The University of South Carolina School Of Medicine (SOM) recognizes its responsibility to provide leadership and share expertise and knowledge with the private sector, government and society in general. It encourages research, teaching, service, and consulting activities by its faculty that are designed to enhance the participant's competence; contribute to and more widely disseminate the store of human knowledge; promote effective and efficient use of society's resources; and help society define ethical standards.

As an important part of its research, education, and public service missions, the SOM actively participates in, and encourages, faculty interactions with the private and public sector. However, the SOM recognizes that in some circumstances, the mission or values of the SOM and University as well as the professional and ethical conduct of its faculty or staff might be compromised or appear to be compromised.

The SOM has an obligation to see that fair and reasonable standards and procedures covering both internal and outside professional activities are developed, disseminated and implemented. This Conflict of Interest Policy is designed to approach these issues in ways that address both individual and institutional conflicts of interest. This policy becomes effective February 1, 2011. It shall be deemed a “work in progress,” open to improvement as we pursue the goal of achieving the highest quality of teaching, research, service and patient care unfettered by Conflicts of Interest (COI).

***A. Scope of Policy***

This policy applies to all faculty, staff, trainees and students of the SOM, and to all professionals and staff employed and/or contracted by the SOM, and to all facilities owned or controlled by the SOM, including the Educational Trust and related Practice Plan units.

In all cases where this policy is more restrictive than the University of South Carolina’s conflict of interest policy, this policy shall control. This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry. For purposes of this policy, “Industry” is defined as all pharmaceutical manufacturers, and biotechnology, medical devices (Note 1), and hospital equipment supply industry entities and their representatives as well as other business entities that market or sell research related products, equipment or supplies. Industry also includes those individuals whose purpose is to provide information to clinicians, even though such personnel are not classified in their company as “sales or marketing.”

*Note 1: For purposes of this Policy, the definition of “medical devices” will follow the definition and any available guidance related thereto of the Federal Safe Medical Device Act of 1990, as amended, (21 CFR 821.1, http://www.fda.gov.cdrh/comp/guidance/169.html).*

***B. Statement of Policy***

It is the policy of the SOM that all clinical, education, and research activities and decision-making be free from influence created by financial relationships with, or gifts provided by, Industry or any other entities that might also engage in creating such influence. The following policy principles should guide all potential relationships or interactions between SOM personnel and Industry representatives. The specific limitations and guidelines presented are directed to certain specific types of interactions. For other circumstances, SOM personnel should consult in advance with the Deans, their department chair or unit head to obtain further guidance and clarification. Charitable gifts provided by Industry in connection with fundraising done by, or on behalf of, the SOM shall be subject to other policies adopted from time to time by the SOM Office of Development.

***C. Specific Activities***

1. Purchasing

All purchasing and procurement decisions must be made in a manner consistent with State of South Carolina and SOM purchasing and procurement policies and procedures in order to be compliant with state regulations and to promote the best interests of the University and the SOM.

Any SOM personnel, or their spouses, domestic partners, or dependent children (collectively “related parties”) who have any personal financial interest or indirect financial interest as defined by University policy, in companies, activities, or organizations that might substantially benefit from the purchasing decisions made within the scope of their official duties, must refrain from participating in or influencing these purchasing decisions. This includes those who are involved in institutional decisions concerning the purchase of, or approval of, medications or equipment, or the negotiation of other contractual relationships, whether research, education and/or clinically based with industry or other organizations. Individuals and other related parties as previously defined must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, members of a speakers’ bureau, a paid consultancy or other forms of compensated relationship) in the vendor or other organization (any non-SOM based group, individual or entity) that might benefit from the institutional decision.

To the extent an individual’s expertise is necessary in evaluating any product, that individual’s financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision. The COI must be address and resolved. A record of the resolution must be kept in an office designated by the Dean of the SOM (Note 2).

Site visits to observe vendor products and/or services are sometimes an appropriate part of a purchasing decision. When such visits are necessary, they must be approved by the department head and/or the Office of the Dean, as applicable. Vendor offers to pay for site visits cannot be accepted because these offers may be designed to influence a purchasing decision or the institution's relationship with other vendors; the cost of the trip should be paid with departmental funds.

Individuals must disclose their actual and potential conflicts of interest related to any institutional purchasing deliberations to the SOM and generally may not participate in deliberations in which he or she has an actual or potential conflict of interest. The SOM will decide whether the individual must be excused from the purchasing decision. The SOM will maintain a record of all such decisions and will provide the Dean with that information in an annual report.

This provision is not intended to preclude an individual’s indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded companies. This does not apply to financial interests in investment funds where the individual does not have separate and direct control over the investment in the company.

