

**UNIVERSITY OF IOWA HEALTH CARE CONFLICT OF INTEREST AND
CONFLICT OF COMMITMENT
POLICY REGARDING INTERACTIONS WITH INDUSTRY**

January 20, 2009

Introduction

The success of University of Iowa Health Care depends on a talented and creative faculty and staff who earn regional, national and international recognition for their contributions to teaching, research, clinical care and the advancement of their diverse clinical and scientific specialties. As a result of their expertise and experience, faculty and staff have opportunities to engage in professional activities with commercial entities, professional and scientific organizations and journals, as well as other universities and governmental agencies. Such activities can help faculty and staff develop their knowledge and skills; contribute to the growth and development of their area of expertise; enhance the academic and clinical missions of the department, college and university; and improve patient care. Participation in these activities may also create real and perceived conflicts of interest and conflicts of commitment. For the reasons outlined, University of Iowa Health Care must continue to make it possible for faculty and staff to advance teaching, service and research through collaborations with industry in a manner that avoids real or perceived conflicts of interest or commitment.

Definitions

"Conflict of Interest" (COI) involves a situation in which faculty, staff, or student employees have financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment or integrity in teaching, clinical care, conducting or reporting research, or performing other University obligations. (Adapted from UI Operations Manual; <http://www.uiowa.edu/~our/opmanual/ii/18.htm>)

"Conflict of Commitment" (COC) occurs when an employee engages in an outside activity that interferes, or appears to interfere, with fulfillment of the employee's obligations to the University, even if the outside activity is valuable to the University or contributes to the employee's professional development and competence. (From UI Operations Manual; <http://www.uiowa.edu/~our/opmanual/ii/18.htm>).

"Industry" is defined as any person or company seeking to do or doing business with University of Iowa Health Care, including any pharmaceutical, medical device, medical publishing, or medical equipment companies.

Purpose and Scope

This policy establishes guidelines for interactions with the health care industry for faculty (including adjunct faculty), fellow and resident physicians, all staff employed by UI Health Care and all of its student trainees. Associated entities include: all departments within The University of Iowa Roy J. and Lucille A. Carver College of Medicine (CCOM), University of Iowa Hospital and Clinics (UIHC), UI Physicians (UIP), and the University of Iowa Children's Hospital. The Policy is intended to supersede existing departmental policies on COI and COC and it complements existing University of Iowa policies related to COI and COC. It provides additional specification for UI Health Care employees and students on issues related to unique complexities within our medical care, education and research endeavors. Individual departments within UI Health Care may choose to adopt more stringent boundaries or monitoring based on unique specialty-based circumstances or local faculty preferences.

Interactions with industry in an academic medical center may contribute to research, education, and patient care and some of these interactions may lead to important clinical and educational innovations. However, these interactions must be held to high ethical standards including complete transparency to ensure that they do not create unintended conflicts of interest or compromise the integrity of the institution's mission. A growing body of literature suggests that because academic physicians have allowed themselves to be exposed to the "profound influence from the pharmaceutical and medical device industries" (DeAngelis, JAMA 2008), academic medical centers need to take seriously the possibility of unintentional bias in favor of industry that results from such interactions (Cain & Detsky, JAMA 2008).

UI Health Care has a professional responsibility to provide exceptional patient care, outstanding educational programming, and rigorous independent scientific inquiry – and to accomplish these missions with high ethical standards. To ensure the integrity of UI Health Care's core missions, its interactions with industry must prevent conflicts of interest as well as avoid the appearance of such conflicts.

The relationship we have with our patients is in part a *fiduciary* relationship. Patients trust us and rightly expect us to act in their best interest. Patients should be confident that decisions regarding their care are not influenced by the self-interest of their health care providers.

COC is another important component of this policy and is often closely linked to conflict of interest. The primary responsibility of faculty, staff, and trainees at UI Health Care is to participate in core missions of UI Health Care; extramural activities that create conflicts of commitment must be disclosed (whether such conflicts occur inside or outside of official employment hours or during vacation).

