

## **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)