

	MOREHOUSE SCHOOL OF MEDICINE/MOREHOUSE MEDICAL ASSOCIATES, INC. OFFICE OF COMPLIANCE AND INTERNAL AUDIT POLICY AND PROCEDURE MANUAL	POLICY NUMBER	COMPLIANCE
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	SUBJECT INSTITUTIONAL CONFLICTS OF INTEREST	SUPERSEDES	5-1-97

## OVERVIEW:

Morehouse School of Medicine and Morehouse Medical Associates, Inc. ("MSM") has a responsibility as a steward of public funds to ensure that all its activities including those related to research reflect its primary goals of education and scholarly inquiry. The public has endowed MSM with certain privileges and entrusted it with resources in the expectation that no single party will derive sole benefit or be unjustly enriched from its investment in MSM. The public should be confident that MSM research remains a rigorous and open inquiry, unencumbered by potential conflicts of interest that might affect the sound judgment of the faculty, students, staff, administrators, officers and other senior managers.

As the potential value of knowledge that schools create increases, so do the opportunities for collaboration between schools and private enterprises and corporations. Whether through corporate sponsorship of research or licensing of inventions to private industry partners, schools can translate their knowledge into useful products; enrich their teaching and research with practical experience; and support their research and educational mission.

Developing innovations through industry partnerships can pose challenges to the core values of schools, notably to their commitment to pursue and disseminate knowledge independent of economic pressures. MSM is by nature and by law an educational, not-for-profit institution. The educational and research activities of MSM should be, and should appear to be, motivated primarily by a concern for the advancement of knowledge and the pursuit of truth, not by the pursuit of financial reward. MSM therefore seeks to ensure that any partnerships involving a substantial technology-development element, as well as any economic activities it undertakes on its own, are consistent with the following core values:

**Objectivity and integrity of the research, itself:** The advancement of knowledge depends on the ability of individual scholars to formulate ideas free from the influence of conflicting interests.

**Open publication and sharing of research results:** Agreements with outside entities and other economic activities of MSM should preserve an open environment for the conduct of teaching and research and the public dissemination of the results of these activities.

**Appropriate use of sponsor or MSM funds:** MSM must ensure that the institution, its leadership, faculty and staff do not enter into a relationship where there may be an actual or perceived conflict of interest with their primary responsibilities and fiduciary obligations to MSM.

**Fulfillment of obligations to colleagues and students:** The student-faculty relationship lies at the heart of the academic enterprise. Insulating that relationship from inappropriate pressures is vital to the educational welfare of individual students and to the quality of teaching that the institution provides.

**Integrity of academic and administrative decision making:** MSM's leadership and administration must be aware of and deal appropriately with potential conflict of interest situations, both real and perceived, which may arise in connection with extramural activities.

Partnerships with outside enterprises and other economic activities of MSM itself should be constituted so as to maintain public confidence in MSM as an institution committed to the pursuit of truth and advancement of knowledge. Schools depend on the goodwill and steady support of their alumni, community and government leaders, and many members of the public, who rely on the institutions to uphold standards of academic integrity.

Two general types of Institutional Financial Conflicts of Interest may be identified. First, MSM itself, as represented by its leaders, may find that its professional judgments with respect to its academic and public obligations may be affected by its entrepreneurial and its financial aspirations. Second, individuals with supervisory and administrative roles in MSM (president, dean, vice deans, vice presidents, chairs, division chiefs, center directors and other administrators) may become involved in situations in which their academic, administrative or supervisory function is conflicted by or perceived to be conflicted by, the opportunity for personal gain.

Each institutional financial interest that presents a potential for financial conflicts of interest, whether real or perceived, must be fully disclosed to MSM, and managed, reduced, or eliminated before any contract, sponsored project, dedicated gift, or transaction is executed, any contractual relationship is initiated, or any action is taken that might be influenced or appear to be influenced by the conflict of interest.

Individual conflicts of interest involving the personal financial relationships of MSM trustees, administrators, faculty, staff or students with entities that conduct business with MSM are regulated by MSM's Individual Conflicts of Interest and Commitment Policy and are generally outside the scope of this Policy except in cases where individual employees with wide administrative authority possess personal financial interests that intersect with their MSM duties, as explained below.

