



## **Graduate Medical Education Medical Industry Interaction Policy and Procedure**

**December 18, 2008**

**Purpose:** To ensure that all residents' and fellows' interactions with representatives of the pharmaceutical and other medical industries shall be conducted so as to avoid or minimize conflicts of interest and to support the mission and values of the School of Medicine.

**Scope:** This policy and procedure applies to all residents and fellows in ACGME accredited programs sponsored by UMKC School of Medicine.

The University of Missouri—Kansas City School of Medicine Medical Industry Interaction Policy (developed jointly with Truman Medical Center and University Physicians Associates) provides the guiding principles for housestaff interaction with pharmaceutical and other medical industry representatives. The faculty at the School of Medicine recognizes, however, that the residents and fellows in its sponsored training programs are exposed to a variety of different training environments, each with its own policy on this matter. Further, the faculty recognizes the inherent unfairness of expecting its trainees to abide by standards different than those expected of its faculty at its affiliated clinical institutions.

Given these considerations, residents and fellows in ACGME accredited programs sponsored by UMKC School of Medicine are expected to adhere to the following standards of conduct:

1. Following the University of Missouri—Kansas City School of Medicine Medical Industry Interaction Policy will always be acceptable and is required when at the School of Medicine or Truman Medical Center. A copy of the policy is included in this document.
2. During time spent at other clinical affiliates of the School of Medicine, the resident or fellow may choose to follow that affiliate's policy governing interaction with the pharmaceutical/medical industry. A table, summarizing each affiliate's policy, is included in this document.
3. None of the current policies govern a resident's or fellow's behavior during personal time away from the institutions. It is hoped that each trainee will recognize their responsibility, as a physician, to behave in a manner that upholds the values and standards of the profession. Both the American Medical Association and the Association of American Medical Colleges have developed guidelines for physicians in their efforts to avoid conflicts of interest. These guidelines serve as excellent standards for the trainee's reference.
4. Violations of this policy will be viewed as an opportunity to educate the resident or fellow on appropriate standards of professionalism. Repeated, egregious violations, however, may be referred to the training program's education committee for possible disciplinary action as a breach of the core competency of professionalism.

Reference:: UMKC, GME Drug Industry Guidelines, June 17, 2004.  
TMC, Medical Industry Interaction, Draft, June 2008.

Follow-up Responsibility: Director, Graduate Medical Education Operations

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Date: December 18, 2008



**Subject: MEDICAL INDUSTRY INTERACTION**

**Originator: Mark T. Steele, M.D., Chief Medical Officer**

**Approval Date:**

**Approved By: Mark T. Steele, M.D., Chief Medical Officer**

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**Policy:**

Interactions between employees and other persons connected with Truman Medical Centers (TMC), University of Missouri-Kansas City School of Medicine (UMKC) and University Physician Associates (UPA) (collectively, “the Institutions”) and representatives of the pharmaceutical and other medical industries shall be conducted so as to avoid or minimize conflicts of interest and to support the Institutions’ missions and values.

**Purpose:**

The primary objective of professional interactions between the Institutions and Industry shall be the advancement of the health of the population rather than the private good of either the Institutions or Industry. The Institutions intend by this Policy to promote the health of their patients, to protect the confidentiality of their patients, to ensure the integrity of their research activities, to slow the rising cost of healthcare, and to avoid perception of inappropriate financial gain by faculty, students, residents, and employees. The Policy, more specifically, should prevent any real or perceived undue influence by Industry Representatives and to establish guidelines for appropriate interactions with Industry Representatives.

**Scope:**

Except as otherwise specified in this Policy, Covered Persons are subject to this Policy only when present at property or facilities owned, leased or operated by the Institutions or at activities primarily sponsored by one or more of the Institutions. This Policy applies to the following interactions with Industry:

1. Gifts, compensation, and meals.
2. Access by Industry sales and marketing representatives.
3. Support for medical educational and professional activities.
4. Disclosure of relationships with Industry.

**Definitions:**

Conflict of Interest – a situation in which someone or some entity has professional, financial, or personal interest(s) that compete significantly with the interests of the Institutions or their patients. Such competing interests can make it difficult to fulfill a Covered Person’s duties impartially. Even if there is no evidence of improper actions, a Conflict of Interest can create an appearance of impropriety that can undermine confidence in the ability of that Covered Person to act properly.

Covered Persons – all employees, volunteers, board members, members of medical staff, faculty, students, residents and fellows of the Institutions, and other individuals and entities working at property and facilities owned, leased or operated by the Institutions. Covered Persons include all Institutional entities and units consisting of one or more individual who is a Covered Person.

Family – spouse, partner, parent or dependent child.

