



CONFLICT OF INTEREST POLICY

INTRODUCTION

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

A conflict of interest (COI) is a set of conditions in which one's primary interest (as determined by one's professional duties) tends to be unduly influenced by a secondary interest. For members of the SOM, primary professional interests include (a) the provision of patient care that reflects best practices, (b) student, fellow and resident education that is free from bias, and (c) the ethical conduct of research. An important secondary interest that has the potential to influence these primary interests is financial gain.

The purpose of this conflict-of-interest policy is to provide guidance to ensure that these secondary interests do not dominate or undermine the primary goals of excellence in patient care and the integrity of education and research. Adherence to this policy will also protect the integrity of the SOM, its faculty, and students and will serve as a public statement of the SOM's commitment to unbiased clinical practice.

The SOM anticipates that in its role in advancing research and engaging industry that potential conflicts of interest can and will occur. Relationships with industry are not inherently problematic and will present opportunities for our school and individuals but these relationships need to be disclosed and effectively managed.

SCOPE OF POLICY

This policy applies to all faculty, staff, trainees (e.g., residents, fellows, 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.

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In all cases where this policy is more restrictive than the University of South Carolina's conflict of interest policy (BTRU 1.18), this policy shall control. This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry.

When SOM students rotate with clinicians who are not SOM faculty, student trainees should continue to follow the principles established in this policy. For example, the trainee should not accept gifts provided by a pharmaceutical representative at an outside site. Trainees who perceive that such refusal might jeopardize their evaluations should report their concerns to the medical school's associate dean for medical education, the student clerkship director of the relevant specialty, the medical school's associate dean for graduate medical education, or the residency/fellowship program director.

Faculty with outside appointments (e.g., the VA Health System, Prisma Health or McLeod Health) are also responsible to be compliant with those institution's respective policies.

1. 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, other gifts or hospitality funded by Industry, whether on-campus or off-campus. Healthcare systems where SOM personnel are providing patient care are not considered as part of Industry. The only exceptions to this general rule are off-campus events that are in full compliance with all the provisions of subsection eight below.

Textbooks, access to on-line content and other educational-related materials are often gifted by Industry representatives to clinicians and trainees. 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.

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2. Consulting Relationships

The SOM recognizes that the importance of establishing consulting relationships to make the special knowledge of its members available to government, industry, and civic organizations. The ultimate objectives of such consulting relationships should be to enhance medical education, advance scientific research, or improve clinical care or public health. In contrast, consulting relationships with industry that are designed primarily as marketing tools to increase product penetration for a drug or device are prohibited.

When SOM personnel have been engaged to provide consulting services, the consulting contract must provide specific tasks and deliverables, with payment commensurate with the assigned tasks. Consulting arrangements that simply pay SOM personnel without establishing specific meaningful duties shall be considered gifts and are consequently prohibited (e.g., membership on advisory boards that do not regularly meet or provide scientific advice).

Consulting arrangements involving SOM personnel must be reviewed and approved by the appropriate department chairperson and legal counsel before the arrangement is accepted. SOM leadership (e.g., the Dean or their designee) has authority to require personnel to change the terms of consulting agreements to bring those agreements into compliance with this policy. SOM leadership may authorize the Conflict-of-Interest Committee (see "Reporting and Enforcement" section near the end of this policy) to adjudicate problematic cases.

3. Intellectual Property and Biotechnology Startups

As part of the SOM mission, our faculty are encouraged to pursue innovative ideas and innovations. The University's intellectual property (IP) policy seeks to encourage and reward research and scholarship that results in the creation of intellectual property, and to recognize the rights and interests of the Creator(s), the public, the external sponsor, and the university.

To protect potential IP, all faculty must follow University policy which requires disclosure of IP interests to the University's Technology Commercialization Office ("TCO") (see University Policy ACAF 1.33) prior to public disclosure,

If a faculty member intends to pursue specific IP as the basis for a start-up entity, the TCO must be consulted. Often the intent of these startups is to obtain NIH funding for advancing the technology to a commercialization stage (e.g. SBIR and STTR Funding).

