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	<u>POLICY</u> RESEARCH CONFLICTS OF INTEREST	SUPERSEDES	7-3-2009

**OVERVIEW:**

Relationships between private industry and academic and clinical research endeavors are often essential for fruitful drug and medical device development. Although many of these relationships are constructive, public perception has been undermined by a small minority of academic researchers and clinicians who have been financially compensated by industry for promoting their products. In 1995, the Public Health Service (PHS) agency issued regulations requiring Institutions that receive PHS-funding to develop conflict of interest policies. For this reason, Morehouse School of Medicine and Morehouse Medical Associates, Inc. ("MSM") have instituted research conflicts of interest policies in order to maintain public trust in basic and clinical research by this Institution, as well as serve as a reference to the researcher for maintaining complex and fruitful relationships with industry while maintaining their highest integrity and impartiality in research. In 2011, the Department of Health and Human Services (DHHS) and PHS published amendments to these rules in the "Responsibilities of Applicants for Promoting Objectivity in research for which Public Health Service Funding is Sought (Title 42, Code of Federal Regulations, Part 50, Subpart F) for grants and cooperative agreements; and Responsible Prospective Contractors, Final Rule." The regulations establish new standards and clarify previously established standards for unbiased design, conduct, and reporting of research funded under PHS grants, to be followed by the awardee Institution, and are detailed in this policy.

Conflicts of interest are defined as circumstances that create a risk that professional judgment or actions regarding integrity in research, quality of medical education, or welfare of patients will be influenced by other secondary interests. The severity of the conflict of interest depends on both the probability that professional judgment will be compromised and the resulting potential harm to the integrity of research, medical education or welfare of patients. MSM's research policies have been invoked to maintain public trust and the integrity of research and clinical practice at MSM by managing potential conflicts through disclosure and independent oversight in a transparent and accountable way.

Of particular concern is research involving human subjects. MSM, and its faculty, staff, and students who conduct research involving human subjects, must commit to the safety and welfare of those subjects and the integrity of the research above their own financial interests or the pursuit of personal gain. The safety and welfare of human subjects, institutional integrity and the public trust are the researcher's highest priority. Any conflict that threatens these objectives must be eliminated or strictly managed. The financial interests of investigators must be managed so that they do not adversely affect participant protections or the credibility of the research protections program. Opportunities to profit from research may affect - or appear to affect - a researcher's judgments about which subjects to enroll, the clinical care provided to subjects, even the proper use of subjects' confidential health information.

Accordingly, it is the policy of MSM to regard **all** financial interests in human subjects research as potentially problematic and, therefore, as requiring strict scrutiny. This policy and the related implementing documents of the Research Conflicts of Interest Committee ("RCOIC") establish the rebuttable presumption that an individual who holds a financial interest in research involving human subjects may **not** conduct such research. The intent is not to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research, but rather to ensure that 1) any and every financial interest that might give rise to the perception of a conflict of interest is reported and systematically reviewed, and 2) that the conduct of human subjects research by Interested Investigators is limited to those situations in which the circumstances are compelling. The presumption against financial interests in human subjects' research applies whether the research is funded by MSM, any other public agency, a non-profit entity, or a commercial sponsor, and at every site where the research may be carried out.

In the event of compelling circumstances, a Principal Investigator may be permitted to conduct research involving human subjects. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. When the financial interest is directly related to the research and may be substantially affected by it, the risk is greatest and the bar must be high.

If the research proposal involves research with human subjects, any financial interests associated with the research proposal must be reviewed by the RCOIC prior to final IRB review/approval of the research. RCOIC findings and determinations should guide the IRB's review of any research protocol or proposal, and the IRB may require additional safeguards or demand reduction or elimination of the financial interest. The IRB, in accordance with PHS regulations, will have the final authority to decide whether the interest and its management plan will allow the research to be approved.

**PURPOSE:**

This policy establishes standards and procedures to ensure that the design, conduct and reporting of sponsored research and educational activities will not be compromised by any conflicting financial interest on the part of the Principal Investigator(s) or Key Personnel by implementing a system for the disclosure, evaluation, management, reduction, and/or elimination of potential conflicts of interest. This policy complies with federal regulations regarding objectivity in research (42 C.F.R Part 50 Subpart F and 45 C.F.R Part 94). These regulations decide the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS-funded grants, cooperative agreements, research contracts (but not Phase 1 SBIR or STTR program grants), and subawards where the originating sponsor is the DHHS.

