**UNC Continuing Professional Development (UNC CPD)**

**Policy on Disclosure and Resolution of Conflicts of Interest**

The UNC School of Medicine (UNC SOM) requires that all CME activities held under its accreditation be scientifically rigorous, balanced, objective, and independent of any commercial interest. In order to avoid any appearance of bias, and to comply with the ACCME Standards for Commercial Support, UNC CPD has implemented the following policy to identify and resolve conflicts of interest (COI) on the part of all individuals who plan and present educational activities sponsored by UNC SOM.

**Section 1: Disclosure of COI to UNC CPD**

*Who must provide their COI information:*

* UNC CPD Staff: Annually.
* Activity Course Directors: With the submission of an application.
* Activity Planning Committee / other staff in control of content:

At the beginning of the person’s involvement in the activity (usually with the submission of an application)

* Activity Presenters / Content Developers (including but not limited to speakers, moderators, panelists, authors, and anyone else providing information on behalf of the activity; including faculty, staff, residents, medical students, other health care professionals, or members of the general public.): Prior to the publication of any promotional materials listing the person’s involvement; or prior to the beginning of the activity, if their involvement is not published.
* Note: UNC CPD has special rules for certain types of regularly scheduled series, defined as “activities with active moderation”. Refer to Section 4 for these rules.
* Note: In the event that a person’s COI changes after they have disclosed, they must provide an update prior to their involvement in any activities.
* Note: UNC CPD must be able to review disclosure information for a given individual before the individual can participate in the activity. **Any individual who does not provide disclosure information in a timely fashion or who refuses to disclose cannot be involved as a planner or presenter; UNC CPD will not provide credit to any parts of an activity that have presenters who have not disclosed.**

*What must be disclosed:*

* All financial relationships with commercial interests, as defined by the ACCME in the Standards for Commercial Support, that existed within the 12 months prior to the person’s involvement in a UNC CPD activity. COI on the part of a person’s spouse or partner must also be disclosed.
* If a COI is no longer active, but existed within the 12 month period, it must be disclosed, and the end date given.
* UNC CPD requires disclosure of all COI, regardless of ‘relevance’ to the activity.
* Relationships with organizations that are not defined as commercial interests by the ACCME are not considered COI under this policy.
* If the person is uncertain whether a particular organization with which they have a financial relationship is a commercial interest as defined by the ACCME, they should disclose the relationship; UNC CPD will determine the status of the organization and whether it represents a COI by ACCME standards.
* If a person and their spouse/partner have no COI, this must be stated explicitly; if a person does not disclose that they have no COI, this will be considered failure to disclose (as above.)

*How the disclosure should be made:*

* The official UNC CPD Disclosure Form should be used for all COI disclosures.
* If the person completing the form has no financial relationships, they only need to complete the first page.
* If the person does have financial relationships, they must complete both pages and sign at the bottom of the second page, indicating agreement with the conditions listed on the form. Either written or electronic signatures can be used—in the former case, the page must be scanned and emailed along with the first page.
* These forms should be filled out electronically (except for the signature, if applicable) and emailed to UNC CPD.
* UNC CPD is willing to consider disclosure via online surveys, direct emails, phone conversations, and even in person, but permission to make disclosure without using the official form must be requested in advance, and approval is not guaranteed.

**Section 2: Resolution of COI**

In accordance with ACCME Standard 2.3, UNC CPD has “implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.” COI is identified according to the process above; this section discusses the various methods of resolution.

*Resolution of COI on the part of course directors:*

* Employees of commercial interests may not serve as course directors.
* Individuals who hold unpaid positions with a commercial interest may only be course directors with the express permission of UNC CPD, and under the condition that the activity is unrelated to products and services offered by the commercial interest.
* Individuals with other types of COI may be course directors; however, a co-course director, with either different or no COI, must be appointed, and the two course directors must recuse themselves from handling content related to their COI. The course directors are responsible for monitoring each other’s compliance. This must be documented on the UNC CPD Post-Activity Review Form.

*Resolution of COI on the part of activity planners:*

* Employees of commercial interests may not serve as activity planners.
* Individuals who hold unpaid positions with a commercial interest may only be planners with the express permission of UNC CPD, and under the condition that the activity is unrelated to products and services offered by the commercial interest.
* Individuals with other types of COI may be planners, but must recuse themselves from handling content related to products or services offered by the companies with which they have a financial relationship. Course directors are responsible for monitoring the compliance of planners. This must be documented on the UNC CPD Post-Activity Review Form.

