

Conflicts of Interest Policy

UMMC Policy and Procedure Manual	A-OIC-GEN-GEN-PO-00011
Subject: Conflicts of Interest Policy	
Revised Date: 12/15/2017	Effective Date: 11/30/2017
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Executive Summary

- Conflicts of Interest and Related Party Transactions 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 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, related party transactions and financial interests at time of hire, annually, at the time of application for Public Health Services (PHS) funded research and within 30 days of discovering/acquiring a new financial interest.
- The Conflicts of Interest (COI) Working Group 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. Unresolved conflicts will be referred to the Conflicts of Interest (COI) Committee.¹ Management plans will be developed and implemented as needed to manage financial conflicts of interest.

¹ The Institutional Compliance Committee serves as the Conflict of Interest Committee.

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 conflicts of interest and objectivity in research, education, community service and clinical care.

Conflicts of Interest Policy

Conflicts of interest, associated and not 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 Conflicts 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, but all interest in any outside entity should be reported. Employees and academic/clinical units will report conflicts of interest, related party transactions and financial interests at time of hire, 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.

III. Persons Covered

This policy applies to employees of the University when they are:

- A. responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity; or
- B. teaching or advising; or
- C. in direct contact with suppliers or potential suppliers to the University; or
- D. have direct or indirect influence over purchasing decisions or contracts, or otherwise have official involvement in the purchasing or contracting process; or
- E. employed by outside entities and acting within the realm of their major expertise for which they are employed by the University; or

Conflicts of Interest Policy

F. a covered Institutional Official.

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 or institutional gain by doing business with (compensated or not) or having ownership in this outside entity or affiliates of the entity.

B. **Conflicts of Interest:** A commercial relationship in which an employee's or an employee's family's personal interest (financial or otherwise) **may** or **may not appear to** influence or compromise the employee's professional judgment or ethics.

C. **Employee:** Any faculty (full-time or part-time) member, or faculty agent, including faculty serving as an investigator or co-investigator of human subject or animal research, or any staff, fellow, trainee, contractor, or administrator.

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

E. **Family:** For the purpose of this policy, family includes an employee's spouse, siblings, parents, children or domestic partner and spouses of any of the above.

F. **Related Party:** Family, business partner or any entity in which an employee or a member of his or her family or business partner has a beneficial interest

G. **Related Party Transaction:** any business deal, transaction, agreement or arrangement in which a Related Party and UMMC or any affiliate is a participant.

H. **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 does or does not appear to benefit from the conduct or the outcome of the proposed activity.

I. **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
- enrolling research subjects (including obtaining subjects' informed consent)
- making decisions related to eligibility to participate in research

Conflicts of Interest Policy

- analyzing or reporting research data
- submitting manuscripts concerning the research for publication.

J. 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 other-wise 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 ensure effective management and credible oversight of the research must be applied.

K. 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.

L. Institutional Responsibilities: Employee's professional responsibilities on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, operational responsibilities or decision-making, and service on panels such as IRB or DSMB.

M. Institutional Official: Includes vice chancellor, associate vice chancellor, dean, department chair, institutional chief, center and institute directors, chair of the IRB, director of the Human Research Office, executive director of research, chair of the COI Committee, and any other UMMC official or employee so designated by the vice chancellor.

N. Institutional Conflicts of Interest: A situation in which UMMC's research, education or healthcare mission activities, or its institutional reputation, may be compromised because of external financial or business relationships held at the institutional level that may bring financial gain to the institution, any of its units, or the individuals covered by this policy.

Institutional Financial Conflicts of Interest may occur when UMMC: receives royalties from a technology invented by staff and licensed to a commercial entity; starts a company based on technology developed at UMMC; approves participation by its lenders to serve as a member of the board of directors for a commercial entity; enters a joint venture, collaboration or partnership with a commercial entity.

O. Investigator: Project Director/Principal 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 sub-grantees, contractors, collaborators, or consultants (or, in the case of PHS contracts, subcontracts, collaborators or consultants.)

V. Reporting and Management of Conflicts of Interest

Conflicts of Interest Policy

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 Working Group will be responsible for review of COI 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, and the Office of Sponsored Programs. The COI Committee shall have representation from the IRB.

A. Conflicts of Interest Reporting Guidelines:

- The reporting limit, as determined by the COI Committee, is zero dollars.
- The following should be used to determine reporting:
 - A 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)
 - Reasonable costs for conducting research or educational activities are not considered a financial interest
 - In the case of a relationship between a single associated company and a specific academic or clinical unit, the existence of a financial interest is determined on the basis of the total benefit received by the relevant academic or clinical unit.
 - 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:

- Consulting activities. 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).
- Paid authorship
- 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.²
- Equity interest, including stock options, of any amount in a non-publicly-traded and associated company (or entitlement to the same).²
- 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.
- Any Related Party Transaction.
- Royalty income, or the right to receive future royalties under a patent license or copyright, where the

Conflicts of Interest Policy

activity is directly related to the licensed technology or work.

