Name: ________________________________________________________________

Your role in the CME Activity:  __ Presenter  __ Author  __ Planning Committee  __ Moderator  __ Program Director

Title of CME Activity: ____________________________________________________________________________

Activity Date: ___________________________________________________________________________________

Presentation Title/Topic(s): _______________________________________________________________________

Allegheny General Hospital (Hospital) has a policy to insure balance, independence, objectivity, and scientific rigor in all Hospital sponsored or jointly sponsored educational activities. All individuals involved in the planning and/or delivery of a Hospital sponsored CME activity are required to disclose to the Hospital and the audience any relevant financial interest or other relationship within the past 12 months, for yourself or your spouse/partner with: (1) the manufacturer(s) of any commercial product(s) and/or (2) the provider(s) of commercial services discussed in this educational activity, as well as any commercial supporters of the activity. (Policy on Disclosures of Proprietary or Financial Conflicts in Continuing Medical Education (CME), Graduate Medical Education (GME) and Continuing Education for Nurses and Allied Health Professionals (CE) Programs attached.)

Please be assured that having an affiliation with an entity, or discussing off-label uses of products and/or medical devices, does not imply in any way that something is improper. Rather, we are requesting that you provide appropriate information so that any conflicts of interest can be resolved prior to the beginning of the activity. Please complete either Section I or Sections II and III.

SECTION I
Neither I, nor any member of my immediate family, have any relevant conflicts of interest in relation to the content of this program.

Signature_________________________________________________________ Date ________________

SECTION II
I, or a member of my immediate family, have a financial interest/arrangement or affiliation with one or more organizations.

<table>
<thead>
<tr>
<th>Affiliation/Financial Interest</th>
<th>Name of Organization(s)</th>
</tr>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>________________________</td>
</tr>
<tr>
<td>Consultant</td>
<td>________________________</td>
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<tr>
<td>Speakers’ Bureau</td>
<td>________________________</td>
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<tr>
<td>Stockholder or other ownership interest</td>
<td>________________________</td>
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<tr>
<td>Board membership</td>
<td>________________________</td>
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<tr>
<td>Other financial or material support</td>
<td>________________________</td>
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</tbody>
</table>

I plan to discuss off-label uses of products and/or medical devices in my lecture. ___ Yes ___ No
If yes, please attach an explanation.

I plan to discuss unpublished research data in my lecture. ___ Yes ___ No
If yes, please attach an explanation.

Signature __________________________________ Date ______________________________

SECTION III
RESOLUTION OF CONFLICT OF INTEREST Check all that apply

Presenters/Authors
- I will change my presentation to eliminate relevance to the products/services of my commercial interest
- I will select a co-presenter to control the segment of the presentation in question
- I will change my role to one that precludes me from making clinical recommendations
- I will support my presentation and clinical recommendations with the “best available evidence” from the medical literature.
- I will refrain from making recommendations regarding products or services
- I will have divested myself of this financial relationship
- I will recommend an alternative presenter for this topic for the planning committee’s consideration
- Other ________________________ ___________________________________________________________________________________

Planners
- To the best of my ability, I will ensure that any speakers or content I suggest is independent of commercial bias
- I will recuse myself from planning activity content in which I have a conflict of interest

Signature ___________________________________________ Date __________________________

Please return this form to Continuing Medical Education, Allegheny General Hospital, 320 East North Avenue, Pittsburgh, PA 15212 ASAP so that the proper notifications related to the program may be made. Phone: 412-359-4952, Fax: 412-359-8218.

Revised 11/06
Policy on Disclosures of Proprietary or Financial Conflicts in Continuing Medical Education (CME), Graduate Medical Education (GME) and Continuing Education for Nurses and Allied Health Professionals (CE) Programs

**Purpose:** To identify and address conflicts of interest when receiving financial support or grants from vendors for continuing and graduate medical education and continuing education for nurses and allied health professionals.

