MUSC Research Conflict of Interest Committee Guidelines
(version 7/30/09)

Introduction

An important goal of the Medical University of South Carolina is to make scientific discoveries that will benefit the sick and the suffering. For many years, the faculty and staff have worked hard to achieve this goal. In 1980, the United States Congress explicitly sanctioned and facilitated this process with the passage of legislation designed to stimulate the commercialization of university inventions by permitting academic institutions and scientists to benefit financially if their federally sponsored research led to commercial products. Moreover, during the past decade the rate of growth of biomedical research has outpaced federal funding, compelling universities and hospitals to develop alternative sources of revenue to support the expenses associated with their educational, research and clinical missions.

Effective interaction between universities conducting research and industry is essential to ensure the rapid application of scientific discoveries to the needs of the nation and to maintain the international competitiveness of domestic industry. Nonetheless, prudent stewardship of public funds includes protecting integrity of sponsored research from being compromised by the personal financial interests of an investigator who may be responsible for the design, conduct, or reporting of sponsored research.

These guidelines define general MUSC policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, and university service. Their purpose is to protect the credibility and integrity of the University's faculty and staff so that public trust and confidence in the University's sponsored activities is ensured.

In accordance with Federal regulations as prescribed by 42 CFR Part 50 Subpart F, the University has a responsibility to manage, reduce, or eliminate any conflicts of interest that may be presented by a financial interest of any investigator. Thus, the University requires that investigators disclose any financial interest that would reasonably appear to be affected by sponsored research.

Definitions

The definition of terms used in describing conflicts of interest and referenced in the Annual Conflict of Interest Disclosure as well as in other related documents are as follows:

(1) A Conflict of Interest in science refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research. For purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.
(2) **Investigator** means the principal investigator/project director, co-principal investigator, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term "investigator" includes the investigator's immediate family as defined below.

(3) An **Associated Entity** of an Investigator means any trust, organization, or enterprise other than the University or any affiliated hospital over which the Investigator alone or together with his/her immediate family exercises a controlling interest.

(4) A **Business** or company means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes, but excluding the University, any affiliated hospital, any private medical practice, or any other entity controlled by, controlling, or under common control within the MUSC enterprise.

(5) **MUSC Enterprise** includes the Medical University of South Carolina (MUSC), Medical University Hospital Authority (MUHA), as well as the MUSC Affiliates, e.g., University Medical Associates (UMA).

(6) **Immediate Family Members** include the employee's parents, spouse, siblings, children, stepchildren, and grandchildren. In responding to conflict of interest survey questions, "you" and "your family" include both you individually and your family as defined here.

(7) **Clinical research** means any research or procedure involving human subjects in vivo or the use of patient samples for the development of diagnostic tests. It includes early clinical studies, evaluative research and clinical trials. It does not include an Investigator's participation in the design of a clinical study for which he is subsequently neither a participant nor an author.

(8) **Financial Interest** is defined as anything of monetary value received either directly by you as the employee or by a family member from any business or company. Excluded is any salary, royalties, stipends, honoraria, reimbursement for expenses, or any other remuneration from the MUSC enterprise. Also excluded is interest income, investment income, or other personal income that is not related to your MUSC sanctioned activities.

---

**Guidelines**

Disclosures of individual and institutional Conflicts of Interest (COI) are made through a variety of venues, including the Annual Conflict of Interest Survey. The disclosures that are related specifically to research are processed for review through the MUSC Research Conflict of Interest Committee (RCOI). The RCOI may receive disclosures related to research through the Annual COI Disclosure Process, the Institutional Review Board, the Office of Research and Sponsored Programs (ORSP), and/or by a variety of MUSC Officers and administrators who request a review for potential or real conflicts. These requests are initially reviewed by the MUSC/MUHA Triage Group as part of the MUSC-enterprise Conflict of Interest process.
It is the RCOI Committee's responsibility to review these requests in a timely manner, to maintain confidentiality, and to communicate their recommendations, findings and actions to the requesting unit and/or impacted unit in either detailed or summary form, as appropriate, and to copy the written committee deliberations to the responsible University Officer. The RCOI Committee shall include a current member of the Faculty Senate.

In 2009, an annual conflict of interest disclosure and review process was implemented for all part-time and full-time faculty and staff of the MUSC enterprise. This process involves the investigator as well:

1. As an MUSC-enterprise employee, each Investigator is required to complete the Annual COI Disclosure Survey (2009 edition).

   The following four (4) questions refer to any company that does business with the MUSC Enterprise and in which you or a family member may have a material role or a financial interest. To the best of an Investigator's knowledge:

   Are you involved in purchasing or procurement decisions that involve this company?

   Do you prescribe, use or implant products, e.g., drugs or devices, made by this company?

   Have you received a 2008 IRS Form 1099, W-2 or K-1 from this company?

   Do you have a role in any regulatory activities of the MUSC enterprise that involve this company?

