

GUIDELINES FOR MANAGEMENT OF POTENTIAL CONFLICTS OF INTEREST WITH HEALTH CARE INDUSTRY*

Introduction

The University of Illinois at Chicago College of Medicine Task Force on Relationships with Industry was established to develop guidelines to manage interactions between health care industry and our faculty, residents and students. The Task Force reviewed the current policies from each regional site, the AMSA PharmFree scoring system, and the AAMC document on Industry Funding of Medical Education June 2008. Topics covered came from the AMSA scoring system and the AAMC document. The task force realizes that there may be some regional differences needed in these guidelines. However, the agreed upon college standards should be adhered to as much as possible at each site. Members of the task force are Janet Jokela (Urbana), Sarah Kilpatrick (Chicago), Mitch King (Rockford), Brian McIntyre (Peoria), Linda Rowe (Peoria), and Mike Warso (Chicago). These guidelines pertain to all salaried faculty, residents, medical students, and graduate students of University of Illinois College of Medicine.

Objectives

It is recognized that interactions between the health care industry and faculty, residents, and students are multi-layered and complex. No set of rules or policies can cover or anticipate all exigencies. Therefore, each situation should be managed with the aim of ensuring that our educational curriculum, research and patient care decisions are independent of industry influence and that they allow appropriate opportunities for faculty and trainees to interact with industry to foster collaborations in a creative, scientific, and conflict free environment. In summary, each interaction should be managed so as to:

1. Prevent health care vendors from exercising influence over how faculty, residents and students practice medicine / treat patients, especially when such practice or treatment is delivered under the auspices of the U of I COM;
2. Prevent health care vendors from influencing how faculty, residents and students conduct research;
3. Prevent health care vendors from influencing the content of the curriculum of the U of I COM;
4. Prevent quid pro quo arrangements

5. Eliminate the actual or apparent endorsement by the U of I COM of any commercial health care product, service or for-profit corporation.

A. Compensation or Gifts

1. Personal gifts from an industry representative may not be accepted by any faculty, trainee, student or staff at any College of Medicine site, or at any location when participating in any University-related activity.
2. Individuals may not accept compensation, including reimbursement for expenses associated with attending a CME or other activity in which the attendee has no other role. Reasonable honoraria and payment of expenses may be provided for speakers at accredited educational meetings, consistent with guidelines developed by the Accreditation Council for Continuing Medical Education (ACCME) and University policy.
3. No gifts or compensation may be accepted in exchange for listening to a sales talk or similar presentation for a commercial interest that produces or distributes health care goods and services.
4. Faculty, trainees, students and staff are **strongly discouraged** from accepting gifts of any kind from industry as part of non-professional activities. Individuals should be aware of and comply with applicable policies, such as the:
 - AMA Statement on Gifts to Physicians from Industry (<http://www.ama-assn.org/ama/pub/category/8484.html>)
 - Accreditation Council for Continuing Medical education Standards for Commercial Support (<http://www.accme.orf>).
 - State of Illinois ethics regulations
5. Meals and other gifts or donations funded directly by industry may not be provided at any UIC College of Medicine location, including any site where UIC educational or social activities occur. Vendors and other industry representatives may provide unrestricted funds to departments or divisions for educational programs. The funds will be managed according to the Standards for Commercial Support of the ACCME and University policy.

6. No gifts may be accepted in exchange for modifying patient care, such as prescribing a specific medication. Support for research and educational programs must be provided without influence on clinical decision making.
7. Free samples, supplies or equipment designated for an individual are considered a gift and are prohibited. Vendors may donate products to a department or division when the intent is for evaluation or education regarding the product, if the University invites the donation, and if there is a formal evaluation process. Sample donations are restricted to the amount necessary to complete the evaluation. Other policies related to the management of samples must comply with the specific policies and procedures of each Medical Center. Faculty must abide by the policies developed at the clinical sites in which they practice.

