

Commercial Support Policy and Procedures

To ensure independence in development and implementation of CME activities from the control by commercial interests, the Case Western Reserve University CME Program complies with the *Standards for Commercial Support* of the Accreditation Council for Continuing Medical Education as approved and adopted September 28, 2004. The CME Program is committed to being an uncompromised provider of educational activities, life-long learning curricula and performance improvement strategies for practicing physicians through the dissemination and adoption of learning content based on the most recent, high quality scientific evidence.

Policy

All Activity Directors, planners and activity faculty involved in decisions about activity educational content must recognize and agree in writing to abide by the following policy provisions and procedures:

(1) Requirements for activity content:

- The educational content and related materials of all activities sponsored by the Case Western Reserve University CME Program must be independent of the control or influence of commercial interests in planning and implementation.
- Content and related materials must promote improvements or quality in healthcare.
- Content must provide a balanced view of therapeutic options.
- Content must be based on the most recent, high quality scientific evidence.
- Activity participants must be provided with the source and type of evidence.
- Content that is not established medical practice must be so identified.
- Discussion of unlabeled or investigational uses of a commercial product must be identified as such.

(2) Requirements for disclosure of relevant financial relationships:

- Anyone who is in a position to control or influence the content of an educational activity must disclose in writing all relevant financial relationships (paid speaker, consultant, research grant holder, etc.) and positions (e.g. employee, shareholder, director, etc.) A “relevant financial relationship” is any financial relationship in any amount occurring within the past 12 months or known to be forthcoming in the next 12 months that relates to the content or commercial supporter(s) of the activity that creates a conflict of interest or the appearance of a conflict of interest. Relationships of the person involved in the CME activity are considered to include those financial relationships of a spouse or partner of the person involved in the CME activity.
- Any individual who refuses to disclose relevant financial relationships will be disqualified from participating in the development, planning, implementation, provision or evaluation of CME activities.
- All relevant financial relationships must be disclosed in a written format (print, slide, Web page) to participants prior to the presentation of content of the

activity, including name of the individual, name of the commercial interest and the relationship between the two. If no relationships exist, this must be disclosed in the same manner.

- All sources of commercial support, both monetary and in-kind, must be disclosed to participants prior to the presentation of the content of the activity.

(3) Prevention strategies and monitoring to safeguard against commercial bias:

- Education concerning this Policy and its related Procedures will be made available by the CME Program to all Activity Directors, content planners and faculty.
- Anyone who is in a position to control or influence the content of an educational activity must agree in writing to adhere to this policy and the ACCME's *Standards for Commercial Support*. [Disclosure of Relevant Financial Relationship Form]
- The Case Western Reserve University CME Program will ensure the disclosure in writing to participants of each activity the financial relationships of all individuals involved in the development and presentation of content.
- The Case Western Reserve University CME Program will assess all activities for the potential for commercial bias and stratify the risk for bias in order to focus scrutiny on activities identified as having the greatest risk.
- The CME Activity Director and his/her Department Chair in the Case Western Reserve University School of Medicine or other institutional program director will be required by the CME Program to attest in writing that they have reviewed the activity planning process and educational content and found both free of control by commercial interests or bias. [Sponsorship Agreement]
- All activities sponsored by the Case Western Reserve University CME Program are subject to monitoring to ensure compliance with this policy, participant evaluation and peer-review to determine whether or not commercial bias is in evidence.

Procedures

All activities sponsored by the Case Western Reserve University CME Program must meet the following expectations:

(1) Education: The Case Western Reserve University CME Program must provide the Activity Director, planning committee and faculty with documentation of CWRU's Commercial Support Policy and complementary education to aid in understanding the Policy and its implications.

(2) Commercial Support: All commercial support, both monetary and in-kind, must be paid or contributed to Case Western Reserve University, one of its teaching affiliates or an entity subject to direct financial oversight by Case Western Reserve University.

Documentation must include:

- A **Commercial Support Agreement** between the provider and the commercial interest providing support.
- All financial contributions must be documented with a photocopy of the check.

- All in-kind contributions must be documented with a Commercial Support Agreement.

