University of Mississippi Medical Center  
Policy on Conflicts of Interest  

Executive Summary  

- Conflicts of interest associated with commercial relationships have the potential to bias the management of grants and contracts, the conduct of research, the selection of equipment and supplies, provision of patient care, the promotion or appointment of faculty, staff or students, and the selection of individuals or organizations to perform various tasks.

- This policy is intended as a resource to employees for the structuring of current and future commercial relationships, and to provide assurance to the faculty, the University, and most importantly the public, that such relationships have been examined and will be conducted in a manner consistent with institutional and public values.

- The simple disclosure of commercial relationships and/or financial interest does not imply any wrongdoing.

- Employees and academic/clinical units will report conflicts of interest and significant financial interests annually, at the time of application for PHS-funded research and within 30 days of discovering/acquiring a new financial interest.

- The COI committee shall review disclosures to determine whether a conflict of interest related to an employee’s institutional responsibilities reasonably appears to exist. The purpose of the review process shall be to identify and resolve conflicts of interest or the appearance of conflicts of interest at the earliest possible stage. Management plans will be developed and implemented as needed to manage financial conflicts of interest.
I. Purpose

The University of Mississippi Medical Center (UMMC) and its employees are committed to conducting themselves and University activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to conflict of interest and objectivity in research, education, community service and clinical care.

Conflicts of interest associated with commercial relationships have the potential to bias the management of grants and contracts, the conduct of research, the selection of equipment and supplies, provision of patient care, the promotion or appointment of faculty, staff or students, and the selection of individuals or organizations to perform various tasks. Commercial relationships also have the potential to negatively impact the training of students and residents. UMMC employees should avoid using, or appearing to use, an official position for personal gain, giving unjustified preferences, or losing sight of the need for efficient and impartial decision making in the institution’s method of operation. However, UMMC does recognize the critical importance of commercial relationships in promoting the missions of the institution.

The purpose of this policy is to provide guidelines for identifying and disclosing potential conflicts, procedures for reviewing and addressing conflicts that may occur and establishing sanctions for the violation of this policy. This policy is intended to comply with the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Funding is sought (42 CFR part 50 Subpart F) (August 25, 2011) (Financial Conflict of Interest Regulations”). The policy is meant to promote transparency and to ensure accountability in our stewardship of institutional resources. It is not the intent of this policy to withhold opportunities to further an employee’s professional competency or render valuable service to the community, nor does this policy intend to imply that the disclosure of conflicts of interest and/or financial interest constitute any wrongdoing. Instead, this policy is intended as a resource to employees for the structuring of current and future conflicts of interest, and to provide assurance to the faculty, the University, and most importantly the public, that such relationships have been examined and will be conducted in a manner consistent with institutional and public values.

II. Policy

University employees are expected to make a reasonable effort to determine whether their relationships and activities create or appear to create a conflict of interest. Employees and academic/clinical units will report conflicts of interest and significant financial interests annually, at time of application for PHS-funded research and within 30 days of discovering/acquiring a new conflict of interest. Potential conflicts of interest will be managed as outlined in the following sections. The Institutional Compliance Committee is charged as the COI Committee.

III. Persons Covered

This policy applies to employees of the University when, on behalf of the University, they are:
(1.) responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity; or
(2.) teaching or advising; or
(3.) in direct contact with suppliers or potential suppliers to the University; or
(4.) have direct or indirect influence over purchasing decisions or contracts, or otherwise have official involvement in the purchasing or contracting process; or
(5.) employed by outside entities (associated companies or otherwise) and acting within the realm of their major expertise for which they are employed by the University.

IV. Definitions

A. Commercial Relationship: For the purpose of this policy, a commercial relationship is an association between a UMMC employee and an outside entity in which there is a potential for personal gain by doing business with (compensated or not) or having ownership in this outside entity or affiliates of the entity. This association becomes reportable to the COI Committee when the outside entity becomes involved with the employee’s institutional duties.

B. Conflict of Interest: A commercial relationship in which an employee’s personal interest (financial or otherwise) may or may appear to influence or compromise the employee’s professional judgment or ethics.

C. Employee: Any faculty (fully-, partially-, or non-salaried) member, or faculty agent, including faculty serving as investigator or co-investigator of human subject or animal research, staff, fellow, trainee, contractor, or administrator.

D. Family: For the purpose of this Policy family includes an employee’s spouse, siblings, parents, children or domestic partner.

E. Associated Employee: Any employee or an employee whose immediate family has a commercial relationship or a significant financial interest in an entity that would appear to reasonably be affected by University business or research.