*Note 2: The Dean of the SOM will issue a set of implementation procedures that will establish the appropriate office, position or personnel to carry out the responsibilities set out in this COI Policy*

2. Gifts and Provision of Meals

SOM personnel shall neither accept nor use personal gifts (including food) from representatives of Industry, regardless of the nature or dollar value of the gift. Such gifts do not improve the quality of patient care, have been shown to subtly influence clinical decisions, and add unnecessary costs to the healthcare system. Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a patient-centered educational and healthcare system. Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated by the SOM. SOM personnel may not accept meals or other gifts or hospitality funded by Industry, whether on-campus or off-campus. The only exceptions to this general rule are off-campus events that are in full compliance with all the provisions of subsection 7 below (Note 3).

Textbooks and other educational-related materials are often gifted by Industry representatives to clinicians and clinicians in training. When these items display Industry logos, they carry the potential to bias prescribing behaviors and clinical practices. If SOM personnel accept such materials, the logos or any other reference which would identify the source of the gift must be rendered unobservable before distribution or use.

Nothing in this policy is intended to diminish the value of charitable contributions. Industry wishing to make charitable contributions to the SOM may do so by contacting the SOM Office of Development.

*Note3: We recognize that medical students receive some clinical or other training off-campus under supervision of volunteer faculty who are not USC employees, and who are not bound by this policy. In those situations, students are expected to excuse themselves from activities that violate the provisions of this document (e.g., free Industry-sponsored lunches).*

3. Consulting Relationships

The SOM recognizes the obligation to make the special knowledge and intellectual competence of its faculty members available to government, industry, labor, and civic organizations, as well as understands the potential value that can accrue to the faculty members and the University. However, consulting arrangements that simply pay SOM personnel without any associated duties (such as participation on scientific advisory boards that do not regularly meet nor provide scientific advice) shall be considered gifts and are consequently prohibited.

Where SOM personnel have been engaged by Industry to provide consulting services, the consulting contract must provide specific tasks and deliverables, with payment commensurate with the tasks assigned. All such arrangements between individuals or units and outside commercial interests must be reviewed and approved in advance of acceptance or execution of the responsibilities by the Dean or the Dean’s designated representative. Documentation of such approvals shall be submitted to the designated authority, which shall be responsible for maintaining a record of them.

The SOM reserves the right to require faculty and employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with SOM policies.

4. Drug or Device Samples

Industry’s willingness to provide samples of prescription drugs or device products is a marketing practice designed to promote the use of these products and to gain access to prescribers to influence their behavior. While samples may be used responsibly, they also create regulatory and security concerns, pose potential safety risks for patients, and encourage the prescribing of new, high cost medications whose safety and efficacy may not be different from existing treatments.

To ensure that clinical decision making is free from interference and that clinical staffs are not targets of commercial inducements, SOM policy requires that samples of prescription drugs or device products provided by manufacturers be stocked in a common institutional pharmacy or other dispensary separated from sites in which patient healthcare services are provided. The specific procedures by which samples are handled will be determined by the Clinical Advisory Committee in consultation with the Dean and such other personnel the Dean determines should participate.

Records of all such actions shall be maintained by the healthcare provider authorizing the distribution of the sample, by the dispensing unit and a report of each shall be provided annually to the SOM Dean.

5. Site Access

Interaction with representatives of Industry is appropriate for the exchange of scientifically valid information and other data, or when it is designed to enhance continuity of care for specific patients or patient populations, as well as for training intended to advance healthcare and scientific investigation (Note 4). However as an educational and charitable institution with responsibility to advance the public interest, the SOM should not allow use of its facilities or other resources for marketing activities by Industry. The SOM always reserves the right to prohibit Industry representatives from having access to its facilities and to limit the activities of Industry representatives to ensure consistency with the University’s non-profit mission. To balance these interests, the USCSOM will develop a registry to assist in the management of site access by Industry representatives for appropriate purposes.

Sales or marketing representatives of Industry may access SOM facilities only: (A) if the company with which they are associated has registered with the SOM or (B) where Industry representatives seek access to the SOM, and they have been specifically invited to meet with an individual healthcare provider or a group of healthcare providers for an authorized purpose. Individual physicians or groups of physicians or other healthcare professionals may request a presentation by, or other information from, a particular company through the SOM designated authority, though these presentations or information exchange should take place in areas not involved in patient care, the conduct of research, or clinician training. (Note 5) The SOM will maintain the names of registered Industry companies and representatives and provide them to the Dean on an annual basis or upon request.

