



**POLICIES**

Effective Date: January 1, 2008

Retired:

Revised: January 1, 2011

Approved by: WAYNE J. RILEY, M.D., MBA, PRESIDENT & CEO

Subject: CONFLICT OF INTEREST AND CONFLICT OF COMMITMENT POLICY and ANNUAL DISCLOSURE

**PURPOSE:** To ensure that all faculty, officers, trainees and staff of Meharry Medical College (the Meharry Community) make decisions and conduct the affairs of the College based solely upon a desire to promote the best interests of the College and to achieve the goals of its mission.

This policy provides guidelines that govern the behavior and actions of officers, faculty, trainees and staff of the Meharry Community; and is intended to aid in avoiding, managing and eliminating conflict of interest and to provide assurance to the public of Meharry's compliance.

**POLICY STATEMENT:**

No member of the Meharry Community as herein defined under "covered persons" may engage in any transaction or undertaking that may give rise to a conflict of interest or conflict of commitment, without prior disclosure of the potentiality of the conflict to Meharry Medical College.

Each member of the Meharry community has a duty and obligation to Meharry to exercise their professional judgment in a manner unaffected by individual financial, professional or personal considerations. (Including the appearance of such influence). Therefore, members are obligated to report actual or potential conflicts of interests and commitment consistent with this policy and to cooperate in the remedy of any actual or potential conflicts.

**COVERED PERSONS:**

**This Policy applies to the following members ("Members") of the Meharry Medical College (MMC) community:**

1. Executive officers
2. Deans
3. Senior management officers (Assistant, Associate, Senior Associate, and Vice Presidents)
4. Chairpersons
5. Faculty
6. Directors
7. Academic staff

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8. Non-academic staff (to include all professional staff)
9. Trainees (medical students, residents, graduate and post graduate students)
10. Any member of another institution who is engaged in research at facilities owned, leased or operated by MMC and who contributes substantively to the design, conduct or reporting of research; and which research is supported by MMC or funds designed for MMC's use.

## **1. Definitions**

### **Conflict of Interest**

A Conflict of Interest arises when a Member has the opportunity to influence MMC's business, administrative, academic, or other decisions in ways that could lead to personal gain. A Conflict of Interest may exist if a Member, *or any of his or her family or associates*, either (1) has an existing or potential financial or other material interest which impairs or might appear to impair the Member's independence and objectivity of judgment in the discharge or responsibilities to MMC, or (2) may receive a financial or other material benefit from the release of knowledge or information confidential to MMC or patients or clients of MMC.

### **2. Conflict of Commitment**

A separate, but equally important type of conflict of interest is a conflict of commitment. A conflict of commitment potentially arises when an employee's obligation to the employer is compromised by commitments of time to other entities. The conflict of commitment is based on the legal obligation an employee makes to devote "full-time" obligations to the employer (32-40 hours). Commitments to "other" entities may include, but is not limited to, consulting, "moonlighting", part-time employment; obligations to or with professional societies, work on review panels, community service, attendance at conferences and meetings, and outside obligations (compensated or uncompensated).

**Each member is required to disclose outside commitments on the annual disclosure form and to discuss such activities with their supervisor.** Similarly, members are obligated to immediately update disclosures when new commitments arise.

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### **3. Closely Related Persons**

Include spouse, parent, sibling, child, grandparent, parent-in-law, brother/sister-in-law, step parent, step child, step brother/sister, step parent-in-law or legal guardian.

#### **Conflict of Interest Guidelines**

**Disclosures (and approval) are required before engaging in activities inconsistent with these guidelines.**

**The following listings of possible conflict situations are provided as guidance and are not exhaustive of all possible situations.**

#### **A. Business Relationships**

Each member who has a personal financial or management interest, or who's closely related relatives have a financial interest in a private business must be sensitive to the possible creation of a conflict of interest when business relationships exist or are proposed with Meharry. In such cases, such relationships and/or ownership stakes must be disclosed. Members may not review, approve or oversee resulting relationships.

#### **B. Gifts**

Each member of the Meharry community must be cautious and mindful that to receive gifts, free or reduced services because of your position at Meharry will create the appearance and perhaps an actual conflict of interest.

The receipt of gifts is addressed by Meharry regulations based on the nature of the gift:

1. Individual or personal gifts are, per this policy, limited to items, meals, entertainment or other said amenities to a per occasion

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limit of **\$50** and **\$300** a year in aggregate. Documentation of the value of such gifts, including reasonable estimates of value must be maintained by the individual Meharry employee.

