

Policy Name: MUSC/MUHA- Industry Relations Policy			
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1. Purpose and Scope

MUSC recognizes the value of its relationships with the healthcare industry (“Industry”). The University also believes that such relationships must be entered into on the basis of a partnership that advances the benefits of biomedical research, education and clinical care in pursuit of improving human health. Importantly, these activities must avoid either the existence or impression of professional impropriety by University or MUSC individuals who are entrusted with the integrity of the institution’s educational, clinical or research programs.

The purpose of this policy is to establish straightforward, effective and principled guidelines for University-Industry relationships to ensure that individuals who work for MUSC interact with Industry knowing the rules of the University and State that govern such interactions. This is critical to protect the interests of the individual, the University and our patients as we undertake these activities to achieve our ultimate goals of promoting scientific research, evidence based clinical care, and educating trainees. The University recognizes the importance of mutually beneficial relationships with Industry as long as those relationships do not compromise the integrity of our missions. Rather, one of the overarching aims of the policy is for full disclosure of consulting and educational activities by MUSC personnel to help ensure that these activities meet the guidelines set forth in this policy.

2. Covered Persons

This policy applies to all Trustees, Officers, Faculty, Administrators, Staff, Students and Trainees including all full-time, part-time, temporary and contract employees of the Medical University of South Carolina. The Medical University Hospital Authority and affiliates of the University (including but not limited to University Medical Associates of the Medical University of South Carolina, the MUSC Foundation and the Foundation for Research Development), which derive their not for profit status from MUSC, shall as a condition of conducting business with MUSC, develop and implement policies and procedures substantially similar to and consistent with this policy.

3. Definitions

For purposes of this policy:

Industry refers to any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, trust, enterprise, or other legal entity, including for profit and not for profit entities that are engaged in 1) the manufacture, distribution or sale of diagnostic or therapeutic drugs, medical/dental devices or equipment, supplies, or information technology, 2) medical testing, or 3) providing services for clinical care, research, or education. Industry also refers to entities that provide services to MUSC in the areas of physical plant, university and hospital administration, human resources, project management, clinical services and regulatory services. The term industry does not include professional associations and societies, not for profit foundations, law offices, not for profit volunteer health organizations, academic institutions or not for profit hospitals that provide medical research/education-related products and services.

Conflict of Interest is defined as the circumstance that arises when an individual has an opportunity to influence patient care, research and education of trainees regarding the purchase or use of products or services of an industry with which he/she has a secondary interest (financial relationship, or research support, or personal benefit).

Consulting (Consulting Services, Consultant, etc.) is defined as all activities where the external entity furnishes a Personal Financial Benefit or Economic Benefit and/or other Personal Benefit such as reimbursement/compensation for the exchange of clinical, educational, professional and/or scientific information or activities by Covered Persons.

Educational Programming is defined as medical, healthcare and scientific speaking engagements or educational presentations where Industry furnishes a Personal Financial Benefit or Economic Benefit and/or other Personal Benefit as reimbursement/compensation for the provision of those presentations by Covered Persons.

Personal Financial Benefit or Economic Benefit is defined as anything of monetary value - including salary, commissions, fees, honoraria, gifts, equity interests (which include any stock, stock option, or other ownership interest), interests in real or personal property, dividends, royalty, rent, capital gains, intellectual property rights, loans, and forgiveness of debt. The term “personal” also includes the Covered Person’s immediate family, including parents, spouse, siblings, children, stepchildren and grandchildren.

Other Personal Benefit is defined as a non-financial benefit to a Covered Person; for example, promise of a job promotion, future grant, research publication, clinical trial or authorship, etc. The term “personal” includes the Covered Person’s immediate family, defined as parents, spouse, siblings, children, stepchildren and grandchildren.

Personal Leave is defined as that time away from work taken as annual leave , or any part of a 24-hour period when there are no MUSC assigned responsibilities (*e.g.*, weekends or after hours when there are no MUSC assigned responsibilities).

Professional Leave includes time away from MUSC to conduct MUSC approved professional activities, while receiving compensation from MUSC. A request for this leave must be approved by the Covered Person’s supervisor.