Representatives without an appointment as outlined above are not allowed to conduct business in patient care areas (inpatient or outpatient), in practitioners’ office areas, or any other areas of the SOM. Representatives are not allowed to be present during any patient care interaction unless there has been prior disclosure to, and consent by, the patient, and then only to provide in-service training or assistance on devices and equipment.

All Industry personnel seeking sales or vendor relationships must work directly with the SOM designated authoritywhen seeking access to any SOM facility or area.

While in SOM facilities, all Industry representatives must be identified by name and current company affiliation in a manner determined by the SOM COI Policy Implementation Procedures. All Industry representatives with access to SOM clinical facilities and personnel must also comply with University of South Carolina institutional ethical standards, organizational policies and procedures.

On-campus vendor fairs intended to showcase Industry products may be permitted if approved by the SOM designated authority, but only in campus areas in which no clinical care is delivered, no clinician training occurs, and in which no research is conducted. Such events must comply with all other provisions of this policy. Vendors are not permitted to distribute samples, raffle tickets, or any other gifts to attendees.

*Note 4: Training by Industry representatives on safe use of a regulated device may be permitted, provided that the registration and other procedures of this section are followed.*

*Note 5: In certain cases, training on vendors’ equipment may be most desirable in a training setting.  Such exceptions to the policy require prior approval of the Department Chair and must be reported to the Dean’s designated representative.*

6. Support of Life Long Learning in the Health Sciences

Accredited continuing medical education (CME) provides healthcare practitioners with critical educational support across the full range of competencies needed to ensure quality care (Note 6). In order to ensure that the potential for Industry bias is minimized and that CME programs are prevented from serving as a guise for marketing, all CME events must be hosted or sponsored by the USCSOM-PHR CME Organization and must comply with all ACCME accreditation standards as well as other similarly rigorous, applicable standards required by other health professions that are relevant to CME activities. All such agreements for Industry support must be negotiated through and executed by the Office of Continuous Professional Development and Strategic Affairs (OCPDSA), and must comply with all OCPDSA policies for such agreements.

Industry funding for such programming should be used to improve the quality of the education intervention provided and should not be used to support hospitality, such as meals, social activities, except at a modest level. Industry funding may not be accepted solely for social events; nor may it be accepted for activities focused on promotion. Industry funding may not be accepted to support the costs of department, faculty, student or staff meetings or retreats (either on- or off-campus). SOM facilities (clinical or non-clinical) may not be rented by, or used for, Industry funded and/or directed programs, unless there is a Letter of Agreement for Industry support that complies with the policies of the OCPDSA. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

*Note6: The specific competencies are Patient Care; Medical Knowledge; Practice-Based Learning and Improvement; Systems Based Practice; Professionalism; and Interpersonal Skills and Communication.*

7. Industry Sponsored Meetings or Industry Support for Off-Campus Meetings

SOM personnel may participate in or attend Industry-sponsored meetings or other off-campus meetings where Industry support is provided so long as: (A) the activity is designed to enhance the quality of clinical care and/or advance scientific research; (B) the financial support of Industry is prominently disclosed; (C) Industry does not pay attendees’ travel or attendance expenses; (D) attendees do not receive gifts or other compensation for attendance; (E) meals provided are modest and consistent with the educational or scientific purpose of the event.

In addition, if a SOM representative is participating as a speaker: (A) all lecture content must be determined by that SOM speaker; (B) the content must reflect a balanced and, to the extent possible, evidence-based assessment of current science and of treatment options; (C) the speaker must also make clear that the views expressed are solely the professional views of the speaker; and (D) compensation is reasonable and limited to reimbursement of travel expenses and a modest honorarium.

For travel or other expenses directly related to a clinical or basic research project, the contractual agreement for that research project, duly executed with approval from the SOM, shall determine the terms of funding.

8. Industry Support for Scholarships or Fellowships or Other Support of Students, Residents, or

Trainees

The SOM, through its Office of Development, may accept Industry support for student scholarships or discretionary funds to support travel or non-research funding support, provided that all of the following conditions are met: (A.1). Industry support for scholarships must comply with all University requirements for such funds, including the execution of an approved gift agreement among the University, donor and USC Educational Foundation. (A.2) Funds will be received, held and managed by the Foundation, and maintained in an appropriate restricted Foundation account. (A.3) Selection of recipients of scholarships will be at the sole discretion of the SOM Scholarship and Loan Committee, based on written eligibility and selection criteria. Written documentation of the selection process will be maintained by the Office of Student and Career Services. (A.4) Fellowship selections will be at the sole discretion of the department where the fellowship is assigned based upon written eligibility and selection criteria. Written documentation of the selection process will also be maintained by the department.

