POLICY INDEX

1. Purpose and Scope
2. Covered Persons
3. Definitions
4. Consulting and Educational Programming
   a. Consulting
   i. Approved consulting activities
   ii. Prohibited consulting activities
   b. Educational Programming
   i. Approved educational speaker activities
   ii. Prohibited educational speaker activities
   iii. Attendance at educational meetings sponsored by Industry
   c. Payments for Consulting and Educational Programming Activities
   d. Leave Status Requirements for Consulting and Educational Programming Activities
   e. Consulting or Educational Programming Conducted with Concurrent Research
   f. Consulting or Educational Programming Contracts
   g. Approval Process for Consulting and Educational Programming
5. Gifts
6. Food, Beverages and General Hospitality
7. Industry Supported Continuing Education Programs
8. Educational Materials and Equipment
9. Scholarships and other Educational Funding for Students and Residents
10. Charitable Contributions
11. Pharmaceutical Samples
12. Site Access
13. Use of Confidential Information
14. Purchasing
15. Exceptions
16. Disclosure and Notification
17. Sanctions for Violations
18. Office Responsible for this Policy
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 and Staff 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 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 MUSC employees.

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 employee’s immediate family, including the employee’s parents, spouse, siblings, children, stepchildren and grandchildren.

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

Personal Leave is defined as that time away from work taken as vacation, 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 MUSC employee’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.

Policy Statement
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 MUSC employees (see also above).
The provision of bona fide Consulting Services by MUSC personnel 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 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 MUSC personnel 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 the employee 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 the employee’s work. Education provided by MUSC employees shall be in the best interest of the public, independent from commercial interest, and refrain from product promotion. Additionally, MUSC recognizes the benefits that employees obtain by attending educational programs.

Policy Statement
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 MUSC employees. The policy also applies to MUSC employees who attend such educational meetings.

1. 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 \(^1\) or the ADA CERP Continuing Education Recognition Program, 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 MUSC employees for speaking and for travel costs for these approved

\(^1\) Accreditation Council for Continuing Medical Education, Standards to Ensure the Independence of CME Activities (2007)
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 MUSC employee.
- Participating in any speaker’s bureau activities, regardless of the source of the presentation content.
- Providing industry sponsored continuing education (CE) services or scientific or medical training to an audience consisting only of MUSC employees.

iii. **Attendance at educational meetings sponsored by Industry**
MUSC employees 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 only).

The lists of approved and prohibited educational activities are the same whether these activities are done on personal or professional time. All MUSC personnel 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, the employee should coordinate with the Conflict of Interest Office to determine reporting requirements for any industry relationship.

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.
• Employees 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.
• MUSC employees 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 MUSC employee from the external entity. The employee 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 employees performing consulting OR educational programming activities on personal leave.
• MUSC employees 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 employee.
• Employees 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.
• Employees 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 employees 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, the individual employee 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 MUSC
employees 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:**
Employees who consult or provide educational programming on Personal Leave are acting as independent contractors. Employees may not bind or obligate MUSC in any way. Contracts entered into by MUSC employees 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, the employee 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 employees 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**

MUSC employees 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.
Faculty members, staff, students and trainees 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. Students and trainees 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, MUSC employees should not accept food and beverages, support for social events, or other hospitality offered directly by Industry to the employee. Industry support for food and beverages for college, department or division meetings or retreats is prohibited.

MUSC employees 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.

An MUSC employee engaged in off-site consulting may accept food and beverages as a part of a reasonable compensation package for consulting services.

MUSC employees 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. Employees 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 Accreditation Council for Continuing Medical Education, 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 MUSC employees 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 employee. 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. MUSC employees may not independently solicit Industry for these purposes. 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. 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).

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

12. 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.
13. Use of Confidential Information
Unauthorized use of confidential, privileged or proprietary information by MUSC employees 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 employee or their family member.

14. 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.

15. 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, an employee may submit their request in writing to the MUSC Vice President for Academic Affairs & Provost for appeal.

16. Disclosure and Notification
Employees 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 employee 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.

17. 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 affiliate employees 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.

18. **Office Responsible for this Policy**
University Conflict of Interest Office