The engagement of a SOM faculty in a biotechnology startup must include the appropriate licensing and IP agreements, a disclosure of financial interest and a conflicts management plan approved by the department chair and the Dean of the SOM. The maximum amount of time

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allowed for these types of outside professional activities is 20% of a faculty members professional effort.

4. Research

All faculty members who participate in research projects sponsored by the U.S. Public Health Service, including the National Institutes of Health, and the National Science Foundation are required to follow University Conflict of Interest Polices (see RSCH 1.06).

5. Drug or Device Samples

The provision of prescription drug samples or devices by industry is a marketing practice designed to promote the use of these products and to influence behavior of prescribers. Drug samples also create regulatory and security concerns, pose potential safety risks for patients, and encourage the prescribing of new, high-cost medications that frequently are not more effective or safe than less-expensive existing alternatives.

For these reasons, the SOM strongly discourages the general use of drug and device samples. However, samples may be appropriate in exceptional circumstances such as the following: need for clinical providers to directly demonstrate the use of a device to a patient, or provision of sample devices or a product for use in procedure rooms or in the operating room as part of a value analysis for these clinical areas. This list of examples provided is neither comprehensive nor exhaustive. Use in these circumstances should be only when clear patient benefit exists, or other options are not reasonable, and should have approval by the chair or senior medical director of the department.

6. Site Access for Pharmaceutical and Device Sales/Marketing Representatives

Representatives of Industry, including pharmaceutical, device and other medical companies, whose sole purpose is sales and marketing are not permitted to access the SOM's medical education or any patient care areas. Research indicates that interactions with drug sales and marketing representatives do not serve best interests of patients; such interactions may result in lower-quality, higher-cost prescribing, and the information that representatives disseminate may omit or distort information in ways that favor their products. Clinicians have a professional responsibility to obtain drug information from nonbiased sources.

In contrast, it may be appropriate for SOM personnel to meet with device-industry representatives for the purpose of training and technical assistance for medical devices, when such assistance cannot be obtained from other sources. In general, such meetings should be conducted in by appointment only, and at the request of SOM faculty.

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SOM personnel may appropriately meet with drug- and device-industry scientists to discuss potential research collaboration or to receive in-depth scientific and educational information. Such meetings should be conducted by appointment, should be at the invitation of SOM personnel, and should not include sales representatives.

Industry representatives who meet with SOM personnel for permissible reasons (technical assistance with devices; scientific, non-marketing discussions) will require permission from the SOM's Dean and/or applicable department chair.

Companies with a non-medical purpose are also subject to the guidelines of this policy.

7. Support of Education in the Health Sciences

Accredited continuing medical education (CME) provides healthcare practitioners with critical educational support and must be designed to ensure that it serves the needs of patients and the public, is based on valid content, and is free from commercial influence. To ensure that industry-related bias is minimized and that CME programs do not serve as marketing tools, all CME activities must be supported or sponsored by the USC SOM-Prisma Health Midlands CME Organization, which is accredited by the national Accreditation Council for Continuing Medical Education (ACCME). Any agreements for industry support of medical education must be negotiated through and executed by the Office of Continuous Professional Development and Strategic Affairs, of which the CME organization is a part.

Any industry funding for such programming will be used strictly to improve the quality of the educational experience, and not to support hospitality or product marketing. Industry funding may not be accepted to support the costs of departmental meetings or retreats (either on- or off campus).

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

SOM personnel are discouraged from attending off-campus industry-sponsored educational meetings and events unless those events meet standards for accredited CME activities. Those activities must be designed to enhance the quality of clinical care or advance scientific research and must clearly disclose financial support of industry. Attendees must not receive reimbursement from industry for travel or attendance expenses and must not receive gifts or other compensation for attendance but would be able to have reasonable food for lunch or dinner provided by industry. For guidelines on participating as a speaker at such events, see section 9 below.

Industry frequently develops new devices, instruments, or other products that require hands-on

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technical training. The SOM strongly encourages its clinicians to engage in hands-on testing and training when a new technology that is likely to improve patient care is being considered for purchase. When examination and testing of a new device is only available outside the Columbia area, and the device has not yet been purchased by the SOM or its affiliated hospitals, the SOM, or its affiliated hospitals (and not the device manufacturer) may cover travel expenses for clinicians who attend those sessions. However, for devices already purchased or for which approval to purchase has been given, industry may cover travel expenses for ongoing training.