4. Consulting and Educational Programming

a) Consulting

Purpose

Consulting interactions can facilitate the advancement of innovative ideas and discoveries, both of which ultimately benefit the general public through the transfer of scientific discovery. This section of the policy clarifies the terms of interactions with Industry where the primary goal is scientific exchange.

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Consulting refers to all activities where the external entity furnishes a Personal Financial Benefit or an Economic Benefit and/or other Personal Benefit as reimbursement/compensation for the exchange of clinical, educational, professional and/or scientific information or activities by Covered Persons (see also above).

The provision of bona fide Consulting Services by Covered Persons to external entities is consistent with MUSC's mission when those activities:

- (a) involve a two-way exchange of ideas in which each party benefits from the interchange;
- (b) are relevant to and enrich the consultant's research, education or other professional responsibilities;
- (c) do not interfere with the consultant's responsibilities to patients or the institution;
- (d) do not adversely affect the consultant's intellectual independence or the integrity of the institution;
- (e) are confined to the exchange of clinical, educational, professional and/or scientific information.

i. Approved consulting activities include but are not limited to the following:

- Serving on advisory boards, expert panels, leadership groups, data safety monitoring boards, and/or similar groups.
- Providing expert witness testimony. (*See MUSC Faculty Handbook.*)
- Providing scientific or medical presentations or expertise to industry scientists, research and development staff, and/or their staff.
- Providing product review, product evaluation, and product feedback for Industry.
- Demonstrating an Industry product (*i.e.*, teaching when and how to appropriately use a product) for medical or research professionals in the context of medical or scientific education.
- Providing consultation to venture capital firms, and serving as a scientific or medical advisor to Industry for purposes of MUSC intellectual property development.

ii. Prohibited consulting activities include but are not limited to the following:

- Consulting activities requiring or appearing to require MUSC staff to endorse or appear to endorse a particular product, drug, device, or service (either orally or in writing). This includes demonstrating an Industry product for promotional or sales purposes; and appearing (or being quoted) in a video, television, radio, internet-broadcast, web site, or in other publicly-broadcasted or distributed materials for promotional or sales purposes without proper authority or approval.
- Participating in ghostwriting, which is defined as Industry sponsorship for (i) making a major contribution towards the writing and/or research of scientific and medical publications without receiving authorship; or (ii) accepting authorship for a scientific or medical publication without making a major contribution towards the writing and/or the research.
- Serving as an Industry sponsored "named reference" for a product recommendation.

- Providing MUSC slides, videos, pamphlets or any other MUSC logo or copyrighted materials to Industry for marketing or promotional use. Such use must be approved in accordance with MUSC/MUHA policy or procedure.
- Providing services that conflict or appear to conflict with SEC rules and regulations for stock brokers, investment houses, equity management companies, banks, and/or financial institutions.
- Providing services to an Industry that is in a known legal dispute with MUSC.
- Speaking to investors on behalf of a company, except when the company is an MUSC sanctioned and supported faculty start-up company.

The lists of approved and prohibited consulting activities are the same whether consulting is done on personal or professional time. All Covered Persons who participate in consulting activities are subject to the approval procedures outlined in section 4g of this policy.

b) Educational Programming

Purpose

MUSC recognizes the value to the institution and Covered Persons in having such opinion leaders present educational material before professional and lay groups. As noted in the *MUSC Faculty Handbook*, activities such as presentations to professional groups such as other universities, health systems, and professional societies are considered to be within the scope of Covered Persons' work. Education provided by Covered Persons shall be in the best interest of the public, independent from commercial interest, and refrain from product promotion. Additionally, MUSC recognizes the benefits that Covered Persons obtain by attending educational programs.

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This policy applies to all medical, healthcare and scientific speaking engagements or educational presentations, with or without professional continuing education credit, where Industry furnishes a Personal Financial Benefit or an Economic Benefit and/or other Personal Benefit as reimbursement/compensation for the provision of those presentations by Covered Persons. The policy also applies to Covered Persons who attend such educational meetings. Educational programming should be independent from commercial interest and promote evidence-based clinical care and/or advance scientific research. MUSC recognizes that bona fide educational activities typically adhere to ACCME, ADA CERP, ACPE, ANCC or other national accreditation standards and qualify for continuing education credit. Other acceptable activities that do not provide CE credits but would serve recognized educational purposes include presentations to industry (*e.g.*, providing scientific or medical expertise) and training for medical or research professionals (*e.g.*, teaching practitioners when and how to appropriately use a medical device). Otherwise, non-accredited, industry sponsored speaking to healthcare providers is not consistent with the standards of allowable educational programming due to the risk of industry influence.

