The University of Utah
Continuing Medical Education
Policies on
The Standards for Commercial Support

The University of Utah School of Medicine subscribes to and abides by The Accreditation Council for Continuing Medical Education Standards for Commercial Support℠. The ACCME Standards for Commercial Support are detailed on the ACCME website at; http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support The UUCME website also has a link to the ACCME Standards for Commercial Support at: http://medicine.utah.edu/cme/about_us/index.php
The link to the ACCME is in the Related Links section of the webpage.

This UUCME Policy clarifies the following mechanisms: (1) How to implement the disclosure process; (2) The identification of potential conflicts; (3) The resolution of those conflicts; (4) How to handle those that refuse to disclose; (5) Disclosing to the learner; (6) Honoraria and out of pocket expenses; (7) Use of commercial support funding; and (8) Presenters funded by industry.

1. Disclosure Process

The University of Utah School of Medicine policy is that everyone in a position to control the content of a CME activity must make a disclosure of all relevant financial relationships with any commercial interest. The tool used by the UUCME office is the Speaker/Planner Disclosure Form. The steps include:

a. Complete the Speaker/Planner Disclosure Form:
   - Planning Committee: Planning committee members must submit their disclosure before the planning application can be approved.
   - Presenters/ Speakers/ Moderators: disclosure submitted at the time the person accepts the invitation to speak, but minimally no later than 30 days prior to the CME activity.
   - Submit disclosure form electronically to UUCME;

b. Mission Based Management (MBM):
   - MBM disclosure process is utilized for obtaining disclosure for University of Utah faculty; retrieve disclosure from MBM database and CME staff emails the faculty inquiring about their disclosure and that of their spouse particularly regarding contracted research.

c. Identify Potential Conflicts of Interest
   - Review the Speaker/Planner Disclosure Form.
     (1) If there are ‘No’ relevant relationships reported, then disclose to the leaners that no relevant relationships exist. See item #4.
(2) If a relevant financial relationship is reported, then a mechanism to resolve the conflict must be initiated. See item #2 and item #4.

2. Resolving Conflicts of Interest:

Once a relevant relationship is reported it must be reviewed and resolved.
- For planners: the Course Director or non-conflicted planner, if the course director has a conflict, completes the Planning Committee Review Form, entitled, ‘Resolving Conflicts of Interest for Planning Committee Members’. The form is completed indicating the name and date of the activity and the name of the planner with a conflict of interest. Next the strategy used to resolve the conflict is identified. It is either recusing oneself from discussions pertaining to content that relates to their interest or the reviewer describes in free text box the action taken. Then the box is checked that states, ‘This action was discussed with the Planning Committee member’. Lastly the Planning Committee Chair or Reviewer’s name is typed in the box and the form dated.

- For Speakers, presenters, moderators, etc. the Course Director or non-conflicted designee completes the Speaker Review Form, entitled ‘Speaker Disclosure Review Form’. This is accomplished for any speaker reporting a relevant relationship. Five strategies to resolve the conflict are listed on the form with a sixth entitled, ‘Other’ as a free text box. The reviewer selects at least one of these methods or describes a method in the ‘Other’ box. If the strategy of peer review using the ‘Content Review’ Form is selected then the reviewer must complete the ‘Content Review’ Form to resolve the conflict. Similar to the planner review process, the name and date of the activity is identified along with the speaker’s name. As noted previously, the mechanism to resolve the conflict is selected (i.e. content review, refrain from making recommendations, supporting presentation and clinical recommendations with ‘best available evidence”, refraining from making any clinical care recommendations, etc). The instructions given to the presenter must be specific and recorded in the appropriate box on the form. Lastly, document that the instructions were provided to the speaker either verbally, electronically via email, etc. and share that information with the CME office.

Please note that the reviewer must submit a disclosure. If the reviewer is a member of the planning committee this has already been accomplished.