## **PURPOSE:**

This policy is established to provide appropriate institutional safeguards to sustain a climate in which sponsored projects, dedicated gifts, research, scholarship, artistic endeavors, and technology transfer are carried out responsibly, and in so doing foster an atmosphere of openness and integrity.

## **DEFINITIONS:**

### **Covered Individuals**

This Policy covers all MSM personnel including trustees, administrators, faculty and staff who are in a position to make decisions for MSM that affect the following:

- The conduct of research, especially involving human subjects,
- The use of MSM resources, including decisions involving expenditures, purchasing, investments, equity and technology transfer,
- The execution of contracts and grants, or
- The licensing of MSM intellectual property to external parties.

Individuals who hold positions at the Executive level should be especially vigilant.<sup>1</sup>

### **Institutional Conflict of Interest**

An institutional conflict of interest exists where a financial relationship between MSM and an external entity compromises the integrity of institutional decision-making. Such conflicts may arise in situations where 1) MSM enters into a financial or business relationship at the institutional level with an external entity that may bring financial gain to the institution or any of its units; or 2) a MSM trustee, administrator, faculty or staff member holds administrative or decision-making authority of such a scope that MSM cannot engage in a questioned activity or relationship independent of his or her involvement, and at the same time that person has personal financial interests that relate to the proposed activity or relationship.<sup>2</sup> For purposes of application of this Policy, such personal financial interests are deemed to be MSM financial interests.

Institutional conflicts of interest may involve any MSM activity carried out in the pursuit of MSM's mission. Of particular concern are conflicts that arise in the conduct of research involving human subjects, but any activity in which the judgment of those involved becomes affected by MSM financial relationships may lead to a violation of this Policy. (Examples of institutional conflicts of interest are included in Appendix A, attached.)

### **POLICY**

It is the Policy of MSM that in pursuing its mission the school must conduct its business free of improper influence resulting from external institutional financial relationships.

Given the breadth of MSM activities, the variety of its relationships, and the need for the school to act as a wise steward of all its funds, the creation of MSM relationships that could be potential institutional conflicts of interest is unavoidable. This Policy does not require that MSM refrain from conducting school business with entities that have a financial relationship with MSM. However, in such instances, potential institutional conflicts of interest must be identified promptly and resolved appropriately. In particular, MSM must strive to isolate decisions involving school operations and research from decisions regarding the management of financial investments made by or on behalf of MSM, including investments made by or through Merrill Lynch or affiliated entities.

In determining whether a potential institutional conflict of interest in fact constitutes an impermissible institutional conflict of interest, MSM will employ the following test: a financial relationship with an external entity will give rise to an impermissible institutional conflict of interest when the objectivity of the decision-making process or the allocation of resources is influenced in ways that (1) compromise the integrity of MSM in fulfilling its mission, and (2) would not occur but for the expectation of

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<sup>1</sup> These individuals include all senior academic and administrative officers, such as the President, Vice Presidents, the Dean, Associate Deans, among others. Directors, including Center and Institute Directors and Department Chairs, are charged with the same level of care. Any person to whom these individuals delegate any portion of their decision-making authority for any reason or for any amount of time is charged with the same high degree of vigilance in the application of this Policy.

<sup>2</sup> For purposes of this Policy, such personal financial interests shall include anything of monetary value, including salary or other payments for services, equity interests, and intellectual property rights of the MSM employee or of his or her family members. Family members shall include dependent children or spouse. (Spouse shall include a person with whom the employee lives together in the same residence and with whom the employee shares responsibility for each other's welfare and shares financial obligations.) Interests in mutual funds where the employee has no control over the selection of holdings shall not be considered a personal financial interest under this Policy.

financial gain to MSM or one of its internal units from a current or anticipated external financial relationship.

As stated above, collaborations with external entities and public engagement in general are strategic objectives of MSM. This Policy regulates those collaborations that are determined to be actual institutional conflicts of interest. A relationship that may initially appear to result in an institutional conflict of interest may not in fact do so. Determining whether such a conflict exists requires careful consideration of all available relevant information.