F. Associated Company: For the purpose of this policy, the “associated company” applies to the entity doing business with UMMC or funding human subject or animal research, which would appear to benefit from the conduct or the outcome of the proposed activity.

G. Activity, Proposed Activity: This includes teaching, clinical, administrative and purchasing activities. This policy also refers to the research being conducted, or the UMMC business or employee’s institutional responsibilities being carried out, which may be affected by an employee’s commercial relationship, as the “activity” or the “proposed activity”.

- When the “activity” is applied to conducting research, this term includes:
  - designing research
  - directing research or serving as the principal or co-investigator

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• enrolling research subjects (including obtaining subjects’ informed consent)
• making decisions related to eligibility to participate in research
• analyzing or reporting research data
• submitting manuscripts concerning the research for publication.

H. Compelling Circumstance Disclaimer: The institution will presume, in order to assure that all potentially problematic circumstances are reviewed, that an associated employee with personal interest may not conduct the activity in question. This rule is not intended to be absolute: an associated employee may rebut the presumption by demonstrating facts that, in the opinion of the COI Committee, constitute compelling circumstances (e.g., the employee is uniquely qualified by virtue of expertise and experience and the activity could not otherwise be conducted as safely or effectively without that employee). The associated employee may be permitted to conduct the activity under conditions specified by the COI Committee, and/or the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC). Conditions that insure effective management and credible oversight of the research must be applied.

I. Summary Report: A description of the commercial relationship involved in a proposed activity and the recommendations of the COI committee for management, reduction, or elimination of the conflict. This report will be provided to the COI Official to assist in making the final determination on the matter. The summary report will also be provided to the authorities having jurisdiction over the activity as determined by the COI committee.

J. Institutional Responsibilities: Employee’s professional responsibilities on behalf of Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as IRB or DSMB.

K. Investigator: Projector Director/Principle Investigator as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, including persons who are subgrantees, contractors, or collaborators, or consultants (or, in the case of PHS contracts, subcontracts, collaborators or consultants.)

V. Reporting and Management of Conflicts of Interest

Full disclosure is necessary for successful implementation of the conflicts of interest policy. The responsibility for avoiding conflicts of interest rests with the UMMC employee. Employees will disclose any relationships which could reasonably be expected to create the appearance of a conflict of interest. Minimum reporting guidelines are outlined in this policy.
The COI Committee will be responsible for review of Conflict of Interest Disclosure forms and reported or suspected violations of this policy. The COI Committee will report findings and recommendations to the Vice Chancellor’s designee, the associated employee’s appropriate authority and, if applicable, the IRB, IACUC the Office of Research, and Grants and Contracts. The COI Committee shall have representation from the IRB.

A. Conflict of Interest Reporting Guidelines:

The COI committee will annually review and revise all reporting limits as appropriate.

The following guidelines should be used to determine reporting:

a. A significant financial interest with a single associated company exists in the prior year or is expected to exist in the next twelve months (from the time of reporting)

b. Reasonable costs for conducting research or educational activities are not considered a significant financial interest

c. If two or more family members are employed by UMMC, each employed individual will be considered separately for purposes of reaching the reporting limit. For example, if no single individual in the family meets the reporting threshold, then no one in the family is required to disclose even if the combination of two individuals exceeds the threshold. However, if any individual family member exceeds the threshold for reporting, then every family member must disclose the relationship.

d. In the case of a relationship between a single associated company and a specific academic or clinical unit, the existence of a significant financial interest is determined on the basis of the total benefit received by the relevant academic or clinical unit. The reporting requirement shall be the responsibility of the appropriate administrator of that unit.

e. Report any situation for which it is felt that disclosure and review is needed to assure high standards of integrity and ethics.

B. Reportable issues:

a. Consulting activities with an associated company. This may include but is not limited to fees, honoraria (including from a third party, if the original source is an associated company), gifts, emoluments, or “in kinds” compensation whether for consulting, lecturing, travel (including purpose of the trip, identity of sponsor, destination and duration), service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research or educational activity (as specified in the research or education agreement) in excess of the reporting limit.

b. Paid authorship
c. Receipt of gifts, meals, loans, special favors, entertainment, or paid (by non-UMMC agency) educational activities by an associated company to an individual employee for any purposes other than in the direct support of research or educational activities. 1

d. Equity interest, including stock options, of any amount in a non-publicly-traded and associated company (or entitlement to the same). 1

e. Equity interests (or entitlement to the same) in a publicly-traded associated company that exceed the reporting limit in value or represent more than a 5% ownership interest in that company. 1

f. Royalty income in an amount greater than the reporting limit, or the right to receive future royalties under a patent license or copyright, where the activity is directly related to the licensed technology or work. 1

g. Non-royalty payments greater than the reporting limit, or entitlements to payments in connection with the activity that are not directly related to the reasonable cost of the research (as specified in the research agreement between the sponsor and the institution). This includes any bonus or milestone payments to the employee in excess of reasonable costs incurred, whether such payments are received from an associated company or from the institution.

h. Service as an officer, director, or in any other fiduciary role for an associated company, whether or not compensation is received for such service. 2

i. Paid expert testimony for legal or medical case review. 2

j. Independent faculty ownership of any clinical facilities.

k. Compensation from employment by other than UMMC in the employee’s field of expertise. 2

l. Other potential conflict of interest may be identified and added to the list by the COI committee.