Explanation of process:
Everyone in a position to control content is required to disclose using the Speaker/Planner Disclosure form. If an individual refuses to disclose, that individual is automatically disqualified from participating in the CME activity. Disclosures are required as part of the CME activity planning application. The disclosure form can be submitted electronically or via email as a PDF document. The activity is not approved without planning committee disclosures that are noted on the planning application. All disclosures for presenters, moderators, or others in control of content are made prior to the activity taking place.
The University of Utah School of Medicine uses the Speaker/Planner Disclosure Form mentioned previously. On the disclosure form the individual reports whether they have a relevant relationship to disclose or if they have nothing to disclose. If a relationship is disclosed the Course Director will be asked to resolve the potential conflict of interest.

If a relevant relationship is reported on the Speaker/Planner Disclosure Form, then the mechanism to resolve the potential conflict is initiated. If the relationship is reported by a planner, then the ‘Resolving Conflicts of Interest for Planning Committee Members’ is completed by the course director and the action taken discussed with the conflicted individual. If the relationship is with a presenter, the ‘Speaker Disclosure Review’ form is completed by a non-conflicted peer (normally the course director or designated planning committee member). Conflict resolution instructions are given to the presenter and the method of resolution is clearly delineated on the form. If the method chosen is peer review of the presentation the reviewer completes the ‘Content Review’ form. The action taken is communicated to the presenter. All forms are submitted to the UUCME office prior to the CME activity taking place.

The process is summarized in the ‘Flowchart Summary for Conflict of Interest (COI) Decision-Making.’. See attached flowsheet.

3. Individuals that Refuse to Disclose

A refusal to disclose will automatically disqualify an individual from participation in the activity as a planning committee member, a teacher, or an author of CME, and the person cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

4. Disclosing to the Learner

Everyone in control of content must disclose. Individuals that report no relevant relationships must also disclose and that disclosure is shared with the learners prior to the activity taking place. For live courses, the UUCME office requires every live course activity as part of the syllabus or handout material to include with it the ‘Speaker/Planner Disclosure Summary’. This document summarizes everyone by name that had control over content. It reports their disclosure, the nature of the relationship, and the name of the company. The summary also includes everyone that reported nothing to disclose. For live courses this is the most common method of informing the learners. Other methods for live courses include: preparing a summary disclosure statement that is included on the CME statements page (this is most useful when no one has anything to disclose or the nature of the content of the activity does not intersect with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients. See item #5).
In less common circumstances making an announcement prior to a presentation, or inclusion of the disclosure statement on a slide in the presentation are also methods but, are not encouraged because there is little time to adequately resolve a conflict of interest if one exists. These latter forms of disclosure also must be well documented with the person’s name, the company name, and the nature of the relationship as well as a signed and dated statement from the course director or coordinator that they witnessed the disclosure being made. This is to be done within 30 days of the conclusion of the activity.

For RSS activities the UUCME has instituted a flyer methodology as the preferred method of informing learners of the disclosures. This includes anyone in control of content (i.e. planner, speaker, etc.). The flyer for each session is sent to all learners by e-mail prior to the activity taking place. In addition to the flyer, as a last resort (i.e., due to last minute change in speaker) a disclosure can be made verbally and via a slide as part of the presentation, but same documentation rules apply as described in the previous paragraph for the live courses.

For Enduring Material, disclosures will be contained on the web site or in printed material that the learner must view prior to engaging with the content of the activity.

5. Disclosure when the presentation or activity content does not have any relationship with goods or services consumed by or used on patients. In this situation the content does not have any relationship to commercial interests’ goods or services consumed by or used on patients.

This statement is a valid approach in cases where the content has no relation (does not intersect) to health care goods or services being produced, marketed, re-sold, or distributed that are consumed by or used on patients. This statement can satisfy two purposes: (1) First, it can be used as a disclosure for presenters and planners (and others in control of content) since the topic/content is not about products/services of commercial interests. You can say something similar, or say something like, “None of the faculty or planners have any relevant financial relationships to disclose since the content does not cover any products/services of a commercial interest; (2) Second, it can be used as your process for resolving conflict of interest, by simply stating that the content has nothing to do with products/services of a commercial interest, therefore, there are no relevant financial relationships with commercial interests, thus no COI to resolve.

6. Policy Governing Honoraria and Out of Pocket Expense for Planners, Teachers and Authors

The UUCME has established this policy to govern honoraria.

