

# Conflict of Interest: The Policy

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## University of Iowa Health Care Conflict of Interest and Conflict of Commitment Policy Regarding Interactions with Industry

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See [Summary of Changes](#) in the revised policy

### 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/or 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>). A conflict of interest depends on the situation, and not on the character or actions, of the individual.

“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 (adapted from the UI Operations Manual, <http://www.uiowa.edu/~our/opmanual/ii/18.htm>).

“Industry” is defined as any person or company that produces health care goods and services, including any pharmaceutical, medical device, medical publishing, or medical equipment company, or any Medical Education Communication Company (MECC). It also includes any person or company seeking to do or doing business with University of Iowa Health Care.

“Gift” is defined as any item, product, or service, regardless of the nature, purpose, or value. The term includes, but is not limited to, pens, notepads, post-its, coffee mugs, calendars, refrigerator magnets, and other promotional items; cash; medication or product samples; vouchers or coupons; food and drink, except in the limited circumstances described in Section I) B); entertainment such as tickets to events, golf, and other sports outings; hotels, transportation, and other travel expenses, except in the limited circumstances described in Section I) C); stock, equity, and other ownership interests; and discounts on products or services.

“Speakers’ Bureau” involves a situation in which an employee provides services as a speaker for industry and the arrangement has any of the following characteristics:

- The company has the contractual right to dictate or control the content of the presentation or talk.
- The company creates the slides or presentation material.
- The employee is expected to act as the company’s agent or spokesperson for the purpose of disseminating company or product information.

## **Purpose and Scope**

This policy establishes guidelines for interactions with the health care industry and other opportunities for outside professional compensated activities. It applies to faculty (including adjunct faculty), fellow and resident physicians, all staff and trainees 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 Hospitals and Clinics (UIHC), UI Physicians (UIP), and 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 specifications 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 "profound influence from the pharmaceutical and medical device industries" (DeAngelis, JAMA 2008), academic medical centers must 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.

COC is another important component of this policy and is often closely linked to conflict of interest. Outside professional relationships can result in conflicts regarding time and energies which may represent conflicts of commitment. 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).

## **Disclosure**

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.

The following employees and trainees, if employed 50 percent time or greater, must complete a conflict of interest disclosure in the eCOI electronic disclosure system at least annually:

- Faculty
- Professional and Scientific Staff
- SEIU Staff
- Merit Exempt Staff

Additionally, the disclosure must be updated quarterly, if necessary, to reflect any new relationships or changes to existing external relationships. Data from the disclosure will be published on a public web site. This information is available at <https://www.healthcare.uiowa.edu/UIHCPortal/coi.aspx>.

## **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 through 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. Patients, trainees, and the public should be aware of this principle.
- Gifting relationships—regardless of the size of the gift—are well-documented as influencing a recipient’s decision-making. Since all gifting has the potential to induce feelings of a need for reciprocity, faculty, trainees, and staff should not accept gifts from industry sources. However, unrestricted educational grants may be donated by industry to department, division or Foundation accounts.
- 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 through 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.
- In the course of their work as UI Health Care employees, faculty and staff may not refer anyone to outside businesses if the referral will generate a benefit to the employee.
- University resources are acquired and maintained to carry out the education, research, patient care, and public service missions of the University. Except for insignificant and incidental use, an employee may not use University resources for non-University purposes. If a question arises regarding what constitutes other than insignificant and incidental use, the employee should consult a supervisor for clarification.

## **I) Gifts**

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

### **A) Small Gifts**

- Gifts cannot be accepted from industry representatives, including small gifts that would otherwise be permissible under the Iowa Gift Law.

#### B) Meals

- Industry-supplied or supported food or drinks are considered personal gifts and may not be accepted by faculty, staff, trainees, and departments or divisions on-campus or off-campus, except in any of the limited circumstances listed below:
  1. if provided in connection with attendance at programs compliant with the Accreditation Council on Continuing Medical Education (ACCME) Standards for Commercial Support or other accrediting bodies
  2. as a reasonable and necessary travel expense associated with services rendered in accordance with Section V of this Policy (i.e., approved consulting activity)
  3. if provided in connection with attendance at scientific or professional society meeting events open to all meeting attendees
  4. if provided at UI Health Care events, meals, snacks, or refreshments are allowable only when purchased through a UI Health Care department, division, or Foundation account

