

	MOREHOUSE SCHOOL OF MEDICINE/MOREHOUSE MEDICAL ASSOCIATES, INC.	POLICY NUMBER	COMPLIANCE
	OFFICE OF COMPLIANCE AND INTERNAL AUDIT	EFFECTIVE DATE	7-3-2009
	POLICY AND PROCEDURE MANUAL	PAGE(S)	
	<u>SUBJECT</u> INDIVIDUAL CONFLICTS OF INTEREST AND COMMITMENT	SUPERSEDES	5/1/1997

OVERVIEW:

Consistent with Morehouse School of Medicine and Morehouse Medical Associate's ("MSM") research, teaching, patient care, and public service mission, MSM encourages faculty, staff and students to engage in appropriate professional and business interactions with public and private entities. However, such activities can create conflicts of interest or the appearance of conflicts of interest that have the potential to directly and significantly affect MSM's interests, compromise objectivity in carrying out MSM's responsibilities or otherwise compromise performance of MSM's responsibilities, unless such conflicts are reported, reviewed, and managed in accordance with this Policy. This Policy on Individual Conflicts of Interest and Commitment (the "Policy") describes MSM's approach and process for identifying, reviewing, and managing such relationships to help assure the integrity of MSM's academic and administrative endeavors.

A member of the MSM community – trustee, administrator, faculty, staff, student or trainee – may be deemed to have a conflict of interest when he or she or any of that person's family possesses a personal financial interest or external executive position related to an activity that involves his or her MSM responsibilities. Included in these responsibilities are all activities in which the individual is engaged in the areas of teaching, research, patient care and administration.

It is the purpose of this Policy to minimize the most obvious and avoidable conflicts of interest that have potential for serious negative effects on the performance of MSM's mission. The requirement that an individual's potential conflicts of interest be reported and evaluated by others is not a commentary on the integrity of the individual. As members of a scientific and intellectual community we recognize that objectivity about one's own situation and credibility with external observers requires an evaluation external to oneself. Moreover, the fact that an individual may be determined to have a conflict does not imply that the conflict is unethical or impermissible; it only means that the relation of the conflict to the individual's school responsibilities must be carefully examined and in some cases managed, because conflicts – real or perceived – may impair performance of our mission of teaching, research, patient care, and public service, as well as jeopardize public trust and support.

DEFINITIONS:

Covered Individual refers to any MSM trustee, administrator, faculty, staff, student or trainee in the performance of the teaching, research, patient care, public service, administration, and business operations of MSM.

Family or Family Member of a covered individual includes his or her spouse, domestic partner, children (including stepchildren), parents, siblings, grandparents, grandchildren, father-in-law and mother-in-law or any other in-law.

Business means any company or corporation, partnership, sole proprietorship, firm, franchise, association, organization holding company, joint stock company, receivership, trust (business, real estate, estate planning or otherwise), enterprise or any other legal entity.

Conflict of Interest means any situation where there is a divergence between the individual's private interests and his or her professional obligations to MSM such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. In federally sponsored research, actual conflicts of interest are prohibited by federal law.

The potential for conflicts arises because of the nature and scope of activities engaged in by MSM and its faculty members and staff. MSM assumes that the potential for conflicts of interests will occur regularly in the normal conduct of activities. However, it is essential that the potential for conflicts of interest be disclosed and reviewed by the appropriate individuals at MSM prior to entering into the situation or relationship. After a disclosure, an informed judgment about a particular case can be made and the appropriate oversight, limitations or prohibitions on the activity can be implemented in accordance with federal and state law, as well as MSM policy.

Significant Financial Interest in a business is anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); that exceeds \$5,000 or equity interests (e.g., stocks, stock options or other ownership interests) that exceed \$5,000 or represent a five (5%) percent or more ownership interest in any single entity during the 12-month period ending June 30. It excludes any interest arising solely by reason of investment in such business by a manual, pension or other institutional investment fund over which the employee does not exercise control.

For the purposes of this policy, disclosure is required when the interest in a business by an employee or family member in aggregate exceeds \$5,000 or ownership interest of five (5%) percent or more in any single entity during the 12-month period ending June 30.

Please refer to the Faculty Handbook for the MSM policy on intellectual property.

Human Subjects Research means any systematic investigation (1) that is designed to develop or contribute to generalized knowledge and (2) that obtains data through intervention or interaction with living individuals and/or obtains identifiable private information about living individuals, including by means of the observation or recording of behavior. Intervention includes both physical procedures and manipulations of the subject or subject's environment that are performed for study purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information that individuals can reasonably expect will not be made public.

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

Investigator means the principal investigator and any other person who is responsible for the design, conduct or reporting of research. Note that **financial interests** of the **investigator** include financial interests of the investigator's **family**, as defined above.

University Project means any research, testing, evaluation, training, and/or instructional project conducted under the auspices of the University.

Compelling Circumstances are those facts that convince the reviewer that a **covered individual** who has a **financial interest** should be permitted to conduct **human subject research**, taking into account the following factors:

- (1) the nature of the research,
- (2) the magnitude of the **financial interest** and the degree, to which it is related to the research,
- (3) the extent to which the **financial interest** could be directly and substantially affected by the research,
- (4) the degree of risk to the human subjects involved that is inherent in the research protocol,
- (5) the extent to which the investigator is uniquely qualified to perform a research study with important public benefit, and
- (6) the extent to which the interest is amenable to effective oversight and management.

IRB (“Institutional Review Board”) means any board, committee, or other group formally designated by MSM to review human subjects research, and which was established and which functions and operates in conformity with Part 46 of Title 45 and Part 56 of Title 21 of the Code of Federal Regulations. IRB Members are those persons who comprise the IRB.