It is the policy of MSM that an employee who is responsible for the design, conduct, or reporting of a sponsored research project under the auspices of MSM must disclose financial or other interests that are, or may be perceived to be, related to the project and, when appropriate, work cooperatively with the Vice President for Research Affairs ("VPRA") and Chief Compliance and Internal Audit Officer ("CCIO") to develop and implement plans to manage, reduce or eliminate conflicts of interest. Existing or potential conflicts of interest must be disclosed prior to the submission of a proposal for funding. Actual or potential conflicts of interest that develop during the conduct of a funded project must be disclosed as soon as the conflicts occur. If MSM determines that such interests may affect the design, conduct, or reporting of the project, steps will be taken to manage or eliminate the conflict.

The approval of the MSM Office of General Counsel and the CCIO is also required for employees who are pursuing sponsored research agreements or licensing agreements for intellectual property with entities where they have equity or serve as a board member, officer or key employee.

This policy deals exclusively with financial interests related to research. Conflicts of interest related to an individual's status as an employee of MSM are discussed in MSM's Individual Conflicts of Interest Policy, and conflicts of interest related to the Institution are discussed in MSM's Institutional Conflicts of Interest policy.

### **SCOPE OF POLICY:**

This policy applies to all medical staff, faculty, staff, residents, interns, students, and trainees of MSM. It supplements the existing conflict of interest policies of MSM:

- Institutional Conflict of Interest
- Individual Conflict of Interest
- Policy and Guidelines for Interactions with Pharmaceutical, Biotechnology, Medical Device, and Hospital and Research Equipment Supply Industry

### **DEFINITIONS**

- Financial Conflict of Interest (FCOI)** - means a Significant Financial Interest that could directly or significantly affect the design, conduct, or reporting of PHS-funded research.
- Financial Interest** – anything of monetary value, whether or not the value is readily ascertainable. Includes any of the interests in a private sponsor of research held by the Principal Investigator or the Principal Investigator's spouse, domestic partner and/or dependent children within the 12 months prior to the date of the offer of research funding.
- Institutional Responsibilities** - an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- Key Personnel** - any person, other than the Principal Investigator, who is independently responsible for the design, conduct or reporting of sponsored research or educational activities conducted in whole or in part at MSM.
- Management Plan** - the written plan for the management, reduction or elimination of a potential or actual conflict of interest.
- Principal Investigator** - The Project Director or Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- Research** - a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
- Significant Financial Interest (SFI)** - A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
4. The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available); provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research Institute that is affiliated with an Institution of higher education. At a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the monetary value must be disclosed in order to determine whether the travel constitutes an FCOI with the PHS-Funded research.

Significant financial interest does NOT include:

1. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
2. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
4. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
5. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

6. A percentage of income received from the Veteran's Administration Medical Center as part of physician reimbursement for MSM faculty; or
  7. Interest in a business entity if the business entity is an applicant for Phase I support under the Small Business Innovation Research (SBIR) Program.
- H. **Small Business Innovation Research (SBIR) Program** - the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

## **POLICY**

- A. When a research project is sponsored by a nongovernmental entity:

All Principal Investigators and Key Personnel must disclose any Significant Financial Interests related to the research project or that could reasonably appear to be affected by the sponsored research project.

- B. For research programs and educational activities sponsored by the federal government, Principal Investigators and Key Personnel must disclose their Significant Financial Interests that are related to the sponsored research project or educational activities or that could reasonably appear to be affected by the sponsored research project or educational activities.
- C. When it is determined that a sponsored research project may reasonably appear to be affected by a financial interest disclosed pursuant to paragraph A or B above, MSM shall take steps to reduce, manage or eliminate the conflict to assure objectivity.

## **PROHIBITED ACTIVITIES**

The following activities are prohibited because they present conflicts of interest that are contrary to MSM's central mission:

- A. Academic Freedom Restrictions
1. Investigators may not enter into secrecy or confidentiality agreements if the agreement:
    - a. Impacts the evaluation of a student, faculty member, or other employee.
    - b. Delays the protection of intellectual property rights or the fulfillment of degree requirements by more than the time contractually allowed for pre-publication review.
  2. Investigators may not agree to arrangements that permit a sponsor to interfere in the scientific analysis or publication of research results or conclusions.
  3. Professional evaluation of faculty, postdoctoral appointees, or staff, or academic evaluation of students may not be based upon participation in (or refusal to participate in) a Principal Investigator's or Key Personnel member's outside activities.

