

# **Policy and Guidelines for Interactions between Georgia Health Sciences University School of Medicine with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")**

## **1.0 Purpose of Policy**

The purpose of this policy is to establish guidelines for interactions with Industry representatives throughout the Georgia Health Sciences University. Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and hospital and research equipment and supplies on-site, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with Industry off campus and in scholarly publications.

Many aspects of these interactions are very positive and important for promoting the educational, clinical and research missions of the GHSU Enterprise. However, these interactions must be ethical and cannot create conflicts of interest (COI) that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain.

## **2.0 Policy**

This policy concerning Industry interactions is intended to be more specific and stringent than the GHSU Individual Conflicts of Interest policy and other similar policies. It is the policy of the Georgia Health Sciences University that interactions with Industry should be conducted so as to avoid or minimize conflicts of interest. When conflicts of interest do arise they must be disclosed and managed appropriately, as described herein.

## **3.0 Procedure**

This policy incorporates the following types of interactions with Industry. In addition, faculty must comply with GHSU's Outside Professional Activities policy <http://georgiahealth.edu/aaffairs/policies/pdfs/p719.pdf>, and faculty, staff and all others performing work on behalf of GHSU must all comply with GHSU's Individual Conflicts of Interest Policy <http://policy.georgiahealth.edu/2010/09/23/individual-conflicts-of-interest-policy/>; Institutional Conflicts of Interest Policy <http://georgiahealth.edu/policies/documents/InstConflicts.pdf>; and Ethics Policy <http://policy.georgiahealth.edu/2010/03/29/ethics/>. Additional information specifically related to industry interactions involving ACCME – accredited educational activities (also called CME) can be found at <http://publish.mcg.edu/aaffairs/policies/>. This policy also does not address relationships with other entities that are not encompassed by "Industry." Any restrictions in this policy applicable to individuals applies also to their immediate family members and any business in which the individual or

family has a significant financial interest, as defined in the GHSU Individual Conflicts of Interest Policy, referenced above. In addition, medical staff of GHSUHI must also comply with relevant hospital policies, including but not limited to the policies referenced herein.

#### I. **Gifts and Compensation**

- A. Medical staff, faculty, staff, students, residents, trainees and employees may not accept improper gifts or compensation from Industry. Gifts (including meals) from Industry must not exceed \$25 in fair market value.
- B. Philanthropic gifts from Industry may only be accepted through the GHSU Office of University Advancement, or the GHSU HI Office of Strategic Support and Philanthropy.
  - 1. The limitation on gifts from Industry reflects a more stringent standard than the gift policy of GHSU in other contexts. For example, GHSU's Ethics Policy permits gifts (including meals) from vendors, patients, students, lobbyists, and other parties must not exceed \$100 in fair market value accepted under any circumstances. [http://www.mcg.edu/policies/documents/ethic\\_spolicy.pdf](http://www.mcg.edu/policies/documents/ethic_spolicy.pdf). In addition, GHSUHI has policies concerning employee acceptance of gifts (\$25 limit). Individuals should be aware of other applicable policies, such as the [AMA Statement on Gifts to Physicians from Industry](#) and the [Accreditation Council for Continuing Medical Education Standards for Commercial Support](#).
  - 2. Free drug samples given directly to members of the Georgia Health Sciences University are considered gifts under this policy and may not be accepted. However, free samples can sometimes be an important source of pharmaceuticals for needy patients and they may be accepted and dispensed by the GHSU Health pharmacy if processed in accordance with applicable hospital policies and procedures.  
[http://www.hi.mcg.edu/hospital/pharm/policies/PharmAdmin/PH\\_01\\_02\\_Vendor\\_Mgmt.pdf](http://www.hi.mcg.edu/hospital/pharm/policies/PharmAdmin/PH_01_02_Vendor_Mgmt.pdf)
  - 3. Examples. Gifts or compensation are not acceptable:
    - a. At a clinical facility such as other hospitals, outreach clinics and the like.
    - b. For listening to a sales talk by an industry representative.
    - c. For prescribing or changing a patient's prescription.
    - d. For simply attending a CME or other activity or conference, including the defraying of costs (that is, if the individual is not speaking or otherwise actively participating or presenting at the event). Exception: Promotional items of minimal value that are provided to all attendees may be accepted.

#### II. **Site Access by Sales and Marketing Representatives**

- A. Sales and marketing representatives are not permitted in patient care areas except to provide in-service training on devices and other equipment and then only by appointment as per hospital policy.  
[http://hi.mcg.edu/hospital/pharm/policies/pharmadmin/ph\\_01\\_02\\_vendor\\_mgmt.pdf](http://hi.mcg.edu/hospital/pharm/policies/pharmadmin/ph_01_02_vendor_mgmt.pdf)
- B. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments will normally be made for such purposes as:

1. In-service training of GHSU Health Hospital personnel for research or clinical equipment or devices already purchased.
2. Evaluation of new purchases of equipment, devices, or related items.
3. Appointments for these purposes may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion of the faculty member, his or her division or department, or designated hospital personnel issuing the invitation and with the approval of appropriate hospital management.

**III. Provision of Scholarships and Other Educational Funds to Participants in School of Medicine Educational Programs**

- A. Industry support of students and trainees in the School of Medicine educational programs should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:
  1. The School of Medicine department, program, division or institute selects the student or trainee.
  2. The funds are provided to the School, department, program, division or institute and not directly to the student or trainee or to an individual faculty member.
  3. The department, program, division or institute has determined that the funded conference or program has educational merit.
  4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo."
  5. Notification of receipt of Industry support should be submitted at the time of receipt to the office of the Senior Associate Dean for Clinical Affairs, who will provide the Dean and the GHSU Conflict of Interest Panel with an annual summary of this information for review.
- B. This provision does not apply to national or regional merit-based awards.