Leadership Role means employment, consulting in any administrative or executive capacity, or serving as

- (i) a member of a board of trustees or board of directors,
- (ii) an officer, or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees or a board of directors, whether remunerated or non-remunerated, in a research **Sponsor** or research-related organization.

Research Financial Interest means any investments (whether in the form of debt, stock or other equity ownership; options or warrants to purchase stock or other securities or similar instruments) or any interest in a sponsor, research or healthcare-related organization; royalties on any patent or intellectual property interests, unless paid by MSM; or income, salary or remuneration in cash or kind, emoluments, benefits, gifts, honoraria, travel expenses, goods or services received from a sponsor or research or healthcare related organization. Research financial interest does not include holdings in mutual funds or other equity funds in which day-to-day control of investments is held by a person not covered by any MSM Conflict of Interest policy.

Research Oversight Official means personnel and staff of any institutional office or body at MSM who perform research oversight functions in which they exercise professional or administrative-level discretion. All designated officials in the Policy of MSM on Conflicts of Commitment and Interest are also research oversight officials.

Sponsor means the entity that is sponsoring or funding the research and the entity's affiliates and subsidiaries, and any entity that monitors research, collects or arranges data for research or otherwise performs any services related to or supporting research, including assisting in applications or responses to the FDA.

CONFLICT OF INTEREST GUIDELINES

MSM strives to ensure that all of its activities are conducted in accordance with high ethical standards and with federal and state law and regulation. Some activities by their nature require particular scrutiny for potential conflicts of interest. The following are guidelines that members of the MSM

community should follow. Disclosure and approval are required before engaging in activities that are inconsistent with these guidelines.

A. Conflict of Commitment

The term conflict of commitment relates to an individual's distribution of effort between MSM duties and external professional activities. All MSM employees are expected to devote their primary professional loyalty, time and energy to their MSM responsibilities; accordingly, outside professional activities and outside financial interests must be arranged so as not to interfere with the primacy of MSM responsibilities.

Each member of the faculty shall advise the department chair and dean in advance of any activities in which he/she engages which will or may result in rendering less than full-time service to MSM. External opportunities will not be allowed to interfere with the responsibilities of the faculty member to the department or major academic unit. The chair of each major academic unit, after consultation with the dean, shall approve such outside employment and commitments by the faculty member and report this approval to the dean. MSM policy does not provide that a faculty member is entitled to engage in external professional activities for pay for any specific or set percentage of time. Rather, an employee's supervisor always has the discretion to determine whether a proposed external activity is appropriate in scope and duration or constitutes excessive time away from MSM duties. Furthermore, the name of the school may not be used for propaganda purposes or for personal gain.

Staff/Administrative employees who hold full-time appointments are expected to devote their full-time professional loyalty, time and energy to their MSM position. Outside employment is permitted as long as the nature of the employment is not in direct competition or conflict with MSM's mission or the mission of the employee's department. Furthermore, the time and effort required by the outside employment must not in any way restrict or prevent the employee from performing his/her MSM duties and responsibilities. Some departments may require employees to obtain preapproval by the Director or Unit Head before beginning outside employment. In no case are a full-time or part-time staff/administrative employee permitted to perform duties for another employer (including self-employment) during his/her normal working hours at MSM.

Required Reporting and Action:

Faculty or non-Faculty employees are required to file a "Notice of Intent" with her/his department head at least ten (10) days before engaging in an external professional activity for pay. A MSM inventor seeking to engage in external professional activity with an entity that proposes to license, has licensed or has otherwise acquired rights to his or her invention must also file a copy of the "Notice of Intent" with MSM's Chief Compliance and Internal Audit Officer ("CCIO") at least 10 days in advance of engaging in the external professional activity (See section "Intellectual Property Transactions" below). The department head is required to respond with approval or disapproval of the external professional activity for pay within 10 days of the filing of the "Notice of Intent." See the *MSM Policy on External Professional Activities of Faculty and Other Professional Staff* for more detailed information.

B. Acceptance by Individuals of Gifts, Favors from External Entities

Generally, MSM employees may neither accept nor offer, either directly or indirectly, any personal gift or favor or loan to or from an organization, entity or person that is conducting or seeking to conduct business with MSM, unless the gift is nominal. A "nominal" gift occurs where the fair market value of all payments, gifts or favors from the same or related source within a single

calendar year is less than forty dollars (\$40.00). Cash gifts of any size are **not** considered nominal. However, meals, texts, or customary honoraria may be provided to MSM faculty or non-faculty employees in connection with activities allowed under the *MSM Policy on External Professional Activities of Faculty and Other Professional Staff*. Although customary honoraria and reimbursement for actual costs generally are not considered to be gifts, if reimbursements or honoraria are significantly in excess of fair market value or customary amounts (e.g. expensive resort sojourns, coverage of family member expenses, etc.), they are defacto gifts.

MSM employees also may not accept any financial or other favors in exchange for privileged access by current or potential MSM vendors to MSM facilities or employees. Any personal compensation a MSM Project sponsor pays to or for the benefit of a covered individual outside of contracted project support to MSM must be reported by the covered individual as applicable under the *MSM Policy on External Professional Activities of Faculty and Other Professional Staff* and this Policy. A MSM employee may not receive compensation from an external source for performance of MSM work except through a MSM contract or grant.

C. Gifts to MSM or an Affiliated Foundation for the Benefit of an Individual Employee or Student.

For purposes of this Policy, gifts and donations that have been made to MSM or to a MSM-affiliated foundation for the benefit of the professional activities of a specific faculty or staff member or student or trainee are considered to be a personal financial interest of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary. Such gifts and donations, where they coincide with MSM activities undertaken by the beneficiary that relate to the entity making the gift or donation, may create a conflict of interest, and they shall be reported by that individual as required under this Policy for any other personal financial interest.

