

Mitigation of Relevant Financial Relationship Speaker Form			
Activity Title:		CID No.:	Activity Date:
Name:			

Defining Conflict of Interest

Financial relationships are relevant if the following three conditions are met for the prospective person who will control content of the education:

1. A financial relationship, in any amount, exists between the person in control of content and an ineligible company.
2. The financial relationship existed during the past 24 months.
3. The content of the education for specific activity is related to the products of an ineligible company with whom the person has a financial relationship.

According to the Accreditation Council for Continuing Medical Education (ACCME), a conflict of interest occurs when an individual has a financial relationship with an ineligible company and can influence the content of CME about that company's products or services.

The ACCME defines an ineligible company as "those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients."

Examples include:

Advertising, marketing, or communication firms whose clients are ineligible companies

Bio-medical startups that have begun a governmental regulatory approval process

Compounding pharmacies that manufacture proprietary compounds

Device manufacturers or distributors

Diagnostic labs that sell proprietary products

Growers, distributors, manufacturers or sellers of medical foods and dietary supplements

Manufacturers of health-related wearable products

Pharmaceutical companies or distributors

Pharmacy benefit managers

Reagent manufacturers or sellers

Please submit this form to the CWRU CME Program with the completed sponsorship agreement.

Step 1: Review Disclosure Form and Content

Activity Director reviewed the disclosure form and content (slides, videos, etc.) before the activity.

Step 2: Please indicate whether the disclosed financial relationships are relevant.

Does the company have business lines/products relevant to the educational content of this course?

No

If no, please provide a rationale statement below. Explain the business line of the company and the scope of the topic to demonstrate that they are unrelated (*e.g., The presenter's relationship is with a medical device company that creates surgical clamps, and the presentation is about vascular disease assessment.*)

Yes

If yes, please select a mitigation strategy below:

All clinical recommendations will be evidence-based and free of commercial bias. Content will adhere to evidence-based practice guidelines, and peer-reviewed literature will be used. Please provide a rationale statement below. (*e.g., The presenter's relationship is with an assessment tool company and the content of the activity is about vascular disease assessment, but the presentation is focused on peer reviewed literature and no therapeutic recommendations will be made.*).

Divest the financial relationship (to end the financial relationship)

Please indicate the date by which the relationship will end. Confirmation will be required prior to approval.

Individual's conflict has been deemed immitigable, and they will be considered ineligible to plan, present, author, or review any aspect of this activity.

Use Other Methods (please describe):

If the Owner, Employee or Executive Board Member also complete Step 3.

Step 3: Owners, Employees, Executive Boards Members

Is the relationship current?

Yes – the relationship is still current

This relationship falls under a category prohibited by ACCME from participation in the activity. There are only three exceptions that allow for owners/employees/executive board members of ineligible companies to participate as planners or faculty in accredited continuing education.

Please select the exception criteria that best applies to this activity:

1. When the content of the activity is not related to the business lines or products of their employer/company.

2. 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, they do not make care recommendations.

3. 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.

None of the above

Please provide additional supporting details for your above selection, such as type of company, rationale for exception:

Company Website Link:

No –the relationship has ended

Date the relationship ended:

Activity Director

Date

CME Director

Date

Peer Reviewer
(if applicable)

Date

Case Western Reserve University School of Medicine
Continuing Medical Education Program
Mechanisms for Mitigation of Relevant Financial Relationships with Ineligible Companies
(Appendix A)

- A. Divest or alter the relevant financial relationship.** Individuals may change their relationship with ineligible companies (e.g., discontinue contracted services). This way no duty, loyalty, or incentive remains to introduce commercial bias into the CME content. However, disclosure that such a relationship had existed within the preceding 24 months must still be made to the audience.
- B. Alter control over content.** An individual's control of content can be altered in several ways to remove the opportunity to affect content related to the products and services of an ineligible company. These may include:
- **Disqualify the speaker, author or planner and select a replacement.** If a relevant financial relationship cannot be mitigated, the speaker, planner or author must be disqualified. If a speaker, planner or author refuses to disclose they will automatically be disqualified from participating in the CE activity. Failure to submit a disclosure form will be considered a refusal to disclose.
 - **Recusal from controlling aspects of the activity with which there is a relevant financial relationship.** If a proposed presenter, author, or planner has a relevant financial relationship related to the content, someone else who does not have a relationship with the ineligible company related to the content may present or plan this part of the content.
 - **Change the focus of the CME activity** so that the content is not about products or services of the ineligible company that is the basis of the relevant financial relationship.
 - **Change the assigned content** so that it is no longer about products or services of the ineligible company. For example, an individual with a relevant financial relationship regarding products for treatment of a condition could address the pathophysiology or diagnosis of the condition rather than the therapeutics.
 - **Limit the content to a report without recommendations.** If an individual has been funded by an ineligible company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else may be assigned to address broader implications and recommendations.
 - **Limit the sources for recommendations.** Rather than having a person with a relevant financial relationship present personal recommendation 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).
- C. Independent Content Validation.** A relevant financial relationship may be mitigated if the presentation is peer reviewed and;
- All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.
 - All scientific research referred to, reported, or used in accredited education in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.
 - Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.
 - Content cannot be included in accredited education if it advocates for unscientific approaches to diagnosis or therapy, or if the education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.
- D. Committee Consensus.** The Activity Director, in consultation with already-vetted planning committee members, will review any recommendations made by that planning member with the conflict to ensure that it is free from bias and mediate, if necessary, by committee consensus. Mediation could include removal of a) planner b) suggested speaker or c) suggested topic.

- E. Peer Review.** Peer review is the process where an individual with no relevant financial relationships reviews the content developed by a faculty member who has disclosed a relevant financial relationship.
- F. Review and Resolution**
Identified conflicts of interest may be reviewed by the Activity Director, Co-Director, Planning Committee Member, or Independent Peer Reviewer in the field. (Reviewers will also be asked to disclose their relevant financial relationships.) Additional information on a presentation may be collected for review. **If a relevant financial relationship cannot be mitigated through the mechanisms described above, AMA Category 1 credit will not be approved.**
- G. Oversight.** All financial relationships will be disclosed to CME activity participants. Activities will be evaluated by participants to determine if the content was free of bias and met acceptable scientific standards.