(3) **Disclosure and Agreement:** All individuals involved in the development and implementation of educational activities must agree in writing (Disclosure of Relevant Financial Form) to the following principles:

- Disclose any financial relationship related to (a) the activity's content, or (b) the activity's commercial supporters.
- Deliver balanced and evidence-based content.
- Offer the source and type of evidence (i.e. animal study, meta-analysis, RCT, etc.)
- Identify any discussion of unlabeled or investigational uses of a commercial product as such.

(4) **Resolving Conflicts of Interest:** The Activity Director and CME Associate Director are responsible for resolving conflicts of interest identified during the disclosure process by completing the Resolution of Conflict of Interest Form using one of the following Mechanisms for the Resolution or Management of Conflict of Interest with Commercial Entities. Conflicts must be resolved to assure that every reasonable effort is made to prevent or eliminate any commercial bias. The CME Advisory Committee in a peer review capacity has final oversight and discretion with respect to the resolution of any conflict. Conflicts of interest may be resolved in many ways, including:

- A. **Alter the financial relationship.** Individuals may change their relationship with commercial interests (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 12 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 a commercial interest. These may include:
 - **Disqualify the speaker, author or planner and select a replacement.** If a COI cannot be resolved, 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 return a disclosure form will be considered to be a refusal to disclose.
 - **Choose someone else to control that portion of the content.** If a proposed presenter, author, or planner has a conflict of interest related to the content, someone else who does not have a relationship to the commercial interests 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 commercial interest that is the basis of the COI.
 - **Change the assigned content** so that it is no longer about products or services of the commercial interest. For example an individual with a conflict of interest

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 a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and recommendations.
- **Limit the sources for recommendations.** Rather than having a person with a conflict of interest present personal recommendations 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. Conflict of interest may be resolved if the presentation is peer reviewed and;

- All the recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients **or**
- All scientific research referred to, reported, or used in CME in support or justification of patient care recommendations conforms to generally accepted standards of experimental design, data collection and analysis.

D. Review and Resolution

Identified conflicts of interest may be reviewed by the Activity Director, CME Director, CME Associate Director, CME Medical Director, Chair of the CME Committee and/or identified experts(s) in the field as appropriate. (Reviewers will also be asked to disclose their relevant financial relationships as a precaution against any COI they may have.) Additional information on a presentation may be collected for review. **If a COI can not be resolved through the mechanisms described above, AMA Category 1 credit will not be approved or will be withdrawn.**

E. Oversight

All financial relationships will be disclosed to CME activity participants. Activities will be evaluated by participants and peer reviewers to determine if the content was free of bias and met acceptable scientific standards.

(5) Evaluation and Monitoring: It is essential that participants actively participate in the monitoring process. All activities must have participant evaluations submitted to the Case Western Reserve University CME Program that address whether or not commercial bias of content was perceived. If an answer is 'YES', specifics are required.

All activity evaluation summaries that indicate that commercial bias was perceived by more than 5% of the participants will be reviewed by the CME Program and the Activity Director. Appropriate action to address the instance of bias as well as prevent further bias will be taken.

(6) Procedures:

- All commercial support must be in the form of a grant from the commercial interest. (Exhibit fees—which are not treated like commercial support—may also be obtained.)
- Except for a jointly accredited activity, all grants must be payable to **Case Western Reserve University**, the accredited CME provider. No direct payment from an ACCME-defined commercial interest may be given to the director of an activity, any planning committee members, teachers or authors, or any others involved in an activity.
- All grants must include a letter of agreement (LOA) stating conditions under which the grant is made.
- Letters of agreement from commercial interests should be forwarded to the CWRU CME Program immediately upon receipt for review by the CWRU Office of Counsel for legal acceptability. Authorization can be made **only** by the Vice Dean, School of Medicine, and a University Vice President or his delegate. Direct LOAs to Amy Pisman (amy.friedman@case.edu) or Joan Farmer (joan.farmer@uhhospitals.org). Or fax to Amy or Joan's attention at 216-201-6749.
- If the CWRU CME Program's letter of agreement is used instead of an LOA provided by a commercial interest, review by CWRU Office of Counsel is unnecessary. Authorization is made by the CME Director and the Chief Financial Officer of CWRU.
- When grants are received by the department providing the education, documentation for the CME Program must include (a) a fully executed letter of agreement; (b) a photocopy of the grant check; (c) itemized reconciliation of how the funds were spent (honoraria, travel-reimbursement, catering, etc.) Item (c) may be part of your income and expense summary; and (d) completed commercial support and honorarium trackers.