B. Industry Support for Educational Programs

1. Commercial support for educational programs must be free of actual or perceived conflict of interest.
2. All educational programs within the College of Medicine must abide by the Standards for Commercial Support established by the ACCME. This requirement applies to all undergraduate, graduate and continuing medical education programs regardless of whether continuing medical education credit is offered.
3. All funds provided by industry or an industry representative to support educational programs must be given to the University as an unrestricted grant. The funds can be provided to the Department, Program or Division, but cannot be given to an individual faculty member, student or staff. This requirement applies to all funds for meals or refreshments, speaker honoraria, or any other expense related to an educational program and includes noon conference, grand rounds and lectures at all UIC sites. Funds that are provided by educational groups or other entities that act as "intermediaries" for industry must also be provided as unrestricted grants.

4. No gifts may be accepted in exchange for listening to a lecture or presentation by a representative of a commercial entity that produces health care or medical goods and services.
5. Vendors may provide educational activities on a UIC site only if they are requested to do so by the department chair or designee. Participants in an educational program may not be required to attend any educational session in which industry representatives disseminate information about their products or services except when such services are provided as part of a contract for in-service or other training as part of an executed purchase decision.
6. The content of all educational programs will be determined by UIC faculty and, when appropriate, the CME office. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs.
7. These requirements do not apply to meetings governed by ACCME Standards or meetings of professional societies and other professional organizations that may receive partial industry support. Individuals who actively participate in meetings or conferences that are supported in whole or in part by industry, including lecturing, organizing the meeting or moderating sessions should abide by the following requirements.
 - Financial support should be fully disclosed by the meeting sponsor
 - The content of the meeting or session should be determined by the speaker. If the sponsor dictates content of a session or talk, the faculty speaker must clearly delineate what information is so dictated.
 - The speaker must provide a fair and balanced discussion
 - The speaker must make clear that the comments and content reflects the individual views of the speaker and not the University of Illinois, the UIC College of Medicine or the Department
8. Faculty, trainees, students and staff should **carefully evaluate whether it is appropriate** to participate in off-campus meetings or conferences that are fully or partially sponsored by industry because of the high potential for real or perceived conflict of interest.

C. Provision of Scholarships or Other Educational Funds for Students and Trainees

1. Industry support for students and trainee participation in education programs must be free of any real or perceived conflict of interest. All educational grants or support of educational programs must be specifically for the purposes of education and must comply with the following requirements.
 - The College of Medicine, Department, Program or Division must select the student(s) or trainee(s) for participation
 - The funds must be provided to the Department, Program or Division and not directly to the student or trainee
 - The Department, Program, or Division must determine that the education conference or program has educational merit
 - There is no implicit or explicit expectation that the participant must provide something in return for participating in the educational program

2. This provision does not apply to regional, national or international merit-based awards that will be considered on a case-by-case basis.

D. Disclosure[#] of Relationships with Industry

Faculty and staff must disclose all financial interests with outside entities in accordance with UIC and University of Illinois policies. The specific disclosure obligation and method is dependent on the activity. The place of disclosure currently is according to university policy.

- Member of the academic staff must complete an annual report disclosing and seeking approval for non-university income producing activity (RUNA). This requires retrospective and prospective disclosure of external activities. Prior written approval from the University is required before undertaking, contracting for, or accepting anything of value in return for consulting or research from any external person or organization. Additional disclosure is necessary whenever a substantial change in external activities occurs or when required by granting agencies. The University Policy on Conflicts of Commitment and Interest is available at:

