



OFFICE OF CONTINUING PROFESSIONAL DEVELOPMENT

Conflict of Interest and Disclosure Policy

INTRODUCTION

Everyone in a position to control the content of an accredited educational activity must disclose all financial relationships with a commercial interest ***related to the content of the presentation or subject matter of the educational activity*** to USF Health's Office of Continuing Professional Development prior to participating in any USF Health sponsored accredited educational activity.

Financial relationships are defined as those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honorarium, ownership interest (i.e. stocks, stock options, or other ownership interest, excluding diversified mutual funds) or financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research, which includes research funding where the institution receives the grant, manages the funds, and the individual is the principal or named investigator), consulting, speaking and teaching, membership on advisory committees or review panels, board membership and other activities for which remuneration is received or expected. Relationships of the individual involved in the an accredited activity: 1) include those of a family member (including a spouse or partner); 2) do not have a minimum dollar amount for them to be considered significant since inherent in any amount is the incentive to maintain or increase the value of the relationship; and 3) have occurred within the past 12 months.

It is the responsibility of the OCPD, in collaboration with the course director, planning committee and the CPD advisory committee to review the disclosure statements and assure that educational activity sponsored by USF Health are free of commercial bias and that clinical recommendations are based on evidence that is accepted within the profession of Medicine, Pharmacy, and/or Nursing as adequate justification for the care of patients.

The purpose of this policy is to describe appropriate processes and procedures to identify and resolve all potential conflicts of interest (COI) prior to the start of an accredited activity and to fully comply with the *2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure the Independence of accredited Activities.*

CLARIFICATION

Who Must Disclose? Disclosure must be obtained from everyone in a position to control the content of an accredited educational activity. This includes the course directors, moderators, speakers, authors, planning committee members and OCPD staff.

What is a commercial interest? The ACCME defines a commercial interest as "any entity producing, marketing, reselling or distributing health care goods or services consumed by, or used on, patients."

POLICY

1. All requests for sponsoring of an accredited activity and *AMA PRA category 1 credit™*, ACPE, ANCC, or any other accreditation submitted to the OCPD and USF Health's CPD advisory committee for review must include all completed disclosure forms. Potential conflicts must be identified and resolved prior to convening members of a planning committee or inviting a speaker/author to participate in an accredited activity.
2. An individual who refuses to disclose relevant financial relationships will be disqualified from being an activity director, planning committee member, speaker or author for an accredited activity and cannot have control of or responsibility for the development, management, presentation, or evaluation of an accredited activity.
3. The content or format of an accredited activity and its related materials must promote improvements or quality in healthcare and not a specific proprietary commercial interest an accredited activity activities must be compliant with the ACCME, ACPE or ANCC content validation statements which are:
 - All recommendations involving clinical medicine must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

All scientific research referred to, reported, or used in an accredited activity.

- In support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis.
 - Accredited educational are not eligible for certification if they promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, CNE, CE, or CPE; are known to have risks or dangers that outweigh the benefits; or are known to be ineffective in the treatment of patients.
4. Educational materials that are part of an accredited educational activity such as slides, abstracts, and handouts cannot contain any advertising, trade names without generic names or product-group advertising.
 5. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the accredited educational material or content includes trade names, trade names from several companies should be used and not just trade names from a single company.

RESOLUTION OF CONFLICTS OF INTEREST (COI)

Successful resolution of a COI may require a combination of strategies. The following are potential strategies for resolving a COI:

1. *Altering financial relationships:* An individual may change his/her relationships with commercial interests, i.e. discontinue contracted services, and in doing so, no duty, loyalty or incentive remains to introduce bias into the educational content. However, when an individual divests themselves of a

relationship, it is immediately not relevant to conflict of interest but it must be disclosed to the learners for 12 months.

2. *Altering control over content:* An individual's control of the educational content can be altered in several ways to remove the opportunity to affect content related to the products/services of a commercial interest. These include:

- *Choosing someone else to control that part of the content* – If a proposed teacher/author has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interests related to the content.
- *Change the focus of the educational activity* – The provider can change the focus of the activity so that the content is not relevant to the products/services of the commercial interest that is the basis of the conflict.
- *Change the content of the person's assignment* – The role of a person with a conflict of interest can be changed within the accredited activity so that he/she is no longer teaching about issues relevant to the products/services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a disease state could address the pathophysiology or diagnosis of the disease 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 clinical 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). For example, the individual could present summaries from the systematic reviews of a peer reviewed source, i.e. the Cochrane Collaboration (www.cochrane.org).

3. *Independent content validation:* An independent review by a content expert not involved with the educational activity may resolve conflicts of interest by ensuring the content is valid, aligned with the interests of the public, and:

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

4. *Elimination:* Activity directors, planning committee members, teachers and authors who are perceived as either having conflicts of interest or being biased may be eliminated from consideration as resources (committee members, teachers, authors, etc.) in subsequent certified educational activities.

PROCEDURE

The following describes the procedures for implementing USF Health's system for identifying and resolving conflicts of interest in an accredited educational activity.

1. Obtain completed disclosure forms from everyone involved in planning and presenting the activity prior to initiating the planning process.

- All *disclosure forms* will be reviewed by the activity director and/or OCPD staff submitted with the application for credit. Conflicts of interest should be resolved prior to submitting the activity for review and approval by the CPD advisory committee. Prior to approval of the activity, the CPD advisory committee will determine whether conflict of interest resolution actions are sufficient or additional interventions are required. The CPD advisory committee will withhold approval until the activity director has used appropriate mechanisms for resolving all identified conflicts of interest. In the case of regularly scheduled conferences (RSC), applications for credit will be approved contingent that all disclosure information is submitted to the OCPD at least 1 week prior to the RSC activity and all potential conflicts of interest have been resolved.
- The activity planning committee and activity director are to document how the identified conflicts of interest are resolved. This documentation is to be submitted with the application for credit to the OCPD and the CPD advisory committee prior to the approval of the activity. Additional information about the CME, CPE, CNE or CE activity may be collected, as needed, for review by the OCPD staff and the CPD advisory committee.
- *Attestation:* Persons who indicate the existence of a potential or actual conflict of interest will be asked to attest in writing, by signing the disclosure form; that said, conflicts or relationships will not bias or otherwise influence their involvement in the accredited activity.

2. *Faculty Letter:* Once presenters for the accredited activity are selected, a faculty letter is sent that includes a request that all clinical recommendations should be based on the best available evidence.

3. *Disclosure:* The activity syllabus must contain written disclosure of financial relationships to alert the learner to potential COI and commercial bias. When a syllabus is not prepared as part of an accredited activity, as in RSCs or visiting professor series, verbal disclosure must occur. Verbal disclosure must be documented by an individual representing the OCPD and must include the presenter's name, financial relationship and commercial interest that the relationship is with. Such documentation must be signed, dated and placed in the file within 30 days of the date of the accredited activity.

4. *Evaluation:* Learners will be queried regarding their impressions concerning the objectivity of the presentation and to identify any perceived bias within the activity. Course director(s), planning committee, presenter(s) and authors will receive copies of the evaluation summary.

5. *Peer Evaluation:* An informed learner or peer (not involved in the planning and/or teaching of the activity) will be present, to the fullest extent possible, at accredited activities. The evaluator will be asked to complete a formal, detailed evaluation to identify any bias in the activity. The evaluation will be shared with the course director(s), planning committee, and presenter(s).