CORE VALUES:

- Faculty and staff should be contributing to advances in teaching, research and clinical care and their clinical and research specialties. In some instances, these advances will

best be accomplished by collaboration with industry. The value of these efforts should be recognized by the University and the public.

- Decision-making about the core missions of UI Health Care - patient care, educational programming, and research activities – should be unfettered by relationships with industry and the conduct of UI Health Care employees and trainees should avoid even the appearance of a COI. The public, patients and trainees should be aware of this principle.
- Gifting relationships – regardless of the size of the gift – are well documented to influence decision-making of the recipient. Since all gifting has the potential to induce feelings of a need for reciprocity, even indirect gifts from industry (e.g. unrestricted educational grants) can invoke a gifting relationship. For this reason, faculty, trainees and staff should not accept gifts from industry sources.
- Faculty and staff employment within UI Health Care is usually a full-time appointment and endeavor. Reimbursed activities with industry ‘after hours’ or during ‘vacation time’ have the potential to affect an employee’s behavior and decision-making during an employee’s regular working hours. The conduct of UI Health Care employees and trainees should avoid COI or the appearance of COI.
- Faculty and staff who choose to engage in outside compensated professional activities must be able to document clearly what services were provided and any compensation received. Any potential COI and COC must be disclosed and managed.
- Complete avoidance of financial conflicts with industry can be accomplished only by eschewing financial ties with industry. However, the risk of conflicts may be minimized by full disclosure and adherence to the parameters of this policy. Full disclosure of potential conflicted relationships is critical, but disclosure alone does not eliminate COI or constitute its full management.

I) GIFTS

- Faculty, staff, and trainees may not accept any gifts from industry.
- Faculty, staff and trainees may not accept any compensation for attending marketing programs and may not attend hospitality events funded by industry.

A) Small Gifts

- Gifts may not be accepted from industry representatives, including small gifts that would otherwise be permissible under the Iowa Gift Law. Accepting trinkets such as pens, post-its, coffee mugs, notepads, calendars, and refrigerator magnets is not allowed.

B) Meals

- Faculty, staff, and trainees may not accept food provided at no cost by industry representatives. This includes both meals brought on-site and meals provided at local restaurants or national meetings.

C) Travel Stipends, Educational Scholarships, Visiting Professorships, and GME Stipends

- Industry support for travel stipends, educational scholarships, and visiting professorships may only be provided in the form of unrestricted educational grants managed by the Vice President for Medical Affairs (VPMA), or his/her designee, with monies going directly into an educational account and not directly to individuals, divisions, or departments.
- Explicit written agreements must accompany such interactions and include justification of the educational merit of these opportunities.
- Decision-making about who receives a stipend or scholarship must occur without any input from industry representatives. No quid pro quo can be required or expected from awardees.
- No stipend, scholarship, or professorship at UI Health Care can be labeled as an industry-sponsored award without the approval of the Departmental Executive Officer and the VPMA, or his/her designee.

D) Medical or Educational Equipment, Supplies, Resources, or Programming

- A written Letter of Agreement must accompany gifts of equipment and materials from industry to clarify the intention and to document that no quid pro pro is expected. The agreement must be approved by the Departmental Executive Officer prior to being forwarded for approval to the VPMA, or his/her designee. Obtaining equipment for patient care must also be vetted with institutional purchasing and/or procurement departments.
- Gifts of textbooks or medical journals may not be accepted from industry representatives by individual faculty, staff, and trainees, or by their departments, divisions, or units.
- UI Health Care will accept for distribution to patients only those industry-supplied patient education materials that relate to therapies approved by the appropriate reviewing body, e.g., UIHC Pharmacy and Therapeutics

Subcommittee. Marketing materials will not be accepted for distribution to patients.

E) Drug Samples

- Industry-supplied drug samples and vouchers may not be accepted or distributed to patients at UI Health Care.
- UI Health Care faculty, staff, and trainees may not seek or accept industry-supplied drug samples for personal or family use.
- UI Health Care staff may assist patients in applying for pharmaceutical companies assistance programs.