- i. ***Approved educational speaker activities include but are not limited to the following:***

Providing continuing education (CE) services, scientific or medical presentations or

expertise at academic meetings and professional societies, at other universities or research institutions, and at lay organization meetings as long as the following conditions are met:

- These activities are designed to promote evidence-based clinical care and/or advance scientific research;
- The presentation is made in accordance with professional accreditation standards such as the ACCME's *Standards for Commercial Support*,¹ the ADA CERP *Continuing Education Recognition Program*, or other national accreditation standards including those set by the ACPE and the ANCC, *i.e.*, the educational content, including handouts and visual-aids, must be determined entirely by the speaker; and
- The financial support of industry, if provided, is clearly disclosed. Payments to Covered Persons for speaking and for travel costs for these approved educational activities are permitted for approved speaker activities (see section C for rules about payments).

ii. Prohibited educational speaker activities include but are not limited to the following:

- Speaking at any educational meeting where the content of the presentation, including handouts and visual-aids, is not determined entirely by the Covered Person.
- Educational speaking should be independent from commercial interest, and refrain from product promotion. As such, speaking activities frequently referred to as speakers' bureaus are prohibited. Speakers' bureaus are typically characterized by, but are not limited to, the following attributes:
 1. promotional educational activity concerning a biomedical or pharmaceutical product;
 2. the company has the contractual right to dictate or control the content of the presentation or talk;
 3. the company creates the slides or presentation material and/or restricts or otherwise limits the Covered Person's intellectual independence over the educational content of his or her presentation; and/or
 4. Covered Persons are expected to act as a company's agent or spokesperson for the purpose of disseminating company or product information (*e.g.*, the presentation is focused on a healthcare product made by the sponsor and does not include a balanced representation of alternative products or services).If you have questions about whether a speaking activity is a speakers' bureau, you should consult with the COI Office for guidance.
- Providing industry sponsored continuing education (CE) services or scientific or medical training to an audience consisting only of MUSC attendees.

¹ Accreditation Council for Continuing Medical Education, *Standards to Ensure the Independence of CME Activities* (2007)

iii. Attendance at educational meetings sponsored by Industry

Covered Persons may attend any educational meeting sponsored by industry but may not undertake the following:

- Receive gifts, other compensation, or travel costs for attendance;
- Participate in industry sponsored food, beverages or entertainment events if the audience is restricted to MUSC personnel only (*i.e.*, MUSC personnel can only accept industry sponsored meals, beverages and entertainment events if the audience is not restricted to MUSC personnel and is open to members of the professional community at large).

The lists of approved and prohibited educational activities are the same whether these activities are done on personal or professional time. All Covered Persons who participate as speakers in Educational Programs are subject to the approval procedures outlined in section 4g of this policy.

c) Payments for Consulting and Educational Programming

Payments for consulting and educational services should be at a level commensurate with effort. If done on professional time, the distribution of payment to either the individual or the institution will be at the discretion of each college or department. For all outside activities, Covered Persons should coordinate with the Conflict of Interest Office to determine reporting requirements for any industry relationship.

Senior institutional officials (defined here as the President, Vice Presidents, Deans and Associate Deans) who conduct outside activities that fall within the institution's missions and/or relate to their service as institutional leaders must conduct those activities under a written agreement with the institution. Remuneration for the outside activity must be paid to the institution and cover the senior official's time and effort for the work; compensation should not be in addition to the senior official's institutional salary.

d) Leave Status Requirements for Consulting and Educational Programming Activities

Consulting and Educational Programming activities may occur on either *Personal Leave (time)* or *Professional Leave*. Please refer to section 3 of this policy for specific definitions.

