

Drexel University College of Medicine

CME Policy and Procedures on Disclosure, Mitigation of Conflicts of Interest and Content Validation

Section I Goal

A potential conflict of interest is created when an individual is in a position to control the content of CME programs and the individual has a financial relationship with a commercial interest (which is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients). A financial relationship is defined as a commercial interest within 24 months prior to the educational activity where the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fees, honoraria, stock ownership (excluding mutual funds) or other financial benefits. Financial benefits include compensation through employment, contracted research, consulting, speaker's bureau, teaching, membership on boards and panels and other activities for which remuneration is received.

Potential bias in a CME presentation can be introduced when limiting treatment options to those of one particular company, omitting information about products of competing companies, omitting unfavorable research about the company's products or emphasizing a single product. We rely on the professionalism of our distinguished presenters and recognize that professionals associated with CME do not knowingly bias information. However, we also acknowledge that the appearance of bias is an equally important concern, and the appearance of a conflict of interest may affect the perceived objectivity of a presentation and reflect the rudiments of a "marketing" rather than "educational" event. Full disclosure of relationships, disclosure of conflicts of interest and resolution of conflicts are the primary strategies mandated by the Accreditation Council for Continuing Medical Education (ACCME) to protect the integrity of CME activities.

Section II Procedure for Identifying and Mitigation Conflicts of Interest

There are three levels in the review and resolution process, the individual, the Activity Director, and the Peer Review Committee.

Level 1 - the individual in a position to control content of the CME activity (including the Activity Director, planning committee members, speakers, moderators, authors, etc. or "speakers et al.") are required to disclose commercial relationships (or the lack of) by completing and submitting (no later than eight weeks prior to the activity) the *Disclosure and Declaration Form* and a current curriculum vitae. The disclosure form instructs the respondent to identify commercial relationships, report potential conflicts and identify how the conflict will be mitigated. Disclosures must be updated annually or more frequently if relationships change. Strategies for mitigation conflicts of interest are outlined in **Section III**.

Level 2 - the Activity Director, who is in charge of the review and resolution process, reviews the disclosure form to determine if relationships have been identified and potential conflicts adequately mitigated. The Activity Director may elect to request additional materials for review. Speakers et al. are asked to submit their disclosures no later than eight weeks prior to the activity. If the speakers et al. either fail or refuse to identify relationships or are unable to mitigate conflicts, the Activity Director will have ample time to find a substitute or notify attendees that the presentation will not carry CME credit. If there are extenuating circumstances requiring the last-minute addition of faculty, the disclosure form must be reviewed and potential conflicts identified and mitigated. If time does not permit correction of the written materials, disclosure for the additional faculty shall be made either verbally or in writing prior to the speaker's presentation and noted in the activity program file.

If the speakers et al. have no relationships or there is no relationship between the speaker's financial interest and the program topic, there is "no conflict of interest" and this outcome should be noted on the *Verification and Resolution Form*. If there is a potential conflict which has not been satisfactorily mitigated by the individual, the Activity Director will mitigate the conflict utilizing one of the strategies outlined in **Section III**.

Level 3 - If the Activity Director is unable to mitigate the conflict, he/she will refer the issue to the Peer Review Committee. The Peer Review Committee, which may include individuals from the sponsoring department, recommendations of the department chair, approved members of the planning committee, members of the CME Committee and/or other experts as needed, will follow the strategies outlined in Section III and forward the decision to the Activity Director.

Reporting and Documenting the Outcome

The Activity Director is responsible for informing the speaker of the outcome and strategy to be used to mitigate the conflict of interest. Conflicts must be identified and mitigated prior to the presentation. The name of the commercial interest(s), the nature of the relationship (speaker's bureau, research grant, consultant, etc.) and the method of mitigating conflicts must be disclosed to the audience prior to the presentation. If the speaker has no relationship, this too must be disclosed to the audience. The Activity Director acknowledges these procedures were completed by signing and submitting to OCME the *Verification and Resolution Form*, the *Disclosure and Declaration Forms* (for each speaker et al.) and the CVs (electronic version of CV preferred in Word format). Resolution of conflicts must be documented in activity file and must be on file in OCME before credit can be awarded for the presentation.

Section III Strategies for Mitigating Conflicts of Interest

1. **Attestation:** Individuals in a position to control CME content are required to complete the *Disclosure and Declaration Form* at least eight weeks prior to the activity, identify commercial relationships (or the lack of), identify how conflicts will be mitigated and attest that relationships will not bias or otherwise influence their involvement in the CME activity. Individuals will be required to focus practice recommendations on the best available evidence and be consistent with generally accepted medical practice.
2. **Alter control over content:** An individual's control of CME content can be altered in order to eliminate potential bias.
 - Change the focus of the CME activity - The CME provider can change the focus of the activity so that the content is not relevant to the products/services of the commercial interest that is the basis of the conflict.
 - Select a co-presenter to control the part of the content in question - If a proposed speaker has a conflict of interest related to the content, select a co-presenter who has no commercial relationship which potentially conflicts with the presentation topic,
 - Change the role of the individual involved in the activity – Revise the role of the individual with the conflict to one which precludes her/him from making clinical recommendations.
 - Support the presentation and clinical recommendations with the "best available evidence" from medical literature - Provide two recent citations from peer-reviewed scientific literature that supports research referenced in the presentation. Evidence based references are available from a variety of resources including the Evidence Based Medicine Resource Center, <http://www.ebmny.org>; DUCOM's Evidence Based Medicine Subject Guide, <http://libguides.library.drexel.edu/az.php?s=37735>; the Cochrane Collaboration, <https://www.cochrane.org/evidence>; or other scholarly resources.

- Refrain from recommending specific products and/or services, limit the presentation to pathophysiology, diagnosis and/or research results - Presenters will be required to limit practice recommendations to those based on the best available evidence; discuss reasonable clinical alternatives/products and be consistent with generally accepted medical practice. If, within 24 months prior to the educational activity, the presenter has received a research grant from the commercial entity, the presentation may be limited to referencing the data and research results. A co-presenter can address inferences and recommendations.
3. Independent content validation: Enduring materials including scientific abstracts, journals, articles, monographs, and web-based activities will be peer-reviewed or judged against predetermined criteria before they are accepted for presentation, publication or renewal. The Peer Review Committee can mitigate conflicts of interest by ensuring the content is valid, aligned with the interests of the public, and:
 - All the recommendations involving clinical medicine are current and based on best available evidence - evidence that is generally accepted within the profession of medicine.
 - All scientific research referenced in support of patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis.
 4. Alter financial relationships: An individual may change his/her relationships with commercial interests by discontinuing the financial relationship, thereby eliminating the perceived incentive to introduce bias into the CME content.
 5. Recused: Individuals who refuse or fail to disclose relationships, or fail to mitigate conflicts of interest will be recused from participating in the CME activity.

Section IV Process for Monitoring Programs

- Attendees will be queried on the evaluation form regarding their perceptions of commercial bias during the activity. Faculty will receive copies of evaluation summaries and comments.
- Peer Review: Periodically, informed faculty will observe CME activities and provide feedback regarding impressions of commercial bias or conflicts of interest. Typically, such faculty will be the Activity Director, CME Committee Members, faculty attendees or moderators.
- Program Survey: Periodic faculty surveys will be conducted. Such surveys will include questions on perceived bias in the overall CME program.

Approved by the Drexel University College of Medicine Executive Committee of the Faculty – September 23, 2014