#### C) Travel Expenses

- Employees may not accept travel funds from industry, except for legitimate reimbursement of reasonable and necessary travel expenses in any of the following circumstances:
  1. to provide services rendered in accordance with Section V of this Policy (i.e., approved consulting activity)
  2. as described in Section I) H)
  3. as described in Section IX

#### D) Educational Scholarships or Educational Events, Training, Visiting Professorships, and GME Stipends

- Industry support for these items and events may only be provided in the form of unrestricted educational grants with monies going directly to the UI Foundation or into a department or division account. While requests for unrestricted grants and gifts may be directed in a specific area, they should be worded in general terms, e.g., “for trainee travel to meetings,” “for trainee educational retreats,” “for the purchase of textbooks,” “for grand rounds speakers,” “for support of CME activities,” clearly indicating that department, division, and/or individual recipients will be completely free of any industry influence in all of their decision-making relative to the disbursement of the educational grant.
- 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 (DEO) and the VPMA/Conflict of Interest Office.

#### E) Medical or Educational Equipment, Supplies, Resources, or Programming

- A written [Letter of Agreement](#) must accompany gifts of equipment and materials from industry to clarify intent and to document that no quid pro quo is expected. The agreement must be approved by the DEO prior to being forwarded to the VPMA/Conflict of Interest Office for signature. Obtaining equipment for patient care must also be vetted by institutional purchasing and/or procurement departments.

- Departments may accept gifts of textbooks, medical journals, or educational devices to be used in skills laboratories, if they do not contain promotional pages or logos.

#### F) Patient Education Materials

- 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., the UIHC Pharmacy and Therapeutics Subcommittee.
- Marketing materials cannot be accepted for distribution to patients.

#### G) Drug Samples

- Industry-supplied drug samples and vouchers cannot be accepted or distributed to patients at UI Health Care.
- UI Health Care faculty, staff, and trainees cannot seek or accept industry-supplied drug samples for personal or family use.
- UI Health Care staff may help patients apply for pharmaceutical companies' assistance programs; the [Medication Management Policy](#) provides more information regarding this.

#### H) Training Assistance

- Training on equipment or devices cannot be provided at industry expense except in any of the situations outlined in 1-3 below. This applies to both on-site training, which may include food or meals brought on-site, and travel expenses for off-site training.
  1. Training is specifically included in the contract under which the equipment or device is acquired
  2. The product is under specific consideration for purchase through the product evaluation committee
  3. In conjunction with a written letter of agreement as described in Section I) E)
- Industry representatives providing on-site training or assistance must comply with applicable policies regarding vendor representative presence in the hospital and operating rooms.
- Training activities must be clearly differentiated from sales activities.

### II) Services Provided to Professional Organizations and Academic Institutions

- Outside professional service activities provided to professional organizations and/or academic institutions are a normal expectation of employees at an academic medical center. Participation in, and receipt of compensation for, these activities is allowed and generally does not require disclosure or an approved consulting contract.
- The following activities generally do not require disclosure:
  1. Holding office in, or undertaking an editorial office or duties for a scholarly journal, academic press, or professional organization
  2. Serving as a referee for a scholarly journal or an academic press
  3. Serving on a professional review board or peer review bodies
  4. Attending or presenting at events sponsored by professional organizations or academic institutions, such as professional meetings, workshops, colloquia, symposia, seminars, or training programs
  5. Visiting other sites in connection with accreditation, audits, sponsored project reviews, or like activities

### III) Outside Non-Professional Activities

- Participation in outside non-professional activities generally does not require disclosure unless the time devoted to them interferes with the employee's university obligations.

### IV) Compensation for Serving as an Expert Witness

- 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 outside professional compensation also must be disclosed and monitored.

### V) Industry Compensation

- Consultative relationships between faculty, staff, and trainees, and industry may provide valuable avenues to speed development and dissemination of innovations.

