



Conflicts of Interest Action

All CE-designated activities must be developed free from the control of a commercial interest and be balanced, objective, and scientifically rigorous.

DEFINITION OF CONFLICT OF INTEREST (COI)

A conflict of interest exists when individuals in a position to control the content of a CE activity have a relevant personal financial relationship with a commercial interest that benefits the individual and may ultimately bias the content being presented. The following factors serve as part of the foundation for potential COI:

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

When the individual's interests are aligned with those of a commercial interest the interests of the provider are in 'conflict' with the interests of the public. The interests of the people controlling CE must always be aligned with what is in the best interests of the public

DEFINITION OF A COMMERCIAL INTEREST

A commercial interest is defined as "any entity producing, marketing, selling, or distributing healthcare goods or services consumed by, or used on, patients."

Duke Health is responsible for creating a mechanism to identify, manage, and resolve all conflicts of interests for all individuals involved in the planning and implementation of a Joint Accredited activity.

We incorporate the following strategies as part of the overall planning process of CE activities:

- Identify financial relationship that may constitute a potential conflict of interest for all individuals involved in the planning and implementation of the proposed CE activity (planning committee members, faculty presenters, authors, etc.).
- Disqualify any individual who fails to provide disclosure from participation in the planning and/or implementation of the proposed CE activity.
- Implement educational planning and design strategies that work to ensure that content is balanced, scientifically rigorous, and evidenced-based and reflects the current standards of care and/or future directions of medicine and healthcare.
- Monitor and manage CE activities in accordance with the current standards, regulations and guidelines outlined by the constituencies involved in the delivery of continuing 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 CE activities to validate the presence/absence of commercial bias and the consistent application of the standards of quality education for physicians, nurses, pharmacists, and other healthcare professionals.
- Seek feedback from the learners on the effectiveness of all activities through an activity evaluation. Specific components of the evaluation include, rating how well each of the learning objectives was met, quality of the instructor (knowledge, clarity, responsiveness to questions, etc.), quality of learning materials, effectiveness of learning activities, perceptions of bias or commercialism, etc.



PROCEDURES FOR IDENTIFYING, MANAGING, AND CONFLICTS OF INTEREST ACTIONS

All individuals in a position to control the content of a CE activity (planning committee members, speakers, authors, etc.) are required to complete a disclosure and attestation form in which they disclose their financial relationships as well as attest that any and all clinical recommendations made for patient care will be based on the best available evidence, that a balanced view of therapeutic options will be given, and that the content will be developed in accordance with Joint Accreditation criteria. Duke Health implements primary and secondary COI resolution methods for all CE-designated activities; the primary resolution method is implemented for all individuals in a position to control the content of a CE activity. The secondary resolution methods are implemented for all individuals who have identified financial relationships with commercial interests through the primary resolution method.

Primary COI Action Method for All Activity Types:

Completion of the disclosure and attestation form as described above. In addition, learners will have the opportunity to identify any perceived commercial bias through the course evaluation.

Secondary COI Action Method Options by Activity Type:

Directly Provided, Live Courses (including regularly scheduled series [RSS]¹):

- Course Director(s) prospectively review the content and complete a “Resolution of Conflict of Interest” form stating the action taken to resolve the COI
- The speaker(s) prospectively provide slides for review prior to presenting; content is revised as needed according to the results of the review.

Directly Provided, Enduring Materials (i.e., print, Internet-based):

- Course Director(s) prospectively review the content and complete a “Resolution of Conflict of Interest” form stating the action taken to resolve the COI
- The authors prospectively provide slides for review prior to presenting; content is revised as needed according to the results of the review.

Jointly Provided Activities (Duke designates CE credits with external entity):

- All content will be prospectively reviewed and approved by Course Director(s) AND an independent content validation reviewer prior to the release of the activity; content will be revised as needed according to the results of the review.

Note: if the activity involves a moderator who has identified conflicts of interest and has no identifiable content to be reviewed, then the resolution method for that moderator consists of completion of the disclosure and attestation form as well as completion of the course evaluation by the activity learners.

