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 relevant financial interests or relationships from any individual in a position to control the content of a CME activity sponsored by OCME. Individuals who refuse to disclose relevant 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 (or 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, and CRADAs are also considered financial relationships even if the financial support is not received by the individual directly 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)

NIH ID#: ____________________

SPEAKER’S NAME: ____________________
(PLEASE PRINT OR TYPE)

TITLE OF CME ACTIVITY: ____________________

ACTIVITY DATE: ____________________

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, royalties or gifts-in-kind, or are you a Principal Investigator or named in grant/research support received by your institution, including CRADAs? YES □ NO □
If YES, go to question #2.
If NO, skip to Section E as you have no relevant 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 NO, go to question #3.
If YES, but the relationship is a CRADA, or is money received as a patent royalty, go to Section B to proceed with full disclosure.
If YES, and the relationship is neither a CRADA nor is money received as a patent royalty, skip to Section E as you have no relevant conflict of interest to disclose.

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 E as you have no relevant conflict of interest to disclose.
SECTION B:

Presentation title: ________________________________________________________________

NOTE: Section B must be completed separately for each individual presentation.

Are the funds or gifts-in-kind that you received or expect to receive “relevant” to the above titled presentation?

YES ☐ NO ☐

If YES, please proceed with full disclosure to Section C.
If NO, skip to Section B for your next presentation. If you have no more presentations, skip to Section E.

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

Grants/Research Support and CRADAs (Cooperative Research and Development Agreements)* – 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

Patent Royalties (note #6 at end of document)

Speaker Bureau

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 D:

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 relationship

Explain: ____________________________________________________________

☐ Alter control over content

Explain: ____________________________________________________________

☐ Independent Content Validation

Explain: ____________________________________________________________

☐ Eliminate CME credit (from your specific lecture)

Explain: ____________________________________________________________

☐ Other

Specify and Explain: __________________________________________________

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.
SECTION B:

Presentation title: __________________________________________

NOTE: Section B must be completed separately for each individual presentation.

Are the funds or gifts-in-kind that you received or expect to receive “relevant” to the above titled presentation?

YES ☐ NO ☐

If YES, please proceed with full disclosure to Section C.

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YES □ NO □

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YES ☐ NO ☐

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   Explain: ______________________________________________________________

☐ Other
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Approved April 18, 2005 by OCME Advisory Board
Updated 10/28/08
SECTION B:

Presentation title: ____________________________________________

NOTE: Section B must be completed separately for each individual presentation.

Are the funds or gifts-in-kind that you received or expect to receive “relevant” to the above titled presentation?

YES ☐ NO ☐

If YES, please proceed with full disclosure to Section C.
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Explain:____________________________________________________________________

☐ Other

Specify and Explain:____________________________________________________________________

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Approved April 18, 2005 by OCME Advisory Board
Updated 10/28/08
SECTION E:

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.

I hereby attest that the information provided in this document is legitimate and true to the best of my knowledge.

SIGNATURE: ______________________________ DATE: __________________________
Policy on Disclosure of Relationships between Commercial Entities and Educational Faculty

Johns Hopkins OCME requires written, signed disclosure of the existence of relevant financial interests or relationships from any individual 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
- Direct Grant/Research Funding
- 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 including patent royalties 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) or funder, and the nature of the relevant relationship the individual has with each commercial interest or funder. 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), 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 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. Financial interests or relationships are defined as receipt of funds (money, gifts, travel, directly purchased stock) 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 educational activity. Royalties, although commonly received indirectly, are also considered financial relationships.

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) 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.

6. Inventions made as full-time employees of the US government under 45 Code of Federal Regulations Part 7. All rights, title, and interest to these patents have or should by law be assigned to the U.S. Department of Health and Human Services. The government conveys a portion of the royalties it receives to its employee inventors under the Federal Technology Transfer Act of 1986 (P.L. 99-502).