

Conditions of Agreement for CME Activities

STATEMENT OF PURPOSE:

University of Pennsylvania School of Medicine (U of Penn SOM) is committed to providing CME activities that are linked to quality and safety, are effective in improving medical practice, are based on valid content, and are independent of commercial interests. Our CME-certified activities are for scientific and educational purposes only and will in no way promote products and services of the commercial interests* either in the content or selection of topics.

1. INDEPENDENCE:

ACCME Accredited Sponsor, U of Penn SOM will ensure that the following decisions are controlled by the accredited sponsor and are completely free of the control of a commercial interest*:

- Identification of CME needs and selection of target audiences;
- Determination of educational objectives;
- Selection and presentation of content;
- Selection of all persons and organizations that will be in a position to control the content of the CME;
- Selection of educational methods;
- Evaluation of the activity;

2. RESOLUTION OF PERSONAL CONFLICTS OF INTEREST:

- U of Penn SOM as an ACCME accredited sponsor will require "meaningful disclosure" of relevant financial relationships** with any commercial interests from faculty, joint sponsors, and others in a position to control the content of CME activities sponsored;
- An individual who refuses to disclose his or her relationships will be disqualified from any involvement in the planning, development, teaching/presenting, managing, or evaluation of the CME activities;
- Based on the disclosures provided, U Of Penn SOM will be responsible for identifying and resolving all conflicts of interest *** prior to the educational activity being delivered to learners;

3. APPROPRIATE USE OF COMMERCIAL SUPPORT:

- A U of Penn SOM Office of CME must make all decisions regarding the disposition and disbursement of commercial support.
- B There will be no conditions from commercial interest(s) attached to provision of support for educational programs.
- C Funds should be in the form of an educational grant made payable to the **Trustees of the University of Pennsylvania/CME** unless otherwise designated.
- D The terms, conditions and purposes of the educational grant will be documented in a **written letter of agreement** between the commercial supporter and the U of Penn SOM and include CME provider's educational partners or joint sponsors.
 - **THE AGREEMENT MUST INCLUDE THE PROVIDER EVEN IF THE SUPPORT IS GIVEN DIRECTLY TO THE JOINT SPONSOR**
 - **THE AGREEMENT MUST BE SIGNED BY BOTH THE OFFICIAL REPRESENTATIVE OF THE SPECIFIED COMMERCIAL INTEREST THAT IS THE SOURCE OF THE COMMERCIAL SUPPORT AND THE CME DIRECTOR OR THE ASSOCIATE DEAN OF CME AT THE U OF PENN SOM OFFICE OF CME**
- E All support associated with this CME activity must be given with the full knowledge and approval of the University of Pennsylvania School of Medicine, Office of Continuing Medical Education.
- F Payment of honoraria and reimbursement of out-of-pocket expenses for planners, teachers, and authors will be provided directly by U of Penn SOM OCME or its joint sponsor/educational partner and never directly by the commercial supporter. These payments will always be in compliance with the U of Penn SOM written policies and procedures governing honoraria and reimbursement of associated expenses.
- G No other payment shall be given to the program director, faculty, joint sponsors, or others involved with the CME activity (e.g., additional honoraria, extra social events, etc.).
- H Funds originating from a commercial source may not be used to pay for travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees.
- I U of Penn SOM and its educational partners will be accountable for documenting the receipt and expenditure of the commercial support.

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Commercial Supporter's Initials _____

University of Pennsylvania SOM OCME Initials _____

4. APPROPRIATE MANAGEMENT OF ASSOCIATED COMMERCIAL PROMOTION:

- A Arrangements for commercial exhibits or advertisement cannot influence planning or interfere with the presentation, nor can they be a condition for the provision of commercial support for CME activities.
- B Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
 - i. For **PRINT**, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **AND** are not paid for by the commercial supporters of the CME activity.
 - ii. For **COMPUTER BASED** activities, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer “windows” or screens of the CME content.
 - iii. For **AUDIO and VIDEO RECORDING**, advertisements and promotional materials will not be included within the CME. There will be no “commercial breaks.”
 - iv. For **LIVE, FACE-TO-FACE CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Representatives of commercial interest(s) are not allowed to engage in sales or promotional activities while in the space or place of the CME activity.
- C Educational materials that are part of a CME activity, such as slides, abstracts, syllabi and other handouts, cannot contain any advertising, trade name or a product-group message.
- D Commercial interests will not be allowed to act as agents providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.
- E Upon a written request from the U of Penn SOM OCME, commercial supporters may help in supplemental distribution of promotional materials for CME activities, e.g., “save-the-date cards” and brochures provided that they are in compliance with the U of Penn SOM OCME written policy about the role of representatives of commercial supporters in U of Penn SOM sponsored CME activities.

5. CONTENT AND FORMAT WITHOUT COMMERCIAL BIAS:

The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not specific proprietary business interest of a commercial interest.

Presentations that are part of the CME activity must provide a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company

Balanced view means that recommendations or emphasis must fairly represent, and be based on, a reasonable view and valid interpretation of the information available in the subject and that no single product or service is over represented in the educational activity when other equal but competing products or services are available for inclusion.

6. DISCLOSURES RELEVANT TO POTENTIAL COMMERCIAL BIAS:

Relevant financial relationships of those with control over CME content

A disclosure must be made to the learners of any relevant financial relationship(s) for all individuals who have control over CME content. The disclosure must include the following information:

- The name of the individual
- The name of the commercial interest(s)
- The nature of the relationship the person has with each commercial interest

For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

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Commercial support for the CME activity

The source of all support from commercial interest(s) must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.

Disclosure must never include the use of a trade name or a product-group message.

Timing and format of disclosure

The individual and commercial support disclosure must be made available to the learner in writing and prior to the beginning of the educational activity. In all educational formats, the learner should not be able to proceed with the activity without reasonably being expected to have encountered the disclosure information.

7. REQUIREMENTS ON VALIDATION OF CLINICAL CONTENT IN CME :

All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contradictions in the care of patients.

All scientific research referred to, reported or used in CME in support or justification of patient care recommendations must conform to the generally accepted standards of experimental design, data collection and analysis.

There will be no U of Penn SOM certified CME activities that promote:

- Recommendations , treatment or manners of practicing medicine that are not within the definition of CME, *or are*
- Known to have risks or dangers that outweigh the benefits, *or are*
- Known to be ineffective in the treatment of patients

The accredited sponsor, the joint sponsor, all educational partners, and commercial supporters agree to abide by the above outlined terms of agreement and by all relevant ACCME guidelines, policies, and The Standards for Commercial Support.

Questions concerning the conditions outlined above should be directed to: Mila Kostic, Director, Office of Continuing Medical Education, University of Pennsylvania School of Medicine, 333 Blockley Hall, 423 Guardian Drive, Philadelphia, PA 19104-6021, (215) 898-8005, or at mkostic@mail.med.upenn.edu

* **Commercial Interest:** The ACCME defines a “commercial interest “ as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

** **Relevant 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.

*** **Conflict of Interest:** The ACCME considers circumstances to create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

Revised on February 17, 2005

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