

CME DISCLOSURE FORM



Center for Continuing Education

(504) 988-5466 (504) 988-1779 FAX

NAME: _____

ROLE/S (please check all that apply):
 Speaker Author Activity Director Moderator
 Planning Committee Joint-Sponsor Faculty Liaison

[Regardless of role, Disclosure Forms for Tulane faculty and staff participating in a CME activity will be forwarded to the university's COI committee.]

ACTIVITY NAME/DATE: _____

TITLE OF PRESENTATION: _____

DISCLOSURES

[A] **YES** or **NO** – My presentation / participation will involve comments or discussion concerning unapproved or off-label uses of a medical device or pharmaceuticals. If any unapproved or off-label uses of products will be discussed, **disclosure must be made to the participants regarding the unapproved or off-label use.** If you will be discussing any such uses, please indicate the products to be discussed and the unapproved and/or off-label uses. **If any other comments concerning unapproved or off-label uses of products take place during your discussion, you are advised that you must disclose this information to the attendees.**

Product to be discussed

Unapproved or off-label use

[B] **YES** or **NO** – I [and/or an immediate family member including my spouse/partner] have a financial interest, arrangement or affiliation with a commercial organization (currently or within the past 12 months) that may have a direct or indirect interest in the subject matter of my presentation. If YES, the financial relationships are identified as follows [if needed, attach an additional list]:

Commercial Interest	Relevant Financial Relationships				Other? * (Identify, e.g. employee)
	Grant/Research Support	Consultant	Speaker's Bureau	Stock Shareholder	
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____

*** Please note: The ACCME does not allow CME credit to be awarded to presentations made by employees of commercial interests (as defined by the ACCME), i.e., pharmaceutical, medical device, or biotech companies, etc.**

****If the focus of your presentation is a commercially funded study, please list the funding company or source and your affiliation with the funding company or source:** _____

Answer the following questions to identify and/or resolve potential CONFLICTS OF INTEREST:

- G YES** **G NO*** 1] My presentation/participation will be educational, not promotional, based on the stated purpose and objectives of the program and the identified educational needs of the target audience. [*Presentation review required.]
*If NO, attach explanation.
- G YES** **G NO*** 2] My presentation/participation will be unbiased and free of commercial influence. [*Presentation review required.]
*If NO, attach explanation.
- G YES*** **G NO 3]** Commercial interest(s) provided the data for my presentation.
G N/A *If YES, attach explanation/documentation. [*Presentation Review Required.]
- G YES*** **G NO 4]** Commercial interest(s) generated content and/or provided slides.
G N/A *If YES, attach explanation/documentation. [*Presentation Review Required.]
- G YES*** **G NO 5]** Commercial interest(s) provided speaker training for this lecture/presentation.
G N/A *If YES, attach explanation/documentation. [*Presentation Review Required.]
- G YES** **G NO*** 6] My presentation/participation will discuss products in generic terms, when applicable. *If NO, please answer the following —
G N/A **G YES** **G NO*** -- Several specific products will be discussed to provide balance.
*If NO, attach explanation.
- G YES** **G NO*** 7] My presentation/participation will discuss a balanced view of therapeutic options, when applicable.
G N/A *If NO, attach explanation.
- G YES** **G NO*** 8] My presentation/participation is intended to promote improvements or quality in healthcare and in the public's best interests. [*Presentation Review Required.]
*If NO, attach explanation.

If disclosure information and/or the nature of your presentation/participation changes prior to the CME educational activity, you must notify Tulane's Center for Continuing Education. All identified conflicts of interest must be resolved and documented by one of the methods defined under Procedure #3 in the Tulane Policy and Procedure for Identifying and Resolving Conflicts of Interest for CME Educational Activities (found at end of the policy that follows). Additional information may be requested.

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**[C]   Read and initial the following representations, sign, and date**

\_\_\_\_ I **will be responsible** for disclosing information from A and B to the audience on a slide (Procedure #5) at the beginning of the presentation; for reading and complying with the Tulane CME Conflict of Interest Policy; and for complying with the requirements to protect health information under the **Health Insurance Portability & Accountability Act of 1998 (HIPAA)**.

\_\_\_\_ To the best of my knowledge, I **have not engaged** in any activities that violate the American Medical Association's Ethical Opinion on Continuing Medical Education and Gifts to Physicians from Industry ([www.ama-assn.org](http://www.ama-assn.org)), the Food

and Drug Administration's regulations regarding industry-supported scientific and educational activities ([www.fda.gov](http://www.fda.gov)), the Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers ([www.oig.hhs.gov](http://www.oig.hhs.gov)), and the PhRMA's Code on Interactions with Healthcare Professionals ([www.phrma.org](http://www.phrma.org)). **I further represent that I have not violated or received notice of violation of any laws or ACCME policy or other relevant accreditation body or standards in the last two (2) years.**

\_\_\_\_ I acknowledge that **I am not included** in either the OIG Exclusion List (<http://exclusions.oig.hhs.gov/>) or the GSA Debarment List (<http://www.epls.gov/>)."

\_\_\_\_ I further represent that information contained in my presentation will be based on research that, to the best of my knowledge, does not involve fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the academic research community for proposing, conducting or reporting research.

