

Disclosure of Relationships for

Activity Directors and Planners

Identifying and Resolving Conflicts of Interest in Continuing Medical Education

Be sure to fax ALL PAGES to 410/614-8613.

TITLE OF CME ACTIVITY: \_\_\_\_\_

ACTIVITY DATE: \_\_\_\_\_

ACTIVITY PLANNER NAME: \_\_\_\_\_

(PLEASE PRINT OR TYPE)

As a provider approved by the Accreditation Council for Continuing Medical Education (ACCME), Johns Hopkins University School of Medicine Office of Continuing Medical Education (OCME) requires written, signed disclosure of the existence of financial interests or relationships with commercial interest from any individual in a position to control the content of a CME activity sponsored by OCME. Individuals who refuse to disclose financial relationships will be disqualified from all aspects of associated CME activities.

Definitions:

- Financial interests or relationships are defined as receipt of funds or "gifts-in-kind" by the individual (and his/her spouse, partner or immediate family) in any amount over the past 12 months, or for a Principal Investigator or an individual named in grant/research support to that individual's institution, directly from a commercial interest. Patent royalties, although commonly received indirectly, are also considered financial relationships even if the financial support is not received directly by the individual from a commercial interest.
"Commercial interests" are defined as any proprietary entity producing health care goods or services consumed by, or used on patients, with the exemption of non-profit or government organizations or non-health care related companies.
"Gifts-in-kind" are defined as any gift of material value given in lieu of financial remuneration for your services by a commercial interest (i.e. mailing labels, audio equipment, travel, etc)

SECTION A:

1) Financial Relationship

Have you or your spouse/partner or immediate family member received in the last 12 months or do you expect to receive in the upcoming months any financial remuneration or gifts-in-kind, or are you a Principal Investigator or named in grant/research support received by your institution? YES [ ] NO [ ]

If YES, go to question #2.

If NO, skip to Section D as you have no conflict of interest to disclose.

2) Is all of the money you receive paid by a not-for-profit or a government entity? YES [ ] NO [ ]

If YES, and the money received is a patent royalty, go to Section B to proceed with full disclosure.

If YES, and the money received is not a patent royalty, skip to Section D as you have no conflict of interest to disclose.

If NO, go to question #3.

3) Is some component of your funding or gift-in-kind from a commercial entity? YES [ ] NO [ ]

If YES, please proceed with full disclosure, Section B.

If NO, skip to Section D as you have no conflict of interest to disclose

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**SECTION B:**

**(NOTE: There is no need to disclose the actual financial value of any affiliation.)**

Grants/Research Support\* – list all companies for which you are the principal investigator or named on the grant:

_____	_____
_____	_____
_____	_____

Indicate companies with which you have the following relationships:

Consultant	_____
Stock Shareholder (directly purchased)	_____
Honorarium	_____
Speaker Bureau	_____
Patent Royalties	_____
Other Financial or Material Support	_____
_____	

\*Grants to investigators at The Johns Hopkins University are negotiated and administered by the institution which receives the grants, typically through the Office of Research Administration. Individual investigators who participate in the sponsored project(s) are not directly compensated by the sponsor, but may receive salary or other support from the institution to support their effort on the project(s).

**SECTION C:**

**All financial relationships will be reviewed for potential conflicts of interest, and identified conflicts of interest must be resolved. To ensure a fair and balanced activity, please check one or more of the options below to indicate how you think the potential conflict will best be resolved, and explain the suggested course of action. Attach additional documentation if necessary. We will consider your response when working to resolve the conflict.**

- Alter financial relationships  
Explain: \_\_\_\_\_
  
- Alter control over content  
Explain: \_\_\_\_\_
  
- Independent Content Validation  
Explain: \_\_\_\_\_
  
- Eliminate CME credit from specific lecture(s)  
Explain: \_\_\_\_\_
  
- Other (specify)  
\_\_\_\_\_  
\_\_\_\_\_

**Note:** Complete explanations of the above-mentioned potential resolutions can be found at the end of this document. Your suggested resolution will be taken into consideration during the COI Resolution Process.

