management Staff or Staff within 14 business days of the Compliance Officer's decision to the applicable Compliance Committee; or
 - ii. Have the matter reviewed at the next available agenda of the applicable Compliance Committee meeting. The applicable Compliance Officer will present the appeal to the Compliance Committee for its review. The Compliance Committee may accept, modify or reject the decision of the supervisor or Compliance Officer. The decision of the applicable Compliance Committee must be set forth in writing to the aggrieved Management Staff or Staff within 14 business days of its decision. This opinion shall be final and binding absent a written appeal from the aggrieved Management Staff or Staff to the COI Board.
 - iii. Any decisions of a UMHS Compliance Officer and/or Compliance Committee will be reported as an informational item at the next

available agenda of the Compliance Officers' meeting. The intention is to ensure consistency in the handling of Conflict of Interest or Conflict of Commitment issues across UMHS.

- 2) If the Management Staff or Staff disagree with the decision of the Compliance Officer or Compliance Committee, then the aggrieved Management Staff or Staff can appeal the decision to COI Board. This appeal must be set forth in writing within 14 business days of the Compliance Officer's or Compliance Committee decision.
- 3) At the next available agenda of the COI Board, the appeal will be presented to the COI Board. The COI Board may accept, modify or reject the decision of the Compliance Officer or Compliance Committee. The decision of the COI Board will be set forth in writing to the aggrieved Management Staff within 14 business days of the COI Board's decision. Any decision made by the COI Board shall be final and binding.
- Conflict of Commitment Appeals Process. Disputes or appeals related to Conflicts of Commitment will be handled according to existing UMHS policies and processes. The appeal process for Faculty, located at http://www.med.umich.edu/medschool/faculty/handbook/school.html#dispute. Information related to the appeal process for Management Staff and Staff can be found through the University of Michigan Health System Human Resources
 Department website located at http://www.med.umich.edu/umhshr/index.htm

3. UMHS Committees and Committee Recommendations

- A. <u>UMHS Committees designated by UMHS</u> must require that committee members, consultants and staff with Conflicts of Interest relevant to the specific committee topic declare them before the discussion. At the UMHS Committee Chair's option, this procedure may apply to individuals who have been invited to speak before the committee or attend the committee meeting as a guest.
- **B.** Any Conflict of Interest by committee members, consultants, staff or guests must be managed by the Chair of the UMHS Committee by any of the following actions:
 - Participating in committee discussion but recusing him or herself from voting;
 - 2) Recusing him or herself from both committee discussion and voting;
 - 3) Leaving the room during the committee discussion and/or voting; or
 - 4) Taking other appropriate actions in consultation with the appropriate Compliance Officer.
- C. The minutes for the UMHS Committee must document any conflict management strategies used to resolve any Conflict of Interest of the UMHS Committee's members, consultants, staff or quests.

Revised June 2016