**Scope:** This policy applies to officers, board members, medical staff members and employees of ALLEGHENY GENERAL Hospital.

**Definitions:** A conflict of interest can arise when an individual in a position to control the content of CME/GME/CE (or their spouses/partners) has a relevant personal financial relationship with a commercial entity that benefits the individual and may ultimately bias the presentation of that content to colleagues and participants.

Direct relationships between the proprietary entity and the individual, and its affect on the individual’s primary professional role, commitments, responsibilities and the content of the continuing medical education activity must be considered during the planning phase of the CME/GME/CE activity and communicated to participants. Examples of direct relationships include:

- Employment and management positions
- Independent contractor (contracted research and clinical trials)
- Consultant
- Speaker’s bureau and teaching engagements
- Membership on Advisory Committees or review panels
- Other activities when remuneration is received or expected

In all of these situations, the individual may receive financial benefits that can be described as salary (retainer), royalties, intellectual property rights, consulting fees, honoraria, ownership interests (stocks, stock options, etc.).

**Policy:** The West Penn Allegheny Health System (WPAHS) recognizes the need for disclosure and monitoring of proprietary and financial interests that may affect the scientific integrity and balance of content delivered in continuing education activities whether accredited or non-accredited. Therefore, it is the policy of Allegheny General Hospital that educators and presenters of continuing and graduate medical education, and nurses and allied health professionals continuing education will disclose any relevant proprietary or financial relationship(s) they may have related to their presentation. This includes funding from a commercial interest to support hospital-sponsored CME/GME/CE activities, as well as financial support from commercial entities which could affect the presentations of faculty members. Commercial interest is defined as any proprietary entity producing health care goods or services consumed by, or used on, patients. Proprietary or financial interests will be identified, reviewed and resolved prior to the execution of educational programs.

Although West Penn Allegheny Health System does not consider that such relationships necessarily give rise to a biased presentation by faculty members, it is the policy of Allegheny General Hospital (hospital name) that any such relationships be identified to the audience prior to commencement of the education so that any conclusions regarding conflict of interest can be left to the individual members of the audience. In order to achieve this goal, the following conditions must be met for all CME/GME/CE activities:

1. **Statement of Purpose:** The educational activity is for scientific and educational purposes only and will not promote the commercial supporter’s products, directly or indirectly.

2. **Control of Content and Selection of Presenters and Moderators:** The sponsoring hospital is ultimately responsible for control of content and selection of presenters and moderators. The commercial supporter, or its agents, will respond only to the sponsoring hospital’s initiated requests for suggestions of presenters or sources of possible presenters. The commercial supporter will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between itself and speaker, and will provide this information in writing. The sponsoring hospital will record the role of the commercial supporter, or its agents, in suggesting presenter(s); will seek suggestions from other sources; and will make selection of presenter(s) based on balance and independence.

3. **Disclosure of Financial Relationships:** The sponsoring hospital will ensure disclosure to the audience of (a) company funding and/or (b) any significant relationship between the sponsor and the company (e.g., grant recipient) or between individual speakers or moderators and the company.

4. **Discussion of Unapproved Uses:** The sponsoring hospital will require that presenters disclose when a product is not approved in the United States for the use under discussion.
5. **Involvement in Content:** There will be no “scripting”, emphasis, or influence on content by the commercial supporter or its agents.

6. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room as the educational program. No product advertisements will be permitted in the room where the educational program is conducted.

7. **Objectivity & Balance:** The sponsoring hospital will make every effort to ensure that data regarding the commercial supporters’ products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.

8. **Limitations of Data:** The sponsoring hospital will ensure, to the extent possible, disclosure of limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.

9. **Opportunities for Debate:** The sponsoring hospital will ensure opportunities for questioning or scientific debate.