## **POLICY IMPLEMENTATION**

### **A. Strategies for Resolution of Potential Institutional Conflicts**

Potential institutional conflicts of interest may be resolved in a variety of ways, including but not limited to the following mechanisms:

- (1) Where MSM proposes to conduct school business with an entity with which it has a financial relationship, the entire transaction between the parties must be included in a written contract. Inclusion of all points of agreement between MSM and such entities is critical to avoiding the appearance, whether or not warranted, that MSM may have conferred improper benefits on an entity with which it has a financial relationship.
- (2) Where a contract is appropriate to the relationship, such contracts should be awarded through use of transparent procedures for solicitation and award of contracts, such as those used by the MSM Procurement Process. However, this approach is generally not feasible with certain MSM contracts, such as contracts for licensing MSM inventions or funding MSM research. Special care must be taken to separate decisions regarding such contracts from the impact of institutional financial interests.
- (3) All Covered Individuals must report any potential institutional conflict of interest arising from their personal financial interests to their immediate supervisors at the earliest opportunity. Where such a potential institutional conflict meets the test set forth in the Policy section above, such employees should, where feasible, recuse themselves from involvement in MSM business involving entities with whom those officers have financial relationships. An employee's supervisor must concur in the employee's decision to recuse him or herself. In some cases, it will be impossible for such officers to recuse themselves and conduct their school duties effectively, and in such instances they must divest themselves of the personal financial interest creating the institutional conflict. Both the disclosure to the employee's supervisor and the decision to recuse or divest should be documented in the employee's personnel file.
- (4) In all instances, MSM must segregate decisions involving the management of its investments and the solicitation of contributions from decisions regarding school operations or research that are or may be affected by those investments or contributions. For example, MSM employees directly or indirectly responsible for creation and management of research contracts should not be involved in oversight of the management of MSM investments. In addition, MSM employees involved in the solicitation of contributions or in the management of investments must not seek to influence the terms of research grants or contracts or the conduct of research.

- (5) Direct investments by MSM in school-related start-up companies warrant particular sensitivity to ensure that no violations of this Policy occur as a result of such investments.
- (6) Because research involving human subjects warrants the highest level of protection, a special set of procedures that govern such research is attached in Appendix B. Please also refer to the Research Conflicts of Interest Policy for further detail.

## **B. Procedures for Reporting Concerns of Potential Institutional Conflicts and Mechanisms for Review.**

Any MSM official or employee who has concerns about the permissibility of any relationship or activity on the part of MSM or its personnel involving an external relationship should consult the Chief Compliance and Internal Audit Officer ("CCIO"). If, after examination of the situation, the CCIO determines that a potential institutional conflict of interest may exist or that a situation poses significant potential for public perception of an institutional conflict of interest, the CCIO shall refer the matter to the Institutional Conflict of Interest Review Committee ("ICOIC").

The ICOIC shall be composed of five members who will each serve for a three-year term; in the President's discretion, three of the initial members of the committee may be appointed to four-year terms in order to assure continuity of membership. The President shall appoint three members from within the school, and in order to bring a non-University perspective, shall appoint two members from the community to serve on the committee. Community ICOIC members shall be required to execute appropriate confidentiality statements in order to safeguard information that is confidential under governing law. The ICOIC shall evaluate potential conflicts of interest that are referred by the CCIO. The CCIO shall also provide periodically to the committee a list of matters he or she considered, but that in his or her opinion did not rise to the level of a potential institutional conflict of interest, along with a description of the issues involved and the reasons for not referring them to the ICOIC. The ICOIC may consider any of the non-referred matters in its sole discretion.

Following evaluation, the ICOIC shall make a recommendation to the President concerning the disposition of the potential institutional conflict of interest. If the ICOIC deems it necessary, it may also forward the recommendation to the Board of Trustees.

In instances where matters that are or have the potential to be institutional conflicts of interest come before the Board of Trustees, the Board must request the advice and counsel of the ICOIC concerning the disposition of such matters.