For travel or other expenses to attend meetings that involve funded research in collaboration with industry, the contractual agreement for the research project - duly executed according to requirements of the University, and the SOM, shall be determined by the terms of the grant. Compliance with University disclosure policy ACAF 1.50 (<http://www.sc.edu/policies/acaf150.pdf>) is mandatory for all University employed Faculty. Compliance with University research policy RSCH 1.06 (<http://www.sc.edu/policies/rsch106.pdf>) is mandatory for all University affiliated Faculty participating in grants or research disbursing federal funds.

9. Industry-Supported Speaking

SOM personnel are prohibited from participating in industry-related "speakers' bureaus". Because presentations given through speakers' bureaus are reviewed and approved in advance by drug or device companies (which typically prepare slides and other materials), these presentations are essentially academic endorsements of commercial promotional interests. In addition, public listing of SOM faculty members' involvement in drug- or device-company's speakers' bureaus creates an undesirable public perception of strong industry influence on the SOM.

Single speaking engagements at single industry-supported events are permissible only if the following criteria are met: (a) content is independently created by the speaker, and not reviewed in advance by the company; (b) content is balanced, evidence-based, and reflective of best practices; (c) the speaker makes it clear that the content reflects their independent professional views; and (d) compensation is reasonable and limited to reimbursement of travel expenses and a modest honorarium. Any such speaking engagements must be approved by the chairperson of the speaker's clinical department.

For travel or other expenses related to speaking at meetings that involve funded research in collaboration with industry, the contractual agreement for the research project - duly executed according to requirements of the SOM shall be determined by the terms of the grant.

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10. Authorship for industry sponsored research

Under no circumstances may SOM personnel be listed as authors or co-authors on manuscripts wholly or partially ghostwritten or whose content has been unilaterally altered by industry representatives. SOM personnel who publish in medical journals should follow guidelines published by the International Committee of Medical Journal editors (<http://www.icmie.org>), which define authorship and appropriate disclosure of conflicts-of- interest.

11. Purchasing

Employees of the SOM who have financial or non-financial relationships with companies or organizations that might substantially benefit from purchases by the University or SOM must refrain from participating in (or influencing) these purchasing decisions or contractual negotiations. The same rule applies if a SOM employee's spouse, domestic partner, or other related party has a relationship with such companies or organizations.

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 to be compliant with state regulations and to promote the best interests of the University and the SOM.

Any SOM personnel or 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 defined must not have any financial interest 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.

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

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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.

12. Foreign Influence

SOM personnel are expected to comply with any applicable Federal or sponsor requirements pertaining to conflict of interest in their research activities. Compliance with federal requirements includes timely disclosure of all relevant sources of support, including support from foreign entities. Examples of foreign support that must be disclosed by all Investigators on federal grants (and that may need to be disclosed to other sponsors), include: (a) all positions and affiliations, including volunteer positions, relevant to an individual's research endeavors; (b) relevant appointments at foreign Institutions – even if labeled as “guest,” “adjunct,” “honorary,” with or without salary support; (c) income, salary, consulting fees, and honoraria in support of an individual's research endeavors; (d) participation in a foreign talent or similar-type programs; (e) all resources and other support, both domestic and foreign, for ongoing research projects, including those conducted at a different Institution; (f) in-kind contributions from domestic and foreign Institutions or governments that support research activities; (g) travel paid by a foreign Institution or government; and (h) financial interests received from a foreign Institution of higher education or a foreign government. Activities responsive to reporting under this section are not inherently problematic, and indeed, will present opportunities for individual members.

REPORTING AND ENFORCEMENT

Consistent with University policy, SOM personnel shall report their outside relationships at least annually and more often as needed to disclose new relationships.