- Non-royalty payments, 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.
- Service as an officer, director, or in any other fiduciary role for an associated company, **whether or not** compensation is received for such service.³
- Paid expert services for legal or medical case review.
- Independent faculty ownership of any clinical facilities.
- Compensation from employment by other than UMMC
- Other potential conflicts of interest may be identified and added to the list by the COI Working Group.

² Employees must make their best reasonable estimates of expected income in determining whether salary, royalties or other payments constitute "financial interests."

³ UMMC policy requires that any employment outside this institution must first be approved by the Chief Human Resource Officer and the COI Working Group. See UMMC Employee handbook.

C. Exceptions: Financial interests do not include the following:

- Interest of any amount in publicly traded, diversified mutual funds as long as the investigator does not directly control the investment decisions made.
- 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.
- Salary and other payments for services from the institution.

D. Procedures for Reporting Conflicts of Interest:

- The disclosure will be used either to declare that there are NO conflicts of interest or to report all conflicts of interest in which the employee and/or the employee's family may have.
- Disclosures will be required at time of hire, at least annually, within thirty days of a change or acquiring a new conflict of interest, or before engaging in any new outside employment. (The time of reporting and the definition of the year to be reviewed will be determined by the COI Committee.)
- Any new commercial relationship or financial interest should be reported promptly. Complete and submit an updated COI Disclosure form prior to engaging in any activity that may pose a conflict of interest. The

Conflicts of Interest Policy

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.

- The disclosure must be completed during Annual Compliance Training. The disclosure form is available on the Office of Integrity and Compliance and the Office of Sponsored Programs sites on the UMMC Intranet.
- For any disclosure that involves a contractual relationship, a copy of the contract should be submitted to the Office of Integrity and Compliance.
- The Office of Sponsored Programs, IRB or the IACUC will forward any information that it receives concerning a financial interest in research to 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 there are no conflicts, conflicts have been resolved, or that conditions for management have been established.
- When a research project is submitted to the Office of Sponsored Programs or IRB, the investigator will be asked to disclose any conflicts of interest.
- When a request is made for the purchase of goods or services, the requestor or anyone involved in the procurement process shall disclose any potential conflicts of interest related to the company. If a requestor or anyone involved in the procurement process discloses a conflict, they will recuse themselves from the process. If the person cannot recuse themselves, the purchasing authority will forward any disclosure it receives to the Office of Integrity and Compliance. The request will not be approved until the Office of Integrity and Compliance reports that there are no conflicts, conflicts have been resolved, or that conditions for management have been established.

E. Management of Conflicts of Interest:

- Disclosures involving a conflict of interest will be forwarded to the COI Working Group. The COI Working Group 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 design conduct or reporting of the research).
- 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 and to develop and implement management plans, as needed, to manage the conflicts of interest.
- The following are examples of conditions or restrictions, which may be applied to manage, reduce, or eliminate conflicts of interest:
 - a. Public disclosure or disclosure to the appropriate authorities;
 - b. Monitoring by independent reviewers;
 - c. Modification of research plan, program, or activity;
 - d. Disqualification from participation in portions of the activity;

Conflicts of Interest Policy

- e. 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 a COI that was not managed or reported by the Institution as required, the Investigator involved will be required to:
 - a. Disclose the COI in each public presentation of the results of the research, and
 - b. To request an addendum to previously published presentations.
 - Conflicts of interest will require management if any of the following criteria are met:
 - a. The conflict of interest will adversely affect the protection of participants in terms of the criteria for IRB approval, or
 - b. The conflict of interest will adversely affect the integrity of the research, or
 - c. Any situation for which it is felt that disclosure would compromise high standards of integrity and ethics.

The COI Working Group will recommend a management plan, if required. The COI Committee determines that the management plan is adequate. The evaluation and management plan of a conflict of interest will be documented.

If the COI Working Group determines that a research-related COI exists, the IRB or IACUC will be notified that the researcher has a conflict of interest and the management plan of that conflict has been developed by the COI Committee. The IRB or IACUC will then have the authority to determine if the research can be approved.

F. Classification and Oversight of Conflicts 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.

- 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:

- a. Nature of the activity.
- b. Magnitude of the interest and the degree to which it is related to the activity.
- c. Extent to which the interest could be directly and substantially affected by the activity.
- d. For research activities, the degree of risk to the human subjects involved that is inherent in the research protocol.

Conflicts of Interest Policy

e. The extent to which the interest is amenable to effective oversight and management.

f. 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 conflicts 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.

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

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

h. UMMC shall require that human subject research consent forms disclose the existence of any 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.

