

## **THE METHODIST HOSPITAL SYSTEM OFFICE OF CME CONFLICT OF INTEREST DISCLOSURE AND RESOLUTION POLICY**

### **Purpose:**

In accordance with the ACCME's Standards for Commercial Support, the Methodist Hospital Office of CME must provide guidance for staff, faculty, planners, and managers of CME activities is sponsors or joint sponsors.

This policy will outline the mechanisms used to collect disclosure information from all parties involved in the development of a CME activity, and the mechanisms used to resolve any COI identified.

It is the responsibility of the Office of CME to ensure all CME activities are balanced, planned independently, are objective, scientifically rigorous and in the best interest of the public. The content and format of CME activities should address the educational needs of physicians and, ultimately, promote improvement in the quality of health care. Therefore, all CME activities and materials must be free of commercial bias cannot advance the financial interests of any commercial entity or individual instructor.

### **Identifying Conflict of Interest:**

A conflict of interest disclosure form shall be provided to individuals involved with a CME activity that have the following roles:

1. Instructor/Faculty
2. Planner/Course Director
3. Joint sponsor,

Recipients of COI forms must complete and return the document within two weeks of receiving it as a condition for participation in the role of faculty/instructor/planner for the CME activity

### **Reporting guidance is as follows:**

1. Any personal financial relationship during the previous 12-month period represents a potential conflict of interest, and therefore must be reported. This also includes spouses and life partners.
2. A COI is present when both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

## Guidelines for Interpreting COI

The guidelines for interpreting COI are illustrated below:

Reported COI	Guidelines for Interpreting COI	Prescribed Action for Resolution
<b>Level 1:</b> No reported COI	<ul style="list-style-type: none"> <li>◆ NA</li> </ul>	No action required; faculty letter instructs presenter on rules
<b>Level 2:</b> Has relationships with multiple commercial interests (e.g. speakers' bureaus, advisory board, consultancies, research, etc.)	<ul style="list-style-type: none"> <li>◆ Validate expertise with review of CV</li> <li>◆ Assess prior relationships with potential commercial supporters.</li> <li>◆ Review database for learner comments about faculty/planner.</li> </ul>	Course chair reviews content of presentation materials; or, faculty restricted to discussion of evidence-based information
<b>Level 3:</b> Planner/faculty has significant relationship primarily with commercial supporter of current activity	<ul style="list-style-type: none"> <li>◆ All of #2 above</li> </ul>	Triggers independent review
<b>Level 4:</b> Faculty or planner has employment relationship with commercial supporter	<ul style="list-style-type: none"> <li>◆ Based on expertise and clinical knowledge that is not replicable by another presenter</li> </ul>	Presentation of scientific data only, no discussion of treatment options permitted

In order to determine the level of conflict, we require all prospective faculty and planners of a CME activity to disclose in advance any financial relationships they have with the commercial supporters of an activity or with any commercial entity whose products or services may be discussed in that activity.

### Processing COI Forms

- Staff have primary responsibility for initial processing of COI forms and documenting level 1 resolution.
- In addition, staff will provide COI documentation for levels 2, 3 and 4 to the CME Committee for resolution when necessary.
- Options for resolution of COI include:
  1. Substitution of a person with no COI or minimal levels of COI
  2. Development of a stringent Peer Review Process in which content is validated
  3. Referencing the best available evidence in all CME activities in which potential conflicts exist
  4. Requesting the instructor or planner to sever financial relationships with the

commercial interest

5. Relegating the person with COI to a role in which therapeutic options will not be recommended
6. Excluding that part of the instruction or disqualification of the presenter

## **IMPLEMENTATION**

1. For internal activities where the department activity director is leading the activity, the activity director will be tasked with the responsibility of reviewing content and completing a Clinical Review Form.
2. For activities that are jointly sponsored or for which faculty is not internal staff or the activity director, a liaison from the joint sponsor will be appointed who shall observe the planning process, review course materials and complete the Clinical Review Form.
3. Course materials will include a one-sentence Content Validation statement in which learners are advised that course materials have been reviewed for quality and content validation by either the joint sponsor or the activity director..
4. The Methodist Hospital Office of CME is committed to resolving all potential conflicts of interest. However, if a faculty or planning committee member has substantial financial interests that cannot be reconciled with the goals and integrity of the CME activity, we reserve the right to prohibit that individual from participating in the activity.

### **Documenting Resolution of COI**

- Completed COI disclosure forms will be maintained in the activity file
- The resolution of COI by staff and/or the CME Committee will be documented on the resolution of COI form and placed in the activity file.

### **Institutional COI**

- Matters of institutional COI shall also be reported to the learner
- Institutional COI includes research grants, financial relationships with the commercial interests overt and above the grant related to the CME activity, and relationships of members of the CME Committee.

**Disclosure to the Learners**

- Disclosure provided by all those involved in the development of a CME activity will be provided to the activity learners in the course syllabus or handout.
- The disclosure will include information provided by the faculty as well as planners, independent reviewers, activity directors and CME committee members.
- Discussions of unlabeled, unapproved uses of drugs or devices will also be provided to the learners prior to the execution of the CME activity.

***\*Please retain this document for future reference***

**Name of Program:**

**Name of Speaker:**

**Date of Program:**

**Program Content:** I have developed my own content for this activity and I have not used “scripts” from pharmaceutical and/or device manufacturers.

Yes  No

**Objectivity and Balance:** My data is based on scientific evidence and will be presented to include favorable and unfavorable information (when available). I agree to present a balanced discussion of prevailing information on any product(s) and/or alternative treatments in this session.

Yes  No

Should several products be approved for treatment use, a balanced discussion of all available products will be included.

Yes  No

**Educational Materials:** Handouts and slides will use generic product names and/or all available products for treatment unless there is only one particular drug approved for use.

Yes  No

Handouts and slides will not include any advertising, trade name, or product group message.

Yes  No

**Off-Label/Investigational Use:** I will inform the audience when I discuss off-label or unapproved uses of devices or drugs. Devices or drugs that are still undergoing clinical trials will be identified as such and will not be portrayed as standard, accepted therapy.

Yes  No

**HIPAA:** My presentation in this CME activity will not disclose the names or other unique identifiers of patients referenced in syllabus material and/or audio/visual aids without expressed permission from the identified patient or his/her guardian/agent.

Yes  No

**Copyright:** If your presentation is to include copyright information you will obtain permission from the copyright holder.

Yes  No

***I have read this Policy Statement and requirements of The Methodist Hospital System Office of CME and agree to comply with the conditions set forth in it. Please sign, retain a copy for your file and return original to the Course Coordinator along with the signed Conflict of Interest Disclosure form.***

Name: \_\_\_\_\_ Date: \_\_\_\_\_