

Frequently Asked Questions for Disclosure and Resolution of Conflicts of Interest for CME Activities



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As an organization accredited by the Accreditation Council for Continuing Medical Education, Harvard Medical School's Department of Continuing Education (HMS DCE) is required to ensure that all educational activities are fair-balanced, scientifically rigorous, objective, and independent of any commercial influence. The purpose of this form is to help us identify and resolve all relevant conflicts of interests for all individuals who influence or control any aspect of a CME activity.

The ACCME defines a commercial entity as any entity producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients¹. The ACCME requires that CME providers identify "relevant financial relationships"—defined as financial relationships in any amount occurring within the past 12 months that create a conflict of interest—of the individual involved in CME and his or her spouse or partner and resolve the reported conflicts prior to the commencement of the CME activity.

What is a "conflict of interest?"

The ACCME considers that financial relationships create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

Where is the "conflict?"

When an individual has an opportunity to affect CME content with respect to products or services of a commercial interest with which he/she has a financial relationship, this presents a conflict of interest. The interests of the individuals in a position to control the content of the CME must always be aligned with what is in the best interest of the learner.

How do these circumstances create a conflict of interest?

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME. Commercial bias is prohibited in CME.

When a conflict of interest exists, it must be resolved prior to participation in the CME activity. Thus, the first step in this process is identifying such conflicts so that they may then be resolved through Harvard's conflict of interest resolution process.

What are you asked to disclose?

Please list the relevant financial relationships for either yourself or spouse/partner on the grid of the *Disclosure and Resolution of Financial Relationships* form. You are asked to provide the name of the commercial interest, the type of financial relationship and the content area of the relationship. The ACCME mandates that individuals who refuse to disclose need to be disqualified from participating in the CME activity.

The ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner. You will need to consider those relationships when you are meeting the requirements for disclosure of relevant financial relationships and identification and resolution of conflicts of interest. For example, if an individual in control of content discloses that their spouse or partner is an employee of an ACCME-defined commercial interest, you must consider the individual as an employee and take measures to ensure independence in the activity.

Examples of the types of relationships are: employee, ownership interest (e.g. stocks, stock options, or other ownership interest, excluding diversified mutual funds), consultant, contracted research/investigator, membership on boards, advisory committees or review panels, intellectual property rights, patent holder, royalty recipient, speaker's bureau, etc.

Indicate the clinical content area of the financial relationship so that reviewers may have an understanding of the relationship versus the content of the educational activity.

When should the Disclosure and Resolution of Conflicts of Interest Forms be submitted?

Disclosure forms for Course Directors and Planners: Disclosure forms for course directors and planners must be completed and submitted with the Activity Proposal. HMS DCE will review and resolve conflicts of interest before planning takes place.

Disclosure forms for Faculty/Speakers and Moderators: Disclosure forms for faculty/speakers and moderators must be submitted to the course director(s). A non-conflicted course director or designated non-conflicted physician will review and resolve all conflicts of interest at least 30 days prior to the CME activity. For those faculty or speakers with conflicts of interest, a non-conflicted

¹ For the purposes of this form do not consider providers of clinical service directly to patients to be a "commercial entity."
Disclosure and Resolution of COI Form

course director or designated non-conflicted physician must review the content or slide presentations prior to the CME activity. Appropriate resolution methods must be used and documented in the lower section of the *Disclosure and Resolution of Financial Relationships for CME Activities form*.

Disclosure forms for Reviewers: Disclosure forms for reviewers must be submitted to HMS DCE at least 30 days prior to the CME activity. A reviewer is a designated non-conflicted physician who is not serving as a director, planner, or faculty member, or moderator of the activity.

Disclosure to the Learners: Relevant financial relationships (or lack thereof) for all individuals in a position to control are disclosed to the learners prior to the start of the activity for all HMS certified CME activities.

For additional information, refer to the HMS Policy on the Identification and Resolution of Conflicts of Interest for CME activities.