

MUSC Office of CME (OCME) Conflict of Interest Policies and Procedures

Policy

The Medical University of South Carolina, as an ACCME accredited provider, endorses and strives to comply with the Accreditation Council for Continuing Medical Education Standards of Commercial Support, South Carolina statutes, Medical University of South Carolina policies and procedures, and associated federal and private regulations and guidelines on the need for disclosure and monitoring of proprietary and financial interests that may affect the scientific integrity and balance of content delivered in continuing medical education activities in our name.

The MUSC College of Medicine requires that all CME activities accredited through this institution be developed independently of a commercial interest and be scientifically rigorous, balanced and objective.

Definition of Conflict of Interest (COI)

According to the ACCME Standards of Commercial Support (approved September 2004), a **conflict of interest** is present when individuals in a position to control the content of CME (**or their spouses/partners**) have a relevant personal financial relationship with a commercial entity that benefits the individual and may ultimately bias the presentation of that content to colleagues and participants. The factors listed below serve as part of the foundation for development of fair and balanced education:

- both a financial relationship (**in any amount**) with a commercial interest occurring within the past 12 months
- and the opportunity to affect the content of CME about the products or services of that commercial interest.

These relationships must reflect **direct** relationships between the proprietary entity and the individual. The nature of the relationship and its effect on the individual's primary professional role, commitments and responsibilities on the content of the continuing medical education activity must be considered during the planning phase of the CME activity and communicated to participants.

Examples of **direct** relationships may be found in the following scenarios:

- Employment, management positions
- Independent contractor (*including contracted research, which includes research funding where the institution receives the grant, manages the funds, and the individual is the principal or named investigator*)
- Consultant
- Speaker's Bureaus and teaching engagements
- Membership on Advisory Committees or review panels
- Other activities when remuneration is received or expected

In all these situations, the individual may receive financial benefits that can be described as salary (retainer), royalties, intellectual property rights, consulting fees, honoraria, ownership interests (stocks, stock options, etc. excluding diversified mutual/retirement funds not under the individual's control).

When a conflict of interest is identified, the MUSC Office of CME will work with the department and divisions to resolve this conflict in a variety of methods established by ACCME.

Medical University of South Carolina Office of CME Responsibilities

MUSC Office of CME, as the designated Accreditation Council for Continuing Medical Education (ACCME) entity for the College of Medicine, is responsible for creating a mechanism to identify, review and resolve all conflicts of interests **for all individuals involved in the planning and implementation of an ACCME certified activity**. It is the responsibility of the Office of Continuing Medical Education, in collaboration with the course director, planning committee and CME advisory committee to review the disclosure statements and assure that CME activities sponsored by the Medical University of South Carolina are free of commercial bias and that clinical recommendations are based on evidence that is accepted within the profession of Medicine as adequate justification for the care of patients.

MUSC Office of CME incorporates the following strategies as part of the overall planning process of CME activities:

- Identify the presence or absence of any financial relationship that may constitute a potential conflict of interest for all individuals involved in the planning and implementation of the proposed CME activity (planning committee members, faculty presenters, authors, etc.).
- Failure of any individual to provide disclosure immediately disqualifies that individual from participation in the planning and/or implementation of the proposed CME activity.
- Implement educational planning and design strategies that work to ensure that content are scientifically rigorous, evidenced-based and balanced, and reflect the current standards of care and/or future directions of medicine and healthcare.
- Monitor and manage its CME activities in accordance with the current standards, regulations and guidelines outlined by the constituencies involved in the delivery of continuing medical education, research and patient care.
- Document the processes for needs assessment, gap analysis, content validation, and educational design that provide for fair and balanced discussion of the desired topics.
- Monitor the execution of CME activities to validate the presence/absence of commercial bias and the consistent application of the standards of quality education for physicians and other healthcare professionals.

RESOLUTION OF CONFLICTS OF INTEREST (COI)

Disclosure and Resolution

The Medical University of South Carolina Office of Continuing Medical Education identifies the presence or absence of relevant financial relationships for all planning

committee members, course directors, invited faculty presenters/authors, and staff through the use of a standardized disclosure form. If a COI is identified, one of the mechanisms listed below may be used to resolve it:

1. *Altering financial relationships:* An individual may change his/her relationships with commercial interests, i.e. discontinue contracted services, and in doing so, no duty, loyalty or incentive remains to introduce bias into the CME content. However, when an individual divests themselves of a relationship, it is immediately not relevant to conflict of interest but it must be disclosed to the learners for 12 months.
2. *Altering control over content:* An individual's control of CME content can be altered in several ways to remove the opportunity to affect content related to the products/services of a commercial interest. These include:
 - *Choosing someone else to control that part of the content* – If a proposed teacher/author has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interests related to the content.
 - *Change the focus of the CME activity* – The CME provider can change the focus of the activity so that the content is not relevant to the products/services of the commercial interest that is the basis of the conflict.
 - *Change the content of the person's assignment* – The role of a person with a conflict of interest can be changed within the CME activity so that he/she is no longer teaching about issues relevant to the products/services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a disease state could address the pathophysiology or diagnosis of the disease rather than the therapeutics.
 - *Limit the content to a report without recommendations* – If an individual has been funded by a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and clinical recommendations.
 - *Limit the sources for recommendations* – Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (evidence-based). For example, the individual could present summaries from the systematic reviews of a peer reviewed source, i.e. the Cochrane Collaboration (www.cochrane.org).
 - *Evaluation:* Attendees will be queried regarding their impressions concerning bias (or the absence of bias) and scientific integrity within the