Formulary – the current active medication or drug list maintained by the TMC Pharmacy and Therapeutics Committee.

Industry – Organizations and individuals that manufacture or sell pharmaceuticals or equipment, devices, supplies or other products that have a direct impact on patient care.

Industry Representative – a sales or marketing representative of an Industry member.

Research – a systematic investigation designed to develop or contribute to generalizable knowledge.

Significant Financial Interest – receipt in the past year, or expectation of the receipt, of value, including salary or other payments for services (e.g., consulting fees, honoraria, payments for advisory roles); research funding; equity interests (e.g., stocks, stock options, dividends or other ownership interests), and intellectual property rights (e.g., patents, copyrights or royalties from such rights) for a Covered Person. This does not include:

- (a) salary, royalties, or other remuneration from a Covered Person’s employer;
- (b) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (c) income from service on advisory committees or review panels for public or nonprofit entities;
- (d) an equity interest that when aggregated for the Covered Person or Family is not more than a \$10,000 ownership interest in any single entity; or

- (e) pooled resources directly held through funds such as mutual funds, pension funds, or other institutional investment funds in which the Covered Person or the Family does not control the selection of investments.

### **Gifts, compensation, and meals**

- A. Except as otherwise permitted by this Policy, Covered Persons shall not request or accept any gifts from Industry Representatives, including payments, travel, hospitality, meals, tickets, favors or other goods or services, extending even to “reminder” items like pens and notepads. This prohibition shall not apply to gifts to patients, except sample medications, as set forth in the following Subsection I.B.
- B. At TMC LW and TMC Behavioral Health, sample medications and vouchers may be accepted only by the TMC Pharmacy Department. If Industry Representatives request a physician signature for delivery of samples (which is not required by law), the physician may meet with them in non-clinical areas (see Sub-section II.B. below). Prescriptions for medication samples may be written by individual practitioners as long as the samples are maintained and dispensed by the TMC Pharmacy Department at TMC LW and TMC BH. Except at TMC outreach clinics that are distant from any TMC pharmacy, Covered Persons shall not dispense sample medications or vouchers directly to patients. At TMC HH, medication samples may be stored and dispensed in outpatient clinics after Representatives first check in and leave the samples at the TMC HH Pharmacy Department. See TMC Policy on the *intranet* – [Drug Samples](http://tmcpolicy/Corporate/Corporate%20Policies%20and%20Procedures/Drug%20Samples.doc)  
<http://tmcpolicy/Corporate/Corporate%20Policies%20and%20Procedures/Drug%20Samples.doc>
- C. In addition to the terms of this Policy, all TMC personnel are bound by the TMC Code of Conduct (see heading “Gifts and Gratuities, Bribery”).
- D. Covered Persons may refer to the interaction and gift policies of the American Medical Association; U.S. Department of Health and Human Services Office of Inspector General - Compliance Program Guidance for Pharmaceutical Manufacturers; Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support; and Association of American Medical Colleges (AAMC).  
See: [www.ama-assn.org/ama/pub/category/8484.html](http://www.ama-assn.org/ama/pub/category/8484.html)  
[www.ama-assn.org/ama/pub/category/4263.html](http://www.ama-assn.org/ama/pub/category/4263.html)  
<http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>  
[www.ACCME.org](http://www.ACCME.org)  
[www.AAMC.org](http://www.AAMC.org)

- E. The prohibitions in this Part I do not apply to a charitable gift to the TMC Charitable Foundation or other fund raising organizations, so long as the gift is not channeled to individuals for direct promotion of Industry products.

### **Access by Industry sales and marketing representatives**

- A. Prior to interacting with any Covered Person or visiting any unit of the Institutions, pharmaceutical Industry Representatives shall register with the TMC Pharmacy Department and non-pharmaceutical Industry Representatives shall register with the TMC Purchasing Department. All Industry Representatives shall pay the required annual fee, if not already paid, and receive a name badge to wear for appropriate identification while present at the Institutions.
- B. Industry Representatives shall not enter clinical areas of the Institutions for any purpose with one exception. In the sole case of non-pharmaceutical products, Industry Representatives may access clinical areas by appointment, with approval from the appropriate Department Chair or Program Director, in coordination with the TMC manager/director of the clinical area, if the purpose is either
  1. to provide needed in-service training or assistance on Industry products already purchased, or
  2. to assist Covered Persons to evaluate new Industry products before purchasing them.
- C. Appointments by Industry Representatives to discuss pharmaceutical information about non-Formulary drugs shall be issued only for non-clinical areas and only by the TMC Pharmacy Department or the TMC Pharmacy and Therapeutics (P&T) Committee. This sub-section does not, however, limit meetings between Industry Representatives and faculty in faculty offices or other private, non-clinical locations.
- D. Announcements to Covered Persons about off-site events sponsored or funded by Industry shall not be made using Institutional communication mechanisms such as email, regular mail, flyers, brochures, bulletin boards, and posters, unless an Institution is the sponsor and the Industry support is regulated under one of the aforementioned guidelines, e.g., ACCME.
- E. Industry Representatives shall comply with all laws and policies concerning patient confidentiality and shall not interact with patients,

review any part of the medical record, attend patient rounds, or attend surgery, without written patient authorization.

