

Speaker - Author CONTENT PROPOSAL/DECLARATION FORM
PLEASE TYPE OR PRINT CLEARLY

ACTIVITY TITLE _____

ACTIVITY DATE _____

Individual Presentation Outlines/Descriptions are required to meet Continuing Education Accreditation Requirements.

Please complete Parts 1-3 in their entirety.

If you have been requested to participate in more than one area please complete Part 2 ONLY for any additional presentations.

PART 1

NAME: _____

ACADEMIC TITLE: _____

EMAIL: _____ **PHONE/FAX:** _____

NAME/NUMBER OF ADDITIONAL OFFICE CONTACT: _____

***** For non- University of Rochester faculty BIOGRAPHICAL INFORMATION IS REQUIRED please attach CURRENT CV *****

PART 2

SUGGESTED CONTENT AREA: _____

TOPIC/TITLE OF PROPOSED PRESENTATION: _____

PLEASE PROVIDE FOLLOWING PRELIMINARY INFORMATION TO FACILITATE CE CREDIT PROCESSING

1. **Content Outline** (Please be brief)

2. **One to two objectives for proposed presentation** (in behavioral terms, i.e. list, identify, describe)

3. **One to two references for proposed presentation (to be used for content validation and/or verifying evidence-based approach)**

Please return both sheets by <<date>> to:

**University of Rochester School of Medicine & Dentistry
Office of Continuing Professional Education
601 Elmwood Avenue, Box 677
Rochester, NY 14642-8677
Fax: 585.275.3721**

PART 3: Speaker – Author DECLARATION FORM

Please complete as it relates to ALL relevant financial relationships with any commercial interests in relation to your involvement with the content of this activity. Attach additional sheet(s) if needed.

1) Complete **Section A** if relationships exist. -OR- 2) Initial **Section B** if no relationships exist. Then sign, date and return.

ACTIVITY TITLE _____
ACTIVITY DATE _____

First, list the names of proprietary entities producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies 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.
Second, describe **what** you or your spouse/partner received (ex: salary, honorarium etc). **Do NOT indicate how much (the value) you received.**
Third, describe your role.

• Section A:

| The following could be perceived as a potential conflict of interest (COI). | Nature of Relevant Financial Relationship (Include all those that apply) | |
|---|---|-------------------|
| | Name of Organization(s) | What was Received |
| <input type="checkbox"/> Grant/Research Support | | |
| <input type="checkbox"/> Consultant | | |
| <input type="checkbox"/> Speakers' Bureau | | |
| <input type="checkbox"/> Major Stock Shareholder | | |
| <input type="checkbox"/> Other Financial or Material Support | | |
| <input type="checkbox"/> Other (please identify) | | |

• Section B:

| | |
|--------------------------------|--|
| Initial if NO COI: _____ | 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. |
|--------------------------------|--|

Name (please print) _____

Signature _____

Date _____

Example terminology

Role(s): Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and 'other activities (specify).

What was received: 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.

 This Section to be Completed by Activity Director: << (Name) _____ >>

After review, please initial the appropriate Conflict of Interest statement from the following options: _____ (initials)

(A) I have reviewed the above information and feel that no further examination is required pertaining to this individual's involvement with the proposed activity. _____

(B) I have reviewed the above information and feel that further examination of identified conflict(s) is necessary. Please explain concerns and suggest a review process based on the accompanying *Policy for Identifying and Resolving COI in CME, Sec. IV.* _____

(C) I have reviewed the above information and feel that this person's identified conflict(s) are not resolvable. _____

Your cooperation in complying with these guidelines is appreciated.

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*.

III. Policy:

1. The University of Rochester Office of Continuing Professional Education (CPE) 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 *Speaker-Author Declaration Form*.
3. The primary responsibility to identify, address and attempt to resolve any COI belongs to the Activity Director. The CPE 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.