# *PLANNER / PRESENTER DECLARATION FORM*

**University of Rochester School of Medicine & Dentistry Center for Experiential Learning**

*This form must be completed by the individual contributing to the activity listed below.*

**Persons who fail to complete this form will not be allowed to participate in the CME activity.**

| | |
|---|---|
| Name | |
| Email Address | |
| Phone Number | |
| Activity Title | |
| Date of Activity or Academic Year | |
| Your Role in the Activity | ☐ Presenter ☐ Author ☐ Moderator ☐ Planning Committee |

☐ **To the best of my knowledge, I attest that the information provided below is correct and I will notify the CEL Office if there are any changes.** **DATE: _____**

**First**, Check the box(es) that most accurately describe your role. YOU MUST CHECK EITHER THE 'NONE' BOX OR 1 OR MORE OF THE OTHERS.

**Second,** list the names of Commercial Interests with which you or your spouse/partner have, or have had, a relevant financial relationship within the past 12 months. For this purpose the ACCME considers the relevant financial relationships of your spouse or partner that you are aware of to be yours.

| **Nature of Relevant Financial Relationship**<br>**The following could be perceived as a potential conflict of interest (COI).** | **Name of Commercial Interest Organization(s)** |
|---|---|
| | |
| ☐ Grant/Research Support | |
| ☐ Consultant | |
| ☐ Speakers' Bureau | |
| ☐ Major Stock Shareholder | |
| ☐ Other Financial or Material Support | |
| ☐ Other* (please identify) | |

| | |
|---|---|
| ☐ NONE | **Neither I nor my spouse/partner has any RELEVANT financial relationships with any commercial interests in relation to my involvement with the content of the proposed activity.** |

Glossary of Terms

Commercial Interest

Entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients; with the exemption of non-profit or government organizations and providers of clinical services directly to patients. * *Note: Employees of Commercial Interests are excluded from participation if the content relates to the business lines and products of their employer.*

Financial Relationships

Financial relationships are those 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.

Relevant Financial Relationships

ACCME focuses on financial relationships with commercial interests in the twelve-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past twelve months that create a conflict of interest.

Conflict of Interest (COI)

When an individual's interests are aligned with those of a commercial interest the interests of the individual are in "conflict" with the interests of the public. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest **and** the opportunity to affect the content of CME about the products or services of that commercial interest. The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

University of Rochester School of Medicine & Dentistry (URSMD)
**Center for Experiential Learning (CEL)**

# Policy for Identifying and Resolving Conflicts of Interest in CME

## *I. Background:*

This policy is designed to assist the institution in pursuing its academic and educational missions with regard to continuing medical education (CME) without undue influence by any individuals or groups associated with these CME activities. It is recognized that faculty and staff – both from the University of Rochester and from other institutions – may enter into financial and other materially beneficial relationships with commercial organizations. It is important, however, that CME content be based on learner needs and not be biased by commercial or marketing interests.

Although a conflict of interest may create the potential to bias a presentation, it is accepted that most professionals associated with CME do not knowingly bias information. They recognize the conflicts of interest and put their reputations, their institutions' reputations, and their positions of trust ahead of personal gain from their relationships with a commercial organization. In addition, the appearance of bias is an equally important concern, as the mere appearance of a conflict of interest may cast doubt on the objectivity of a presentation and undermine public trust.

Full disclosure of conflicting or potentially conflicting interests, and then the resolution of those conflicts, has been advanced as the primary and usual means to protect the integrity of CME activities.

## *II. Goals:*

The purpose of this policy is to describe appropriate processes and procedures to identify all actual and/or potential conflicts of interest and describe ways to resolve them prior to the CME activity, resulting in a successful conclusion.

Any relationship that exists between an individual and a commercial organization that suggests or implies a financial or contractual relationship or one that if brought to the public attention would in any way diminish the reputation of the individual, the institution, or the commercial organization should be reported to the institution sponsoring the CME activity. In addition, teachers/authors will be expected to offer CME that is objective, balanced, scientifically rigorous, and in compliance with the *2004 Updated ACCME Standards for Commercial Support.*

ACCME Standards for Commercial Support of CME require that presentations be free of commercial bias and that any information regarding commercial products/services be based on scientific methods generally accepted by the medical community. When discussing therapeutic options, speakers are requested to use only generic names. If they use a trade name, then those of several companies should be used. If a presentation includes discussion of any unlabelled or investigational use of a commercial product, speakers are required to disclose this to the participants.

## *III. Policy:*

1. The University of Rochester Center for Experiential Learning (CEL) will provide a process for identifying, and mechanisms for resolving, actual or potential conflicts of interest (COI) prior to awarding AMA PRA Category 1 credit for CME activities.

2. Anyone in a position to control the content of a proposed CME activity will complete a *Planner/Presenter Declaration Form.*

3. The primary responsibility to identify, address and attempt to resolve any COI belongs to the Activity Director. The CEL staff will be available to assist with this process.

4. All identified actual and potential COI, along with resolution mechanisms, will be disclosed to CME activity participants.

## *IV. Mechanisms for Resolving Conflicts of Interest:*

The following are suggested mechanisms for resolving conflicts of interest (COI).

*A. Attestation:*

Persons who indicate the existence of potential or actual COI will be asked to agree in writing that said conflicts or relationships will not bias or otherwise influence their involvement in the CME activity. Furthermore, teachers/authors will be required to limit practice recommendations to those based on the best available evidence (or absence of evidence) and that such recommendations be consistent with generally accepted medical practice. The activity director will review and approve this approach on a case basis.

*B.* *Evaluation:*
Attendees will be queried regarding their impressions concerning bias (or absence of bias) within the activity. Activity Directors and teachers/authors will receive copies of the evaluation summaries and comments.

*C.* *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 a particular CME activity. This evaluator will be asked to complete a formal detailed evaluation to measure any bias in the activity. This evaluation will be submitted to the activity director to determine further action.

*D.* *Independent content evaluation:*
Scientific abstracts and free-standing papers or articles in enduring materials are often peer-reviewed or judged against predetermined criteria to ensure the data supports the conclusions before they are accepted for presentation or publication. Similarly, individuals working together to do reviews of activity content can resolve COI by ensuring the content is valid, aligned with the interests of the public, and:

- All the recommendations involving clinical medicine are based on the 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 a CME activity in support or as justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis.

*E.* *Altering financial relationships:*
An individual may change his/her relationships with commercial interests, e.g. discontinue contract services, and in doing so, no duty, loyalty, or incentive remains to introduce bias into the CME content. However, when individuals divest themselves of a relationship, it is immediately not relevant to conflicts of interest, but still must be disclosed to learners for 12 months.

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

- *Choose someone else to control that part of the content* – if a proposed teacher/author has an irresolvable COI related to the content, choose someone else who does not have a such a relationship
- *Change the content of the person's assignment* – The role of the person with a COI can be changed within the CME activity so that he/she is no longer teaching about issues relevant to the product/services of the commercial interest. For example, an individual with a COI 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 recommendations.
- *Limit the sources for recommendations* – Rather than having a person with a COI present personal recommendations or personally select the evidence to be presented, limit the role of that individual 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, e.g. the Cochrane Collaboration (www.cochrane.org).

*G.* *Elimination:*
Activity Directors, activity planning committee members, and/or teachers/authors who are perceived as either manifesting irresolvable COI or being biased may be eliminated from consideration as resources for the CME activity.