## B. Human Subjects Research

1. Principal Investigators and Key Personnel involved in research with human subjects may not:
  - a. Directly or indirectly accept any gifts or payments from the sponsor of the research except for payments that are commensurate with their efforts on behalf of the sponsor.
  - b. Buy or sell common stock (as opposed to mutual funds) in the sponsor of the research until their involvement in the research ends and the results of the research are published or otherwise disseminated to the public.
2. Principal Investigators and Key Personnel involved in research with human subjects may not perform clinical trials or testing on licensed-products for companies in which MSM holds equity as part of a licensing-related transaction where the technology was developed at MSM.

## C. Intellectual Property

1. An employee who is involved in negotiating a license on behalf of MSM may not have a Significant Financial Interest or other interest in the business entity that is a party to the negotiations.
2. An employee shall not accept a position on the board of directors of a licensee in which MSM holds an equity interest.

## **REQUIREMENTS FOR THE DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

All Principal Investigators and Key Personnel must disclose their financial interests and the interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s) as indicated in Exhibit A:

1. Prior to engaging in research related to the PHS-funded grant or new employment at Morehouse School of Medicine.
2. At least annually during the period of award.
3. Within thirty days of discovering or acquiring a Significant Financial Interest.

## **ROLES AND RESPONSIBILITIES**

### A. Research Conflict of Interest Committee (RCOIC)

1. The RCOIC shall review the positive disclosures of financial interests from Principal Investigators and Key Personnel to determine if a conflict of interest exists, and if so, how to manage, reduce, or eliminate the conflict as described in Exhibit A.
2. The RCOIC members are appointed by the President for three year terms.
3. The RCOIC shall be comprised of seven (7) voting members to include members of the faculty, clinical departments, Office for Sponsored Research Administration, and administrative offices. Other non-voting 'ad-hoc' participants may assist in discussions and decisions as needed.
4. A committee member shall be recused from discussion and voting on a particular case if:

- a. The committee member has a compelling personal interest in the case (such as research or academic collaboration with the individual whose case is under consideration); or
- b. The committee member has a financial interest in the case under consideration.

B. Chief Compliance and Internal Audit Officer (CCIO)

The CCIO is responsible for supporting the RCOIC, and the IRB, ensuring that their decisions, recommended actions and reasons therefore are fully documented and implemented, and that MSM complies with its obligations under state and federal law and this policy.

C. Vice President for Research Affairs (VPRA)

The VPRA is responsible for ensuring that no federal funds are expended before the federal sponsor receives notification when it is determined that a conflict of interest exists.

D. Institutional Review Board (IRB)

1. The IRB will not approve any research involving human subjects where the Principal Investigator or a Key Personnel member has submitted a positive financial disclosure until the RCOIC reviews the disclosure and provides its recommendations to the IRB.
2. The IRB will review recommendations it receives from the RCOIC regarding the management, reduction or elimination of conflicts of interest to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program.

E. Principal Investigators

Principal Investigators are responsible for disclosing all Significant Financial Interest as required by this policy and Exhibit A; ensuring disclosures by Key Personnel, when required by this policy and Exhibit A; and complying with the provision in Section F, below.

F. Principal Investigators and Key Personnel

Principal Investigators and Key Personnel are responsible for the following:

1. Disclosing all Significant Financial Interests when required by this policy and Exhibit A.
2. Upon request, preparing a statement for the VPRA and/or the CCIO regarding how they intend to manage, reduce, or eliminate a conflict when it is determined to be necessary by the RCOIC.
3. Cooperating with the RCOIC, VPRA and/or CCIO in providing reports and documents as requested.
4. Conducting the sponsored research or educational activity in a manner that will avoid a perception that the project could be influenced or biased by conflicts of interest.
5. Fulfilling all conditions necessary to manage a conflict of interest as determined by the RCOIC, VPRA, and /or CCIO, and in the case of research involving human subjects, the IRB.

## G. Subrecipients

Subrecipients (subgrantees, contractors, or collaborators) are responsible for providing contractual assurances to MSM that the subgrantee, contractor, or collaborator investigators are in compliance with the NIH's regulations on conflict of interest in the PHS-funded research prior to the execution of the subcontract or within 60 days of identification of new FCOI. This contractual obligation includes a requirement that the subrecipient report to MSM's office for Sponsored Research Administration the following information for any financial conflict of interest of subrecipient personnel: (a) Subrecipient contract number, (b) Name of subrecipient 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 report, (e.g. managed, reduced or eliminated). The Office of Sponsored Research Administration will forward a copy of each subrecipient report, to the PHS funding agency along with a copy to the PI and the Chief Compliance and Internal Audit Officer.

## **TRAINING BY INVESTIGATORS**

Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstance, when:

- MSM FCOI policies change in a manner that affects Investigator requirements.
- An Investigator is new to MSM.
- MSM finds an Investigator noncompliant with this FCOI policy or management plan.