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date*

### **Tulane Policy and Procedure for Identifying and Resolving Conflicts of Interest for CME Educational Activities**

The ACCME Standards of Commercial Support ("SCS") describe six Standards: (1) independence (2) resolution of personal conflicts of interest (3) appropriate use of commercial support (4) appropriate management of associated commercial promotion (5) content and format without commercial bias and (6) disclosures relevant to potential commercial bias. These updated Standards underscore continued voluntary self-regulation by the CME community, ensuring that physicians have opportunities to engage in commercially unbiased life-long learning facilitated by accredited providers. The purpose of this policy is twofold: [1] to establish guidelines and a mechanism for identifying and resolving conflicts of interest in CME educational activities as required in Standard 2 (see below), and [2] to be consistent with Tulane University's institutional policy for resolving conflicts of commitment and interest

**Standard 2: Resolution of Personal Conflicts of Interest in the Standards for Commercial Support** requires the following of ACCME accredited providers –

- Documenting that everyone who is in a position to control the content of an education activity has disclosed to the provider all relevant financial relationships with any commercial interests in any amount within the past 12 months that creates a conflict of interest. (SCS 2.1)
- Disqualifying individuals who do not disclose from participating in a CME education activity. (SCS 2.2)
- Identifying and resolving all conflicts of interest prior to the education activity. (SCS 2.3)

#### **Terms as defined by the ACCME:**

1. **Commercial Interest:** any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. [October 2007]
2. **Financial Relationships:** relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.
3. **Relevant financial relationships:** financial relationships with commercial interests in any amount occurring within the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity that create a conflict of interest.
4. **Individuals with potential for influence or control of CME content:** Planners and planning committee members, authors, teachers, educational activity director(s), educational partner(s), and others who participate, e.g. facilitators and moderators.

#### **Procedure:**

1. All individuals with potential for influence or control of content (defined in #4 above) must fill out a Tulane CCE Disclosure Form prior to the education activity as a condition of invitation and acceptance to participate. CCE staff and CME Advisory Committee members will be required to fill out an annual disclosure form.

2. Employees of commercial interests may not participate in any role in a CME-certified session / activity. If a session presentation, after review, is determined educational, the session may be offered but noted that no credit is available. If, after review, the session and/or presentation are deemed promotional, as defined by the ACCME, the session and/or presentation must be removed and held at a time that is not connected to the CME-certified activity and content. (SCS 4.2) [*ACCME, August 2008*]
3. Program application and disclosure forms of activity director and/or planning committee members are reviewed by the CME Advisory Committee.
4. An independent and unbiased assessment of content will be documented by one of the following methods to identify and resolve COIs –
  - a. Content review by the program planning committee consisting of at least one faculty member without the same commercial interests.
  - b. Peer review committee not participating in the specific educational activity.
  - c. Review of comprehensive questionnaire completed by speakers, activity director, planning committee members (when applicable), and others involved in the development of content as a confirmation of conflict resolution.
  - d. Content review by an independent faculty expert in the discipline without commercial interests.
  - e. Evidence-based medicine documentation or grounded in other accepted literature databases.
  - f. Other review methods with prior CCE approval.
5. Disclosures of all individuals participating in the educational activity will be made known to the audience as required by the ACCME in addition to a disclosure by Tulane's CCE that any COIs have been resolved with independence and without bias.
6. Speakers will be required to have a disclosure slide (1<sup>st</sup> or 2<sup>nd</sup> slide) identifying commercial relationships/interests in addition to any discussion of off-label use.
7. The audience will provide validation of absence of bias and COI for each speaker by the following summative methods:
  - a. Activity Evaluations
  - b. Focus Group Interviews (if applicable) or alternative immediate feedback method
  - c. Post-Activity survey or outcomes activity

**Consequences of non-adherence to the Tulane policy consist of:**

- Disqualified from speaking if no disclosure form is completed (SCS 2.2)
- Warning letter if the activity evaluation by the audience indicates conflicts are present. (1<sup>st</sup> occurrence)
- Not invited to speak or participate in any other role in a Tulane CME-certified educational activity. (2<sup>nd</sup> occurrence)

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[A] \_\_\_\_\_ No relevant financial relationships to disclose or COIs to resolve REVIEWER INITIALS \_\_\_\_\_

---OR---

[B] \_\_\_\_\_ RESOLVED \_\_\_\_\_ NOT RESOLVED REVIEWER INITIALS \_\_\_\_\_

COMMENTS BY CME REVIEWER: \_\_\_\_\_

Presentation review required: \_\_\_\_\_ YES \_\_\_\_\_ NO \_\_\_\_\_ Not Applicable

**Method(s) of COI Resolution:**

- \_\_\_\_\_ Disclosure Questionnaire
- \_\_\_\_\_ Content review by the program planning committee consisting of at least one faculty member without the same commercial interests.
- \_\_\_\_\_ Peer review committee not participating in the specific educational activity
- \_\_\_\_\_ Content review by an independent faculty expert in the discipline without commercial interests

\_\_\_\_\_ Evidence-based medicine documentation or grounded in other accepted literature databases.

\_\_\_\_\_ Other approved method: \_\_\_\_\_