Institutional Conflicts of Interest Policy

Introduction: The Medical University of South Carolina has an obligation to the citizens of South Carolina and to the public at large to conduct its activities properly. Accordingly, the University must provide clear standards aimed at preventing financial conflicts of interests (FCOI) from compromising its objectivity in the performance of its responsibilities. This Policy on Institutional Conflicts of Interest (the “Policy”) concerns conflicts that arise from the University’s financial relationships with external entities. It is intended to provide guidance to the Board of Trustees, administrators, faculty and staff to enable them to recognize and deal with institutional conflict of interest (ICOI), both real and perceived, that may arise in the course of business relationships between the University and private entities outside of the University.

Consistent with its obligation to uphold the public trust, the University is committed to extending the reach of its research and learning activities beyond the campus community and to enriching the education of its students and the professional lives of its faculty and staff through public engagement. The University’s mission of research, teaching and service is well served through the creation of collaborations with people and entities outside the University that better enable all concerned to meet the challenges of an increasingly complex world. Collaboration, particularly where external financial sponsorship is involved, may result in the creation of inherent tensions between the University’s role as an independent creator and evaluator of knowledge and the interest of the parties to the collaboration in achieving a positive outcome. Where such tensions have or appear to have the potential to interfere with independent decision-making on the part of University personnel or to compromise the objectivity of research, the University must examine whether an institutional conflict of interest exists.

Such conflicts of interest may be individual conflicts of interest involving the personal financial relationships of University trustees, administrators, faculty, staff or students with entities that conduct business with the University. Individual financial conflicts of interest are regulated by the MUSC/MUHA – Conflicts of Interest Policy, originally dated February
13, 2009 and any subsequent modifications thereafter and generally are outside the scope of this Policy except in cases where individual employees with wide administrative authority possess personal financial interests that intersect with their University duties, as explained below.

This Policy defines institutional conflicts of interest, provides examples and sets out rules for the guidance of University trustees, administrators, faculty and staff. The Policy is intended to help the Institution identify and examine potential conflicts, and manage such conflicts through disclosure, separation of responsibilities, and other measures as appropriate. It is hoped that by increasing awareness of the potential for such conflicts and providing a process to address them, this Policy will both protect the integrity of the University and will encourage University personnel to enter into and conduct University activities involving engagement with outside entities with transparency, confidence and integrity. However, this Policy cannot anticipate every situation that may present a potential Institutional conflict of interest, and so the intent is to articulate general principles and guidance that will inform the ongoing review of diverse Institutional activities.

Gifts, pledges, and solicitation of gifts to MUSC are important to its missions. However, no charitable donation is allowed to be contingent upon the outcome of any research or business transaction conducted at or by the Institution. The Institution hereby affirms that it will not solicit or accept gifts that in any way limit the ability of its investigators to conduct and/or report the results of research in accordance with the highest scientific, medical, professional, and ethical standards. Nor will the Institution solicit or accept gifts (including gifts to support research) that are contingent upon any particular business or purchasing decision(s). All gifts to MUSC must be handled in accordance with the institutional fund raising and gift acceptance guidelines and should be forwarded to the appropriate administrative office for processing and record-keeping purposes. Faculty and staff members are accountable for adhering to institutional gift policies. Solicitation and receipt of gifts and other industry support on behalf of the Institution should be consistent with the MUSC/MUHA Conflict of Interest Policy, the MUSC/MUHA Industry Relations Policy and the South Carolina Ethics, Government Accountability and Campaign Reform Act.

In some cases, the Institution may enter into arrangements involving the donation of all or a portion of capital equipment, with the expectation that the equipment will be used for research or patient care. Such arrangements are appropriate, provided they do not limit the professional independence of faculty and staff.

**Policy:** It is the policy of MUSC that, in pursuing its missions of education, research, and clinical care, the University must conduct its business free of improper influence resulting from Institutional conflicts of interest. Potential conflicts of interest between the Institution’s primary missions or objectives and its financial interests must be identified, reviewed, and properly managed or eliminated. Such Institutional conflicts of interest are not inherently unethical; however, they may introduce risks to the integrity of the Institution.
This Policy should not be interpreted to allow anything that is prohibited in the MUSC/MUHA Conflict of Interest Policy or the MUSC/MUHA Industry Relations Policy.

Definitions: For purposes of this Policy, the following definitions apply:

Institutional Conflicts of Interest (ICOI): An institutional conflict of interest exists where a financial relationship between the University and an external entity compromises the integrity of institutional decision-making. Such conflicts may arise in situations where an Institutional Official holds administrative or decision-making authority of such a scope that the University cannot engage in a questioned activity or relationship independent of his or her involvement, and at the same time that person has personal financial interests that relate to the proposed activity or relationship.

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

For purposes of this Policy, University employees shall be defined as trustees, officers, faculty, administrators, and staff, including all full-time, part-time, temporary, and contract employees. MUSC affiliates, e.g., MUSC Physicians, MUSC Foundation and MUSC Foundation for Research Development, shall adopt a policy substantially similar to this Policy. Financial interests shall include anything of monetary value, including salary or other payments for services, equity interests, and intellectual property rights of the University employee or of his or her immediate family members. Immediate family members shall include an employee's parents, spouse, siblings, children, stepchildren, and grandchildren. Interests in mutual funds or similar type of investments where the employee has no control over the selection of holdings shall not be considered a personal financial interest under this Policy.

