Conflict of Interest (COI) & Disclosure Process

What is a Conflict of Interest (COI)?

Conflict of interest is created when individuals in a position to control the content of CME, (or their spouses/partners) that have a relevant personal financial relationship within the past 12 months with a commercial interest that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on patients that benefits the individual in any financial amount and therefore, may bias their opinions and teachings. and other activities for which remuneration is received or expected.
Who Needs to Disclose?

*Everyone involved in planning and delivery of the activity!*

All persons involved in the planning and presentation of the RSS (including course directors, planners/coordinators, speakers, committee members, residents, and staff) must provide conflict of interest disclosure information prior to participating and presenting.

- For many RSS, collecting one disclosure per year for the entire series is adequate as long as all potential conflicts are disclosed.
- Additional disclosure information must be provided if any changes are made throughout the year, such as faculty taking on a new financial relationship that is presenting a COI.

Overview of Disclosure Process

- **Collect**
- **Review**
- **Disclose to Participants**
- **Resolve**
- **Disclose to Participants**
- **Evaluate if commercial bias was detected**

Continuous process
When are Disclosures Due?

<table>
<thead>
<tr>
<th>Course directors, planners/coordinators and planning committee</th>
<th>Must be submitted at time of application submission and once a year after that. Must be updated throughout year if new COI are added.</th>
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<tr>
<td>Speakers, moderators, and other persons engaging in the RSS and controlling content</td>
<td>May be collected at a later date, ideally 4 weeks prior to activity/session (at a minimum 5 days prior to the activity/session).</td>
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Step #1: Collect Disclosures

Disclosures can be collected by two methods:

- **Paper Format**
- **Web-based Disclosure Database**
Disclosure Database

- Online disclosure database allows for completion and updating of disclosure information online at any time.
- Current RSS are pre-populated into the database and you may enter disclosure information at any time.
- For administrator access, please contact our office.
- https://cme.ucsd.edu/faculty_disclosure/account/login.aspx

Disclosure Database: Highlights & Features

- User friendly web-based disclosure collection
  - 24/7 access for all users
  - Centralized system to collect disclosure information
- Database is required to be used for other UC San Diego CME Live and Enduring Activities
  - Many faculty members are familiar with using database and have existing user profiles
- Coordinator has ability to:
  - Access disclosure information regarding faculty
  - Download reports (activity and faculty level)
  - Send reminders to faculty to complete disclosure via one click on database
Disclosure Form

- Paper based Disclosure Form, may be used for RSS and can be found at http://cme.ucsd.edu/tools_PlannersRSS.html.

Step #2: Review Disclosure Detail

If NO is checked, no further review action required.

If YES is checked, conflict(s) must be further reviewed by course director (or other faculty without COI).
Step #2a: COI Review by Course Director

- Management of all conflicts of interest disclosed is the responsibility of a course director without a COI and is an ongoing process throughout the year.

- Each disclosure form should be accompanied by a Disclosure Review Form for all persons who have a financial relationship with a commercial interest and, if applicable, a Peer Review Form.

- Evidence that adequate resolution of COI took place is required and must be provided to the CME office.

Important Considerations

- Management of all COI and associated resolution mechanisms must be performed by a Course Director (or other faculty member) without relevant COI.

- Any invited presenter who has a financial relationship with a commercial interest also providing commercial support to the series should undergo peer review.

- Any invited presenter with a speakers’ bureau level conflict of interest should undergo peer review.

- At no time can an employee/owner of a commercial interest be allowed to participate in an accredited session.
Step #2b: Peer Review by Course Director

For presenters with conflicts that are such that peer review of presentations are warranted, a Peer Review Form should be completed.

When to do Peer Review

- In all “high risk” scenarios
- Always assess the COI of individual in relationship to activity and topic of presentation and commercial support awarded (if applicable)
- Example: Speaker is on the speaker’s bureau of the company providing support to the series
- Example: Speaker is talking about a topic that relates to the companies that he has a COI with
- If in doubt, do peer review or contact the CME office for help

Note: employees of industry cannot present at CME activities.
Step #3: Disclose to Participants

- Disclosure of all financial relationships to participants must take place prior to each session.
- Can be achieved through one of the following mechanisms:
  - Sign-in Sheet
  - Disclosure Summary Form
- Disclosure provided must include all persons involved in the planning, development and presentation of content, not just the presenter.
- Evidence of disclosure provided at each session is required and must be provided to the CME office.