B. Industry support for other student, resident or trainee activities, including lodging, meals and travel expenses or attendance fees at conferences, must be accompanied by an appropriate written agreement and may be accepted only into a SOM common pool of discretionary funds, which shall be maintained under the direction of the dean or department chair (as specified in the memorandum of understanding or agreement). Industry may not earmark contributions to fund specific recipients, activities or to support specific expenses. Departments may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or others to attend conferences or training that have legitimate educational merit. Attendees will be selected by the department chairman, based upon merit and/or financial need, with documentation of the selection process provided with the request. Approval of particular requests shall be at the discretion of the dean.

9. Frequent Speaker Arrangements (Speakers Bureaus) and Ghostwriting

Speakers Bureaus sponsored by Industry serve as promotional activity and are an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration must be given to determine whether the event meets the criteria set forth in Section 7 of this policy, relating to Industry Sponsored Meetings. SOM personnel may not participate in, or receive compensation for talks given through a speakers bureau or similar frequent speaker arrangements if: (A) the events do not meet all the criteria of Section 7 ***or* (B**) the content of the presentation is not based on the best available scientific evidence.

Speaking agreements with company or company event planners are subject to review and must have received prior approval of the participant’s Dean and/or other designated authorities as stipulated in the COI Policy Implementation Procedures. Such agreements are subject to review by the SOM or USC legal office.

Under no circumstances may SOM personnel be listed as authors or co-authors on manuscripts wholly or partially ghostwritten or whose content has been altered by Industry representatives. In addition, SOM personnel are always responsible for the entire content of any authored or co-authored papers they circulate or publish or talks that they present, including the content of slides or other materials or handouts.

10. Other Industry Support for Research

The University has established policies and contract forms to permit Industry support of basic and clinical research in a manner consistent with the educational and non-profit mission of the University. True philanthropic gifts from Industry may be accepted through the SOM Office of Development

All SOM employees involved in research activities are required to disclose any significant financial interests on the part of the principal investigator, co-investigator, or any other person, (e.g., post doctoral fellow) responsible for the design, conduct or reporting of research or scholarly activities which are funded or proposed for funding by a sponsor. This is done to ensure the integrity and objectivity of research and other scholarly activities. If at any time there is a change in the facts reported in the initial disclosure the form must be updated.

Upon disclosure of a significant financial interest, the employee’s COI shall be subject to the COI resolution process as designated in the COI Policy Implementation Procedures. Alternatives for resolution of conflicts of interest may include: public disclosure, monitoring, modification of the research plan, disqualification of the researcher from participation, and divestiture of any financial interest. Failing to comply with this policy could include disciplinary action. Additionally, if any federal funds are involved, federal regulations may apply which carry penalties including financial penalties, a ban of the investigator from applying for future grants and significant penalties against USC.

***D. Reporting and Enforcement***

SOM personnel shall report their outside relationships with Industry at least annually and more often as needed to disclose new relationships. Alleged or suspected violations of this policy within the SOM shall be referred to the Dean, their department chair or to their immediate supervisor who shall determine what actions, if any, shall be taken. Violations of this policy by SOM personnel may result in actions ranging from counseling to termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University.

Industry representatives who violate this policy may be subject to penalties outlined below, as well as other actions or sanctions imposed at the discretion of the Dean of the SOM or imposed due to other applicable University policies. Such penalties may include, but shall not be limited to, verbal and written warnings to the representative, notification to the district manager or representative’s supervisor, or suspension from the SOM of that representative and all other sales/marketing representatives from that company.

Representatives found trespassing as defined in this policy will be escorted from the premises and their companies notified as appropriate.

E. Definitions:

1. “University” means the University of South Carolina as an entity and acting through its authorized agents.

2. “School of Medicine” (SOM) personnel means all faculty, staff, students, trainees, Fellows, including the Educational Trust and related Practice Plan units as well as any other persons who are employed by the SOM, whether full or part time, regardless of their geographic location or work situation.

3. “Faculty” includes all administrators holding academic appointments and all professors, associate professors, assistant professors, full-time academic instructors and full-time lecturers who are not degree candidates at the University of South Carolina. The definition includes faculty holding clinical and research appointments as well.

4. “Industry” means pharmaceutical companies; biotechnology companies; medical device companies; and hospital equipment and supplies companies, as well as the representatives of any of these companies. In addition, it includes other business entities that market or sell research related products, equipment or supplies.

5. “Significant financial interest” means anything of monetary value including salary, equity interest, (e.g., stock or stock options) and intellectual property rights (e.g., patents or copyrights).

6. “Modest meal” means the value is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service.

Adopted by the USC School of Medicine Executive Committee, February 1, 2011