## **RECORDS**

### A. Confidentiality

All records and information provided by a Principal Investigator and Key Personnel for the purpose of disclosure and management of a research conflict of interest and all official records of disclosure and management of a conflict of interest shall be considered personal information. The unauthorized disclosure of any such information by an employee, except as required for official business purposes or by law, shall be grounds for discipline.

### B. Records Retention

Official records regarding individual conflicts of interest shall be maintained by the Office of Compliance and Internal Audit and retained for 7 years or as otherwise required by state and federal law.

## **VIOLATIONS**

- A. Failure to file disclosures or provide information required by this policy or to comply with any conditions or restrictions imposed by the RCOIC, the VPRA, or CCIO constitute violations of this policy, which may be grounds for discipline pursuant to the appropriate MSM, State and Federal policies.
- B. State and/or federal regulations may require reports to the project sponsor regarding violations of this policy. Project sponsors may impose additional sanctions including the suspension or termination of an award or debarment from receiving future awards.

MSM is required to conduct a retrospective review in those cases of non-compliance with PHS regulations but is not required to report the review to the PHS Awarding Component. MSM is required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

## **FURTHER INFORMATION**

Questions about this policy and the procedures should be directed to the VPRA or the CCIO.

## **REFERENCES**

### A. Office of Compliance and Internal Audit:

1. MSM Individual Conflict of Interest Policy.
2. MSM Institutional Conflict of Interest Policy.
3. MSM Policy and Guidelines on Interactions with Pharmaceutical, Biotechnology, Medical Device, and Hospital and Research Equipment Supply Industry.

### B. Federal Laws and Regulations:

1. Code of Federal Regulations
  - a. Title 21, Part 54, Financial Disclosure by Clinical Investigators.
  - b. Title 42, Part 50, Section 50.604, Institutional Responsibility Regarding Conflicting Interests of Investigators.
  - c. Title 45, Part 94, Responsible Prospective Contractors.
  - d. Title 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS-Funding is Sought.
2. U.S. Code Title 41, Sections 51-58, Anti-Kickback Act of 1986.
3. OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

## **Exhibit A**

## **PROCEDURES FOR REPORTING, REVIEWING, AND MANAGING CONFLICTS OF INTEREST IN RESEARCH**

### **INTRODUCTION**

This document describes the process for reporting, reviewing and managing potential conflicts of interest in sponsored research and educational activities, including the process for disclosing Significant Financial Interests, the referral of positive disclosures to the Research Conflict of Interest Committee ("RCOIC"), the process for reviewing, positive disclosures, and the establishment of management plans for

managing, reducing or eliminating conflicts of interest in sponsored research and educational programs, including research programs involving human subjects.

All Principal Investigators and Key Personnel must disclose their financial interests and the financial interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s) (as indicated below) whenever submitting a proposal for a sponsored project.

### **INITIAL DISCLOSURE BY PRINCIPAL INVESTIGATORS**

- A. Principal Investigators shall complete the Research FCOI form through an electronic disclosure process:
  - 1. Prior to engaging in research related to any PHS-funded grant or new employment at Morehouse School of Medicine,
  - 2. At least annually during the period of the award,
  - 3. Within thirty days of discovering or acquiring a Significant Financial Interest.

### **SUPPLEMENTAL DISCLOSURE BY PRINCIPAL INVESTIGATORS AND KEY PERSONNEL**

Principal Investigators and Key Personnel who make a positive disclosure must also submit a supplemental form of documentation to describe the nature of the financial interest related to the sponsored project. A positive disclosure is made when the Principal Investigator or a Key Personnel member reports a Significant Financial Conflict of interest in or related to the research. At that point the FCOI Administrator will enter this information into eRA Commons.

### **INITIAL DISCLOSURE BY SUBRECIPIENTS**

- A. The RCOIC will review each positive disclosure to determine whether an actual or potential conflict of interest exists. The factors and documents relied upon by the RCOIC will be addressed in the meeting minutes. The RCOIC may consider the following in determining whether a conflict of interest exists:
  - 1. The amount of the financial interest,
  - 2. The role of the reporting individual with respect to the relevant entity,
  - 3. How closely the financial interest is related to the subject of the research,
  - 4. Whether the research involves human subjects,
  - 5. Whether and to what extent students are involved in the research, and
  - 6. Any other factors that may be relevant.
- B. If the RCOIC determines that a potential or actual conflict of interest exists, the RCOIC will consider:
  - 1. Whether the nature of the conflict could potentially influence or bias the outcome of the research,