The following criteria will be used for establishing honoraria fees:
(a) Tasks required and time to complete
   (1) Number of talks to give
   (2) Number of hours speaking
(b) Local speaker vs. speaker out of the local area where travel is required
(c) Subspecialty of Physician
(d) Market Rates

Based on the criteria listed above an honorarium can be set for different types of work. These set of criteria listed above must be used to provide the basis for deciding what amount to pay. The UUCME will track all CME honoraria payments to faculty in the CME activity electronic file folder.

The UUCME office is accountable for establishing the criteria upon which CME honoraria amounts are determined for planners, faculty/speaker, and authors participating in CME activities. The establishment of honoraria guidelines assures fair treatment among departments. The UUCME office delegates the responsibility of determining the CME honoraria to the departments based upon their using the established criteria noted previously in this policy. Any honorarium equaling or in excess of $3,000 will require the review and approval of the Associate Dean, CME. The UUCME Honorarium Review Form is used for this purpose. Out of pocket expenses for planners, teachers and authors will follow the same criteria format as honoraria. Reasonable reimbursement, when requested, for slide printing, handouts, and other educational materials to support the CME activity are authorized. This determination is made by the departments conducting the CME activity.

7. Use of Commercial Support Funding

All commercial support funding for a UUCME accredited activity must be given with the knowledge of the UUCME office. This is accomplished by documenting the support with a signed Letter of Agreement between the commercial support company and the UUCME office. The Letter of Agreement is to be signed by the company, the CME office and a department representative prior to the activity taking place. The educational grant will be acknowledged in the course promotional material.

No funds will be provided to support the CME activity without the knowledge of the UUCME office. All payments must be paid directly by the UUCME office or The University of Utah School of Medicine Departments. No payments can be made directly by a commercial support company in support of the CME activity. Commercial support companies cannot arrange and pay for meals, pay the course director, planning committee, teachers, authors or anyone else in control of content, joint sponsors, or any others involved with the supported activity.

8. Commercial Support and Exhibitor Space

There cannot be any conditions placed on receiving educational grants. Receiving exhibit space in return for providing an educational grant is placing a condition on the grant and that is not allowed. Selling exhibit space to commercial interests is considered to be a business transaction.
Income from selling exhibit space is not considered to be commercial support as defined by the Accreditation Council for Continuing Medical Education (ACCME). Exhibit space is purchased for promotional purposes. Grants are to support the provision of education. The two must be kept separate and distinct.

For live, face-to-face CME activities, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Representatives of Commercial Interests are not allowed to engage in sales or promotional activities while in the space or place of the CME activity. Exhibits and promotional activities are confined to the exhibit space that is separate and outside of the educational space.

9. Presenters Funded by Commercial Interest

The UUCME policy is that any presenter, moderator, author or anyone with control over the content of a CME activity cannot be paid directly by a commercial interest; or have the commercial interest directly pay for travel, lodging, meals, etc. on their behalf to participate in the activity. This policy also applies to the following scenario. If a presenter is paid by a commercial interest to come to the local area for another purpose, the presenter, while they are in the area, cannot be invited to speak at a School of Medicine accredited CME activity. The rationale is that the presenter has been paid to come to the area by a commercial interest.
Flowchart Summary for Conflict of Interest (COI) Decision-making

1. Ineligible to present
   - No
   - Answered screening questions?
     - Yes
     - All "NO"
     - No
     - COI disclosed
   - No
   - Disqualify presenter
     - Can COI be eliminated?
       - Yes
       - COI disclosed
       - Course Director, UUCME Director and Dean for CME select mechanism for eliminating COI
       - Content validation: presenter agrees all therapeutic recommendations will be referenced and based on full range of options in peer reviewed publications or meta-analysis
       - Prior approval: Expert review and approval of content prior to presentation
       - Limit Role: presenter avoids making recommendations relative to nature of conflict
       - Point-Counterpoint
       - Panel of Experts
       - Other

2. Disqualify presenter
   - Appeal Dean for CME decision?
     - Yes
     - Refer to UUSOM Dean
     - No
   - Dean for CME Approval
     - Yes
     - Monitor presentation
     - No
     - Refer to UUSOM Dean