- F. All Covered Persons shall report any violations of this Policy on the TMC Compliance Concern Line – (866) 494-3600 – or another designated Institutional channel.
- G. Industry Representatives shall be informed about this Policy and shall comply with its provisions.
- H. If any Industry Representative violates this Policy, the sanctions shall be a written notice for the first offence, a 6-month suspension from the Institutions for the second offence, and a permanent ban from the Institutions for the third offence.

### **III. Support for medical education and professional activities**

- A. Industry support is solicited and appreciated in Continuing Medical Education (CME) or other professional activities designed to enhance the quality of care provided to patients. Because of the potential for undue Industry influence or speaker bias, the ACCME has strict standards for commercial support and influence in CME. See [www.ACCME.org](http://www.ACCME.org)  
See also TMC Policy on the *intranet* – CME Department Policy  
<http://tmcpolicy/Corporate/default.aspx>
- B. All educational events at TMC shall comply with ACCME Standards for Commercial Support, whether or not CME credit is awarded.
- C. Industry support for the education of Covered Persons shall be channeled through the Institutions' CME Offices, shall be free of any real or perceived Conflicts of Interest, shall be specifically for the purpose of education, and shall comply with all of the following:
  - 1. The funds are provided only to the Institution, not directly to the Covered Person.
  - 2. The Institution selects the recipient of the funds for the educational activity.
  - 3. The Institution, department, or program has determined the funding is for a program that has educational merit.
- D. Covered Persons shall not accept compensation for attending an event or other activity or conference if the Person is not presenting at the event, organizing the meeting or serving in the capacity as a research study investigator or study staff for a funded research project. Even where

compensation is thus permitted, it shall be limited to reasonable payment or reimbursement of ordinary and necessary travel, meals, and conference expenses.

- E. Covered Persons shall carefully evaluate their own participation in off-site meetings or conferences that are fully or partially sponsored or funded by Industry, because of the high potential for perceived or real Conflicts of Interest.
- F. Research grants or contracts from Industry shall require deliverable results of comparable value.

#### **IV. Disclosure of Significant Financial Interests with Industry**

All Covered Persons that conduct or engage in research activities at Institutions shall, in accordance with Institutional policies, disclose any Significant Financial Interest that the Person currently has, or has had within the past year, with the research study sponsor. See TMC Policy on the *intranet* – Research-Protection of Human Subjects and the Conduct of Research

<http://tmcpolicy/Corporate/Corporate%20Policies%20and%20Procedures/Research%20-%20Protection%20of%20Human%20Subjects.doc>

- B. At the time of appointment to the P&T Committee and annually thereafter, all Committee members shall disclose to the full Committee the nature of any current or recent (within the past year) Significant Financial Interest they have with any pharmaceutical manufacturer or seller. This information shall be reiterated to the Committee each time the Committee considers a request for Formulary addition by the manufacturer or seller of a drug in which a member has a Significant Financial Interest. Any member of the P&T Committee who has any Significant Financial Interest shall abstain from discussion and voting on all requests, whether or not a drug under consideration is recommended for addition to the Formulary.
- C. Any Covered Person requesting a Formulary change or otherwise presenting to the P&T Committee shall similarly disclose any Significant Financial Interest and abstain from discussion on all Formulary requests.

Covered Persons are prohibited from publishing articles written or funded in whole or material part by Industry, unless the Industry participation is fully disclosed.

- E. In scholarly publications, Covered Persons shall disclose any related Significant Financial Interest in accordance with the standards of the International Committee of Medical Journal Editors (ICMJE). See [www.ICMJE.org](http://www.ICMJE.org)

Covered Persons that have a direct role in making institutional purchasing recommendations on Industry products shall disclose to the purchasing unit, prior to making a suggestion, any Significant Financial Interest of them or their Family that might substantially benefit from the recommendations. Covered Persons shall also disclose any research or educational interest they or their department have that might substantially benefit from the recommendation.

See TMC Policy on the *intranet* – Conflict of Interest Policy and Procedure for Executives.