#### A) Consulting Expertise

- All consulting arrangements with industry (including, but not limited to, scientific advisory boards, data safety monitoring boards, other advisory/scientific boards, and product evaluation/development) must be accompanied by a time-limited contract or letter of invitation/agreement that outlines specific deliverables, tasks, responsibilities, and compensation that is consistent with the expertise provided. More information can be obtained in this document: [issues the COI Office reviews in an agreement](#).
- Prior to executing a consulting contract (including contract renewals and amendments) and engaging in consulting activity, the faculty/staff member or trainee must submit the agreement to his/her DEO or manager/supervisor, as applicable, for approval of the consulting activity (faculty members who are the DEO should submit the contract to the Dean of the CCOM for approval of the activity). When the DEO or manager/supervisor has approved the activity, the contract must be submitted to the VPMA/COI Office for review and approval.
- Consulting agreements that involve the assignment of intellectual property rights must comply with the University of Iowa Intellectual Property Policy; more information on this can be obtained at <http://www.uiowa.edu/~our/opmanual/v/30.htm>.
- Disclosure of consulting relationships must be fully transparent and documented, including the amount of financial compensation received. "Compensation" may include, among other things, payment in currency, royalties, shares of stock, and travel/meal expenses (both reimbursement for out-of-pocket expenses and any travel arrangements made directly for the employee).
- Employees may not accept payment, gifts, or other benefits, in return for completing evaluations or surveys developed by a business entity unless this activity meets the requirements for consulting agreements.

#### B) Speaking and Training for Industry

- UI Health Care faculty, staff, and trainees may not participate on industry speakers' bureaus.
- Participation on informal or loosely defined 'advisory boards' must comply with the requirements for consulting agreements.
- Faculty, staff, and trainees who provide training and/or educational presentations for industry, Medical Education Communication Companies (MECCs), or similar commercial enterprises must comply with the requirements for consulting agreements.
- Presentations or training in which the primary purpose is to promote company products is prohibited.

- Content of training or educational presentations must be controlled by the trainer/educator and must be the original work of the trainer/educator.

### C) Attendance at Industry-Sponsored Events

- UI Health Care faculty, staff, and trainees cannot accept any form of compensation (e.g., travel expenses, lodging, meals, or gifts) directly from industry, MECCs, or similar commercial enterprises for attending a professional meeting or conference.
- Educational or promotional programs developed by industry representatives, MECCs, or similar commercial entities are not allowed at a UI Health Care event, whether the event is held within or outside of UI Health Care facilities. Training programs on equipment purchased by UI Health Care is allowed if the training is included in the purchase agreement.
- All outside speakers must disclose to the audience any relevant relationships they have with industry prior to their presentation.

### VI) Formulary Review and 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 five 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.

### VII) Site Access and Industry Displays

- Industry displays must meet the following requirements:
  1. Compliance with the UIHC Vendor Policy (e.g., no displays in patient areas, or at patient/family educational events)
  2. Permission from the DEO
  3. Compliance with the Accreditation Council for Continuing Medical Education (ACCME) standards if the event is a CME program
- [Further information](#) on site access and displays is available at UIHC.

### VIII) Continuing Medical Education

- All CME activities sponsored by the Carver College of Medicine must be in compliance with [ACCME regulations, requirements, standards, and guidelines](#).
- Educational grants for CME events must be accompanied by a [Written Agreement of Commercial Support](#) signed prior to the event by a representative of the college and a representative of the company providing the grant.
- Continuing education efforts within other UI Health Care departments (e.g. nursing, pharmacy, social services) are expected to adhere to the guidelines 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.

### IX) 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, available at <http://www.uiowa.edu/~our/opmanual/ii/18.htm>.

University of Iowa Health Care employees who are also engaged in research are governed by both this policy and the University of Iowa's Policy on Conflicts of Commitment and Interest, Operations Manual II-18.6.

- Research-related travel expenses to investigator meetings prior or subsequent to the establishment of a research contract may be paid for by industry.

## **X) Basic Research/Non-Clinical Product Evaluation**

- All gifting rules and regulations apply to basic/non-clinical research except where noted below.
- No gifts/donations of any value that are personal in nature (e.g., coffee mugs, calendars, T-shirts, food, etc.) may be received.
- A vendor may donate laboratory consumables for evaluation purposes only by completing the [Product Donation Form](#) available from the UI Purchasing Department.
- Donations exceeding \$5,000 (vendor list price or equivalent) must receive prior approval from UI Purchasing by completing the [Product Donation Form](#) and returning the form to the Purchasing Department prior to making the donation.
- A vendor can offer promotional discounts, but gifts of a personal nature (e.g., gift cards, T-shirts, etc.) cannot be included with the promotion.

## **XI) Publishing**

- Faculty, staff, and trainees cannot participate in ghost authorship. Ghost authorship is the failure to name, as an author, an individual who has made substantial contributions to a scientific manuscript.
- 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 can be accessed at <http://www.uiowa.edu/~our/opmanual/ii/18.htm#186>, the University of Iowa's policy on COI in Research.

## **XII) Policy Violations**

- Any UI Health Care employee who violates this policy is subject to disciplinary action in accordance with university policy.