Reported COI	Prescribed Prospective Actions
<i>Level 1:</i> No financial relationships	<ul style="list-style-type: none"> • No action required; designation letter provides guidelines for content development

¹ Because presentations given as part of RSS’s primarily consist of case discussions, presentation of clinical research findings, morbidity and mortality discussions, tumor boards, etc. the secondary resolution method will be utilized at Duke Medicine’s discretion.

<p><i>Level 1A:</i> Financial relationships with commercial interests but not related to content</p>	<ul style="list-style-type: none"> • No action required; designation letter provides guidelines for content development
<p><i>Level 2:</i> Individual has financial relationships with one or more commercial interests and related to content</p>	<ul style="list-style-type: none"> • Course director reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken
<p><i>Level 2A:</i> Individual has financial relationships with one or more commercial interests, including relationships with commercial supporter(s) of CE activity.</p>	<ul style="list-style-type: none"> • Course director reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken
<p><i>Level 3:</i> Course Director has financial relationships with one or more commercial interests related to content</p>	<ul style="list-style-type: none"> • Selected unconflicted expert peer reviewer reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken • Course director is to recuse self from participating in the planning of content of which there is conflict. • Course director cannot present content in a relevant financial relationship exists.
<p><i>Level 4:</i> Individual is employed by a commercial interest and related to content</p>	<ul style="list-style-type: none"> • The individual is not allowed to participate in the planning or presenting in activities in which credit is provided. • Employees of ACCME-defined commercial interests can control the content of accredited CME activities when the content of the CME activity is not related to the business lines or products of their employer. • Employees of ACCME-defined commercial interests can control the content of accredited CME activities (e.g., as planners, authors, or speakers [including poster presentations]) when the content of the accredited CME activity is limited to basic science research (e.g., pre-clinical research, drug discovery) or the processes/methodologies of research, themselves unrelated to a specific disease or compound/drug. In these circumstances, the accredited provider must be able to demonstrate that it has implemented processes to ensure employees of ACCME-defined commercial interests have no control of CME activity content that is related to clinical applications of the research/discovery or clinical recommendations concerning the business lines or products of their employer. • Employees of ACCME-defined commercial interests can participate as technicians in accredited CME activities that teach the safe and proper use of medical devices. In this circumstance, the accredited provider must demonstrate that it implements processes to ensure that employees of ACCME-defined commercial interests have no control of CME activity content that is related to

TIMING OF THE IDENTIFICATION, MANAGEMENT, AND ACTIONS AS A RESULT OF CONFLICTS OF INTEREST

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

- Completion of the disclosure and attestation at the time of the Joint Accreditation application. Credits will not be designated until disclosure is completed.
- Financial relationship(s) is reviewed:
 - No COI identified: no action will be taken and planning process can continue.
 - COI is identified: CE staff will determine how topics and faculty were determined and obtain evidence that the topics represent a balanced, evidenced-based medicine approach.

Faculty/Speaker/Moderator/Author:

- Completion of the disclosure and attestation at the time of the Joint Accreditation application. .
- Financial relationship(s) is reviewed:
 - No COI is identified: no action will be taken and the individual can proceed with developing content.
 - COI is identified: CE staff will determine the appropriate resolution method as described above.

SITUATIONS WHERE CONFLICT OF INTEREST CANNOT BE EFFECTIVELY RESOLVED

While Duke Health strives to be flexible, accessible and helpful in the development and implementation of CE-designated activities, there are some situations where adequate resolution of COI may not be feasible. In these situations, CE designation will not be provided. Examples of these situations include:

- Requests for CE designation of the content after the majority of the planning for the CE activity has occurred with faculty and/or content selections already determined;
- Short planning timeframes that don't permit adequate planning and implementation of required Joint Accreditation and policies;
- Inappropriate processes in educational planning and/or financial management that are not consistent with Joint Accreditation standards and criteria.