10. **Independence of Sponsor in the Contributed Fund:**
   a. Funds should be in the form of an educational grant, exhibit fee, or other funding opportunities made payable to the sponsoring hospital (including its TAX ID#), and mailed to the Continuing Medical Education (CME/GME/CE) department at the hospital’s address. The CME department will then disperse all funds and compensate faculty as appropriate.
   
   b. All other support associated with this CME/GME/CE educational activity (e.g., distributing brochures, preparing slides) must be given with the full knowledge and approval of the hospital sponsor.
   
   c. No other funds from the commercial supporter will be paid to the director, faculty, or others involved with CME/GME/CE activity (additional honoraria, extra social events, etc.).

*The Commercial Supporter agrees to* abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education (copy available by request).

*The Accredited Sponsoring Hospital agrees to:* 1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; 2) acknowledge educational support, exhibitor funding or services in kind from the commercial supporter in activity brochures, syllabi, and other activity materials and 3) upon request, furnish the commercial supporter a report concerning the expenditure of the funds provided.
A. Procedure for Identifying Proprietary or Financial Conflicts:

1) All faculty members participating in a hospital sponsored CME/GME/CE program are required to complete a Faculty Disclosure Statement (Exhibit I) providing for information of the nature set forth in this policy. If this information is available at the time that course materials and announcements are published, notification of financial support by commercial entities or any potential conflict of interest identified by individual faculty members will be included in brochures and other materials distributed to attendees. If such information is not available at the time of publication of these materials, any such financial support or potential conflict of interest will be announced at the beginning of the activity in order to help ensure that all attendees will have the benefit of such disclosure.

2) In no event may a faculty member participate in a hospital sponsored CME/GME/CE program without having completed the Faculty Disclosure Statement (Exhibit I) prior to commencement of the activity. Failure to return Exhibit I may also jeopardize future educational endeavors with the organization.

3) Each commercial entity providing support of a hospital sponsored CME/GME/CE program is required to enter into an agreement with the sponsoring hospital, with such agreement reflecting information deemed appropriate by the sponsoring hospital for the proper disclosure of financial support (Exhibit II) or an alternative agreement that is mutually acceptable to both parties and meets the requirements set forth in this policy.

4) All faculty members must provide their program content materials by the designated due date for review prior to the session.

B. Procedures for Managing Proprietary or Financial Conflicts in Educational Activities:

1) Conflict Resolution

If a conflict is identified, one of the mechanisms below will be used to resolve it.

a) Altering Financial Relationships - Individuals may change their relationships with commercial interests (e.g. discontinue contracted services) thereby eliminating any bias of the content.

b) Altering Control Over Content - An individual’s control of content can be altered in several ways to remove the opportunity to affect content related to the products and services of a commercial interest. These include the following:

Choose someone else to control that part of the content. If a proposed presenter or planner has a conflict of interest related to the content, someone else who does not have a relationship to the commercial interests related to the content may present or plan this part of the content.

Change the focus of the program so that the content is not about products or services of the commercial interest that is the basis of the conflict of interest.

Change the content of the person’s assignment so that it is no longer about products or services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a condition could address the pathophysiology or diagnosis of the condition, rather than 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 conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria state (evidence-based).

c) Independent Content Validation
   i. All the recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for indications and contraindications in the care of patients.
   ii. All scientific research referred to, reported or used in the activity in support or justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.

2) Review and Resolution

Identified conflicts of interest will be reviewed by the Sandra Johnston, MEd, Administrative Director of Medical Education, educational/operational education program director and planning committee. Department Chairman and/or the Chairman of the CME Committee will be consulted as appropriate. Additional information on the activity may be collected for review. If a conflict cannot be resolved through the mechanisms in 1. A, B and C above, the activity cannot be certified for AMA PRA credit.

3) Oversight

Disclosure information for everyone involved, whether or not they have a financial relationship to disclose must be provided to activity participants before the activity begins. Activities will be evaluated by participants and peer reviewers to determine if the content was free of bias and met acceptable scientific standards.