Any act of retaliation or reprisal against an individual for reporting in good faith a potential institutional conflict of interest or a violation of this Policy shall be a violation of this Policy. Any use of this Policy to report in bad faith an alleged potential institutional conflict of interest shall be a violation of this Policy. Such violations will be dealt with through regular administrative processes for violations of MSM policies.

## **APPENDIX A**

### **EXAMPLES OF INSTITUTIONAL CONFLICTS OF INTEREST**

Financial relationships with external entities give rise to impermissible institutional conflicts of interest when, in the interests of financial gain to MSM or its internal units, the objectivity of the decision-making process or the allocation of resources is influenced in ways that (1) compromise the integrity of MSM in fulfilling its mission, and (2) would not occur but for the existence of the external financial relationship.

The following examples are not intended to be exhaustive:

#### **Conflicts of Interest**

1. Seeking to influence the award or terms of a MSM contract, including but not limited to research contracts, with an external entity because of a past, present or future gift from the external entity.
2. Seeking to influence a MSM research review committee (such as an Institutional Review Board ("IRB")) to grant concessions or exceptions in reviewing or monitoring a research project involving technology in which MSM has an equity interest.
3. Seeking to influence a MSM research review committee (such as Institutional Animal Care and Use committee or IRB) to grant concessions or exceptions in reviewing or monitoring a research project sponsored by an external entity in which MSM has a financial interest.
4. Where a MSM official has made a personal financial investment in a University faculty member's start-up company, involvement by that official in decisions affecting the terms and conditions of that faculty member's University employment.
5. Where a MSM official has made a personal financial investment in a MSM faculty member's start-up company, involvement by that official in decisions affecting the terms and conditions of MSM business relationships with that start-up company.
6. Where MSM, or an entity affiliated with MSM, invests school funds or funds held for the benefit of MSM in an entity in which officials responsible for approving the investment hold a personal financial interest, or makes use of an investment mechanism (including an investment management fund or firm) in which officials responsible for approving the investment hold a personal financial interest.

#### ***Potential Conflicts of Interest:***

1. Where MSM is entitled to receive royalties from the sale of a technology that is proposed to be the subject of a MSM research project.
2. Where MSM, through technology licensing activities, holds an equity interest or an entitlement to equity of any value in a non-publicly traded sponsor of research at the school.

3. Where MSM, through technology licensing activities or otherwise, holds a significant equity interest in a publicly traded sponsor of research at the school and MSM officials responsible for managing that equity interest are also involved in decisions concerning the conduct of MSM research sponsored by the entity.
4. Appointment of a MSM official with broad administrative authority to serve with or without compensation in either a personal or representative capacity as an officer, director, or scientific advisory board member of a sponsor of research conducted at or under the auspices of MSM.
5. Allocation of laboratory or office space by a MSM academic department in a manner that unduly favors investigators whose research is sponsored by an entity that has provided the department with gifts.

## **APPENDIX B**

### **SPECIAL PROCEDURES FOR HUMAN SUBJECTS RESEARCH**

The Chief Financial Officer and Sr. Vice President of Administration ("CFO") shall compile a list of all entities in which MSM holds an equity interest as part of a licensing arrangement and shall provide this list to all IRBs at MSM. The CFO shall supplement the list as equity licenses are issued or as investments are sold.

In the event that MSM or any MSM-related investment entity invests directly in an entity whose stock is not publicly traded, the CFO will provide a list of such entities to all IRBs at MSM. The CFO shall supplement the list as additional investments are made or liquidated.

All human subjects research protocols submitted for regular or expedited review to any IRB must indicate 1) the nature and source of all drugs, devices or biologics to be used in the proposed research, 2) the source of all funding, and 3) whether the proposed project involves the use of an invention or technology that is owned by MSM or has been invented by a MSM employee or student.

An IRB shall refer a proposed research project to the Chief Compliance and Internal Audit Officer for further review under this Policy where:

- (1) The proposed research is funded by an entity on either the list compiled by the CFO; or
- (2) The proposed research studies otherwise involve an invention or technology owned by MSM or invented by a MSM employee or student.

Please refer to the Research Conflicts of Interest Policy for further detail.