Consulting or Educational Programming Conducted on Personal Leave

- MUSC resources (*e.g.*, secretarial assistance, office space, etc.) are not allowed to be used while providing consulting services or educational programming activities performed on personal time.
- Covered Persons considering to undertake consulting or educational programming activities with a company with whom they are performing concurrent research should consult with the Conflict of Interest Office.
- Covered Persons who consult or conduct educational programming while on Personal Leave may retain 100 percent of the fee; this fee must be paid directly to the Covered Person from the external entity. The Covered Person is responsible for securing payment

for these consulting or educational activities, tax liability, and any financial concerns associated with such payments.

- MUSC does not provide liability insurance coverage for Covered Persons performing consulting OR educational programming activities on personal leave.
- Covered Persons may provide consulting or educational services on Personal Leave in conjunction with MUSC approved travel. Additional travel expenses incurred by the consulting or educational activities (*e.g.*, additional hotel night/s, per diem, transportation, miscellaneous) will be the responsibility of the Covered Person.
- Covered Persons should be aware that payments received from medical device, pharmaceutical manufacturers and biomedical suppliers are subject to the **Physician Payment Sunshine Act** and **will be made publicly accessible via a Centers for Medicare and Medicaid Services website.**

Consulting or Educational Programming Conducted on Professional Leave

- MUSC resources may be utilized to conduct consulting or educational programming on professional leave.
- Covered Persons considering to undertake consulting or educational programming activities with a company with whom they are performing concurrent research should consult with the Conflict of Interest Office.
- If the consulting or educational programming is completed on MUSC time while on professional leave, payment must be made to MUSC and allocated to an account within the college, department or division. Each college, department or division will be responsible for the disbursement of funds.
- Consulting or educational programming conducted on professional leave requires a contract or agreement; please see section 6 of this policy.
- MUSC provides liability insurance coverage for Covered Persons performing consulting activities or educational programming on professional leave.

e) Consulting or Educational Programming Conducted with Concurrent Research

For consulting or educational activities that occur with concurrent research with the same company, Covered Persons should consult with the Conflict of Interest Office.

f) Consulting or Educational Programming Contracts

Professional Leave Status:

All formal consulting and educational programming relationships approved for Covered Persons that are conducted while on **Professional Leave** must be formalized in a fully executed contract. All such agreements must be channeled through the appropriate contract approval process.

- All agreements must clearly describe the services and deliverables to be furnished by the consultant or speaker, including the time required for such services or method of calculating compensation, a description of the compensation due under the agreement, a

declaration regarding disposition of intellectual property rights if applicable, and a provision to protect the use of the MUSC name if appropriate. The agreement should be consistent with MUSC policies and eliminate unauthorized transfer of MUSC intellectual property.

- An agreement must be signed and dated by all parties prior to the commencement of any of the consulting or educational programming activities. All agreements must be consistent with MUSC's policies, mission and duties to its stakeholders.
- The consultant or speaker is expected to maintain records of the consulting or educational programming activities for 6 years after the termination of the contract.

Personal Leave Status:

Covered Persons who consult or provide educational programming on **Personal Leave** are acting as independent contractors. Covered Persons may not bind or obligate MUSC in any way. Contracts entered into by Covered Persons acting as independent contractors should not contain any references to MUSC or its Affiliates; this includes an individual title (*i.e.*, Professor, Director etc.) or work addresses.

g) Approval Process for Consulting and Educational Programming

All consulting and educational programming whether occurring on Personal Leave or Professional Leave must not impact negatively on MUSC or MUSC's research, educational or clinical missions. For all outside activities, Covered Persons should coordinate with the Conflict Of Interest Office to determine reporting requirements for any industry relationship. Requests for consulting and educational programming occurring on Professional Leave must be approved by the department chair or appropriate supervisor during the university's contract approval process. It is recommended that Covered Persons notify their department chair or supervisor of any consulting or educational programming occurring on Personal Leave, as individual departments and/or colleges may have additional requirements.

5. Gifts

Covered Persons and their immediate family members may not accept gifts of value exceeding \$10 from vendors or other representatives of industry. Examples of gifts include, but are not necessarily limited to, travel and lodging expenses; membership dues; admission fees; preferential terms on a loan, goods or services; or the use of real property; for this section, "gifts" does not include food and beverages which is a subject handled in Section 6 below.

Acceptance of travel funds to participate in meetings or training directly related to ongoing sponsored research is not considered a gift and is allowable.

