Purpose: To identify and address conflicts of interest when receiving financial support or grants from vendors for continuing medical education for physicians and dentists and continuing education (CME/CE) for nurses and allied health professionals. Any financial support or grants received for graduate medical education (GME) must follow the Allegheny General Hospital – Western Pennsylvania Hospital Medical Education Consortium policy on Industry Funding of Medical Education.

Scope: This policy applies to officers, board members, medical staff members and employees of WPAHS and is consistent with the WPAHS Code of Ethics.

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

Direct relationships between the proprietary entity and the individual, and its impact/influence on the individual’s primary professional role, commitments, responsibilities and the content of the CME/CE activity must be considered during the planning phase of the CME/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(or their spouses/partners) 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 CME/CE activities whether accredited or non-accredited.
Therefore, it is the policy of WPAHS that educators, planners, and faculty of CME/CE, will disclose any relevant proprietary or financial relationship(s) they may have related to CME/CE activity. This includes funding from a commercial interest to support hospital-sponsored CME/CE activities, as well as financial support from commercial entities which could affect the presentations of faculty members.

Allegheny General Hospital (AGH) is the accredited provider to offer accredited CME activities by the Accreditation Council for Continuing Medical Education (ACCME) for WPAHS. The ACCME defines a commercial interest 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 activities.

Although West Penn Allegheny Health System may not consider that such relationships necessarily give rise to a biased presentation by faculty members, it is the policy of WPAHS 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/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:** AGH is ultimately responsible for control of content and selection of faculty and moderators. The commercial supporter, or its agents, will respond only to AGH’s initial requests for suggestions of faculty or sources of possible faculty. The commercial supporter will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between itself and faculty, and will provide this information in writing. AGH will record the role of the commercial supporter, or its agents, in suggesting faculty; will seek suggestions from other sources; and will make selection of faculty. Faculty will be selected that will present a balanced view of content that promotes improvements in health care and **NOT** proprietary interests of a commercial interest. To ensure the validity of content, an
Subject: Disclosures of Proprietary or Financial Conflicts in Continuing Medical and Dental Education (CME), and Continuing Education for Nurses and Allied Health Professionals (CE) Activities Policy

expert in the field will be requested to complete a Clinical Content Review and Validation Statement. (Exhibit I)

3. Disclosure of Financial Relationships: AGH 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 faculty, moderators or others involved in the activity and the company.

4. Discussion of Unapproved Uses: AGH will require that faculty 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. Social Events or meals at formal CME activities: Cannot compete with or take precedence over the educational events. This includes a commercial entity providing meals or activities that compete with those offered by AGH as a portion of the overall CME activity.

8. Meals at Regularly Scheduled Series (RSS) activities and other internal CME/CE activities are restricted in accordance with individual hospital policies.

9. Objectivity & Balance: AGH 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.

10. Limitations of Data: AGH will ensure, to the extent possible, disclosure of limitations of data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.

11. Opportunities for Debate: AGH will ensure opportunities for questioning or scientific debate.
12. 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 AGH (including its TAX ID#), and mailed to the Continuing Medical Education department of AGH at the hospital’s address. The CME department will then disperse all funds and compensate faculty as appropriate.

   b. All other support associated with CME/CE educational activities (e.g., distributing brochures, preparing slides) must be given with the full knowledge and approval of AGH.

   c. No other funds from the commercial supporter will be paid to the director, faculty, or others involved with CME/CE activities (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).

AGH as the ACCME accredited entity for WPAHS 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.
**Procedures for Disclosing Proprietary or Financial Conflicts in Continuing Medical Education (CME), and Continuing Education for Nurses and Allied Health Professional (CE) Programs**

**A. Procedure for Identifying Proprietary or Financial Conflicts:**

1) All faculty members participating in AGH sponsored CME/CE activities are required to complete a Faculty Disclosure Statement (Exhibit II) 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 or anyone with any role in the activity participate in an AGH sponsored CME/CE program without having completed a Disclosure Statement prior to commencement of the activity. Failure to sign a disclosure statement may also jeopardize future educational endeavors with the organization.