The Dean shall refer specific issues to the COI Committee for evaluation. When a COI is determined to exist, COI Committee shall develop and implement a management plan that specifies actions taken and/or will be taken to manage the COI. In addition to the actions specified

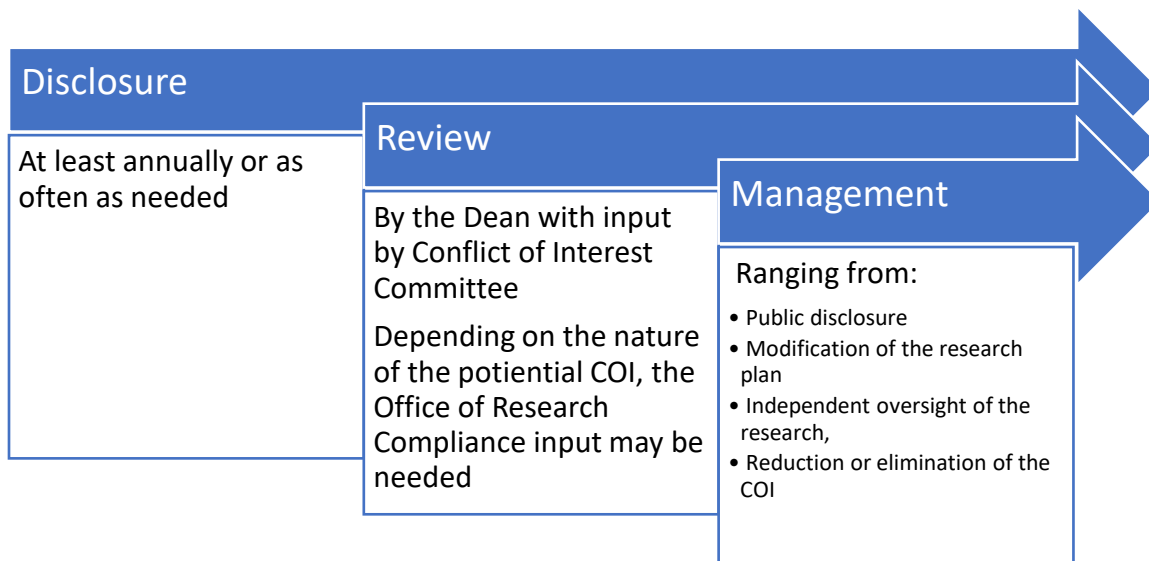
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in the policy, examples of actions that may be taken to manage an identified COI include but are not limited to the following:

- Public disclosure of the financial conflict of interest FCOI
- Disclosure to the research team
- Modification of the research plan
- Independent oversight of the research, including appointment of an independent monitor
- Change of personnel or personnel responsibilities
- Disqualification from participation in the research
- Reduction or elimination of the COI, or severance of the relationship that creates the COI

Following review of a specific issue, the COI Committee will make a formal recommendation to the Dean as to how the matter should be resolved or managed. The Dean will consider the COI Committee's recommendations prior to instituting any management plan in accordance with this policy.

If a member of the COI Committee has a personal financial interest above thresholds established by this policy or has supervisory responsibility over the SOM member with the potential conflict, the member must recuse himself or herself from acting on the matter and shall refer the matter to his or her supervisor. Limited participation may be allowed if that member possesses expertise or knowledge that would be beneficial to the final decision.



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Glossary

Industry: is defined as all pharmaceutical manufacturers, and biotechnology, medical devices (as defined by the FDA), 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.”

Conflict of Interest: A situation where an individual has financial, professional, or personal considerations that may affect, or have the appearance of affecting, their professional judgment in any University duties.

Conflict of Commitment: means a situation in which an individual engages in external activities, either paid or unpaid, that may interfere with his/her primary obligation and commitment to the University.

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

School of Medicine (SOM): personnel means all faculty, staff, students, trainees, fellows (clinical and research), 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.

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.

Financial interest: means any monetary interest including, but not limited to salary, consulting fees, honoraria, gifts, dividends, paid authorship, ownership interest, stock or stock options, intellectual property rights, royalties, or paid travel (unless reimbursed by federal, state or local government, an institution of higher education, an academic medical center, research institute or professional organization affiliated with institutions of higher education). Financial interest does not include a financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over the management and investments of which the employee or an associated immediate family member does not exercise control; or investments in publicly traded entities as long as the value of the employee’s equity interest in the entity is less than \$5,000.

Related Parties: SOM personnel, or their spouses, domestic partners, or dependent children.