

GUIDELINES on FACULTY DISCLOSURE and FULL DISCLOSURE FORM

Thank you for agreeing to participate in a Weill Cornell Continuing Medical Education activity. In addition to arrangements regarding your participation made with your Course Director, you should be aware of the following:

I. Faculty Disclosure Policy for CME Activities

As a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME), Weill Cornell Medicine must ensure fair balance, independence, objectivity, and scientific rigor in all its individually provided or jointly provided educational activities.

All faculty participating in a CME activity are expected to follow accreditation guidelines and help us create high-quality education that is independent of industry influence. In order to participate as a person who will be able to control the educational content of this accredited CE activity, we ask that you disclose all financial relationships with any ineligible companies that you have had over the past 24 months. We define ineligible companies as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. There is no minimum financial threshold; you must disclose all financial relationships, regardless of the amount, with ineligible companies. We ask you to disclose regardless of whether you view the financial relationships as relevant to the education. For more information on the Standards for Integrity and Independence in Accredited Continuing Education, please visit **accme.org/standards**.

Why do we collect this information?

Since healthcare professionals serve as the trusted authorities when advising patients, they must protect their learning environment from industry influence to ensure they remain true to their ethical commitments. Many healthcare professionals have financial relationships with ineligible companies. By identifying and mitigating relevant financial relationships, we work together to create a protected space to learn, teach, and engage in scientific discourse free from influence from organizations that may have an incentive to insert commercial bias into education.

What are the next steps in this process?

After we receive your disclosure information, we will review it to determine whether your financial relationships are relevant to the education. Please note: the identification of relevant financial relationships does not necessarily mean that you are unable to participate in the planning and implementation of this educational activity. Rather, the accreditation standards require that relevant financial relationships are mitigated before you assume your role in this activity. To help us meet these expectations, please use the form we have provided to share all financial relationships you have had with ineligible companies during the past 24 months. This information is necessary in order for us to be able to move to the next steps in planning this continuing education activity. If you have questions about these expectations please contact the coordinator for the course.

Faculty are also required to disclose any discussions of unlabeled or investigational uses of any commercial products or devices not yet approved in the United States.

As such, you must complete the attached Full Faculty Disclosure Form prior to your course, and return it to your Course Director. The prospective audience shall be made aware of what might be construed as a conflict of interest by acknowledgment in the program and/or verbal introduction of a faculty member in addition to any discussion you are planning of off-label or investigational uses of treatments.

II. Personal Conflicts of Interest, Content of Presentations and Faculty Disclosure

Faculty for all Weill Cornell CME activities are expected to abide by the ACCME New Standards for Integrity and Independence in Accredited Continuing Education. These are available on the ACCME Website at <u>ACCME New Standards for Integrity and Independence in Accredited Continuing Education</u>. The following excerpts, however, are particularly relevant to faculty presenters:

1. Standard 1: Ensure Content is Valid

- a. 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.
- b. 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.
- c. 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.
- d. Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their 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.
- 2. Standard 2: Prevent Commercial Bias and Marketing in Accredited Continuing Education Standard 2 applies to all accredited continuing education. Accredited continuing education must protect learners from commercial bias and marketing.
 - a. The accredited provider must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company.
 - b. Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.
 - c. The accredited provider must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

3. Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships

Standard 3 applies to all accredited continuing education. Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education. 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.

Accredited providers must take the following steps when developing accredited continuing education. Exceptions are listed at the end of Standard 3.

a. Collect information: Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Disclosure information must include:

- i. The name of the ineligible company with which the person has a financial relationship.
- ii. b. The nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.
- b. Exclude owners or employees of ineligible companies: Review the information about financial relationships to identify individuals who are owners or employees of ineligible companies. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion—employees of ineligible companies can participate as planners or faculty in these specific situations:
 - i. When the content of the activity is not related to the business lines or products of their employer/company.
 - ii. When the content of the accredited activity is limited to basic science research, such as preclinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
 - iii. 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.
- c. **Identify relevant financial relationships**: Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.
- d. **Mitigate relevant financial relationships**: Take steps to prevent all those with relevant financial relationships from inserting commercial bias into content.
 - i. Mitigate relationships prior to the individuals assuming their roles. Take steps appropriate to the role of the individual. For example, steps for planners will likely be different than for faculty and would occur before planning begins.
 - ii. Document the steps taken to mitigate relevant financial relationships.
- e. **Disclose all relevant financial relationships to learners**: Disclosure to learners must include each of the following: a.
 - i. The names of the individuals with relevant financial relationships.
 - ii. The names of the ineligible companies with which they have relationships.
 - iii. The nature of the relationships.
 - iv. A statement that all relevant financial relationships have been mitigated. Identify ineligible companies by their name only. Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.

Disclose absence of relevant financial relationships. Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies. Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the accredited education.

III. Educational Objectives and Targeted Audience

The primary goal of all Weill Cornell CME activities is to lead to improved patient care. Faculty for all Weill Cornell CME activities are requested to familiarize themselves with the educational objectives and target audience for activities at which they participate in order to optimize their presentations. These are available

from your Course Director, and should be listed on the Full Disclosure Form attached.

IV. Providing Disclosure

In addition to disclosures that will be provided to all attendees at WCM CME activities, faculty participating in accredited CME activities are encouraged to include a disclosure slide to be shown at the beginning/start of your presentation. This slide should contain not only your disclosure information, but also a statement disclosing off-label or investigational uses of products that you may be speaking about.

The Office of Continuing Medical Education appreciates your lending your skills as an educator to Weill Cornell's Continuing Medical Education Program. Please feel free to contact your Course Director, or the Office of CME, at 646-962-6931, if you have any questions about your participation. You may also visit the CME website at http://cme.med.cornell.edu.