Covered Persons may accept travel funds from scientific or professional societies that are funded by industry, as long as the society controls the selection of the recipient. Covered Persons may not accept travel funds directly from industry but travel support from industry funds provided to MUSC is allowed.

6. Food, Beverages and General Hospitality

Except as noted below, Covered Persons should not accept food and beverages, support for social events, or other hospitality offered directly by Industry to the Covered Person. Industry support for food and beverages for college, department or division meetings or retreats is prohibited.

Covered Persons attending an educational meeting or conference may participate in food, beverages and social receptions sponsored by Industry as long as invitation to these events is open to non-MUSC attendees as well, i.e., the event is open to all meeting attendees.

A Covered Person engaged in off-site consulting may accept food and beverages as a part of a reasonable compensation package for consulting services.

Covered Persons cannot participate in industry sponsored food, beverages and/or entertainment events that are provided only for a select invited individual or group of individuals if the primary purpose of the event is for marketing and promotional purposes. However, this restriction does not preclude allowable activities, such as site visits and meetings with potential vendors, which may occur when obtaining contracted goods and services; these activities are governed by state and MUSC and/or MUHA procurement guidelines. Covered Persons should recognize that attendance at an industry supported event may cause their name and institutional affiliation to be reported as required by federal regulation. This can be avoided by paying for one's own meal at such events, and removing one's name from the attendance list.

7. Industry Supported Continuing Education Programs

- Continuing Education (CE) programs supported by Industry are permitted provided the following criteria are met:
 - Industry sponsored programs offering continuing education (CE) credit must be processed through the Office of Continuing Medical Education if appropriate and adhere to the standards for commercial support established by the ACCME, the ADA CERP, the ACPE, the ANCC, or other such accrediting or licensing body if available.
 - Industry provided food and beverages are prohibited at educational programs in which the only attendees are from MUSC, both on campus and off campus.
 - Students or trainees may participate in the continuing education programs as long as the programs are structured group settings that are supervised by faculty.
 - Appropriate disclosure statements are made in any pre-meeting announcement and by the speaker prior to beginning the program.
 - Companies seeking to provide support for CE programs may do so through unrestricted educational grants.

8. Educational Materials and Equipment

Donations of educational materials and equipment may be accepted. Such donations are expected to be used by faculty, staff, students and trainees and are not expected to be used by a single Covered Person. Donations are expected to be donated directly to an appropriate college or

departmental official within the University or a University affiliate, and documentation of the donation, including the value of the equipment donated and the date of the donation, should be retained. Donations of capital equipment require approval of the Vice President for Academic Affairs and Provost, except in cases of sponsored research, in which equipment donations are managed by the Office of Research and Sponsored Programs.

9. Scholarships and other Educational Funding for Students and Residents

Industry support for student scholarships, residents and fellows should be made in cooperation with the appropriate MUSC entity or University official. This may include the MUSC Foundation or the MUSC Foundation for Research Development, the Development Office, the Office of Research and Sponsored Programs or senior leadership according to the Institution's policies and procedures. Covered Persons must obtain approval from the department chair, division director or college dean before soliciting Industry for these purposes. The appropriate MUSC entity or University Official must manage and oversee the receipt of such Industry support. The evaluation and selection of recipients of such funds and use of such funds must be at the sole discretion of the University, college, or department. All potential industry sponsors should be given the opportunity to contribute.

10. Development Activities

The Institution recognizes that the MUSC Foundation has a unique and integral mission to attract financial support that furthers the research, education and patient care initiatives of the MUSC enterprise. Activities necessary to the successful conduct of advancement and fundraising on behalf of the Institution may continue. However, these activities are not permitted to influence educational, clinical or research operations of the Institution other than providing support to further those missions. No gift shall influence or appear to influence Institutional decision-making related to procurement, patient care, education and research integrity. Any concerns shall be reported immediately to the Conflict of Interest Office. Notwithstanding anything in this section, SC state employees remain subject to the SC Ethics Law and must act in compliance with state regulations.