D. Use of MSM Resources, including Privileged Information

Confidential or privileged information acquired by MSM may not be used by a MSM employee for personal gain, nor may any employee permit unauthorized access to such confidential or privileged information. Insider trading is just one form of impermissible use of privileged information for personal gain. **MSM faculty and staff should be wary of consulting arrangements through which they may risk sharing confidential proprietary information acquired through sponsored MSM projects.**

MSM employees may not use for non-MSM purposes any MSM-funded or supported resources, including but not limited to MSM facilities, work product, results, materials, property records, or information developed with MSM funding or other MSM support except as otherwise allowed under MSM policy. This prohibition includes the use of MSM's name in a manner that may imply that MSM is associated in some way with the employee's external activity or interest. One context in which this might occur is an external professional activity for pay. Mere identification of MSM as one's employer and of one's position at MSM is permitted, provided that such identification is not used in a manner that implies sponsorship or endorsement by MSM.

E. Purchasing, Contracting, Other Business Transactions on behalf of MSM

A MSM employee generally may not participate in awarding, negotiating, reviewing or approving a financial transaction (including but not limited to purchases, contracts, and subcontracts) involving MSM and an entity in which the employee has a personal financial interest without prior review and approval as described immediately below. Where an employee is involved in the

design, conduct or reporting of MSM research related to that employee's personal financial interest, that potential conflict of interest is governed by the sections below entitled "Intellectual Property Transactions" and "Research and Sponsored Projects."

Required Reporting and Action:

MSM employees routinely involved in the negotiation, approval or administration of MSM contracts with external entities must file an annual Conflicts of Interest Evaluation Form with the Office of Compliance and Internal Audit. See the section below entitled "Exercise of MSM Administrative Responsibilities."

If a MSM faculty or staff member has not filed an annual Conflicts of Interest Evaluation Form disclosing a potential conflict of interest but is prospectively involved in awarding, negotiating, reviewing or approving a financial transaction involving MSM and a private interest of that individual, the conflict of interest must be reported to the employee's supervisor. The supervisor shall reassign that transaction to another employee except where prior approval was obtained and where such management is deemed appropriate by the CCIO.

F. Intellectual Property Transactions

MSM's mission includes fostering the invention and development of new patentable and non-patentable technologies. MSM attempts to license many of these innovations to commercial entities so that MSM research results may reach the market for the public good. MSM must be protected from both real and perceived inappropriate "pipelining" of MSM innovations to entities in which MSM inventors have personal financial interests, and MSM facilities and resources must not be used to the advantage of the licensee entity absent specific authorization consistent with MSM policy and procedures.

Required Reporting and Action:

All MSM inventors are required to report their financial interests and those of their **family** in the course of the licensing process. Additionally, external consulting relationships between a MSM inventor and the holder of a MSM license for the inventor's technology are not permitted unless reviewed and approved in advance both as required under the *Policy on External Professional Activities of Faculty and Other Professional Staff* and by the CCIO.

All faculty, staff or student inventors of technologies licensed or otherwise made available through contract by MSM to a third party must complete and submit a Project-Specific Conflict Evaluation Form before execution of the license or other agreement by the Research Affairs Office and the Office of General Counsel. Any MSM faculty, staff or student inventor who holds equity in, is an officer or director of, or provides consultative services to an entity that has licensed or otherwise acquired rights to MSM invention(s) will be deemed to have a conflict of interest under this Policy.

Updated forms must be submitted to the CCIO promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Project-Specific Conflict Evaluation Form previously answered in the negative.

G. Exercise of MSM Administrative Responsibilities

Individuals in administrative positions have substantial influence by virtue of their role in professional appointments, promotions, tenure decisions, allocations of space, determinations of

salary, execution of business contracts, etc., and must take particular care to avoid relationships that have the potential to advantage the individual but adversely affect MSM's interests or inject inappropriate considerations into administrative decisions. They must be vigilant in ensuring that their exercises of administrative decisions are not, and do not appear to be, colored by their personal financial interests. (Such relationships may also be prohibited under the *Policy on Institutional Conflicts of Interest*.)

Required Reporting and Action:

All MSM Deans, Vice Presidents, Directors, Chairs, Department Administrators and Business or Finance Managers, and any other employee deemed by his or her supervisor to be routinely involved in review, award, or administration of MSM contracts must file an Annual Evaluation Form. In addition, because of the sensitivity of their positions, employees in the Office of General Counsel, Office of Compliance and Internal Audit, Office for Research Affairs, and Department of Grants and Contracts also must file Annual Evaluation Forms pursuant to this section. Updated forms must be submitted promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Annual Evaluation Form previously answered in the negative.

Further information on reporting requirements is included in *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy).

H. Exercise of MSM Review Panel Responsibilities

There are also important conflict of interest responsibilities for individuals participating on panels providing administrative review and evaluation on behalf of MSM – such as Institutional Review Boards (IRB), Conflict of Interest review committees, purchase evaluation committees, etc., (“Research oversight officials”), and includes all personnel and staff of any institutional office or body at MSM who performs research oversight functions in which they exercise professional or administrative-level discretion.

Federal law requires that IRB members not have any conflicting interests in the research that they review. MSM is concerned, as are various professional organizations, with the possible influence of such research financial interests on research integrity and on the safety and welfare of human subjects involved in research protocols regardless of the source of research funding. MSM is also concerned with any leadership roles that may be held by IRB members in any entities that sponsor research, or that perform support, marketing, recruitment, data analysis or FDA liaison activities for research. MSM’s policies therefore incorporate those concerns as well.