**IV. Support for Educational and Other Professional Activities**

- A. All ACCME-accredited Continuing Medical Education (CME) activities (further described simply as CME) must be compliant not only with the [ACCME Standards for Commercial support](#) but also with the [School of Medicine CME Commercial Support Policy](#). Further information may be found at [http://www.mcg.edu/ce/overview.html#STANDARDS\\_FOR\\_COMMERCIAL\\_SUPPORT](http://www.mcg.edu/ce/overview.html#STANDARDS_FOR_COMMERCIAL_SUPPORT) and inquiries should be directed to the GHSU Continuing Medical Education office.
- B. All other School of Medicine educational events (non-CME) that are partially or fully supported by Industry must follow these guidelines:

1. Support from Industry may be accepted and managed by the department, program, division or institute but not by an individual faculty member.
  2. Industry supporters must sign a gift letter of agreement acceptable to GHSU.
  3. Support must be designated for a broadly defined topic (e.g., cardiology, psychiatry, neurosurgery) or recurring educational activity (e.g., grand rounds). Support may not be designated for a specific topic, speaker or activity. "In kind" Industry support such as equipment and supplies may be designated to an activity.
  4. Industry support for education must be spent on education.
  5. Industry support may not influence curriculum in any way.
  6. Industry exhibits are not permitted either on or off campus.
  7. Industry promotion or marketing (e.g., corporate logos, slogans) are not allowed.
  8. Industry employees will normally not serve as educators at such activities.
  9. When a faculty member has a financial interest that poses a content relevant conflict of interest, this should be disclosed to the learners.
  10. Receipt of industry support for educational activities for GHSU medical and graduate students and postdoctoral fellows and trainees must be reported at the time of receipt to the Senior Associate Dean for Clinical Affairs.
- C. Costs of meals or other types of food provided by Industry must be consistent with other limitations in this policy.
- D. Meetings and conferences supported in part or in whole by Industry as they relate to School of Medicine faculty, students, staff and trainees
1. School of Medicine faculty, students, staff and trainees should evaluate carefully their attendance at meetings and conferences that are fully or partially sponsored or run by Industry because of the potential for perceived or real conflict of interest. They should be especially cognizant of this potential when considering whether to play a leadership role in such meetings and conferences by giving a lecture, organizing the meeting and the like. These activities are allowed so long as the guidelines listed below (Section D.2) are followed.

Note that this provision does not apply to meetings of professional societies that may receive partial industry support, meetings which provide CME credit and hence are governed by ACCME Standards and the like.

2. Guidelines for participation in meetings and conferences supported in part or in whole by Industry (e.g., by giving a lecture, organizing the meeting):
  - a. The activity is designed to promote evidence-based clinical care and/or advance scientific research;

- b. The activity is not a dedicated marketing and training program designed solely for sales or marketing personnel.
- c. The activity is not an Industry-sponsored “speaker’s bureau” (i.e., a contractual relationship to give talks in which the topic(s) and/or content are provided by the company).
- d. Financial support by Industry is fully disclosed by the meeting sponsor.
- e. The lecturer and not the Industry sponsor determines and prepares the meeting or lecture content.
- f. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.
- g. The GHSU participant is not required by an Industry sponsor to accept advice or services concerning speakers, content, etc., as a condition of the sponsor’s contribution of funds or services.
- h. The lecturer makes clear that content reflects individual views and not the views of GHSU School of Medicine.
- i. The use of the GHSU name in non- GHSU events is limited to the identification of the individual by his or her title and affiliation.
- j. Attendees do not receive gifts or other compensation for attendance. Exception: Promotional items of minimal value that are provided to all attendees may be accepted.

V. **Disclosure of Relationships with Industry**

- A. All faculty, researchers and senior administrators must disclose all individual conflicts of interest, or certify none, on an annual basis to their Responsible Representative.  
<http://www.mcg.edu/Policies/documents/IndividualCOI.pdf> For example, faculty engaged in clinical care activities must disclose on an annual basis any financial relationship with a company, entity, or third party that produces, manufactures, or distributes a medical device, implant, pharmaceutical or other medical care-related product that they recommend or prescribe to their patients.
- B. The following provisions about scholarly and educational activities apply to School of Medicine faculty, students, staff and trainees.
  - 1. Individuals are prohibited from engaging in ghost-writing; in other words, individuals may not publish articles under their own names that are written in whole or material part by industry employees.
  - 2. In scholarly publications, individuals must disclose their related financial interests in accordance with the [International Committee of Medical Journal Editors](#). In scholarly and public presentations faculty should disclose all relevant personal financial interests when appropriate.

3. Faculty with teaching or supervisory responsibilities for students, residents, trainees or staff should ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her teaching or the supervision of the student, resident, trainee, or staff member.

## **VI. Purchasing Decisions**

Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit or selection committee, when the individual is first asked by GHSU to be involved in the decision, any financial interest they or their immediate family have in companies that might benefit from the decision. Additional policy concerning procurement activities at the hospitals can be found in hospital and medical staff policy documents. The purchasing unit, following the applicable guidelines, will decide whether the individual must recuse him/herself from the purchasing decision. State purchasing regulations must be followed where applicable.

<http://www.doas.state.ga.us/StateLocal/SPD/Policies/Pages/Home.aspx>

## **VII. Training of Students, Trainees and Staff Regarding Potential Conflict of Interest in Interactions with Industry**

- A. All School of Medicine students, residents, and trainees will receive this policy document as well as training regarding potential conflict of interest in interactions with industry. School of Medicine staff will receive a copy of this policy document in their initial employment materials. Existing faculty and staff will also receive training on this policy.