2. Whether any harm could come to research subjects if a conflict biased the design, conduct or results of the research,
  3. Whether the potential conflict should be managed, reduced, or eliminated. If none of these options is viable, the RCOIC will consider whether the research should proceed.
- C. If the RCOIC determines there is a potential or actual conflict, the RCOIC will transmit its recommendation as follows:
1. When the case involves research with human subjects, the RCOIC will transmit its recommendation to the Institutional Review Board. The IRB will review the recommendation to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program. After receiving input from the IRB, the RCOIC will transmit its recommendation to the VPRA and the CCIO, who will jointly issue a decision regarding the RCOIC's recommendation.
  2. In all other cases, the RCOIC will transmit its recommendations directly to the VPRA and the CCIO for decision.
- D. If the VPRA decides that a potential or actual conflict of interest exists, the reporting individual will be notified and may be asked to submit a proposed management plan (see "Management Plans" below).

## **REPORTING**

Prior to expending any funds under a PHS-funded research project, MSM shall provide to the PHS Awarding Component an FCOI report via eRA Commons regarding any Investigator's Significant Financial Interest found to be conflicting and ensure that a management plan has been implemented in accordance with PHS regulations within 60 days of identification. In cases in which financial conflict of interest are identified and eliminated prior to the expenditure of PHS-awarded funds, no report to the funding agency is necessary.

## **MANAGEMENT PLANS**

Management Plans are developed to identify actions necessary to ensure objectivity throughout the research project. Components of such plans may include but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Depending on the nature of the SFI, MSM may determine that additional interim measures are necessary with regard to the Investigator's participation in PHS-funded research.

1. Some actions that may be taken to manage conflicts of interest include:

- a. Requiring additional disclosures to relevant MSM committees,
- b. Non-participation of the Principal Investigator/Key Personnel member in any business transactions between the Principal Investigator/Key Personnel member and the business entity/entities,
- c. Disclosure and/or review of relevant publications prior to submission,
- d. Review of financial report on a regular basis by the VPRA and the CCIO,
- e. Submission of reports on a pre-determined basis to the VPRA and the CCIO,
- f. Annual (or other pre-determined timeline) meeting with the VPRA and the CCIO.

2. If the VPRA and the CCIO deem it necessary, they will appoint a monitor or management subcommittee to oversee implementation of the management plan and management of the conflict of interest. The members of the management subcommittee may include individuals from outside of MSM where the VPRA and the CCIO determine that outside expertise is required to manage the conflict.

3. In these cases, the monitor or subcommittee will meet with the Principal Investigator/Key Personnel member and review and approve the management plan. The plan will be signed by the monitor or chair of the management subcommittee and the Principal Investigator/Key Personnel member. Any dispute between the Principal Investigator/Key Personnel member and the monitor or subcommittee will be referred to the RCOIC for a recommended resolution and the VPRA and the CCIO for decision.

4. The monitor/subcommittee and the Principal Investigator/Key Personnel member will agree upon a timeline for reporting and reviewing documentation relevant to the oversight responsibility of the monitor/subcommittee. Documentation will vary depending upon the nature of the research and the conflict.

5. The monitor/subcommittee will review the report and relay the report and any additional relevant information to the RCOIC. Any revision of the plan or apparent deviation from or noncompliance with the plan will be relayed to the RCOIC. If the issues cannot be resolved within a reasonable time frame, the RCOIC will subsequently refer the matter to the VPRA and the CCIO for action.

## **RETROSPECTIVE REVIEW**

A retrospective review will be completed within 120 days of the determination of noncompliance and review the Investigator's activities and the PHS-Funded research project to determine whether any PHS-funded research conducted during the time period of noncompliance, was biased in the design, conduct, or reporting. Based on the results of the retrospective review, MSM will do the following:

- (i) Update the previously submitted FCOI report specifying actions that will be taken to manage the financial conflict of interest moving forward,
- (ii) Notify the PHS awarding component if bias is found and submit a mitigation report,
- (iii) Submit FCOI reports annually,
- (iv) Determine whether additional interim measures are necessary.
- (v) Monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

## **PUBLIC ACCESSIBILITY**

Information concerning identified FCOIs held by Senior/Key Personnel (as defined by regulations) will be publicly accessible prior to the expenditure of funds within five calendar days of a written request and remain available for three years from the date the info was most recently updated. The request must include a named recipient and return address with a physical street address, P.O. Boxes will not be accepted. The information provided may include:

1. Name and role of the Principal Investigator and Key Personnel on the project.
2. Title of the research and a short abstract of the project.
3. Nature of the conflict and the value of the financial interest, or a statement that the interest is one whose value cannot be readily determined.