Consistent with federal laws and the ethical principles of human subject research, MSM seeks to ensure that its research oversight officials can carry out their responsibilities to protect the rights and welfare of human subjects participating in research projects at the University. Since MSM recognizes that real, potential and apparent conflicts of interest may occur during research, this policy is intended to assist IRB members as well as other research oversight officials in determining when they have Conflicts of Interest in research and to guide them in disclosing all potential conflicts and then, as appropriate, cooperating in the management or elimination of the conflicts. While this policy governs the Conflicts of Interest of IRB members and other research oversight officials at MSM, it does not regulate disputes between two or more individuals or disputes between one or more individuals and MSM. Such disputes are to be resolved according to MSM's established dispute resolution procedures.

Because IRB members and other research oversight officials have primary responsibility for protecting the safety and welfare of human subjects participating in research at MSM, it is the policy of MSM that IRB members and research oversight officials may not review any research protocol in which a decision to approve or disapprove the protocol could affect the IRB member's or research oversight official's or their immediate family's research financial interests. In particular, IRB members and research oversight officials may not have research financial interests in any research sponsor or health-care related organization, nor any leadership roles in any research sponsor or research-related organization that could affect their review of research.

Required Reporting and Action:

Disclosure: All IRB members and research oversight officials must complete the Conflict of Interest and Conflict of Commitment Disclosure Form. This form must be submitted to the member or official's department chair or dean in accordance with the process described in the MSM Policy on Conflicts of Interest and Conflicts of Commitment and must be updated on an annual basis (by June 30th of each year) for as long as the IRB member or research oversight official continues to supervise research at MSM. IRB members and research oversight officials who are newly hired by or affiliated with MSM must submit the Form prior to beginning their research oversight duties, and must thereafter comply with the June 30th filing deadline. IRB members and research oversight officials must indicate upon the form any and all research financial interests and/or leadership roles they or their immediate family may have in any research or health care-related organization, including any not-for-profit or tax exempt health care-related companies or foundations. IRB members and research oversight officials must also indicate whether any of their leadership roles could affect, or appear to affect, their review of any particular research projects.

Updating: If at any time over the course of the year one or more research financial interests or leadership roles of an IRB member or research oversight official or their immediate family in any research or health care-related organization changes in any material way, the IRB member or research oversight official must promptly notify the ICOIC of that change by submitting a written statement detailing such change(s).

Confidentiality: All financial and other confidential information disclosed by faculty and staff to the individuals described in Paragraph (1) will be maintained in confidence, to the extent required by law. The ICOIC may need to disclose information to other MSM administrators defined as designated officials in this Policy to carry out the purpose of this Policy. No other uses or disclosures of the financial and other confidential information of a faculty and staff member will be permitted, unless required by law.

Review by the ICOIC: As promptly as practicable after the June 30th filing deadline, the ICOIC will review the Disclosure Form of the IRB member or research oversight official to make certain that the IRB member or research oversight official does not possess any research or health care-related research financial interests, or any leadership roles that could affect the member's or official's review of research. If the ICOIC concludes that the IRB member or research oversight official is devoid of any such research financial interests and that the member or official does not possess any leadership roles that could affect the member's or official's review of research, then the matter will go no further. If, however, the ICOIC concludes that the IRB member or research oversight official possesses one or more research financial interests, and/or that the member or official holds one or more leadership roles that could affect the member's or official's review of research, then the ICOIC will promptly inform the member or official in writing of its determination and of the remedies that must be taken by the member or official to fall into compliance. A Conflict of Interest will be deemed to exist per se if the IRB member or research

oversight official is an inventor or co-inventor of a product or method in a study undergoing review or continuing review by that member or official, and/or where the IRB member or research oversight official is, or expects to be included as, an author on any publication relating to the study under review.

Management or Elimination of Conflicts of Interests: Where an IRB member or research oversight official is out of compliance with this policy due to one or more research financial interests, the ICOIC will require that the member or official reduce every research financial interest in any research sponsor or health care-related organization to a *de minimis* level. The IRB member or research oversight official has the discretion of selecting how to accomplish this obligation (*e.g.*, partial divestiture of the official's research financial interests, and/or partial divestiture of the research financial interests of the official's spouse or dependent children), but the time-frame in which divestiture must occur will be stipulated by the ICOIC, which ordinarily shall not be more than four weeks. Where an IRB member or research oversight official is out of compliance with this policy due to one or more leadership roles that could affect his or her review of research, the ICOIC will require that the member or official either terminate that leadership role or recuse himself or herself from the review of any research protocol that could be affected by that role. While an IRB member or research oversight official may not review a study that is being funded by a sponsor in which he or she holds a leadership role, leadership roles in other research related organizations will be assessed on a case-by-case basis by the ICOIC. If a Conflict of Interest is deemed to exist based on the IRB member's or research oversight official's status as an inventor or co-inventor of a product or method in a study undergoing review or continuing review by that member or official, or is deemed to exist based on the IRB member's or research oversight official's existing or expected status as an author on any publication relating to the study under review, the remedy will be recusal.

Recusal: IRB members and research oversight officials must recuse themselves from reviewing a research protocol whenever they self-identify themselves as possessing a Conflict of Interest in relation to that protocol, and whenever they have been directed to do so by the ICOIC (or the Vice President of Research Affairs in the case of an appeal). In all cases, recusal must occur before the discussion of, and vote on, the research protocol in relation to which the IRB member or research oversight official has a Conflict of Interest. Nevertheless, the IRB member or research oversight official may remain in the room prior to the discussion or vote in order to provide information relating to the protocol, and may, if he or she is an inventor and/or serves as an Investigator on that protocol, present or assist in presenting the protocol to the IRB members.