F) Training Assistance

- Off-site training on new equipment or devices may not be provided at industry expense unless the training is specifically included in the contract under which the equipment or device is acquired.
- Industry representatives providing on-site training or assistance must comply with applicable policies regarding vendor representative presence in the hospital and the operating rooms.
- Training activities must be clearly differentiated from sales activities.

II) INDUSTRY COMPENSATION

- Consultative relationships between faculty, staff, and trainees and industry may provide valuable avenues to speed development and dissemination of innovations.
- Although serving as an expert witness in legal matters is not the focus of this policy on COI and COC associated with industry interactions, this opportunity for outside professional compensation must also be disclosed and monitored.

A) Consulting Expertise

- All consulting arrangements with industry (including scientific advisory boards, data safety monitoring boards, other advisory/scientific boards) must be accompanied by a time-limited contract that outlines specific deliverables, tasks, responsibilities, and compensation that is consistent with the expertise provided.

- Disclosure of consulting relationships must be fully transparent and documented, including the amount of financial compensation received.
- All consulting agreements should be submitted to the Departmental Executive Officer prior to being forwarded to the VPMA, or his/her designee, for review and approval prior to execution.

B) Honoraria/Speakers' Bureau

- Academic institutions and professional associations frequently offer honoraria to faculty, staff, and trainees to recognize special additional effort to travel and make a scholarly presentation. Faculty, staff or trainees may accept honoraria from these entities. All such activities must be disclosed and monitored.
- Faculty, staff, and trainees may not accept honoraria directly from industry.

C) Industry Speakers' Bureaus

- UI Health Care faculty, staff, and trainees may not participate on paid industry speakers' bureaus.
- Participation on informal or loosely defined 'advisory boards' must comply with the requirements for consulting agreements.
- UI Health Care will not facilitate presentations by industry speakers' bureaus. Outside speakers invited independent from industry speakers' bureaus will be asked to disclose any relationship they have with industry speakers' bureaus.

III) FORMULARY REVIEW & PURCHASING COMMITTEES

- Faculty, staff, and trainees are not eligible to participate in Pharmacy and Therapeutics or Product Evaluation Committee meetings if they or members of their immediate family have, or have had within the prior 5 years, a personal financial relationship or funded research with a related pharmaceutical or medical device company that is being considered or discussed at that meeting.

IV) SITE ACCESS & INDUSTRY DISPLAYS

- Industry displays are not allowed in UI Hospitals and Clinics.

- Vendor displays at UI Health Care continuing education events are discouraged. If industry displays are pursued at CME events, they must comply with ACCME Standards for Commercial Support and the UIHC Vendor Policy.
- Non-CME Departmental displays are allowed at the discretion of DEOs if they comply with the UIHC vendor policy.
- Further information on site access and displays is available at <http://www.uihealthcare.com/depts/procurementservices/vendorpolicy.pdf>

V) CONTINUING MEDICAL EDUCATION

- All CME activities sponsored by the Carver College of Medicine must be in compliance with ACCME regulations, requirements, standards, and guidelines.
- Continuing education efforts within other departments of UI Health Care (e.g. nursing, pharmacy, social services) are expected to adhere to expectations of their accrediting bodies and to the requirements of this policy.
- UI faculty, staff, and trainees are expected to comply with the CME regulations (e.g. honoraria limits) at other institutions where they may be invited to make presentations.

VI) RESEARCH

- Conflict of interest in research is governed by the University of Iowa's Policy on Conflicts of Commitment and Interest, Operations Manual II-18.6. <http://www.uiowa.edu/~our/opmanual/ii/18.htm>

VII) PUBLISHING

- Faculty, staff, and trainees may not participate in ghost authorship as either the named or unnamed author. Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself.
- Faculty, staff, and trainees who have a personal financial interest in a company should neither seek nor have authorship in a company-sponsored research publication.

- When submitting manuscripts, UI Health Care faculty, staff, and trainees must disclose all relevant financial interests to journal editors.
- Further information on appropriate publishing practices is contained in UI's policy on COI in Research <http://www.uiowa.edu/~our/opmanual/ii/18.htm#186>