

WSU College of Medicine on the ACCME Standards for Ensuring Integrity and Independence in Accredited CE

The Washington State University (WSU) College of Medicine (COM) Continuing Medical Education (CME) program adheres to the Criteria, Standards, and Policies set forth by the Accreditation Council for Continuing Medical Education (ACCME). See ACCME Standards at <https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>

I. DEFINITIONS

Ineligible Company: The ACCME defines an ineligible company as “any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.” See definition and examples: <https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility>

Educational Grant: Grants awarded, or monies given with nothing provided in exchange for the funds by an ineligible company to support CME are considered “Commercial Support” of CME by the ACCME. Commercial Support is managed under ACCME Standard 4.

Corporate Sponsorship: Funding provided by an ineligible company in exchange for goods or services provided by the WSU COM in connection with a CME activity fall under the following categories: Advertising or exhibiting and is not considered “Commercial Support” – this funding is managed under ACCME Standard 5.

In-Kind Support: Non-cash or non-monetary contributions (e.g., materials, equipment, devices, etc.) provided by an ineligible company. The ACCME considers in-kind support from ineligible companies to be Commercial Support.

Non-CME Informational/Educational Program or Product: ACCME requirements are outlined under Standards to Ensure Independence and Integrity in Accredited Education (<https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-5-manage-ancillary-activities-offered-conjunction-accredited>).

Financial Relationship: The exchange of money or stock directly between an individual and an ineligible company. Financial relationships of any dollar amount are to be disclosed. Research funding given to an institution is only disclosed by the named Principal Investigator.

Relevant Financial Relationships: Per the ACCME, the accredited provider is responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education.

Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company.

Owner/Employee: Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job.

Charitable Contributions (Donations): Funding provided to WSU COM by an organization that does not fall under the definition of an ineligible company.

Mitigation: The process undertaken by WSU COM to manage bias that may be introduced into accredited education as a result of the financial relationships individuals in control of CME content have with ineligible companies. Individuals may not mitigate for their own bias as a result of their relationships; WSU COM must control the process.

II PRINCIPLES FOR INTERACTIONS

1. Independence

1.1 WSU COM is committed to ensuring that its educational activities, scientific programs, products, services, and advocacy positions are independent of ineligible company influence.

1.2 WSU COM will separate efforts to seek Educational Grants, Charitable Contributions and Research Grants from CME programming decisions.

1.3 WSU COM CME program staff will interact with ineligible companies to seek support outlined in Section 1.2.

1.4 No WSU COM member in a position to direct the content of educational programs will participate in the solicitation of entities in section 1.2. All individuals in control of CME content are prohibited from taking any compensation directly from an ineligible company in connection with a CME activity; this includes reimbursement for travel, consulting fees, etc. All funding provided by an ineligible company in connection with a CME activity must be controlled by WSU COM.

1.5 Owners and employees of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty, and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined below:

- a. When the content of the activity is not related to the business lines or products of their employer/company.
- b. When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
- c. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

1.5.1 In accordance with ACCME Standards, compensation (salary or other) received in connection with the provision of healthcare or clinical services to the public or patients (as long as it is not provided by an ineligible company) is not considered to be a disclosable relationship. An individual in control of CME content may own stock in a public ineligible company and may hold stock options (but not own or be a named founder) in a private ineligible company. A WSU COM faculty may receive compensation as consulting fees, as royalties, for participating on data safety or advisory boards, or be the named PI on research funding provided by an ineligible company. All of which must be disclosed to WSU COM and mitigated in accordance with ACCME Standards.

2. Transparency

2.1 WSU COM will disclose to attendees of CME activities, on WSU COM CloudCME page, the relevant relationships of all those in a position to control CME content. This includes, speakers, presenters, abstract presenters, planning committee members, moderators, facilitators, peer reviewers, etc.

2.2 WSU COM will disclose all relevant relationships of committee members to the committees at large as a mechanism for ensuring against bias in CME as a result of financial relationships with ineligible companies of committee members.

2.3 WSU COM CME program, with collaboration by the Vice Dean of GME/CME & Partnerships, will have authority to make decisions regarding the management/mitigation of any relationships that are viewed to bias CME content.

3. Charitable Contributions

3.1 WSU COM will control the use of Charitable Contributions in a manner that is aligned with its strategic plan and mission.

3.2 WSU COM will not accept Charitable Contributions from a Company if the Company expects to influence WSU COM CME programs, or where Company's restrictions would influence CME activities in a manner that is not aligned with the WSU COM CME programs mission.

3.3 WSU COM will adhere to applicable tax rules and legal standards for acceptance of Charitable Contributions and management of institutional funds.

3.4 Charitable Contributions may be designated to support a broad area of WSU COM's mission as long as the donor is not permitted to influence or control any part of the program

3.5 WSU COM will adopt policies for consistent and appropriate recognition of donors.

3.6 WSU COM will maintain a separate line item in the budget to track aggregate charitable contributions as required for reporting to the ACCME.