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**SECTION D:**

**Note: You may be required to sign a separate, lecture-specific disclosure form if you are speaking at this activity and intend to request teaching credit for preparing and delivering an original presentation.**

Content Validation: My recommendations involving clinical medicine in this CME activity will be based on 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 CME in support or justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection and analysis.

**SIGNATURE:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

*FOR CME OFFICE USE -- Conflict of Interest identified that require additional investigation. This was resolved by the following:*

\_\_\_\_\_

*CME Staff signature:* \_\_\_\_\_ *Date:* \_\_\_\_\_

**Johns Hopkins School of Medicine**  
**OFFICE OF CONTINUING MEDICAL EDUCATION (OCME)**

***Policy on Disclosure of Relationships between Commercial Entities and Educational Faculty***

Johns Hopkins OCME requires written, signed disclosure of the existence of relevant<sup>1</sup> financial interests or relationships with commercial interests<sup>2</sup> from any individual<sup>3</sup> in a position to control the content of a CME activity accredited by OCME. Individuals who refuse to disclose relevant financial relationships ***will be disqualified*** from serving as a planning committee member, a teacher, a speaker, a moderator or an author of the educational activity nor will such individuals have control of or the responsibility for the development, management, presentation or evaluation of the CME activity.

Relevant interests or relationships include, but are not limited to, the following:

- Consultant/Advisor
- Grant/Research Funding<sup>4</sup>
- Speakers Bureau membership
- Stock holdings (excluding diversified mutual funds)
- Other
  - Ownership interest
  - Employment (including Board positions)
  - Royalties
  - Intellectual property rights
  - Honoraria (excluding funds received for faculty participation in accredited CME activities)

All relevant financial interests or other relationships with commercial interests must be disclosed to participants of the activity *prior to the beginning of the educational activity*. The disclosure statement must include the individual's name, the name of the commercial interest(s), and the nature of the relevant relationship the individual has with each commercial interest. It should be noted that although simple disclosure remains necessary it is no longer deemed sufficient.

For an individual with no relevant financial or other relationship(s) with commercial interests, the participants must be informed prior to the beginning of the educational activity that the individual has no relevant financial or other relationship(s) with commercial interests.

The purpose of the OCME Policy on Disclosure of Educational Planners and Commercial Entity Relationships is not to prevent an individual with relationships with or interests in commercial entities from participating in an educational activity, but to help OCME identify and resolve any potential conflicts of interest and to inform the participants that such relationships exist. Variation from the above policy will be considered on a case-by-case basis by the OCME in conjunction with the Advisory Board.

## Definitions

1. “Relevant” financial interests or relationships are defined as receipt of funds or “gifts-in-kind” by the individual (and his/her spouse, partner or immediate family) in any amount over the past 12 months, or for a Principal Investigator or an individual named in grant/research support to that individual’s institution, directly from a commercial interest whose products or services are discussed in or pertain to the content of the individual’s specific lecture or contribution to this activity.
2. “Commercial interests” are defined as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations or non-health care related companies.
3. “Individuals” are defined as persons (and their spouse, partner or immediate family<sup>5</sup>) who are in a position to control the content of the educational activity. Such individuals include, but are not limited to: Editorial positions for CME activities, Planning Committee member, freelance writer, author, JHM employee, contributor, joint sponsor personnel, and vendor.
4. “Grant/Research Funding” is defined as funds that are received from a commercial entity for research or clinical trials and/or educational purposes. The principal investigator or any named individual in a grant is considered to have a conflict of interest that requires disclosure and management whether the funds were received directly by an individual or by an institution. Funds from a grant that are in turn used to pay individuals for research or clinical trials that are part of the individual’s employment with the medical institution or medical university/school and for which they were not a named individual in the grant will not be considered a conflict of interest and will not need to be disclosed by the individual or to activity participants.
5. Immediate family is defined at a minimum by minor children. The individual filling out the report is permitted to be more encompassing if they believe a potential relevant conflict exists.