Appeal of COI Decision: An IRB member or research oversight official who disagrees with the ICOIC's findings and/or management strategy may appeal in writing to the Vice President of Research Affairs ("VPRA") and/or the Dean. A copy of the appeal must be sent to the ICOIC. An appeal may lie in regard to whether the IRB member's or research oversight official's leadership role is likely to affect his or her review of research, but IRB members and research oversight officials may not contest the terms and conditions of this policy (*e.g.*, they may not contest the prohibition on research financial interests, nor the remedy for such interests). The VPRA may agree with the ICOIC's findings and/or management strategy, or may amend such findings and/or management strategy, by for example, strengthening or weakening the management strategy. The VPRA shall promptly notify the IRB member or research oversight official and the ICOIC in writing of the conclusions of his or her review, including the actions that must be taken by the IRB member or research oversight official to comply with this policy. Upon receipt of the VPRA written report, the IRB member or research oversight official must promptly comply with the actions specified in that report.

Audits and Sanctions for Non-Compliance

If required by the VPRA or the CCIO, an IRB member or research oversight official may be audited for the purpose of verifying whether the IRB member or research oversight official truthfully and accurately disclosed his or her leadership roles, secondary commitments and financial interests, including research financial interests in the annual research-related financial disclosure form (and in any updates thereto), and for the purpose of verifying whether the IRB member or research oversight official is complying with the actions, if any, that were specified in the written report of the ICOIC (or the VPRA where there has been an appeal). An IRB member or research oversight official who does not comply with the actions specified by the ICOIC or the VPRA will be subject to potential sanctions in accordance with MSM policy and procedures. These sanctions may include: formal admonition or censure; suspension or removal from the IRB or other institutional research oversight body, and/or any other research oversight roles and responsibilities.

Research and Sponsored Projects

All MSM employees, students and trainees involved in the design, conduct or reporting of a MSM research or sponsored project must report any potential conflict of interest that they have related to the research or sponsored project. "Involved in the design, conduct and reporting" means to be part of the project in any capacity that allows for the possibility of affecting results of the project, including but not limited to serving as the principal investigator, co-investigator, research collaborator, research study coordinator, or research assistant. This requirement is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis).

Potential conflicts include any personal financial relationship (as defined by this Policy), regardless of level or type of compensation, and any uncompensated position, board membership, or consultancy with or for an external entity involved in the research or sponsored project in any way, including as a sponsor, subcontractor, sub recipient, or as an owner or licensee of any product, process, or technology studied in the project. Whether a potential conflict of interest will be deemed an actual conflict of interest will depend on the nature of the potential conflict and on the nature of the MSM activities potentially affected by the potential conflict. Where an actual conflict of interest poses the risk that MSM activities may be inappropriately affected, the conflict must be eliminated. Subject to special provisions regarding particular types of MSM relationships (such as SBIR or STTR Agreements, *see below*), the following guidelines are generally applicable:

- (1) Where a Covered Individual proposes to be involved in the design, conduct or reporting of MSM research other than human subjects' research, his or her conflict of interest may be allowed with MSM approval and appropriate management.
- (2) Where a Covered Individual proposes to be involved in the design, conduct or reporting of MSM human subjects research, he or she may not have a personal financial interest of any level or value reasonably judged to be materially related to the outcomes of such research, absent a showing by the Covered Individual of compelling circumstances justifying continuation of involvement in the project notwithstanding the personal financial interest. Please refer to the Research Conflict of Interest Policy for further detail.
- (3) The training experience and academic progress of MSM students and trainees must not be subordinated to personal financial interest of Covered Individuals or commercial interests of research sponsors.

MSM's Principal Investigator bears the responsibility to ensure that any potential conflict of interest that exists in relation to the research project he or she leads is reported as required in this Policy. MSM investigators are required to disclose in any publication or presentation of their research the existence and nature of all related personal financial interests and related external executive positions.

Federal Regulations

Federal regulations require that when federal agencies fund MSM research through grant or contract, each MSM **investigator** must report through disclosure, and MSM must examine, the **investigator's** related **financial interests**, which include those of the **investigator's family** (spouse or dependent children – see definition of **family**), that meet certain thresholds and report them to the federal agency involved. However, this Policy extends to all MSM research responsibilities, not just those that involve federal funding, and MSM requires report and review of all related financial interests, not just of those that meet a given federal agency's threshold.

Subcontracts

In addition, federal regulations require that if MSM carries out any NIH funded research through sub grantees, contractors, or collaborators, MSM must take reasonable steps to ensure that **investigators** working for such entities either comply with MSM's policy on conflict of interest or provide contractual assurances to MSM that the sub grantee, contractor, or collaborator **investigators** are in compliance with the NIH's regulations on conflict of interest in NIH funded research. MSM's Office for Sponsored Research Administration requires that sub recipients provide contractual assurance of their compliance with NIH's policy on Conflict of Interest. This contractual obligation includes a requirement that the sub recipient report to MSM's Office for Sponsored Research Administration the following information for any financial conflict of interest of sub recipient personnel: (a) sub recipient contract number (b) name of the sub recipient investigator with a financial conflict of interest (c) the method by which the conflict of interest has been addressed to protect the integrity of the NIH sponsored project – e.g. managed, reduced or eliminated. The Office for Sponsored Research Administration will forward a copy of each such sub recipient report, identified by NIH grant number, to the NIH with copy to the PI and the Chief Compliance and Internal Audit Officer.

SBIR/STTR

Of special concern is federally sponsored Small Business Innovation Research ("SBIR") or Small Business Technology Transfer ("STTR") research projects, which involve association with small business concerns. Because of the high potential for the appearance of an irresolvable conflict of interest, a MSM employee may not conduct research or administrative activities in conjunction with an SBIR or STTR project on behalf of both MSM and the grantee or sub-grantee company.

