

SPEAKER & FACULTY DISCLOSURE FORM - 1



Health Sciences Center
Center for Continuing Education

NAME: _____

ROLE/S (please indicate all that apply): Speaker Abstract Author Activity Director Moderator
 Planning Committee Member Department CME Liaison

ACTIVITY NAME/DATE: 1ST Annual Scientific Meeting of the Society of Cardiovascular Computed Tomography
(July 13-16, 2006)

TITLE OF PRESENTATION: _____

DISCLOSURE OF RELATIONSHIPS

A. **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				
	Grant/Research Support	Consultant	Speaker's Bureau	Stock Shareholder	Other (Identify)
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____
_____:	_____	_____	_____	_____	_____

- 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 (on reverse). Additional information may be requested.

B. **YES** or **NO** – My presentation 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
_____	_____
_____	_____

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).

ATTESTED TO AND SUBMITTED BY:

Date:

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

The ACCME has issued updated Standards of Commercial Support. The 2004 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 2004 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 proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.
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. Program application and disclosure forms of activity director and/or planning committee members are reviewed by the CME Advisory Committee.
3. 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.
4. 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.
5. Speakers will be required to have a disclosure slide (1st or 2nd slide) identifying commercial relationships/interests in addition to any discussion of off-label use.
6. 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

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. (1st occurrence)
- Not invited to speak or participate in any other role in a Tulane CME-certified educational activity. (2nd occurrence)