Vendor Relations Policy

Policy

It is the policy of the University of Kansas Medical Center (KUMC) that interactions 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 (representatives) are expected to abide by the Vendor Relations Policy (Policy) and applicable laws and regulations while on KUMC premises or while interacting with KUMC personnel (i.e. faculty, staff and students). All gifts (including de minimus gifts), are prohibited and may not be accepted by individual KUMC personnel from representatives.

Purpose

The goals of this policy are to establish guidelines for interactions with industry representatives for KUMC personnel 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 KUMC personnel and marketing of new healthcare, pharmaceutical and medical device products. KUMC personnel 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 KUMC. KUMC 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, 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, KUMC recognizes that ethical interactions are the responsibility of both industry and KUMC personnel.

Scope

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

I. Meals, Gifts and Compensation
II. Promotional Items and Drug Samples
III. Support for Educational and Other Professional Activities
IV. Travel Funds
V. Speakers Bureaus and Ghostwriting
VI. Consulting and Research Contracts
VII. On Site, KUMC-Based Training Programs
VIII. Disclosure of Relationships with Industry
IX. Compliance by sales and marketing representatives
X. Training Regarding Potential Conflict of Interest
XI. Future Directions

I. Gifts
   A. Personal gifts, regardless of value, from vendor representatives to all KUMC Personnel 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. KUMC personnel 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 KUMC 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. KUMC personnel cannot accept gifts or compensation for prescribing or changing a patient's prescription. KUMC personnel cannot accept gifts or compensation for listening to a presentation by a representative.

D. KUMC personnel 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).6

E. Representatives cannot use KUMC personnel or resources to distribute information about vendor-sponsored events. This includes KUMC 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 KUMC personnel, physicians or house staff.

II. Promotional Items and Drug Samples
A. KUMC personnel 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."5 They provide useful guidelines for evaluating all forms of industry interaction, both on and off campus and including both KUMC-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 KU Endowment Association (KUEA), departments or divisions and not by individual faculty. Divisions and departments must maintain records of compliance with the ACCME Standards.

C. KUMC will accept grants for general support of education and research (no specific deliverable products) from pharmaceutical and device companies, provided that the unrestricted grants are made with the approval of the EVC, or designee, to a KUEA 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 KUMC 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 KUMC 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 on the KUMC Web-site by the Office of Compliance.

IV. Funds for Travel
A. Manufacturers interested in having KUMC personnel attend meetings should provide unrestricted grants to a designated fund for educational conferences and meetings. The EVC will then disburse funds to faculty and training program directors. Neither faculty nor trainees will be directly dependent on industry generosity for educational opportunities.

1. With respect to the airfare, lodging, and transportation costs to and from the airport, KUMC personnel 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.6

V. Speakers Bureaus and Ghostwriting
A. The sharing of ideas and information, by experts in a particular field, is valued and supported by KUMC; 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 bureau 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. KUMC personnel 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:7
   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, nonpromotional 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 KUMC 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 KUMC partner institutions.

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

C. KUMC personnel 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 KUMC personnel 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, KUMC 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 EVC, or designee, to KUEA accounts 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. To better ensure independence, scientific integrity and full transparency, consulting agreements and unconditional grants will be posted on the KUMC Web-site by the Office of Compliance.

VII. On Site, KUMC-Based Product Training

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

1. The representative, physician or professional staff member will notify the Office of 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 are appended to this policy and may be found at www.icmje.org.

B. Faculty with supervisory responsibilities for students or staff should ensure that their conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the student, resident, trainee or staff member.

C. Individuals having a direct role making institutional decisions for the purchase of equipment, drug or supplies procurement must disclose to the purchasing unit and the Conflict of Interest Committee (COIC), 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 COIC 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 Representatives
A. Representatives shall comply with all applicable rules, regulations, policies and procedures of KUMC 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 Security or KUMC personnel identify a representative not adhering to this policy, they should report this to the KUMC Office of Compliance, who then notifies the representative of the infraction. Restriction, up to and including the removal of the representative from KUMC premises, is possible based upon the type of infraction or the number of re-occurring infractions of the policy. KUMC retains the sole discretion in making their enforcement decisions.

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

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

X. Training Regarding Potential Conflict of Interest in Interactions with Industry

A. All KUMC personnel will receive annual training regarding potential conflicts of interest in interactions with industry.

XI. Future Directions

A committee will be established, with representation elected by the Faculty Council and members appointed by the EVC, to provide continued, real-time input into this policy. This committee will address issues and questions raised by individual faculty, staff and students regarding the policy, as well as future regulatory or legislative changes that may impact this policy. Vendor Relations Oversight Committee Charter

1Kansas law prohibits any state employees of the executive branch and members of boards, commissions, or authorities of the executive branch from accepting or requesting meals, gifts, entertainment, and travel with a few exceptions. Personnel may accept meals, the provision of which is motivated by a personal or family relationship, or provided at events that are widely attended. An occasion is ‘widely attended’ when it is obvious to the person accepting the meal that the reason for providing the meal is not a pretext for exclusive or nearly exclusive access to the person. (K.S.A.46-237a)

2American Medical Association. “Statement on Gifts to Physicians from Industry.” (http://www.ama-assn.org/ama/pub/category/4001.html) Opinion 8.061, “Gifts to Physicians from Industry” is intended to provide ethical guidance to physicians. Other parties involved in the healthcare sector, including the pharmaceutical, devices and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations. The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

3Accrediting Council for Continuing Medical Education. “Standards for Commercial Support” (www.accme.org) When commercial interests contribute funds and services for the development of CME activities, it is considered commercial support. Commercial support has significantly enhanced the ability of the CME enterprise to fulfill its purpose. However, commercial support has the potential to introduce commercial bias that threatens the integrity of the CME enterprise. When individual’s have financial relationships with commercial interests and are in a position to control the content of CME, there is also the potential for commercial bias. The Accreditation Council for Continuing Medical Education (ACCME) believes that CME must be free of the control of commercial interests. The ACCME believes that this independence from commercial interests will help ensure that CME is free of commercial bias.

4See Kansas Government Ethics Committee Opinions K.G.E.C. 2000-10; 2000-17; 2000-18. Stating in 2000-10 and 2000-17 State employees may accept reimbursement from an external group for the expenses associated with attendance at a conference...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. Stating in 2000-18 that if an employee has been offered a gift, and not because of his/her position with the State, the state level conflict of interest laws would not prohibit that person from accepting the gift. The Commission's advisory opinions serve to interpret the laws under the Commission's jurisdiction.

5See FN 3

6See FN 4.
Industry-Supported Scientific and Educational Activities: [http://www.fda.gov/cder/guidance/isse.htm](http://www.fda.gov/cder/guidance/isse.htm) This guidance was prepared by FDA's Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency's current thinking on industry-supported scientific and educational activities. The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers nonpromotional and those that the agency considers promotional, and to provide guidance on how industry may support such activities without subjection to regulation under the labeling and advertising provisions of the act.

International Committee of Medical Journal Editors ([http://www.icmje.org](http://www.icmje.org)). II. Ethical Considerations in the Conduct and Reporting of Research; II.A Authorship and Contributorship; II.A.1. Byline Authors: An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study... Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

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