1. Employees must make their best reasonable estimates of expected income in determining whether salary, royalties or other payments constitute "significant financial interests."

2. UMMC policy requires that any employment outside this institution must first be approved by the Vice Chancellor for Health Affairs. See UMMC Employee handbook.

C. Exceptions: Significant financial interests do not include the following:

a. Interest of any amount in publicly traded, diversified mutual funds as long as the investigator does not directly control the investment decisions made.

b. Payments to the institution, or via the institution to the employee, that are directly related to reasonable costs incurred in the conduct of the activity as specified in the research or educational agreement(s) between the sponsor and the institution.

c. Salary and other payments for services from the institution.

d. Income from seminars, lectures or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a

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medical center, or a research institute that is affiliated with an institution of higher learning.

D. Procedures for Reporting Conflicts of Interest:

a. The disclosure form will be used either to declare that there are NO conflicts of interest or significant financial interest in outside entities, or to report any/all conflicts of interest, with or without financial interest, in which the employee and/or the employee’s family may have and which may give the appearance of a conflict of interest.

b. Disclosure forms will be required annually. (The time of reporting and the definition of the year to be reviewed will be determined by the COI official and/or the COI Committee.)

c. The disclosure form will be accessible through the Annual Compliance Training site and can be completed during this same training session. The disclosure will also be available on the Office of Integrity and Compliance and the Office of Research site on the UMMC Intranet.

d. For any disclosure that involves a contractual relationship, a copy of the contract should be submitted to the Office of Integrity and Compliance.

e. When a research project is submitted to the Office of Research, IRB or the IACUC for review at initial or continuing review, the investigator will be asked to disclose any conflict of interest. The Office of Research, IRB or the IACUC will forward any information that it receives concerning a significant financial interest in research to the COI Committee, the Office of Integrity and Compliance. The IRB or IACUC shall not grant final approval on the research project until the Office of Integrity and Compliance reports that conflicts have been resolved or that conditions for management have been established.

f. When a request is made to any appropriate UMMC authority for the purchase of equipment or procurement of services, the requesting employee will disclose any commercial relationship or significant financial interest held with the company for which the equipment or service is being sought. The purchasing authority will forward any disclosure it receives to the Office of Integrity and Compliance. The request will not be approved until the COI Committee reports that conflicts have been resolved or that conditions for management have been established.

g. Any new commercial relationship or significant financial interest should be reported promptly. Complete and submit an updated Conflict of Interest Disclosure form prior to submission and approval of any activity that may pose a conflict of interest. The disclosure form should be submitted to the Office of Integrity and Compliance. Those disclosures found to involve an associated employee will be forwarded to the COI committee for review.

E. Management of Conflict of Interest:
a. Disclosures found to involve a conflict of interest will be forwarded to the COI committee. The COI committee shall review disclosures to determine whether a conflict of interest reasonably appears to exist and if the conflict of interest is related to PHS-funded research (directly or significantly affects the designs conduct or reporting of the research).

b. The purpose of the review process shall be to identify and resolve conflicts of interest or the appearance of conflict of interests at the earliest possible stage and to develop and implement management plans, as needed, to manage the conflict of interest.

c. The following are examples of conditions or restrictions, which may be applied to manage, reduce or eliminate conflict of interest:

1. Public disclosure or disclosure to the appropriate authorities;
2. Monitoring by independent reviewers;
3. Modification of research plan, program or activity;
4. Disqualification from participation in portions of the activity;
5. Severance of the relationships that create actual or potential conflicts.

- In any case in which a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required, the Investigator involved will be required to:
  - Disclose the FCOI in each public presentation of the results of the research, and
  - To request an addendum to previously published presentations.

a) Classification and Oversight of Conflict of Interest:

Depending on the circumstances of the relationship, a potential conflict of interest can be classified as acceptable, pending institutional/administrative review, or not acceptable.

