It is the policy of Methodist Healthcare System (MHS) that interaction with industry should be conducted so as to avoid or minimize conflicts of interest and the appearance of conflicts of interest. When conflicts of interest do arise they must be addressed appropriately. All vendor representatives are expected to abide by the Vendor Relations Policy and applicable laws and regulations while on MHS premises or while interacting with MHS personnel (i.e. faculty, staff and students). All gifts (including de minimus gifts), are prohibited and may not be accepted by residents from representatives.

The purpose of this policy are to establish guidelines for interactions with industry representatives for residents and to safeguard education, research and patient care against market driven conflicts of interest. The overriding goal of this policy is to ensure that the integrity of our educational, research and clinical programs are not compromised by financial or other personal relationships with industry. Interactions with industry occur in a variety of contexts including educational and research support of residents and marketing of new healthcare, pharmaceutical and medical device products. Residents also participate in interactions with industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of MHS. MHS fully recognizes that a healthy interaction between academia and industry is part of the mission. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, sway clinical decisions contrary to the patient’s best interests, and alter data integrity or the integrity and independence of our education and research programs or the reputation of the institution. As part of this policy, MHS recognizes that ethical interactions are the responsibility of both industry and residents.

This policy applies to all residents and all industry representatives with whom they may come in contact. This policy incorporates the following:

I. Meals, Gifts and Compensation

a. Personal gifts, regardless of value, from vendor representatives are prohibited, including, but not limited to loans, economic opportunities, meals, tickets or vouchers for entertainment events, pens, notepads or cash. It is strongly advised that no form of personal gift from a vendor be accepted under any circumstances.

b. Residents must consciously and actively divorce clinical care decisions and research activities from any perceived or actual benefits expected from any company. The overriding principle at MHS is that healthcare providers represent their patients’ best interests and not those of vendors. It is not acceptable for patient care decisions to be influenced by the possibility of personal financial gain.

c. Residents cannot accept gifts or compensation for prescribing or changing a patient's prescription. Residents cannot accept gifts or compensation for listening to a presentation by a representative.
d. Residents cannot accept compensation, including the defraying of costs, for attending a CME event or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

e. Representatives cannot use Residents or resources to distribute information about vendor-sponsored events. This includes MHS e-mail, mailings, e-page or other mass notification methods. Departmental and division offices, including residency and fellowship programs, will not circulate announcements of vendor-sponsored events or provide e-mail lists or address lists of MHS personnel, physicians or house staff.

II. Promotional Items and Drug Samples

a. Residents will not accept or distribute items (e.g. pens, note pads, and similar "reminder" items). Promotion of drug or medical device products may not be for uses not reflected in United States Food and Drug Administration (FDA) approved product labeling. Under no circumstances can promotional items be used in patient care areas.

b. Proper discretion will be utilized to assure the distribution of drug samples is for the benefit of the patient, not for product promotion.

III. Support for Educational and Other Professional Activities

a. Individuals should be aware of the Accrediting Council for Continuing Medical Education (ACCME) "Standards for Commercial Support." They provide useful guidelines for evaluating all forms of industry interaction, both on and off campus and including both MHS-sponsored and other events. The standards are appended to this policy and may be found at www.accme.org.

b. Educational, unrestricted grants that are compliant with the ACCME Standards may be received from industry but must be administered through the MHS departments or divisions and not by individual faculty. Divisions and departments must maintain records of compliance with the ACCME Standards.

c. MHS will accept grants for general support of education and research (no specific deliverable products) from pharmaceutical and device companies, to a MHS account not designated for use by specific individuals. Educational and research grants may not be made or conditioned or related in any way to any pre-existing or future business relationship with the company or any business or other decisions MHS has or may make relating to the manufacturer or its products (including coverage or formulary status decisions). The content of the educational program, educational methods and materials should be consistent with applicable rules and requirements for accredited CME programs and controlled by the course provider and not by the company providing the educational grant. This arrangement will permit MHS and the ultimate recipients of funds to remain free from influence by any one donor.

d. To ensure accountability and to acknowledge generosity, the amount of funds contributed and the eventual use of the funds will be posted.

IV. Travel Funds

a. Manufacturers interested in having Residents attend meetings should provide unrestricted grants to a designated fund for educational conferences and meetings. The MHS GME office will then disburse funds to faculty and training program directors.
Neither faculty nor trainees will be directly dependent on industry generosity for educational opportunities.

b. With respect to the airfare, lodging, and transportation costs to and from the airport, residents subject to the provisions of this policy will not solicit or accept free or special discount travel or related expenses from a source outside state government, except when the person's presence at a meeting, seminar or event serves a legitimate state purpose or interest and the person's agency authorizes or would authorize payment for such travel and expenses.