Required Reporting and Action:

All MSM employees, students and trainees involved in the design, conduct or reporting of a MSM research or sponsored project who respond affirmatively to any Conflict of Interest question posed in MSM's research review processes are required to complete and submit the Project-Specific Conflict Evaluation Form for each MSM project at initiation and at annual renewal. The form must be submitted to MSM's Chief Compliance and Internal Audit Officer and processed as specified in *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy).

Updated forms must be submitted to the CCIO promptly when changes arise that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously reported; or (c) result in an affirmative answer to any question on the Project-Specific Evaluation Form previously answered in the negative.

When the need for a Project-Specific Evaluation Form is indicated through the review processes of the Office for Sponsored Research Administration, any of the Institutional Review Boards, or any other MSM office, the research or other contract for which the form is indicated may not proceed until the potential conflict of interest has been reported, evaluated and approved or resolved. Violation of this provision by any MSM employee or student may lead to disciplinary action, up to and including dismissal from employment or enrollment.

Further guidance on disclosure requirements for Evaluation Forms is included in *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy) and in the *Policy on Research Conflicts of Interest*.

POLICY IMPLEMENTATION

The President is responsible for overseeing the implementation of this Policy. Day-to-day responsibility for such implementation is delegated to the Chief Compliance and Internal Audit Officer.

In addition, the President will appoint a MSM Conflicts of Interest Advisory Committee, which will be authorized to make recommendations to the President for appropriate changes to this Policy, including *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy), along with such other recommendations regarding the disclosure, evaluation, approval and management of conflicts of interest as the Committee deems appropriate. Not less frequently than once each calendar year, the Chief Compliance and Internal Audit Officer will submit a report to the MSM Conflicts of Interest Advisory Committee, summarizing disclosures received and decisions made over the preceding year. The Conflicts of Interest Advisory Committee will include the chairs of any college or school COI review committees, as well as such additional members as the President shall select upon advice of the Chief Compliance and Internal Audit Officer in order to represent the interests and viewpoints of the members of the MSM community directly affected by and involved in implementation of this Policy.

POLICY BREACHES

Possible sanctions for violation of this Policy, including furnishing false, misleading, or incomplete information, can range from administrative intervention to termination of employment or of enrollment, all in accordance with applicable MSM policies. The President, or the President's delegate, will review all alleged violations of this Policy, including the provisions of *Procedures for the Policy on Conflicts of Interest and Commitment* (Appendix A of this Policy). Violations may include but are not limited to: (a) failure to comply with the process (by failure to report timely a potential conflict as

required, by failure or refusal to respond to requests for additional information, by providing incomplete or knowingly inaccurate information, or otherwise); (b) failure to remedy conflicts; and (c) failure to comply with a prescribed management agreement or monitoring plan.

APPENDIX A

PROCEDURES FOR THE MOREHOUSE SCHOOL OF MEDICINE POLICY ON INDIVIDUAL CONFLICTS OF INTEREST AND COMMITMENT

INTRODUCTION

These Procedures, adopted by the President, are part of the Policy on Conflicts of Interest and Commitment (“the Policy”) and are intended to provide effective and transparent processes for the reporting, evaluation, approval or disapproval, and management of potential conflicts of interest within the MSM community. The Procedures do not apply to situations arising under the Policy on Institutional Conflicts of Interest.

REPORTING AND REVIEW OF PROJECT-SPECIFIC POTENTIAL CONFLICTS OF INTEREST

A. Potential Conflicts of Interest Reported in Conjunction with Proposed Research Grants and Contracts

In the internal processing form required in conjunction with every proposed grant or contract, the Office for Research Affairs shall include questions supplied by the Chief Compliance and Internal Audit Officer (“CCIO”) and designed to prompt reporting of potential conflicts of interest (“COI”). Where such potential conflicts are detected, the Covered Individual shall submit a full Project-Specific COI Evaluation Form either in paper format or electronically, as specified by the CCIO. While every effort shall be made to construct a practicable and efficient mechanism for detecting potential conflicts among all members of a research team involved, or anticipated to be involved, in the design, conduct or reporting of the research, **it is the ultimate responsibility of the Investigator to ensure that any potential COI among such persons is promptly and fully disclosed.** These procedures shall also be required any time a grant or contract for research is renewed or extended.

Once submitted, a Project-Specific COI Evaluation Form will be promptly reviewed by the CCIO, who will make a threshold determination of whether a potential COI exists. The CCIO may contact the Covered Individual to gather additional or supplemental information necessary to evaluate the disclosure. If the CCIO determines that no potential COI exists, the CCIO will inform the Covered Individual in writing of that determination, with a copy to the appropriate official at the Office for Sponsored Research Administration and to the Covered Individual’s department or unit head. If the CCIO determines that a potential COI exists, the CCIO will forward the Project-Specific COI Evaluation Form, along with an analysis of the facts and issues presented, to the ICOIC for review and advice on an appropriate resolution or, if necessary, management of the conflict.

Taking into account any advice given by an ICOIC or by other officers, the CCIO will determine whether a COI exists and, if so, whether it can be managed or must be resolved in order for the research to proceed. The CCIO may proceed to make a determination if no advice is provided by the applicable ICOIC or other officer within fourteen (14) days of transmission by the CCIO of the COI Evaluation Form, provided that this deadline may be extended by the CCIO for good cause and where doing so will not jeopardize the proposed research relationship.