Covered Individuals: This Policy covers all senior-level personnel who are in a position to make decisions for the University that affect the following:

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

Institutional Officials: For the purpose of this Policy, Institutional Officials are the covered individuals. The University will be vigilant especially of these officials in the review of their individual Annual Conflicts of Interest Disclosure and may require additional information for the purpose of assessing Institutional Conflicts of Interest. These include:
• MUSC President;
• MUSC Provost;
• MUSC Associate Provosts;
• MUSC Vice Presidents;
• Academic Deans;
• Associate Deans;
• Department Chairs;
• Division Chiefs; and
• The Chief Executive Officer (CEO), Chief Financial Officer (CFO) and Chief Operating Officer (COO) of the Medical University Hospital Authority

General Standards and Requirements

Reporting Requirements. Outlined below are reporting requirements for Institutional Officials and Institutional financial interests.

This policy mandates that Institutional Officials report financial and/or fiduciary interests so that ICOIs are identified and addressed in accordance with this Policy and in accordance with the MUSC/MUHA Board of Trustees’ Policy on Conflicts of Interest originally dated February 13, 2009 and approved policy modifications that follow.

Institutional Officials must report their family’s financial interests annually through the standard individual conflicts of interest disclosure and disclosures must be updated within 30 calendar days after their financial and/or fiduciary interest changes. Reporting shall include:

• Equity and/or ownership interests in publicly traded for-profit organizations of any amount. Not included are: 1) equity or ownership interests in mutual funds; and 2) equity or stock holdings for which the Institutional Official has no role or influence over trading decisions;

• Equity (including stock, options, warrants, and the like), ownership, or founders' interests in non-publicly traded companies;

• Any fiduciary interest, such as service on the board of directors of a for-profit and/or not-for-profit organization; and,

• Any income, including royalty, equity, consulting fees or other payments, from for-profit and/or not-for-profit organizations.

Reporting Institution’s Financial Interests. The following financial interests of the Institution must be reported to the Conflict of Interest Office no less than annually in
accordance with procedures coordinated by MUSC's Conflict of Interest Officer, and must be updated within 30 calendar days after actual changes in financial and/or fiduciary interests are known. Specifically, all elements of MUSC shall report the following to MUSC's Conflict of Interest Officer:

- Equity and ownership interest(s) worth more than $100,000 in any and all publicly-traded, for-profit organizations, except for interests held in the Institution’s endowments, and those interests where Institutional Officials have no role in trading decisions;

- Equity and ownership interests of any amount in any for-profit and/or not-for-profit organization that is not publicly traded;

- Gifts of $100,000 or more from any for-profit organization or philanthropic unit associated with a for-profit and/or not-for-profit organization; and,

- Payments, including royalty payments, resulting from technology transfer, licensing, and business activities such as Institutional consulting or service agreements that, for each arrangement, have the potential to exceed $100,000 per year. Clinical care income and tuition income are not included as Institutional interests.

Sanctions for Violations. Violations of this Policy, including the failure to avoid a prohibited activity or disclose a conflict of interest in a timely manner, will be dealt with in accordance with applicable policies and procedures that may include disciplinary actions up to and including termination of employment.

Review Responsibility. ICOIs related to research not involving human subjects are reviewed by the Institutional Conflicts of Interest Committee. ICOIs related to human subjects research will be reviewed by an appropriate MUSC Institutional Review Board as well as the Institutional Conflicts of Interest Committee. The MUSC Institutional Conflicts of Interest Committee is appointed by the President and the Vice President for Academic Affairs and Provost, Medical University of South Carolina. These two MUSC Officers will charge this Committee accordingly. A draft of the Committee’s Charter and Operating Guidelines will be submitted for administrative approval shortly after this Policy is approved.

Institutional Conflicts of Interest Committee Members. It is the responsibility of the President and Vice President cited above to select the members of this Committee. The members will be between three and five in number, and will not be employees of MUSC or its affiliates. It is strongly suggested that the Committee be composed of individuals who (a) can conduct objective reviews, (b) are knowledgeable collectively about the mission and funds flow of academic medical centers, and (c) have a well-grounded understanding of the principles that constitute institutional conflicts of interest. All members will sign appropriate confidentiality statements/agreements.
The assessment in the reviews must consider whether the financial and/or fiduciary interests reported in accordance with this Policy have the potential to appear to affect any of the following:

- Safety of human research subjects;
- Safety of patients; and
- Integrity of research

The standards and evaluation criteria do not vary by funding or regulatory oversight; additionally, the same standards apply to reviews of the financial interests of the Institution and of the financial and/or fiduciary interests held by Institutional Officials.