2. Gifts of any value from pharmaceutical companies, medical device suppliers or medical service providers are prohibited. This category of vendors is collectively referred to as the Health Care Industry. These restrictions apply to individual employees and/or faculty of Meharry.

An exception to this prohibition is recognized for donations from the Health Care Industry, which are given to the College or a sub unit (school or department) as unrestricted contributions toward meals and refreshments at regularly schedule meetings of school's or departments and/or continuing medical education (CME)/continuing dental education (CDE).

3. Gifts to Meharry Medical College of personal property; gifts with donor restriction or conditions; interest in stocks or marketable securities; gifts of future interest or bequests, and gifts of a similar nature are governed by the Meharry Policy on "Advancement and College Relations – Fundraising and Acceptance of Gifts." This policy can be obtained from the office of General Counsel or the Office of the Vice President for Institutional Advancement."

### **C. Teaching, Clinical Services/Patient Care, and Research Activities**

Each member of the Meharry community who is engaged in research activities and who has interest in a business or ownership (full or partial) of intellectual property who are proposed to do business or does business with the College must abstain from any oversight over associated grants, clinical trials or research. Oversight activities prohibited include providing administrative reviews, approval or supervision of research activities.

Federal agencies have specific regulations governing research. Each member, as principal investigators (P.I.), who conduct research must follow the provisions, protocols, procedures, requirements, and mandates of the agency under which funding occurs as stipulated and overseen by Institutional Review Boards (IRBs). Zero tolerance in

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adherence to all areas of compliance is expected and mandated. College researchers are encouraged to check with the office of the Vice President for Research or the Office of General Counsel for specific guidance relating to individual grants.

Below are a few highlighted examples:

**1. Public Health Service (PHS) Disclosure, including the National Institutes of Health (NIH) and the National Science Foundation (NSF)**

Federal regulations require that all applicants for funding by grants, contracts or cooperation agreements from the PHS (including but not limited to NIH and NSF) must disclose to the institution submitting the application any “*Significant Financial Interests*” that would “reasonably appear to be affected by the research proposed” in the application. It should be emphasized that the *Principal Investigator (PI)* and all other persons who are responsible for the design, conduct or reporting of the research must complete a disclosure. Furthermore, since (a) the relationships to be disclosed are specific for the research being proposed in the individual grant, contract or cooperative agreement, and (b) the disclosure must, by Federal regulation, be updated at least annually, a new disclosure must be submitted for every grant application including non-competing or competing continuations.

**2. Food & Drug Administration (FDA) Disclosure**

If you are involved in FDA regulated research, such as clinical trials of drugs, biologicals or devices under an Investigation New Drug Application (IND) or an Investigational Device Exemption (IDE), you will be required to submit a study-specific disclosure on FDA specified forms. The nature and value of holdings, which must be disclosed, are specified in FDA regulations and in the instructions to the disclosure forms. It is the responsibility of the “Sponsor” to collect these disclosure forms from individual investigators and submit them to the FDA. One should complete these forms with care, since

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errors could have serious consequences. If you are the holder of the IND or IDE for a study, you should be especially diligent regarding compliance with FDA regulations since the FDA tends to hold the individual investigator and sponsor responsible for any violations.

### **3. Institutional Review Board (IRB) Disclosure**

MMC's IRB requires a protocol-specific disclosure of any relationships or financial holdings which could give the appearance of a conflict of interest. The disclosure is required of the Principal Investigator, each co-investigator and any other person responsible for the design, conduct or reporting of the research described in the protocol. It is the opinion of the MMC IRB that information regarding possible conflicts of interest of investigators might influence some potential research subjects as to whether to participate in the research and such information should therefore be provided to potential research subjects in order that they can give appropriately informed consent. The disclosure is research study (protocol) specific, so a new disclosure must be submitted with each new IRB Protocol Application. This applies to new submissions, revisions and continuing reviews.

### **4. Industrial Sponsors of Research Disclosures**

Identifying potential conflicts of interest in regard to agreements with industrial sponsors of research is important in negotiation of and compliance with the terms of agreements with industrial sponsors of research. For example, sponsors may require the MMC to confirm that the investigators do not have any potential conflicts of interest related to their participation in the proposed research. A conflict might also arise when a researcher has interests in a parent company that owns the company that is directly sponsoring the study. In addition, the existence of multiple sources for funding, and commitments made in Material Transfer Agreements, can create situations where there are conflicting obligations to different sponsors as well as to providers of materials.