11. Charitable Contributions

Charitable contributions from industry for the benefit of the University or any of its affiliates must be made through the appropriate University channels. This may include the Development Office, MUSC Foundation or University leadership. The distribution of charitable contributions for their intended purposes will be the responsibility of the department, division director, college deans, and administration. Industry funding for sponsored projects (funding provided which is subject to terms and conditions) is accepted and managed on behalf of MUSC by the Office of Research and Sponsored Programs (ORSP).

12. Pharmaceutical Samples

Drug samples that are provided for distribution to patients will be handled in accordance with MUHA Policy C-26, Medication Samples.

13. Site Access

The MUSC Medical Center recognizes the value of information provided by various industry representatives but intends to limit access to its personnel and facilities to prevent interference with patient care activities. All vendors are expected to adhere to policy A-15, Account/Vendor Representatives <https://www.musc.edu/medcenter/policy/Med/A015.pdf> or any applicable contract with the vendor.

14. Use of Confidential Information

Unauthorized use of confidential, privileged or proprietary information by Covered Persons or their family members is prohibited. This includes but is not limited to, disclosure of such information to commercial entities without authorization; unauthorized use of such information to engage in a relationship with a commercial entity that leads to a Personal Financial Benefit or Economic Benefit for the Covered Person or their family member.

15. Purchasing

Covered Persons with any financial interest in any particular manufacturer of pharmaceuticals, devices or equipment or any provider of goods or services, must disclose such interests and recuse themselves from purchasing decisions relevant to the conflicting interests. Any Covered Person whose expertise is necessary to evaluate any product must disclose his/her financial ties to any manufacturer of that or any related product to those charged with the responsibility of making the purchasing decision.

16. Exceptions

The University Conflict of Interest Committee will review/consider requests for exceptions to this policy. Request for exceptions must be submitted in writing to the Conflict of Interest Office. Resolution of such requests will be documented in the minutes of the University Conflict of Interest Committee and reported back to the requestor and their supervisor. If additional recourse is desired after review and action by the University Conflict of Interest Committee, a Covered Person may submit their request in writing to the MUSC Vice President for Academic Affairs & Provost for appeal.

17. Disclosure and Notification

Covered Persons shall disclose all relationships with commercial entities as described in the MUSC/MUHA Board of Trustees Conflict of Interest Policy. This policy can be found at www.musc.edu/coi.

If there is a question about appropriate interaction with a commercial entity or the potential for a Conflict of Interest, the Covered Person should consult with individuals within their chain of command, the MUSC Conflict of Interest Office, MUSC, MUHA or UMA Office of Compliance, or the MUSC General Counsel's Office for guidance.

18. Sanctions for Violations

Violations of this Policy, including the failure to avoid a prohibited activity or disclose relationships with commercial entities will be dealt with in accordance with applicable policies and procedures that may include disciplinary action up to and including termination of employment or medical staff privileges. Sanctions may include suspension or dismissal, non-renewal of appointment, denial of eligibility to engage in research funded through MUSC, denial of merit pay, or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. Termination of medical staff privileges or denial of medical staff privileges under this policy will not be based upon a physician's individual competence, quality of care, or professional conduct. Therefore, the revocation or denial of appointment or reappointment will not be reportable to any agency or databank.

The Vice President for Academic Affairs and Provost will determine the methods of resolving non-compliance with this policy and applying sanctions. The Provost may refer the matter to the appropriate College Dean or in the case of affiliates, to the senior administrative officer of that affiliate, take action on his or her own, or initiate MUSC procedures governing such discipline.

The Board of Trustees, as the ultimate governing body, or its designee, retains authority to make a final determination of any matter covered by this policy.

19. Office Responsible for this Policy

University Conflict of Interest Office

20. References and Resources

- Korn D. Carlat D. Conflicts of interest in medical education: Recommendations from the Pew Task Force on medical conflicts of interest. *Journal of the American Medical Association*. 310(22):2397-2398, 2013.
- Boumil MM. Cutrell ES. Lowney KE. Berman HA. Pharmaceutical speakers' bureaus, academic freedom, and the management of promotional speaking at academic medical centers. *Journal of Law, Medicine & Ethics*. 40(2):311-25, 2012.

For further information regarding conflicts of interest in medicine and academics related to Industry relationships, visit the Industry Relations webpage (www.musc.edu/coi/industryrelations/industryrelations) on the Conflict of Interest website.