**Making Recommendations.** The review of a specific institutional conflict of interest case may result in one of three recommendations:

- No institutional conflict of interest. The arrangement does not represent a significant actual, potential, or perceived institutional conflict of interest that needs to be managed;

- Manageable institutional conflict of interest. The arrangement can be managed with required changes. In cases determined by the Institutional Conflicts of Interest Committee to be manageable, the committee will recommend one or more management measures. These may include, but are not limited to:
  1) effective recusal from decision-making regarding the proposed arrangement by the financially interested Institutional Official and disclosure of the recusal to the appropriate individuals implementing the recusal;
  2) reduction in the magnitude of the financial and/or fiduciary interest;
  3) disclosure of the financial interest in relevant publications, presentations, human subject consent forms, clinical procedure or other consent forms, educational material, etc.;
  4) oversight by a disinterested senior individual or by a committee of senior level, disinterested individuals; and/or,
  5) other measures as deemed appropriate.

- Unmanageable institutional conflict of interest. The arrangement is not manageable and either the activity may not proceed or the financial interest must be eliminated or reduced in a timely manner. In cases judged to be unmanageable, eliminating or reducing the financial interest is preferable to prohibiting the proposed activity. The reviewing bodies and the Institution should generally give precedence to activities that carry out Institutional missions over conflicting financial interests.
In all cases reviewed, the Institutional Conflicts of Interest Committee must retain documentation of the review in accordance with established guidelines. In cases that are considered to be an Institutional Conflict of Interest, a Management Plan must be developed to resolve the conflict, and the implementation and oversight of the Plan must be reviewed periodically by the designated management team with reporting to the Conflict of Interest Office to assure compliance.

All recommendations of the Institutional Conflicts of Interest Committee are presented to the MUSC Vice President for Academic Affairs and Provost, and the MUSC President for a decision. The decision is communicated by the President or the President’s designee to: 1) the individuals affected; 2) the Chair of the Institutional Conflicts of Interest Committee through the MUSC Conflict of Interest Officer; and, 3) the Chair of the IRB through the Director of the Office of Research Integrity when human subjects research is involved.

For any ICOI issue involving human subjects research, the IRB of record will have final authority to decide whether the interest and its management, if any, allows the human subjects research to be approved.

To ensure efficiency, the Institutional Conflicts of Interest Committee is authorized to develop guidelines and procedures for specific categories of ICOI that present minimal risk to the integrity of the research and to human research participants, and that can be handled administratively by the Conflict of Interest Officer with pre-defined management plans and documentation.

**Institutional Investment Assets, including Endowment.** The Institution’s endowment includes assets received from philanthropy, investment, and other sources. The Institution hereby affirms that the individuals charged with managing the investments and endowments of the Institution will not communicate with Institutional Officials or Institutional researchers concerning the conduct and interpretation of ongoing or planned research performed at the Institution for the purpose of influencing investment decisions. Maintaining this robust "firewall" is essential for ensuring that the core activities of the Institution are not affected, or perceived to be affected, by the Institution’s interest in maximizing the value of the endowments. If an individual becomes aware of a situation in which there appears to be a conflict of interest involving philanthropic gifts, solicitation of gifts, or management of the endowments, the individual must notify the appropriate Compliance Officer and/or the MUSC Conflict of Interest Officer who will ensure that a thorough review of the arrangement is conducted, and if necessary, will refer the matter to the Institutional Conflicts of Interest Committee.

**Implementation.** The MUSC Conflict of Interest Officer is responsible for procedures to implement this policy.
Appendix A: Examples of Institutional Conflicts of Interest

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

Institutional Conflicts of Interest Examples. The following examples are not intended to be exhaustive:

1) Seeking to influence the award or terms of a University contract, including but not limited to research contracts, with an external entity because of a past, present or future gift from the external entity.

2) Seeking to influence a University research review committee (such as Institutional Animal Care and Use Committee (IACUC) or an Institutional Review Board (IRB)) to grant concessions or exceptions in reviewing or monitoring a research project involving technology in which the University has an equity interest.

3) Seeking to influence a University research review committee (such as IACUC or IRB) to grant concessions or exceptions in reviewing or monitoring a research project sponsored by an external entity in which the University has a financial interest.

4) Involvement by a University official in decisions affecting the terms and conditions of a faculty member’s University employment when the University official has made a personal financial investment in the faculty member’s start-up company.

5) Involvement by a University official affecting the terms and conditions of University business relationships with a University faculty member’s start-up company when the University official has made a personal financial investment in that start-up company.

6) Involvement by a University official in approving the investment of University funds in an entity in which that official holds a personal financial interest.

Potential Institutional Conflicts of Interest Examples. The following examples are not intended to be exhaustive:

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

3) Where the University, through technology licensing activities or otherwise, holds a significant equity interest in a publicly traded sponsor of research at the University and University Official(s) responsible for managing that equity interest are also involved in decisions concerning the conduct of University research sponsored by the entity.

4) Appointment of a University official with broad administrative authority to serve with or without compensation in either a personal or representative capacity as an officer, director, or scientific advisory board member of a sponsor of research conducted at or under the auspices of the University.

Allocation of laboratory or office space by a University academic department in a manner that unduly favors investigators whose research is sponsored by an entity that has provided the department with gifts.