<http://tmcpolicy/Corporate/Corporate%20Policies%20and%20Procedures/Conflict%20of%20Interest%20Policy%20and%20Procedure%20for%20Executives.doc>

G. Planners of and presenters at lectures and presentations shall disclose to the audience whether or not they or their Family have any financial interest in the manufacturer or seller of any product or service to be discussed in the course of the presentation or in the commercial supporter of the program at which they are speaking. See TMC Policy on the *intranet* – CME Department Policy <http://tmcpolicy/Corporate/default.aspx>

H. Faculty with supervisory responsibility for employees, students, residents or fellows should ensure that any actual or potential Conflict of Interest does not affect or appear to affect the supervision.

## V. Training concerning Conflicts of Interest and interactions with Industry

All Covered Persons shall receive training about potential Conflicts of Interest and interactions with Industry.

Original Approval Date: 2001

Revised Dates: 12/3/2003

Revised Dates: 6/12/2006

Reviewed Date: \_\_\_\_\_

Reviewed Date: \_\_\_\_\_

Initials: \_\_\_\_\_

Initials: \_\_\_\_\_

<b>Comparative table: UMKC-SOM affiliate policies with regard to industry (Oct, 2008)</b>					
<b>Affiliate</b>	<b>Gifts &amp; meals policy (P)</b>	<b>Consulting relationships P (excludes scientific research and speaking)</b>	<b>Industry-funded speaking relationships P Especially "speakers' bureaus"</b>	<b>Disclosure P</b>	<b>Pharmaceutical samples P Should protect the interest of pts and prevent use of smpls as marketing tools</b>
TMC-HH / SOM TMC-LW	<b>Yes.</b> shall not request nor accept anything, including pens or notepads pp. (3 procedure, Ia.)	<b>Mentioned, not proscribed.</b> "research grants or contracts should require deliverable results of comparable value" (III f, pp 5)	<b>Mentioned, not proscribed.</b> Self-evaluation suggested, because of high potential for real or perceived conflicts of interest. (III e, pp 5)	<b>Required annually</b> for all faculty and available upon request, and required for presentations before, or membership on, the P&T committee.	<b>Yes - could be better</b> TMC-HH - samples must pass through the pharmacy dept. They may then be stored and dispensed in the outpatient clinics
Western MO MH	NP	NP	NP	NP	NP
SL's Hospital	NP	NP	NP	NP	<b>Yes</b>
CMH	\$300 limit per staff member/year	NP	NP	NP	NP

<b>2. Comparative table: UMKC SOM affiliate policies with regard to industry (Oct, 2008) cont</b>					
<b>Affiliate</b>	<b>Purchasing &amp; formularies P - conflict-controls over people making purchasing decisions</b>	<b>Site access P</b> Do pharmaceutical reps have free access to the school or medical center?	<b>Education: onsite educational activities P</b> Financial support must not influence educational content. No industry direct support for educational activities, including CME. (Contributions to a central fund are OK).	<b>Compensation for travel or attendance at off-site lectures &amp; meetings P</b> Personnel must not accept payment, gifts, or financial support from industry to attend lectures and meetings.	<b>Industry support for scholarships &amp; trainee funds P</b> Industry should be prevented from earmarking funds for particular fellows, residents. Recipients must be chosen by the school, or the institution must review the handling of funds.
TMC-HH / SOM TMC-LW	<b>Yes</b> Disclosure is required, and for P & T committee. Devices?	<b>Yes</b> Drug co. reps must register with the TMC pharmacy, and device reps must register with purchasing. All industry reps must wear badges, and are in general prohibited from access to patient care areas.	<b>Yes</b> ACCME rules apply to all conferences, including non-CME conferences  III B, pp 5	<b>Yes</b> III D, pp 5	NP
Western MO MH	NP	NP	NP	NP	NP
SL's Hospital	NP	NP	NP	NP	NP
CMH	NP	NP	NP	allowed	NP

<b>3. Comparative table: UMKC SOM affiliate policies with regard to industry (Oct, 2008) cont</b>				
<b>Affiliate</b>	<b>Med school curriculum P - stds must be trained to understand conflict of interest policies &amp; recognize how industry practices can affect judgement</b>	<b>Enforcement and oversight P Is it clear that someone is responsible for general oversight to ensure compliance?</b>	<b>Consequences P</b>	<b>Comments</b>
TMC-HH / SOM TMC-LW	NP	NP	NP	
Western MO MH	NA	NP	NP	
SL's Hospital	NA	NP	NP	
CMH	NA	NP	NP	

NP = no policy, NA = not applicable

J Foxworth, PharmD 9/10/08

Referenced to AMSA scorecard [www.amsascorecard.org](http://www.amsascorecard.org), last accessed 9/10/08