   The following three (3) questions refer to any company with whom you or a family member may have a material role or a financial interest. To the best of an Investigator's knowledge:

   Do you have intellectual property rights, e.g., patents or trademarks, that are held, licensed or optioned to this company?

   Do you serve as a compensated consultant for this company or in any other way advise investors with respect to research outcomes of clinical trials involving drugs or medical devices?

   Does this company sponsor or in any way support research activities in which you are identified as an investigator?

In addition to the Annual Conflict of Interest Disclosure Survey, each Investigator who has Significant Financial Interest requiring disclosure shall complete a Significant Financial Interest Disclosure Form and submit the Form with the proposal and Proposal Data Sheet ("The Blue Sheet") to the Office of Research and Sponsored Programs.

1. "Significant" Financial Interest is defined by federal regulations as an equity interest that, when aggregated for the Investigator and the Investigator's immediate family meets both of the following tests: exceeds $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and represents a five percent or more ownership interest in any single entity. In completing the IRB Application Form for research
involving human subjects, e.g., clinical trials, this threshold does not apply; any and all conflicts of interest must be reported to the IRB.

2. As required by Federal regulations, all Significant Financial Interests must be disclosed annually and updated as appropriate. Whenever a new conflict of interest arises or when a significant change occurs concerning an existing disclosure, a new disclosure form must be completed and submitted for review either in advance of the anticipated change in situation or within 30 days of the event.

3. A conflict of interest exists when the RCOI reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The Committee shall then determine what conditions or restrictions, if any, should be imposed by the institution to manage the perceived or real conflicts.

4. Prior to final consideration by the RCOI, the Investigator, in cooperation with his/her Department Chair shall develop and present to the RCOI a Conflict of Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any conflict of interest presented by a Significant Financial Interest Statement. The Resolution Plan may address such issues as:

- Public disclosure of significant financial interests;
- Review of research protocol by independent reviewers; or,
- Monitoring of research by independent reviewers.

5. The RCOI shall review and approve the Resolution plan, add conditions or restrictions, including the following:

- Modifications of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests; or,
- Severance of relationships that create conflicts of interests.

6. If the RCOI determines that imposing the above referenced conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, the RCOI may recommend that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Vice President for Academic Affairs and Provost shall make the final decision regarding resolution.

7. The approved Resolution Plan shall be incorporated into a Memorandum of Understanding between the Medical University of South Carolina and the faculty member that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. A Memorandum of Understanding shall be signed by the Investigator and the Vice President for Academic Affairs and Provost. Conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines and all required reports regarding the conflict of interest submitted to the sponsor.
prior to expenditure of any funds under an award. The PHS requires the University to make
similar reports to the PHS Awarding Component on subsequently identified conflicts found by
the University (but not the nature of the interest or other details) and assure that the Interest has
been managed, reduced, or eliminated within sixty (60) days of identification. NSF only
requires the University to report conflicts which cannot be satisfactorily managed, reduced, or
eliminated.

8. Records of investigator financial disclosures and of actions taken to manage conflicts of
interest shall be retained by the Office of Research and Sponsored Programs. Records of all
financial disclosures and all actions taken by the RCOI will be maintained for at least three
years from the date of submission of the final expenditures report (s) for the applicable project
(s) or, where applicable, from other dates specified in State law, 45 CFR 50 Subpart F or by
other federal funding or oversight agencies.

9. Whenever an Investigator has violated this policy or the terms of the Memorandum of
Understanding, the RCOI shall recommend sanctions, which may include disciplinary action
ranging from a public letter of reprimand to dismissal and termination of employment. If the
violation results in a collateral proceeding under University policies regarding misconduct in
science, then the RCOI shall defer a decision on sanctions until the misconduct in science
process is completed. The RCOI's recommendations on sanctions shall be presented to the
Investigator's appropriate University official who, in consultation with the Vice President for
Academic Affairs and Provost, shall enforce any disciplinary action. If the research activity
was funded by a PHS awarding component, the University will promptly notify the PHS
awarding component of the corrective action taken or to be taken. After consideration of the
situation and as necessary, the PHS Awarding Component will take appropriate action. These
actions may include referring the matter back to the University for further action, which may
include directions to the University on how to maintain appropriate objectivity in the funded
project.

10. Collaborators/sub-recipients/subcontractors from other academic or not-for-profit institutions
must either comply with this policy or provide a certification from their institutions that they
are in compliance with Federal policies regarding investigator significant financial interest
disclosure and that their portion of the project is in compliance with institutional policies.
Subcontractors from commercial firms need not make a certification, except when the prime
award is from PHS. The PHS requires a certification from any subcontractor, including
commercial firms, stating that it is in compliance with Federal policies regarding investigator
significant financial interest disclosure and that its portion of the project is in compliance with
company policies.

Approved: ____________________________  Date: 7-30-2009

Thomas B. Higard, Ph.D.
Professor and Associate Provost
Chair, MUSC Research COI Committee