The CCIO shall make one of the following determinations and convey the decision in writing to the Covered Individual, with copy to the appropriate official at the Office for Sponsored Research Administration and to the Covered Individual’s department or unit head:

- (i) No COI exists;
- (ii) A COI exists that is not subject to management by MSM, and the COI must be resolved in order for the proposed research to be conducted under MSM auspices; or
- (iii) A COI exists that is subject to management by MSM.

Where a COI is deemed to be subject to management, the CCIO will promptly arrange a meeting with the Covered Individual to create a Management Agreement.

B. Potential COI Detected in Conjunction with Procedures for Review and Approval of Human Subjects Research by the Institutional Review Boards

The Office for Sponsored Research Administration shall include in the application form required in conjunction with every proposed research project under the jurisdiction of the Institutional Review Boards ("IRBs") questions supplied by the CCIO and designed to prompt reporting of a potential COI. Where a potential conflict is detected, the Covered Individual shall submit a COI Evaluation Form to the CCIO. These procedures shall also be required any time renewal of IRB approval is sought. Except as set out in this subsection (c), such Evaluation Forms shall be processed as provided in Section A, above.

No research described in an IRB application as to which a COI Evaluation Form has been submitted may proceed until the potential COI has been evaluated, approved or disapproved, and resolved or managed. The CCIO shall inform the Covered Individual in writing of any decision involving the COI Evaluation Form, with copy to the IRB with jurisdiction and to the Covered Individual's department or unit head. The IRB retains final jurisdiction over human subjects research and may decline to approve an application on grounds of COI notwithstanding a decision by the CCIO that there is no COI or that a COI is present but capable of being managed.

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

C. Potential COI Disclosed by Inventors of Technologies Licensed by MSM

Before executing a license agreement or other agreement making MSM technology available to another entity, the Office for Sponsored Research Administration and the Office of General Counsel shall cause every inventor of the affected technology to complete a form containing questions supplied by the CCIO and designed to prompt reporting of a potential COI. Where such potential conflicts are detected, the Covered Individual shall submit a full Project-Specific COI Evaluation Form to the CCIO. Because the Policy provides that any such Covered Individual who holds equity in, is an officer or director of, or provides consultative services to an entity that has licensed or otherwise acquired rights to MSM invention(s) will be deemed to have a COI, the CCIO may review all such disclosures without advice from the ICOIC or other officer with jurisdiction. In instances where the Covered Individual discloses a COI, the CCIO will meet promptly with the Covered Individual to create a Management Agreement.

When, subsequent to execution of a license or other applicable agreement, the Office for Sponsored Research Administration and the Office of General Counsel agrees to add technologies to those already covered under the agreement, any additional inventors shall be required to complete the required form to screen for potential conflicts. Where potential conflicts are detected the Covered Individual shall submit a full COI Evaluation Form to the CCIO, who shall process it as specified above.

REPORTING AND REVIEW OF ANNUAL COI EVALUATION FORMS

The CCIO shall create a schedule of required submission dates for MSM employees specifically required by the Policy to submit COI Annual Evaluation Forms. Such Forms shall be designed by the CCIO and where practicable shall be filed electronically. **Any employee who fails to file a required form on or before the date specified by the CCIO other than for good cause (as determined by the CCIO) shall be deemed to be in violation of the Policy and subject to disciplinary action up to and including dismissal.**

The CCIO will review all Annual Evaluation Forms and determine whether or not the information disclosed in each represents a potential COI. Upon making the determination that there is a potential COI, the CCIO will forward the applicable Evaluation Form with a preliminary analysis and recommendation for resolution to the Dean or other officer with analogous administrative authority (“the reviewing officer”) supervising the affected Covered Individual.

The reviewing officer shall issue a decision regarding the disclosure within fourteen days of receipt of the Annual Evaluation Form, provided that the deadline may be extended by the CCIO for good cause. Where the reviewing officer agrees with the CCIO’s analysis, the Covered Individual will be required to recuse him or herself from any MSM activities affected by his or her COI. In situations where recusal of the Covered Individual cannot be effected consistent with his or her MSM duties, the Covered Individual will be required to resolve the COI by divestment of the personal financial interest causing the COI.

Where the reviewing officer disagrees with the CCIO’s conclusion that a COI exists, he or she shall set out the basis for that decision in a memorandum to the President, with a copy to the CCIO and the Covered Individual. The President may accept or reject the reviewing officer’s decision and order such further measures to resolve or manage the COI as the President deems appropriate.

MANAGEMENT OF RESEARCH-RELATED COI

A. Management Principles

The CCIO is responsible for designing appropriate management mechanisms for approved conflict of interest activities (hereinafter referred to as an “approved COI”). The CCIO may seek advice from individuals outside as well as within MSM in proposing such mechanisms.

Questions to consider in constructing an optimal management plan may include:

- Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of MSM?
- Will the research work plan receive independent peer review prior to its initiation?
- Are there mechanisms in place to prevent the introduction of bias into research projects?
- Will the project be supervised or monitored by someone with authority over the investigators and no conflicting interests?
- Are there independent means to verify research results?
- Will data and materials be shared openly with independent researchers? If not, who determines accessibility of such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed literature?
- Will the sponsorship and relevant personal financial and executive interests be disclosed in publications and public presentations of the research results?

- In human subjects' research, what are the protections for human subjects in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting?

The goal in addressing these questions should be to determine the appropriate mode of dealing with any real or apparent conflicts. Possible measures to be taken in managing a COI include, but are not limited to, any of the following:

- Public disclosure of financial interests;
- Reformulation of the work plan;
- Close monitoring of the project; independent review committee;
- Substituting supervisors and/or any other research personnel;
- Divestiture of financial interests;
- Termination or reduction of involvement in the relevant projects;
- Termination of inappropriate student involvement in projects;
- Severance of relationships that pose actual or potential conflicts;
- Separation of the Covered Individual from involvement in human subjects' research in the critical areas of recruitment, inclusion/exclusion evaluation, enrollment, and adverse event evaluation and reporting.