*Resolution of COI on the part of presenters / content developers:*

* Employees of commercial interests, and individuals who hold unpaid positions with a commercial interest, may only be presenters/content developers with the express permission of UNC CPD, and under the condition that the content to be presented is either unrelated to any products or services offered by the commercial interest in question, or the content is limited to basic scientific data.
* Individuals with other types of COI may be presenters, but they must agree to the conditions listed on the UNC CPD Disclosure Form (as described in Section 1).
* Whenever an individual with COI presents at a live activity, the course director (or their designated representative) must monitor the presentation to ensure that it is scientifically sound and free of bias. In the event that a presenter begins to present inappropriate content, the monitor must intervene, either instructing the presenter to cease discussing the inappropriate content, or by stopping the presentation. The course director (or designee) must fill out the UNC CPD Monitoring Form or the appropriate section of the RSS roster, depending on the activity.
* If the course director designates a faculty member to monitor a presentation, the faculty member must have a current disclosure on file, and this disclosure information must be provided to the audience. RSS course directors may set up a pool of potential monitors by providing their names and UNC CPD Disclosure Forms to UNC CPD in advance.
* Content for an enduring material (either printed or online) prepared by an individual with COI must be reviewed by the course director to ensure that it is scientifically sound and free of bias; any material that does not comply must be removed or re-written. The course director must document this on the UNC CPD Post-Activity Review Form.

**Section 3: Disclosure to Learners**

* A written summary of the COI information (“disclosure summary”) for all planners and presenters **must** be provided to the participants **prior** to the start of the activity. Verbal disclosure does not meet ACCME requirements. A variety of formats can be used for the disclosure summary, depending on the specific needs of each individual activity. During the initial planning of an activity the CME Coordinator will work with the course director to develop an appropriate summary.
* **The disclosure summary must be submitted to CPD for approval prior to use with the activity.** For regularly scheduled series, CPD will approve a template for use at each session.
* Note: If an individual has no relationships to disclose, this **must** be explicitly stated. Blanket statements can be used when appropriate (e.g. “None of the speakers have any financial relationships with commercial interests.”)

**Section 4: “Active Moderation”**

* Only UNC CPD can designate an activity for “active moderation”.
* To qualify for active moderation, the activity content must focus on active care of current patients, and the activity format must be general discussion of cases, with no clear delineation between presenters and participants.[[1]](#footnote-1)
* Didactic lectures, journal clubs, retrospective case presentations[[2]](#footnote-2), and any other activity with one or more discreet presenters are not eligible for active moderation.
* When an activity is designated for active moderation, the course director and one or more faculty members chosen by the course director will serve as the “moderator pool” for the activity.
* For any given session, one of the members of the moderator pool must be the “active moderator”.
* The active moderator must monitor the discussion and ensure that the information being presented is scientifically sound and free of bias, in accordance with the ACCME Standards for Commercial Support, AMA policies, and government regulations.
* In the event that a participant introduces material that violates this principle, the active moderator should ask the person to recuse themselves, and ask the audience to disregard the comments.
* The active moderator may take any additional action necessary to preserve the integrity of the CME activity.
* For each session, the active moderator must sign the roster or flier, as applicable, and indicate whether active moderation was required. If moderation was required, the moderator should write a brief description of the incident and the action taken.
* When CPD designates an RSS for active moderation, or at the beginning of the fiscal year for ongoing series, the course director must provide CPD a list of faculty in the moderator pool.
* All members of the moderator pool must complete disclosure forms. If any of the moderators have financial relationships with commercial interests as defined by the ACCME, the course director is responsible for ensuring that said moderators recuse themselves from any sessions involved the products or services of the commercial interests in question.[[3]](#footnote-3)
* The disclosures of the moderator pool must be provided to the participants prior to the start of the activity, either on the sign in sheet or flier, as applicable.
* If a new moderator is appointed during the course of the year, the person must submit a disclosure form for review.
* The moderator’s role is similar to, but more expansive than, that of the monitor described in Section 2. Since active moderation only applies to activities without formal presenters, no activity will have both a moderator and a monitor.
* Examples of actively moderated RSS: UNC Tumor Boards (except for Pediatric Tumor Board, which includes a didactic component); UNC Multidisciplinary Child Airway Trauma Team Meeting; Schwartz Rounds (both adult and pediatric); UNC Hayworth General Oncology Cancer Conference.
* Examples of RSS that do not qualify for active moderation: Internal Medicine Grand Rounds; Pediatric Chair Case Conference; Transplant Surgery M&M conference.

1. The presentation of the active cases must be limited to a brief description of the case. If the presentation includes information (literature references or study data) that was *prepared in advance*, it is a formal case presentation, and not eligible for active moderation. *Spontaneous* references to articles or studies by a participant does not disqualify an activity. [↑](#footnote-ref-1)
2. Morbidity and Mortality conferences are a special case, and may qualify for active moderation depending on the amount of general discussion vs. case presentation involved. CPD will make this determination on a case by case basis. [↑](#footnote-ref-2)
3. If the course director has financial relationships, this is handled according to the procedure in Section 2. [↑](#footnote-ref-3)