1) Acceptable: Granted based on acceptable conditions, which manage, reduce or eliminate the conflict. In the event of compelling circumstances (see Compelling Circumstances Disclaimer), an associated employee may be permitted to conduct the activity in question. The following circumstances are considered and evaluated prior to acceptable classification:

- Nature of the activity.
- Magnitude of the interest and the degree to which it is related to the activity.
- Extent to which the interest could be directly and substantially affected by the activity.
- For research activities, the degree of risk to the human subjects involved that is inherent in the research protocol.
- The extent to which the interest is amenable to effective oversight and management.
In the instances that an associated employee is permitted to conduct the activity in question, the COI Committee will determine adequate oversight. A summary report will be prepared describing the nature, the amount of the conflict of interest and the COI Committee’s determination concerning the conflict and recommendations for management of the conflict. This summary report will be submitted to the associated employee, the associated employee’s appropriate administrator, and institutional officials as determined by the COI Committee.

UMMC shall also provide disclosure of significant financial interests in human subject research and animal research as follows:

- To state and federal officials, as required by statute or regulations;
- To sponsors funding the research;
- To the editors of any publication to which an associated employee submits a manuscript concerning the research;
- And in any substantive public communication of the research results, whether oral or written.

UMMC shall require that human subject research consent forms disclose the existence of any significant financial interest held by an associated employee (principal or co-investigator) conducting the human subject research. The IRB will have final approval of consent documents involving human subject research.

The Office of Integrity and Compliance will maintain conflict of interest records and disclosure forms.

2) **Pending Institution/Administrative Review:** (Pending status) A conflict of interest found by the COI Committee shall be reviewed by the COI Official prior to final determination.

   (a) The COI Committee shall inform the associated employee who will then be given the opportunity to meet with the COI Committee for further review of the apparent conflict prior to final determination. As a first principle, the COI Committee shall encourage the associated employee to minimize the potential for conflict of interest by reducing or eliminating the interest or the associated employee’s direct involvement in the activity.

   (b) The COI Committee will submit a summary report describing the nature of the conflict of interest, the amount of the significant financial interest and the COI Committee recommendations to the COI Official.

   (c) The COI Official will make the final determination, after careful review. The COI Official will either recommend acceptability based on conditions or restrictions imposed to manage the conflict, acceptability based on compelling circumstances, or non-acceptability.

   (d) Final determination, whether acceptable or not acceptable, and a copy of the COI Committee summary report will be forwarded to the associated employee, the associated employee’s appropriate administrators and, if applicable, the IRB, IACUC, Office of Research, and Grants and Contracts.
(3) **Not Acceptable:** Conflict of interest found by the COI Committee and COI Official to be beyond the means of adequate management and oversight. The proposed activity can not be allowed to proceed. Notification of this determination will be submitted to the associated employee, the associated employee’s appropriate administrator, and if applicable, the IRB or IACUC, Office of Research, Grants and Contracts, and the sponsor of the research activity.

**IV: Confidentiality**

The disclosure forms will be considered strictly confidential; the information disclosed in the forms is available only to the individuals duly charged with the responsibility for review of conflict of interest.

**V: Sanctions and Appeals**

A complaint or a charge of a violation of this policy shall be made in writing and filed by the appropriate administrator having specific authority over the employee or activity, which is the subject of the complaint or charge. Reports of violations will be processed by the COI Committee and reported to the COI Official.

UMMC will make every effort to protect the rights and reputation of all parties involved including the individual(s) who, in good faith, report(s) the perceived violation.

If the investigation substantiates a violation, findings will be reported to the COI Official and, if applicable, the sponsoring agency of the associated employees’ research activity. If warranted, an investigation for violations of the UMMC Policy on Conduct of Research, and any other UMMC policy that may apply will be conducted.

A retrospective review will be completed and documented within 120 days of UMMC’s determination of noncompliance for interests not disclosed in a timely manner or previously reviewed or whenever a FCOI is not identified or managed in a timely manner.

Violations of this policy include, but are not limited to, failure to file a conflict of interest form, intentionally filing an incomplete, erroneous, or misleading disclosure form, or failing to provide additional information as required by the COI Committee or Official. Appropriate disciplinary actions will be taken against violators of this policy, up to and including termination.

UMMC may pursue legal proceedings for recovery of damages, misappropriated funds or property. Sanctions may also be imposed as the result of violations of other UMMC policies, such as the Policy on Conduct of Research.

Appeals for sanctions imposed due to violations of this policy may be made to the Vice Chancellor for Health Affairs.
Appeals of Not Acceptable classification of conflict of interest may be made to the Vice Chancellor for Health Affairs.

VI. References:

6. Final Rule on Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Funding is sought (42 CFR part 50 Subpart F) (August 25, 2011).