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The disclosure required is specific for the studies to be supported by the proposed industrial agreement.

### **College Conflicts Committee (CCC)**

There shall be established a College Conflicts Committee (CCC) which shall be appointed by the President and which shall serve as a College resource with respect to matters involving the general subject of conflicts of interest and commitment. The CCC shall have oversight and implementation of the College Conflicts Policy, and provide advice on the resolution of specific conflicts of interest.

The standing CCC shall be co-chaired by the General Counsel (or his/her designee) and shall include the Vice President for Research, the Associate Vice President for Faculty Affairs and Development, a representative of the Office of Internal Audit and a faculty representative, chosen by the respective Deans of the School of Medicine, School of Dentistry and the School of Graduate Studies.

#### **The duties of the CCC shall include:**

1. Overseeing the solicitation of a periodic uniform disclosure from all Members that addresses potential or actual conflict of interest and conflict of commitment situations, including: the circulation, collection and retention of disclosure statements;
2. At the request of a Member, providing advice regarding a conflict or potential conflict of interest or commitment;
3. Maintaining an ongoing awareness of MMC procedures, practices, and standards with regard to conflict of interest and commitment with a view to assuring consistency with the terms of the College Conflicts Policy;
4. Maintaining an awareness of externally imposed conflict of interest requirements;
5. Recommending to the President any necessary or appropriate changes to the College Conflicts Policy;
6. Performing such additional functions as may be assigned from time to time by the President;



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7. Reporting to the Audit & Compliance Committee of the Board on an annual basis regarding its efforts and accomplishments.

### **Conflicts Disclosure & Avoidance**

**Disclosure is the initial step in managing and avoiding conflicts, or the appearance thereof.** The concept of disclosure is based upon openness and transparency. If a relationship is open and transparent, it is less likely to lead to improper behavior or to the perception of improper behavior. Accordingly, all Members should timely disclose all relationships that could be viewed as creating a conflict. Disclosures must be in writing and contain sufficient detail to permit the circumstances to be thoroughly reviewed.

The recipient of the disclosure depends upon the position of the Member:

1. Disclosures by the President shall be made to the Board of Trustees (see below).
2. Disclosures by all other Members shall be made to the CCC.

In addition, all Members must complete formal disclosures in the following distinct situations (this listing may be modified as required by institutional, state or federal regulation):

#### **Annual Disclosure**

All Members are required to complete an annual disclosure that identifies potential conflicts involving business interests or research related activities. The disclosure is circulated and collected by the CCC.

#### **Updates**

Members are required to immediately submit supplemental disclosures to the CCC as new conflicts arise during the course of the year.

### **Resolution of Conflicts**

#### **1. Faculty & Staff**

In the event that a disclosure reveals a real or apparent conflict, the CCC or designee thereof shall review the facts with the Member or may seek the



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opinion of the Member's immediate supervisor and attempt to resolve the matter informally. Should the CCC subsequently be called upon to act in its role as fact finder and recommender to the President (as set forth below), the representative who provided advice shall not participate in the committee's later role. If the Member objects to the proposed resolution, the matter shall be referred to the CCC.

The CCC shall consider all matters that cannot be resolved informally as set forth above. The Member shall have an opportunity to present any information to the CCC regarding the circumstances surrounding the purported conflict. The CCC shall determine whether a conflict exists, determine the severity of the conflict, and recommend a resolution to the President. The President, with the advice of the General Counsel, shall then determine whether to adopt the resolution as recommended or with modification. The decision of the President shall be final.

## **2. President**

Any disclosure by the President shall be reviewed by the General Counsel and presented to the Executive Committee of the Board for resolution. If appropriate or necessary, the Executive Committee may present the matter to the entire Board of Trustees for resolution.

### **Penalties**

The failure to file an annual or updated conflict of interest statement or a failure to properly comply with the resolution of a conflict as directed by the President (to include an employee's supervisor) shall subject the employee to a sanction. Such sanction may range from written reprimand to termination and shall be in accordance to the severity of the violation as determined by the President or his/her designee.

**EXHIBITS: Meharry Medical College Declaration on Outside Interests & Activities**