V. Speakers Bureaus and Ghostwriting

a. The sharing of ideas and information, by experts in a particular field, is valued and supported by MHS; accordingly, faculty opinion must be data-driven and not for hire. Faculty should be aware that Speaker's bureaus are typically an extension of manufacturers' marketing apparatus. Though faculty are not prohibited from participating as members of a speaker’s bureaus for vendors such as pharmaceutical or device manufacturers, faculty should consider the guidelines enumerated below before entering into a contract or service agreement with a vendor.

b. Residents who actively participate in meetings and conferences supported in part or in whole by industry (e.g., by giving a lecture, organizing the meeting) should follow these guidelines:

1. Financial support by industry is fully disclosed by the meeting sponsor.

2. The speaker should be solely responsible for designing and conducting the activity and the activity will be educational, non-promotional and free from commercial bias.

3. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and to promote objective scientific and educational activities and discourse.

4. The 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.

5. The lecturer makes clear that content reflects individual views and not the views of MHS partner institutions.

6. The use of the MHS name in non-MHS events is limited to the identification of the individual by his or her title and affiliation.

c. Residents are prohibited from publishing articles under their own names that are written in whole or material part by industry employees. Authors must be responsible for the content and must actively participate in the preparation of the article

VI. Consulting and Research Contracts

a. The process of discovery and development of new drugs and devices benefits from academic participation. However, participation by residents should result in impartial collection and interpretation of data. To ensure scientific integrity, interactions must be
transparent and allow free exchange of ideas. Consulting fees or honoraria for speaking must always take place with an explicit contract with specific deliverables, and the deliverables must be restricted to scientific issues, not marketing efforts. A contract with no identified deliverables is tantamount to a gift and is prohibited.

b. To promote scientific progress, MHS will accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies, provided that the unrestricted grants are made with the approval of the MHS Clinical Trials Office and not designated for use by specific individuals. As long as the institution stands between the individual investigator and the company making the grant, the likelihood of undue influence is minimized.

VII. On Site, MHS-Based Training Programs

a. Occasionally physicians, nurses or other health care professional staff is asked by vendors to provide on-site, training for representatives about new products, drugs or procedures. These usually represent legitimate industry interactions, but residents must comply with the following:

1. The representative, physician or professional staff member will notify Continuing Education (CE) when an educational program becomes available.

2. CE will require the representative to have on file, a brief outline of the project from the company that includes the intent, scope and time line of the educational program.

3. Representatives are not allowed direct contact with patients or their medical records for reasons of confidentiality, nor are they allowed in any patient care area unless the vendor has completed the appropriate training, signed the necessary confidentiality forms and the patient has authorized access or unless the vendor has appropriately executed a Business Associate Agreement (BAA).

VIII. Disclosure of Relationships with Industry

a. In scholarly publications, individuals must disclose their related financial interests in accordance with the recommendations of the International Committee of Medical Journal Editors. The standards may be found at www.icmje.org.

b. Faculty with supervisory responsibilities for residents should ensure that their conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the resident.

c. Individuals having a direct role making institutional decisions for the purchase of equipment, drug or supplies procurement must disclose to the purchasing unit, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The Ethics and Compliance Committee will decide whether the individual must recuse him/herself from the purchasing decision.
1. This provision excludes indirect ownership such as stock held through mutual funds.

2. The term "immediate family" includes the individual's spouse or domestic partner, parents or children.

IX. Compliance by sales and marketing representatives

a. Representatives shall comply with all applicable rules, regulations, policies and procedures of MHS as they exist now and as they may be amended from time to time, including, but not limited to, all policies and procedures relating to ingress and egress to and from the premises, parking, confidentiality of patient information, safety, smoking, waste disposal and infection control.

b. When residents identify a representative not adhering to this policy, they should report this to the MHS Ethics and Compliance Officer, who then notifies the representative of the infraction. Restriction, up to and including the removal of the representative from MHS premises, is possible based upon the type of infraction or the number of re-occurring infractions of the policy. MHS retains the sole discretion in making their enforcement decisions.

c. MHS reserves the right to immediately have any vendor representative removed from the premises for failure to follow this policy.

d. Representatives who violate this policy shall not be permitted to market or detail at MHS and may be barred from the campus.

X. Training Regarding Potential Conflict of Interest

a. All residents will receive annual training regarding potential conflicts of interest in interactions with industry.

XI. Future Directions

References:

1. MHS Ethics and Compliance Program
2. Texas Medical Board (http://www.tmb.stat.tx.us)
4. Accrediting Council for Continuing Medical Education. “Standards for Commercial Support” (http://www.accme.org)
5. Industry-Supported Scientific and Educational Activities (http://www.fda.gov/e/cder/guidance/isse.htm)