activity. CME Associates, Course Directors, and OCME Staff share the responsibility to evaluate the perception of bias by the learners in any CME activity. They further share responsibility to communicate any evidence of bias to those who created the impression of bias. Documentation of the evidence, and any actions taken based on the evidence, must be communicated to the OCME.

3. *Independent content validation:* An independent review by a content expert not involved with the CME activity may resolve conflicts of interest by ensuring the content is valid, aligned with the interests of the public, and:
 - All the recommendations involving clinical medicine are based on best available evidence – evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
 - All scientific research referred to, reported or used in a CME activity in support as a justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.
4. *Elimination:* Activity directors, planning committee members, teachers and authors who are perceived as either having conflicts of interest or being biased may be eliminated from consideration as resources (committee members, teachers, authors, etc.) in subsequent certified CME activities.

Educational planning and design of CME activities

The Medical University of South Carolina Office of Continuing Medical Education will continue its longstanding practice of integral involvement in all of its CME accredited activities. The planning process for both direct and jointly sponsored activities require early involvement of the MUSC Office of CME, active participation in the development and implementation of the CME activity of these activities.

Specific strategies include:

- Implement educational planning and design strategies that work to ensure that content is scientifically rigorous, evidenced-based and balanced and reflects the current standards of care and/or future directions of medicine and healthcare.
- Monitor and manage its continuing medical education activities in accordance with the current standards, regulations and guidelines outlined by the constituencies involved in the delivery of continuing medical education, research and patient care.
- Document the processes for needs assessment, content validation, and educational design that provide for fair and balanced discussion of the desired topics.
- Encourage opportunities for interactivity, differences of opinion and/or dialogue which we believe serve as the foundation for professional development and continuous improvement in approaches to patient care.

- Monitor the execution of CME activities to validate the presence/absence of commercial bias and the consistent application of the standards of quality education for physicians and other healthcare professionals.

Timing of the Identification, Management, and Resolution of Conflicts of Interest

Course Director(s) and Planning Committee Member(s):

- Completion of the MUSC Office of CME disclosure and attestation, if applicable, with submission of the CME application. Applications will not be reviewed until disclosure is completed and submitted to MUSC OCME.
- Financial relationship(s) is/are reviewed by CME staff:
 - No COI identified: no action will be taken and planning process can continue.
 - COI is identified: CME staff will determine how topics and faculty were determined and obtain evidence that the topics represent a balanced, EBM approach.

Faculty/Speaker/Author:

- Completion of the MUSC Office of CME disclosure and attestation, if applicable, upon confirmation.
- Financial relationship(s) is reviewed by CME faculty and staff:
 - No COI is identified: no action will be taken and the individual can proceed with developing content.
 - COI is identified: CME faculty and staff will determine the appropriate secondary resolution method as described above.

College of Medicine CME Advisory Committee Members:

- Disclosure of financial relationships with commercial interest(s) must be obtained from all potential CME Advisory Committee Members.
- The Director reviews the disclosure statements to identify and resolve conflicts of interest.
- If this does not result in satisfactory resolution of all conflicts of interest, the process will continue through the following levels:
 - Director of CME
 - Associate Dean of CME
 - CME Advisory Committee
 - Other resources with appropriate expertise
- After the process, conflicts are considered resolved if it is determined:
 - No conflict exists;
 - No material conflict exists;
 - Material conflict exists but public good outweighs conflict

- If the conflict cannot be satisfactorily resolved, the Dean will request and accept the resignation of the involved CME Advisory Committee member.

IMPORTANT

An individual who refuses to disclose relevant financial relationships will be disqualified from being an activity director, planning committee member, speaker or author for a CME activity and cannot have control of or responsibility for the development, management, presentation, or evaluation of the CME activity.

When Conflict of Interest cannot be effectively resolved

While MUSC Office of Continuing Medical Education strives to be flexible, accessible and helpful in the development and implementation of CME certified activities, there are some situations where adequate resolution of COI may not be feasible. In these situations, CME certification will not be provided. Examples of these situations include:

- Requests for CME certification of the content after the majority of the planning for the CME activity has occurred with faculty and/or content selections already determined;
- Short planning timeframes that do not permit adequate planning and implementation of required ACCME and MUSC Office of CME policies and procedures;
- Inappropriate processes in educational planning and/or financial management that are not consistent with ACCME and/or MUSC Office of Continuing Medical Education policies and procedures.

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Approved by the Medical University of South Carolina
College of Medicine CME Advisory Committee and
Robert Malcolm, MD, Associate Dean for CME

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