3) Each commercial entity providing support of an AGH sponsored CME/CE activity is required to enter into an agreement with AGH, with such agreement reflecting information deemed appropriate by AGH 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 activity content materials by the designated due date for clinical content review and validation 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 stated (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 Administrative Director of Continuing Medical Education, educational/operational education activity director and planning committee. The 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 accredited and/or developed for presentation.

3) Oversight

The conflict will be disclosed to activity participants. Activities will be evaluated by participants and peer reviewers to determine if the content was free of bias and met acceptable scientific standards.
Clinical Content Review and Validation

Instructions to Reviewer: Please review the attached course material for the CME activity named below. As an independent reviewer, your role is to assure that the activity materials are fair, balanced and free of bias toward the commercial supporter(s) or the activity (if any) or manufactures of products discussed in the activity. Moreover, you are being asked to scrutinize patient treatment recommendations to assure us that they represent a standard of practice within the profession in the United States. In addition, we ask that you review the studies cited in these materials upon which recommendations are made to assure that they are scientifically objective and conform to research principles generally accepted by the scientific community. Finally, please look at the materials form the perspective of omissions and commissions.

Name of Reviewer:  ____________________________________________________

Your role in the CME Activity:  □ Author    □ Planning Committee
                                    □ Moderator  □ Activity Director

Institution:  _________________________________________________________

Phone:  __________________________   FAX:  _______________________

E-mail:  ________________________________________________________

Name of Activity:  ________________________________________________________

Lecture Title:  ________________________________________________________

Date of Activity:  ________________________________________________________

Commercial Supporters for this Activity:

1. Review for Fair Balance and Bias.
A. Is this activity fair balanced?  □ Yes  □ No

B. Is this activity free of commercial bias?  □ Yes  □ No

2. Patient Treatment Recommendations

A. Are the patient treatment recommendations included in this CME activity evidence-based?  □ Yes  □ No
If no, please comment below:

B. Are the patient treatment recommendations included in this CME activity appropriate for the target audience?  □ Yes  □ No
If no, please comment below:

C. Are the patient treatment recommendations included in this CME activity contributing to overall improvements in patient care?  □ Yes  □ No
If no, please comment below:


A. Do scientific studies cited in this activity conform to standards accepted by the scientific community?  □ Yes  □ No
If no, please comment below:

4. Learning Objectives.

A. Does the educational content support the learning objectives?  □ Yes  □ No

B. Are there objectives actionable and measurable?  □ Yes  □ No

C. Please comment below and include suggested revisions to objectives if appropriate:
5. Omission and Commission.

   A. Do any slides or materials need to be deleted?  
      ☐ Yes  ☐ No
      If yes, please be specific:

   B. Are there any studies, data, or best evidence that is missing?  
      ☐ Yes  ☐ No
      If yes, please be specific:

   C. Are there any other issues you’d like to raise with regard to the content of this activity?  
      ☐ Yes  ☐ No
      If yes, please be specific:

6. Reviewer’s Certification

   ☐ I certify the above true and accurate

   Signature: _____________________________   Date of Review: _____________
EXHIBIT II

CME FACULTY DISCLOSURE AND CONTENT VALIDATION

Name

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

Activity Title

Presentation Title /Topic(s)

In compliance with the ACCME’s Standards for Commercial Support, everyone in a position to control the content of a CME activity must disclose their relevant financial relationships with commercial interests. “Relevant financial relationships” are defined as financial relationships in any amount occurring within the past 12 months. **Refusal to disclose prohibits participation.**

☐Yes ☐No Currently or in the past 12 months, have you (or your spouse/partner) had a financial relationship with a commercial interest (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by or used on patients; with the exception of providers of clinical service directly to patients)?