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

- Pending Institution/Administrative Review:

(Pending status) A conflict of interest found by the COI Working Group shall be reviewed by the COI Committee prior to final determination.

a. The COI Working Group shall inform the associated employee who will then be given the opportunity to meet with the COI Working Group for further review. As a first principle, the COI Working Group shall encourage the associated employee to minimize the potential for conflicts of interest by reducing or eliminating the interest or the associated employee's direct involvement in the activity. To the extent possible, the proposed activity cannot proceed until a final determination is made.

b. The COI Working Group will submit a summary report describing the nature of the conflicts of interest, additional information obtained from the associated employee, the amount of the financial interest and recommendations to the COI Committee.

c. The COI Committee will make the final determination, after careful review. The COI Committee will make a determination of: 1) acceptability based on conditions or restrictions imposed to manage the conflict, 2) acceptability based on compelling circumstances, or 3) non-acceptability.

d. Final determination, 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 Office of Sponsored Programs and the IRB or IACUC.

- Not Acceptable: Conflict of interest found by the COI Committee to be beyond the means of adequate management and oversight.

Conflicts of Interest Policy

- a. The proposed activity cannot be allowed to proceed.
- b. Notification of this determination will be submitted to the associated employee and the associated employee's appropriate administrator, and if applicable, the IRB or IACUC, and Office of Sponsored Programs and the sponsor of the research activity.
- c. The Office of Integrity and Compliance will maintain effective conflicts of interest records and disclosure forms.
- d. Appeals of Not Acceptable classification of conflicts of interest may be made to the Vice Chancellor for Health Affairs.

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 or notification of conflicts of interest.

V: Education

Education on Conflicts of Interest shall be completed at the following times:

- Upon hire
- Annually – during Annual Compliance Training
- Immediately when this policy is revised in a manner that changes requirements
- Immediately when an employee is non-compliant with this policy, when appropriate

Subrecipients of PHS funded projects choosing to abide by UMMC's COI policy will be required to complete training prior to expenditure of funds and at least annually thereafter.

VI: Suspected Policy Violations

- a. 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. Any complaint or charge of a violation of this policy should be reported to the Office of Integrity and Compliance.
- b. 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.
- c. If the investigation substantiates a violation, findings will be reported to the COI Committee and, if applicable, the sponsoring agency of the associated employees' research activity. If warranted, an investigation for violations of the UMMC Policy on Research, and any other UMMC policy that may apply will be conducted.

Conflicts of Interest Policy

d. 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 COI is not identified or managed in a timely manner.

VII. Sanctions and Grievances

A. Sanctions may be imposed as the result of violations of this policy and/or other related UMMC policies, such as the Policy on Research. UMMC may pursue equitable relief, including but not limited to, recovery of damages, misappropriated funds or property and/or an injunction.

B. Appropriate disciplinary actions will be taken against violators of this policy, in accordance with the Policy on Sanctions for Plan Violations (UMMC Compliance Plan, attachment 2), up to and including termination.

Failure to Disclose a Conflict of Interest

The appropriate sanction for failure to disclose a Conflict of Interest will be determined based upon whether the failure to disclose is a result of Egregious or Non-egregious conduct exhibited by an employee.

Egregious: The reasonable person standard (i.e. if a reasonable person knows or should know that a Conflict of Interest exists and knowingly fails to report the conflict) will be used in determining appropriate sanctions. Knowingly failing to disclose a Conflict of Interest constitutes Egregious conduct. Failure to adhere to a Management Plan constitutes Egregious conduct. Willful refusal by an employee to take action as requested by the Conflict of Interest Committee or Working Group constitutes Egregious conduct.

Egregious conduct will result in appropriate sanctions, up to and including termination.

1. First Offense - Written Warning
2. Second Offense - Suspension & Final Written Warning
3. Third Offense - Termination

Sequential sanctions are not mandatory. UMMC maintains the authority to decide which sanction most effectively addresses the severity of the violation.

Non-egregious: Non-egregious conduct is conduct that does not involve a knowing and willful failure to disclose a Conflict of Interest, such as when a reasonable person may not have known that it was necessary to disclose a potential Conflict of Interest. An example would be a failure to redisclose an identical potential Conflict of Interest that was previously disclosed in years past.

Non-egregious conduct will result in appropriate sanctions.

1. First Offense - Verbal Warning/Counseling
2. Second Offense - Written Warning.
3. Third Offense - Suspension

Conflicts of Interest Policy

C. Grievances for sanctions imposed due to violations of this policy may be made within 30 days of notification of sanction in accordance with the UMMC's Faculty and Staff Handbook.

VI. Record Keeping

UMMC maintains records related to disclosures and management of conflicts of interest for at least three years from completion of the activity or longer if required by law, regulation or other applicable policy.

VII. References:

- AAMC. "Protecting Patients, Preserving Trust, Promoting Progress", December, 2001.
- Mississippi Code of 1972, as amended, §25-4-103, et. seq.
- AAMC – AAU. "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Research", February 2008
- AAMC. "Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council", for consideration June 18-19, 2008.
- AAMC. Industry Funding of Medical Education. Report of an AAMC Task Force", June 2008.
- 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).
- Association for the Accreditation of Human Research Protections Programs, Inc. Tip Sheet 10: Financial Conflict of Interest for Researchers and Research Staff.

Updated: 11/2015; October 2017