B. Management Agreements

The preferred mechanism for managing research related COI will be the management agreement. The management agreement is an agreement entered into by the CCIO on behalf of the President and by the Covered Individual, setting out the terms and conditions under which the Covered Individual will be allowed to continue MSM activities concurrently with a COI. The management agreement should address all relevant aspects of the conflict of interest, including but not limited to any reformulation or termination of the role of the conflicted covered individual in the MSM activity, any divestitures, any required disclosures and recusals, etc.

The following will be required elements of every management agreement:

- (1) Acknowledgement by the Covered Individual that compliance with the terms of the management agreement, the Policy and these Guidelines is a condition of his or her employment or enrollment at MSM, and that violation of those terms, the Policy or the Guidelines may lead to disciplinary action, up to and including dismissal or expulsion.
- (2) Provision for the CCIO to meet regularly with the affected Covered Individual and his or her department or unit head to review the circumstances of the activities addressed by the management agreement and address questions or concerns.
- (3) Provision for the CCIO to meet annually with the Covered Individual together with the covered individual's lab staff (students, trainees, e.g., postdoctoral fellows, residents, or in some cases junior faculty, and technical staff) to review the facts of the COI under management, to inform the lab staff of any management agreement provisions of which they should be aware, and to provide information on how the lab staff can seek advice and assistance on any concerns they may have related to the COI.
- (4) Agreement by the Covered Individual that the COI will be disclosed in all publications or presentations of research results related to the COI. (The Agreement may, but need not, spell out specific language to be used in such disclosures.)
- (5) Agreement by the Covered Individual that he or she will not disclose confidential research information or intellectual property to the entity with which the Covered Individual has a financial relationship giving rise to the COI ("the related entity") except through the Office for Research Affairs or some other appropriate MSM office or official.

- (6) Agreement by the Covered Individual that he or she will not make MSM space, facilities or resources available to the related entity except as allowed under the MSM Leased Space Policy.
- (7) Agreement by the Covered Individual that he or she will submit to the CCIO for review any consulting agreement, employment agreement or agreement for services between the Covered Individual and the related entity in advance of execution of such agreement.
- (8) Agreement by the Covered Individual that he or she will promptly submit an updated COI Evaluation Form should the circumstances of the Covered Individual's relationship with the related entity change in any material respect.

C. Monitoring

The CCIO may monitor an approved COI, appoint an individual to do so, or appoint a monitoring committee of disinterested faculty members or of individuals from outside MSM. Any person appointed to monitor a conflict who is not a MSM employee must sign a statement acknowledging his or her obligation to maintain the confidentiality of employee personnel records and proprietary information and data, including the Conflicts Evaluation Form. Monitors should be disinterested, free of financial or supervisory ties to the Covered Individual whose conflict is being monitored, and should have or have access to expertise sufficient to allow meaningful review of the conflict being monitored. The CCIO, together with any monitoring committee, will design a monitoring plan that will address the principles set out in Section A, above.

D. Auditing

The CCIO shall conduct random audits of approved COI in order to assure (1) that the individual COI is being managed appropriately, and (2) that any systemic weaknesses in COI review, approval and management at MSM are identified and resolved. All Covered Individuals shall cooperate with such audits, including requests for documentation, and failure to do so shall be deemed a violation of the Policy.

INVESTIGATION AND RESOLUTION OF POLICY VIOLATIONS

Any time the CCIO becomes aware of a potential violation of the Policy or of any other situation that could indicate that MSM research, education and training may have been affected inappropriately by a conflict of interest; the CCIO shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

- A. On receipt of such a report, the CCIO shall notify the General Counsel and the Dean. In consultation with those persons, the CCIO may:
 - (1) Investigate the matter and make a written memorandum of his or her conclusions;
 - (2) Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or
 - (3) Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns and a personal interview with the Covered Individual, who should be informed with specificity of the allegations or concerns that have arisen. While the Covered Individual has a right to know the identity of a person making such

allegations, he or she should be informed that MSM policy prohibits retaliation against a person making such allegations in good faith.

- B. Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that MSM research, education, training, business administration or other performance may have been affected inappropriately by a conflict of interest, the CCIO should take any steps necessary to correct the situation, including and up to disallowance of the original conflict of interest being managed. In addition, where appropriate, the CCIO must consider recommending to the relevant officials the imposition of disciplinary or other action under other appropriate MSM policies, including disciplinary policies for faculty, staff or students. The CCIO, in consultation with the Vice President for Research Affairs, shall have the authority to direct that the research activities of the Covered Individual affected by the COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending amelioration of the Policy violation.
- C. Upon determination that no violation of the Policy has occurred, or otherwise at the conclusion of any investigation conducted under this Policy, all materials generated in the course of such investigation should be placed with the Covered Individual's personnel file or, if a student, with the Office of the Associate Dean for Student Affairs, marked as "confidential" and stored in a secure manner, in order to ensure the confidentiality of these records.

RECORDS CONFIDENTIALITY AND RETENTION

A. Confidentiality

The COI Evaluation Form contains information that may have a direct bearing on a Covered Individual's employment and is considered to be confidential personnel information that should be maintained in a secure and confidential file. The information reported in the COI Evaluation Form is available only to individuals duly charged with the responsibility for review, and may be released only in accordance with and as required by Georgia law or lawful court order.

B. Records Retention

All records relating to the reporting of potential Conflicts of Interest and Commitment, and to the actions taken with respect to those reports, shall be maintained for three years following the expiration of their relevance, or as required by applicable government regulations, whichever is greater.