If you checked ‘yes’ above, please list all financial relationships with commercial interests which have occurred in the past 12 months. Attach a separate sheet if necessary.

<table>
<thead>
<tr>
<th>Affiliation/Financial Interest</th>
<th>Name of Commercial Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Grant/Research Support</td>
<td></td>
</tr>
<tr>
<td>2 Consultant</td>
<td></td>
</tr>
<tr>
<td>3 Speaker’s bureau</td>
<td></td>
</tr>
<tr>
<td>4 Stockholder or other ownership interest</td>
<td></td>
</tr>
<tr>
<td>5 Board membership</td>
<td></td>
</tr>
<tr>
<td>6 Other financial or material support</td>
<td></td>
</tr>
</tbody>
</table>

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

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

**Content Validation** I understand that all recommendations involving clinical medicine in a CME/CE activity must 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, used, or reported must conform to the generally accepted standards of experimental design, data collection and analysis. I will comply with the above expectations by supplying sufficient resources within the context of my presentation regarding clinical content and recommendations for patient care. I understand the expectations for clinical content validation and acknowledge my responsibility to abide by these expectations.

**Disclosure**  I understand my disclosure will be communicated to the participants of the activity.

**Copyright**  Any materials provided by me for use as handouts is my original material and if not I have been granted permission to use it.

**Attestation**  I attest that any relationships/affiliations will not bias or otherwise influence my involvement in the activity.

**Signature**  

☐ By checking this box, I am providing my electronic signature approving all the information entered above. (Please enter name and date on signature and date lines above).

Please return the completed form to:
EXHIBIT III

Allegheny General Hospital
Department of Continuing Medical Education
Letter of Agreement
Regarding Terms, Conditions and Purposes of an Agreement to provide funding between:

West Penn Allegheny Health System, Inc. and

d.b.a. Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212

(Company Name)
320 East North Avenue
Pittsburgh, PA 15212

(TAX ID # 25-0969492)

We appreciate your willingness to provide commercial support for the upcoming educational program sponsored by Allegheny General Hospital. Most providers of continuing medical education operate with very limited financial resources, and the support provided by companies like yours is much appreciated. The details are as follows:

Title of CME Activity:

Date:

Location:

Commercial Entity:
(Company name/Branch)

Company Representative:

Address:

City, State, Zip:

Telephone: Fax:
e-mail:

GRANTS
1. The above company wishes to provide an educational grant for support of the Continuing Medical Education (CME) or Continuing Education (CE) activity.

☐ in the actual amount of $____ or ☐ estimated amount of $____

2. The above company wishes to provide a grant to reimburse expenses for: (check items)
Speaker: ☐ Honorarium $____ ☐ Hotel $____
☐ Transportation $____ ☐ Travel $____
OTHER FUNDING

3. The above company wishes to exhibit at the named CME or CE activity:
   □ in the actual amount of $_____ or □ estimated amount of $_____

4. Services in kind (e.g., equipment loan, brochure distribution, etc.).
   Please specify______________________________

Payment should be submitted by:

In compliance with the ACCME Standards for Commercial Support of Continuing Medical Education, Hospital has instituted a policy on disclosure of sponsor relationships with CME or CE Activities (attached). By your signature below, you signify that you have reviewed the Policy on Disclosures of Proprietary or Financial Conflicts in Continuing Medical Education, Continuing Dental Education, and Continuing Education for Nurses and Allied Health Professionals Programs. You and your company agree to comply with all aspects of that policy regarding funding for the above referenced CME or CE program. Please note that failure to return this form may jeopardize future educational endeavors with this organization and/or result in the cancellation of your exhibit space. Again, thank you for your support of this program. If you have any questions concerning the program or the Policy, please do not hesitate to contact the Course Coordinator at the hospital.

AGREED

Commercial Company Representative (name)

Signature □ (checking this box indicates my e-signature)            Date

CME or CE Director or Designee (name)

Signature □                          Date_