

Washington University School of Medicine Disclosure of Interest Policy and Procedures

Statement of Intent

As a provider accredited by the ACCME, Washington University must ensure balance, independence, objectivity, and scientific rigor in all Continuing Medical Education (CME) activities that it provides and credits. The content or format of CME activities and related materials must be crafted to promote improvements in quality of healthcare and not to promote proprietary business or commercial interest.

All persons in a position to influence the content of a CME activity are expected to adhere to the highest standards of academic integrity. Recommendations for medical practice must be based on evidence that is accepted within the profession as adequate justification for their indications. Investigational approaches should be identified as such. Furthermore, all scientific research referred to, reported, or used in CME in support or justification of patient care recommendations must conform to the generally accepted standards of biomedical research. Whenever possible, planners, presenters, and authors of CME activities should reference the best available evidence and describe the level of evidence supporting a particular diagnostic or management strategy.

The intent of disclosure is not to prevent expert faculty with relevant financial relationships from engaging in the planning or delivery of content, but to ensure that Washington University CME accredited activities are in the best interest of the public, promote quality and safety, and present unbiased, valid content.

Definition of Conflict of Interest

In accordance with ACCME criteria, circumstances create a conflict of interest (COI) when an individual has an opportunity to affect CME content about products or services of a commercial interest¹ with which he/she or his/her spouse/partner has a financial relationship.² For example, if you are speaking about treatments for atrial fibrillation at your department's Grand Rounds, and your spouse/partner is a paid consultant for company X on a medication they are developing for atrial fibrillation, this represents a potential conflict of interest and must be disclosed.

¹ 'Commercial interest' is defined as any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by, or used on, patients. This does not include providers of clinical services directly to patients, government organizations, or non-healthcare related companies.

² 'Financial relationships' are those in which the individual benefits by receiving a salary, research support, grant, royalty, intellectual property rights, consulting fee, speaking fee, membership on advisory committee or review panel, ownership interest or other financial benefit in any amount over the last 12 months from a commercial interest whose products or services are discussed. ***This includes the financial relationships of a spouse/partner.**

If an individual is employed by a commercial interest, that individual is prohibited from being involved in the planning or presentation of a CME activity. There are three exceptions in which such an individual can have a limited role:

- 1) when content is not related to the business lines or products of their employer³ OR
- 2) when content is limited to basic science research or the processes/methodologies of research (e.g., preclinical trials or drug discovery) OR
- 3) as a technician that teaches the safe and proper use of devices.

* If the employment is that of the spouse/partner, the actual speaker is not considered an employee and the relationship should now be treated the same as any other relevant financial relationship.

Procedures for Identifying, Managing, and Resolving Conflicts of Interest

All individuals in a position to control the content of a CME activity (chairperson, planning committee members, speakers, moderators, authors, etc.) are required to complete a **Disclosure of Financial Relationships** and a **Washington University CME Standards of Content Agreement** in which they attest that all patient care recommendations will be based on the best available evidence and that a balanced view of therapeutic options will be provided. Disclosure and resolution of potential COI must occur as follows:

Role in activity	When disclosure <i>and</i> resolution must occur
Activity chairpersons and planning committee members	Beginning of the activity planning. Before topics and speakers are chosen.
Activity speakers, moderators or authors	Before presentations are given or enduring materials finalized.

* Anyone who fails to disclose will be disqualified from participating as planner or faculty in the CME activity.

Process

- Activity chairpersons and planning committee members:
 - Complete the Disclosure of Financial Relationship and CME Standards of Content Agreement at the beginning of the planning process.
 - The CME department will review these disclosures and the content agreements
 - *If NO financial relationships exist*, no action is required. Faculty letters will instruct the presenters on the rules for developing CME content.
 - *If potential COI is identified*, the methods of resolution listed below for planners should be followed and documented.

³ Note that for employees of commercial interests, the ACCME views the role of the employee at that organization as immaterial; it does not matter whether the employee is working on a product relevant to the topic being discussed. It also does not matter whether any of the company's products will be discussed at the activity; the key element is whether the company is developing or marketing any product for use in the condition being discussed. For example, if the topic of a planned CME activity is hypertension, an employee of a company that markets or is developing an antihypertensive agent may not participate, even if the individual does not directly work on that product.

- Activity speakers, moderators or authors:
 - CME activity chair/planners/coordinators, in conjunction with the CME department, have primary responsibility for collecting and reviewing disclosures of interest for **speakers, moderators, and authors.**

If ANY relationships are disclosed:	If NO relationships are disclosed:
If the companies with which there are relationships offer any products/services for disease state being presented, this requires a slide review to be done prior to the presentation being given to resolve any potential COI.	No review/resolution is needed
The steps that should be taken to resolve any potential COI are outlined below and the Potential COI Resolution form provided on the CME website must be completed prior to the presentation start and submitted to CME for verification.	This lack of relationships must still be announced to the audience either verbally, printed or in the powerpoint presentation.

* The CME department should be consulted when a resolution is unclear. The CME department and the chair of the proposed CME activity will discuss and resolve COI when necessary.

Mechanisms to Resolve (manage or mitigate) potential COI prior to the activity being delivered

Note that these mechanisms do not apply to employees of a commercial interest since such employment is considered by the ACCME to be a non-resolvable conflict.

Options for resolution for planners having potential COI

- Identify another faculty member with no relevant COI to assist/review planning and ensure independence of content.
- Replace planners having relevant COI with other experts who are not conflicted.
- Choose someone else who is not conflicted to control that portion of the content.
- The CME department will review how topics and faculty were chosen and obtain evidence that the topics represented are balanced and are supported with the best available evidence.

Options for resolution for speakers, moderators and authors having potential COI

- Utilize independent peer review to validate content and verify that all recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and that all scientific research conforms to the generally accepted standards of experimental design, data collection and analysis. Revise content as deemed necessary.
- Reference the best available evidence.
- Substitute an individual with no COI.
- Assign the individual with COI a role in which therapeutic options will not be recommended.
- If COI cannot be mitigated and content is to be presented, eliminate CME credit for that specific activity.

Note that for all CME activities, registrants must be surveyed regarding their perception of whether commercial bias existed, and if so, what the perceived bias was.

Transparency to Learners

Financial interests of all individuals involved with the CME activity, including planners, speakers, moderators, and authors, will be disclosed to the learners. All disclosures, even when there is ‘nothing to disclose’ need to be reported and documented. After all disclosures are received, reviewed and resolved, the financial disclosure listing in handout materials should include the following statement:

“Any potential conflicts of interest regarding this educational activity were addressed and resolved in accordance with ACCME guidelines.”

Regularly Scheduled Series

The above policies and procedures also apply to regularly scheduled series (RSS). The time frame should be as follows: At the beginning of the fiscal year, the activity chair and planning committee members must complete a Disclosure of Financial Relationships and CME Standards of Content Agreement. If the activity chair or planners disclose a potential conflict, a member of the CME department will follow the resolution guidelines for planners.

Disclosure of Industry Support

All industry support for a CME activity must be made known to learners prior to the education activity. See Industry Grant Support Guidelines and Policy for further information.