<http://tigger.uic.edu/depts/ovcr/research/conflict/RNUA/policy/index.shtml>

- All publications must be in compliance with the guidelines of the International Committee of Medical Journal Editors ([sss.icmje.org](http://www.icmje.org))
 - Covered individuals must complete situation specific disclosures of potential conflicts of interest when required (eg procurement, IRB applications, grant proposals)
 - All continuing medical educational activities must be disclosed and resolved as defined by the Office of Continuing Medical Education and the ACCME (<http://www.accme.org>)
2. Faculty or staff who serve as consultants, members of a speaker's bureau, have an equity interest in or another relationship with industry for which they receive personal compensation or other support must recuse themselves from deliberations or decision making regarding the selection of products or services to be provided to the Medical Center or College of Medicine (e.g.; selection of drugs to be added to the formulary) by the company. While requests for formulary inclusion of medications can be made by conflicted faculty, these conflicts must be disclosed at the time of the requests. Faculty with such ties to industry shall not participate in decisions regarding the purchase of related items, drugs, procedures in their department unless specifically requested to do so by the purchasing unit and after full disclosure of the faculty member's industry relationship. Under all circumstances the financial relationship must be disclosed and any conflicts resolved prior to participation in any decision making.
 3. Faculty and staff are prohibited from publishing articles that are substantially or completely "ghost" written by industry representatives. Faculty and staff who publish articles with industry representatives must participate in the preparation of the manuscript and shall be listed as authors or otherwise appropriately cited for their contribution. The financial interest of all authors shall be disclosed in accordance with the standards of the journal.
 4. Faculty with financial relationships with industry must ensure that the responsibilities to the company do not affect or appear to affect the ability to properly supervise and educate students, residents, and other trainees,

nor influence employment decisions for faculty and staff. All such relationships must be disclosed particularly during educational or research activities pertinent to the industry relationship and resolved as defined by ACCME.

E. Access by Sales and Marketing Representatives to Faculty, Trainees, Staff and Students

1. Faculty, trainees, and staff at each UIC site must abide by the policies and procedures for each institution (VA, Chicago, Peoria and Rockford institutions) with regard to meeting with industry representatives. In general, representatives are permitted in non-patient care areas by appointment only. Company representatives are not permitted in any patient care areas except to provide scheduled and approved in-service training on devices and other equipment for which there is an executed University contract for these services. Involvement of students and trainees in such meetings should occur only for educational purposes and only under supervision of a faculty member.

F. Provision of Education by COM to faculty and trainees

Medical school curriculum objectives shall be formulated to train students and residents to understand conflict-of-interest and to recognize how industry promotion can influence clinical judgment. Curricular education on managing the relationship between physicians and industry will be developed for at least two years of medical education. Goal is to have this implemented by 2012.

G. CME

For all CME activities UIC COM follows the Accreditation Council for Continuing Medical Education (ACCME) standards available on their website <http://www.accme.org/>.

H. College Committee on Conflict of Interest

In 2010 the COM will create the COCI which will include at least 5 faculty members with at least one from Peoria, Rockford and Urbana, who are advisory to the Dean. These faculty members will be appointed by the Dean for three year terms. The initial committee will have staggered terms such that the entire committee does not rotate off in a single year. The charge of the committee will

be to review potential conflicts of interest referred to them by the dean or a head and develop guidelines for management. The committee will be staffed by an assistant.

I. Definition of Significant Financial Interest

The current definitions are the same as NIH and are:

- \$10k expected in next 12 months for you and family aggregated
- OR 5% equity for you and family aggregated regardless of value.
- Royalties paid through the university are excluded.

Because this threshold may change, please refer to the following university website to see the most current definition:

<http://tigger.uic.edu/depts/ovcr/research/conflict/RNUA/policy/index.shtml>
http://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm

J. Relationship to Other University Policies

The guidelines supplement University policies on Conflict of Interest and the requirements of the Department Compensation Plan. Faculty and staff should familiarize themselves with the policies and reporting obligations. If the guidelines and University policies conflict, then the more restrictive of the two will apply. Questions about the policies should be discussed with the department chair and/or administrative staff.

Other University documents

<http://tigger.uic.edu/depts/ovcr/research/conflict/RNUA/policy/index.shtml>
http://tigger.uic.edu/depts/ovcr/research/conflict/RNUA/policy/uic_coi_policy.pdf

*For purposes of these guidelines, industry refers to any proprietary entity that produces health care and medical goods and services.

The COM intends to further explore the best sites for disclosure of significant financial relationships with industry.