4. Accepting Corporate Sponsorships

4.1 WSU COM does not accept commercial support.

5. AHS Meetings

5.1 Educational and Informational Programs

5.1.1 When providing CME, WSU COM must comply with ACCME Criteria, Standards, and Policies. (See Section 3 Resources Section).

5.1.2 WSU COM will not seek support for product-specific topics in CME programs.

5.1.3 WSU COM will manage all commercial support in accordance with ACCME Criteria, Standards, and Policies to ensure that educational programs are non-promotional and free from commercial influence and bias.

5.1.4 WSU COM will not solicit Companies' suggestions about topics, speakers or content, nor allow ineligible companies to be a joint provider for CME.

5.1.5 Use of company-created presentation materials and slides, or the inclusion of company logos, trade names, slogans, or trademarks is prohibited at WSU COM CME-accredited educational activities.

5.1.6 Individuals presenting at WSU COM CME-accredited educational sessions will disclose all financial relationships with ineligible companies and explain how any of these are particularly relevant to their presentation or session. (ACCME Standard 3)

5.3 Exhibits

5.3.1 WSU COM will adopt written policies governing the nature of exhibits and the conduct of exhibitors, and require exhibitors to comply with applicable laws, regulations and guidance.

5.3.2 WSU COM will adhere to the ACCME's Criteria, Standards, and Policies pertaining to the separation of promotion and education. ACCME Standards 2 & 5.

III. IMPLEMENTATION PROCEDURES

1. Collection and Review of Disclosures

Disclosure of Financial Relationships is completed by anyone who can control content for a CME activity; the WSU COM CME program will review all disclosures of relationships by presenters and others.

2. Mechanisms to Identify and Mitigate for Bias in Accredited Education

2.1 General Participation in CME Activities

This section lists potential resolution mechanisms for mitigating for bias. Mitigation mechanisms will vary depending on the nature of the financial relationship. WSU COM CME staff, and the Vice Dean of GME/CME & Partnerships will notify contributors of the mechanism selected for their activity and advise contributors if any additional strategies are recommended.

The following mechanisms apply to contributions in all WSU COM CME-accredited activities:

2.1.1 Signed Attestation: By completing and signing the Disclosure Form the contributor agrees that the disclosed financial relationships will not bias or otherwise influence their involvement in the CME activity. Practice recommendations will be limited to those based on the best available evidence (or absence of evidence), and recommendations will be consistent with generally accepted medical practice. They also agree to all other mandatory ACCME disclosure guidelines. See ACCME Standards 1 & 2.

2.1.2 Follow-up Communication: If a relevant relationship is identified, WSU COM CME staff will follow-up with contributor (e.g., faculty, teacher, presenter, author) to discuss ways to avoid the potential for or perception of bias due to disclosed relationships. Staff will document the mitigation with the contributor and committee member on internal records and notify through CloudCME to document the completed mitigation process to the parties directly involved, the Chair of the Program Committee.

2.1.3 Altering the content or control of the activity: An individual's control of CME content can be altered or modified to remove the opportunity to affect content related to the products/services of a Company. For example:

- a. Select someone else to control that part of the content -- if a proposed contributor has a relevant relationship that cannot be satisfactorily mitigated.

- b. Change the content of the person's assignment – the role of a person with relevant relationships can be changed within the CME activity so that he or she is no longer teaching about issues relevant to the products/services of the Company.

Limit the content to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and not make care recommendations.

The owners and employees of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in the limited circumstances outlined in Standard 3.2.

2.1.4 Review of Content: WSU COM CME staff will appoint peer reviewers (defined as individuals free from relevant relationships) to mitigate for bias through a review of presentations submitted by individuals who have disclosed relevant relationships in advance of the CME activity. WSU COM CME program staff will complete documentation to determine whether any bias was in the presentation and, if so, the resolution mechanism provided to the contributor to mitigate for the bias.

The agenda for the CME activity will be reviewed and approved by the CME Committee and WSU COM CME program staff prior to confirmation of speakers.

2.1.5 Altering financial relationships: Relevant relationships must be disclosed to learners for the past 24 months and the existence of no relevant relationships must be disclosed as well. If the contributor's relationship with an ineligible company has changed or been discontinued within the past 24 months, the change should be disclosed.

2.1.6 Elimination: Contributors who are manifesting bias as a result of relevant relationships may be eliminated from consideration as resources (committee members, planners, teachers, authors, etc.) in current and subsequent CME activities as long as the relationship remains in place.

2.1.7 Disclosure to Learners: Disclosures of the presence or absence of relevant financial relationships, for all individuals involved in CME content and their roles, are made prior to the CME activity on CloudCME overview page, and additionally may be included in the printed syllabus, on the slides, on the meeting app (if applicable) and verbally from the podium for faculty/presenters.

2.2 Additional Mitigation Mechanisms for Education Committee, Program Committee and CME Advisory Council Members

2.2.1 Signed Annual Statement: By completing and signing the annual Disclosure of Financial Relationships form, the committee member agrees that he/she may be recused from the discussion and vote on the relevant submitted activity, as a method to mitigate for bias.

IV RESOURCES

Accreditation Council for Continuing Medical Education (ACCME) Policies

<https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>

Policy Approval Process/Date: