

# **Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries**

## **PROLOGUE**

1. This policy aspires to establish management of conflict of interest as a matter of professionalism that is critical to maintain the public trust.<sup>1</sup>
2. This policy aspires to impart the notion that 1) interaction with industry should be reserved for the highest level of medical and scientific collaboration; and 2) these highest level interactions must not be tarnished by low level interactions such as attendance at sales, marketing, or entertainment events, involvement with ghost writing, or acceptance of personal gifts.
3. We aspire only to manage conflict of interest and do not aspire to a state that is absent thereof.
4. This policy does not prohibit collaboration with industry for research or continuing medical education so long as these relationships are managed appropriately as described in this policy.
5. This policy does prohibit interaction with industry for purposes of entertainment, sales, marketing, and the like.

## **APPLICABILITY AND RELATIONSHIP TO OTHER POLICIES**

The University of Chicago has comprehensive policies on faculty and staff conflicts of interest and commitment.<sup>1</sup> The University Academic Policy governs faculty, academic personnel, and postdoctoral researcher conflicts of interest and commitment. Likewise, University staff are obligated to comply with the University Staff Policy on Conflicts of Interest (U600).<sup>2</sup>

This policy supplants *neither* the University Staff Policy nor the primacy of University Academic Policy and the responsibility that faculty, academic personnel, and postdoctoral researchers have to comply with that Policy, including but not limited to the responsibility for timely disclosure and compliance with conflict of interest management

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<sup>1</sup> Recent AAMC documents reflecting the importance of this issue within academic medicine nationally include *Industry Funding of Medical Education*, Report of an AAMC Task Force, June 2008); *Protecting Patients, Preserving Integrity Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC/AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008; and *The Scientific Basis of Influence and Reciprocity: A Symposium*, June 12, 2007.

<sup>1</sup> See *Outside Professional and Commercial Activities of Faculty and Conflict of Interest*, prepared by the Council on Research and approved by the Council of the University Senate on July 27, 2007; and *The Report of the Standing Committee on Conflict of Interest*, dated January 16, 2004 and setting forth recommendations to clarify, streamline, and strengthen the University Policy.

<sup>2</sup> UCMC Staff, Officers, and Influential Medical Staff Members are also obligated to comply with the UCMC Conflict of Interest Policy (A00-12) and the UCMC Vendor Relations Policy (A05-08).

plans. Rather, this policy serves to supplement the University Academic and Staff Policies in areas that are specific to BSD clinical activities and associated relationships with Industry, provide guidelines for certain activities when more restrictive than the University's Policies, and to provide guidance for Medical Center Enterprise staff and trainees. Faculty, academic personnel, and postdoctoral researchers must take affirmative steps to periodically reacquaint themselves with the disclosure and other requirements of the University policy. University staff employees likewise must regularly acquaint themselves with the University Staff Policy.

In addition, as Medical Center employees, medical residents and fellows are subject to the UCH Officer, Employee and Influential Medical Staff Member Conflict and Vendor Relationship Policy (A00-12) as well as the University of Chicago Medical Center Vendor Relations Policy (05-08). While this policy does not supplant the Medical Center policies, it forms the basis of expected behavior of the residents and fellows as members of the treatment team and representatives of the Medical Center Enterprise.

## **PURPOSE**

This Policy is designed to establish principles and guidelines for the interactions between representatives of the Pharmaceutical, Biotechnology, and Medical Device and Research Equipment and Supplies & Purchased Services Industries (collectively, "Industry") with the faculty, other academic appointees, postdoctoral researchers, medical students, residents, fellows, executives, managers, and staff (collectively, "Individuals") of Chicago BioMedicine (the Enterprise) to the extent they are engaged in clinical activities.

This Policy and its guidelines seek to preserve the objectivity—and the appearance of objectivity—of physician decision-making; to foster patient and public trust in the principle that physicians' advice is fashioned solely for the patients' benefit and is not compromised by physician self-interest; and to comply with government regulations applicable to healthcare providers and tax-exempt organizations.

## **OVERVIEW**

Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and research equipment and supplies; on-site training of newly purchased devices; the development of new devices; educational support of medical students, residents and fellows; and continuing medical education. Individuals also participate in interactions with Industry off campus and in scholarly publications. Many aspects of these interactions promote the Enterprise's educational, clinical, and research missions. Indeed, the Enterprise generally encourages appropriate interactions with Industry that may benefit not only the participants, but also the Enterprise and the public at large.

All parties engaged in these activities concur that their interactions will be ethical and avoid actual or perceived conflicts of interest, recognizing that conflicts could endanger

patient safety, and data integrity; the integrity of our education, research, and educational programs; and the reputation of Individuals or the Enterprise.

## **POLICY PRINCIPLES AND SUMMARY**

*By way of overview, this Policy establishes standards in specific areas listed below and offers examples of interactions that commonly arise in matters of business conduct.*

*These examples cannot, however, contemplate every possible dilemma that an individual might face when interacting with Industry. Please keep the spirit of this policy in mind--to preserve the public trust by avoiding even the appearance of impropriety--when interacting with Industry.*

- Individuals may not solicit or accept personal gifts and payments as described in Section I(A).
- Individuals may accept pharmaceutical and device samples in accordance with Section III below.
- Industry sales and marketing personnel may visit the Medical Center Enterprise site subject to both Section III and the University of Chicago Medical Center Vendor Relations Policy (A05-08).
- The Medical Center Enterprise may accept industry-funded scholarships and other educational funds for students, residents and fellows in accordance with Section IV.
- Educational and other professional activities are encouraged. However, Industry payment of fees and expenses associated with these activities are subject to Section V.
- Individuals may not receive payment for passive attendance at Industry-sponsored meetings, but may receive compensation for active participation in such a meeting under certain circumstances set forth in Section V.
- Individuals may not attend Industry events such as lunches, dinners, and panel discussions where the primary intent of the event is entertainment, sales, or marketing. Attendance raises both an actual and an appearance of impropriety, and the potential for misuse of the reputation of both the caregiver, and the Medical Center Enterprise.
- Individuals who have a role in making a Medical Center Enterprise decision or direct recommendation to procure or support medical supplies, equipment, services and pharmaceuticals must disclose Industry relationships.

### **I. Gifts and Payments**

- A. Individuals may not receive or solicit personal items or gifts, gifts for the Medical Center Enterprise, “business courtesies,” discounts, benefits, favors, or other items of value from a representative of Industry regardless of site or circumstance. For the purposes of this Policy, a “Gift” does not have a value

threshold—an item of any value constitutes a gift. By way of example only, but not limitation, this includes:

- 1) Gifts, payments, meals or entertainment provided to listen to a sales talk, presentation, or educational session by an Industry representative.
- 2) Gifts or payments that infer or result in formulary decisions or recommendations or change in the volume of or change in prescription writing practices.
- 3) Gifts or payments for attending a CME, presentation, meeting, conference or other activity if not speaking or otherwise actively participating or presenting at the event (as set forth more fully below in Section V).
- 4) Gifts of anatomical models, textbooks, patient education brochures and displays, or equipment.
- 5) Payment for or provision of meals and entertainment, including, for example, food brought in to a clinic by a sales or marketing representative, dinner, night club or golf outings, and tickets to sporting events, concerts, or plays.
- 6) Cash or cash equivalent, including gift certificates and gift cards.
- 7) Stock, stock options, or other financial interests.
- 8) Access to an item or service that imputes a favor, such as providing sold out tickets to an athletic event at the tickets face value, providing access to a country club or closed nightclub.
- 9) Industry payment for travel to a vendor site or the site of another hospital or clinic to evaluate a product.

B. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from or offered by Industry. However, this limitation is not intended to affect faculty participation in clinical trials or other Sponsored research.

C. Individual sponsored research and payments for services are governed by University Conflict of Interest Policy and residents/fellows governed by UCMC Conflict of Interest policy.

## **II. Pharmaceutical and Device Samples**

Individuals must be aware that the law prohibits them from certain activities associated with the offering and/or receipt of items of value in exchange for referrals of items or services.

- A. The DCAM retail pharmacy will centrally manage pharmaceutical sample distribution of drugs on UCMC formulary utilizing a voucher system administered with

manufacturers. Exceptions to central distribution must be pre-approved by the Chief Pharmacy Officer and the Chair of the Pharmacy and Therapeutics Committee.

- B. The law prohibits the sale or billing for drug samples. Individuals must never sell or bill for drug samples.
- C. The policies above also have the benefit of preventing an Individual's personal use of samples or the use of samples by their family or friends.

### **III. Physician and Site Access by Industry Sales and Marketing Representatives**

The following guidelines are in addition to the requirements set forth in The University of Chicago Medical Center Vendor Relations Policy (A05-08).

- A. Industry sales and marketing personnel, e.g. drug and device representatives, are permitted in non-patient care areas by appointment only. Appointments may be made for purposes such as:
  - 1. In-service training of Individuals for research or clinical equipment or devices already purchased.
  - 2. Evaluation of new purchases of equipment, devices, or related items.
- B. In the specific instance of devices and equipment, industry sales and marketing personnel are permitted in patient care areas (a) by appointment, **and** (b) only when requested by the attending physician, unit/clinic director or vice president, or department chair or division chief, **and** (c) only when the patient care area access is required to provide in-service training, technical support (including, without limitation, evaluating new purchases of equipment, devices, or related items), and maintenance of devices and other equipment.
- C. Appointments to obtain information about drugs will be issued pursuant to policies established by the Pharmacy and Therapeutics subcommittee. This Policy is not intended to restrict the practice of vendors providing valuable information about drugs

to individuals. However, these practices must conform to this Policy and the UCMC Vendor Relations Policy.

- D. Appointments may be made on a per visit basis or as a standing appointment for a specified period of time, at the discretion or request of an attending physician, or his or her section or department chief.
- E. Students, residents and fellows who are to be involved in meetings with industry sales and marketing personnel, e.g. drug and device representatives, may do so only for educational purposes and must do so only under the supervision and with the presence of an attending physician, and subject to Section V below.

#### **IV. Industry-Sourced Student, Resident, and Fellow Scholarships and Other Educational Funds**

- A. Industry support of students, residents, and fellows must be free of any actual or perceived conflict of interest, must explicitly serve an educational purpose, and must comply with all of the following provisions. These provisions apply to on-site and off-site educational programs.
  - 1. The sponsorship, funds, program, or conference are not solicited outside of CME protocol.
  - 2. The Chief of the Biological Sciences Division department, program, or section determines that the CME approved conference or program has the educational merit necessary for the purpose and selects the students or trainees to attend.
  - 3. The funds are provided to a central administrative department identified by the Dean of the Biological Sciences Division of the University of Chicago, and not to a department, program, section, physician, student, or trainee.
  - 4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support (e.g., “quid pro quo”).

- B. This section may not apply to national or regional merit-based awards, which are considered on a case-by-case basis.

## **V. Industry Support for Educational and Other Professional Activities**

Presentations on the use of all healthcare products, regardless of their source, must ordinarily occur in a structured learning environment (e.g. forum or seminar) that is supervised by faculty. Examples of inappropriate learning environments include a vendor talk at a restaurant, a lecture at a vacation resort or country club, and a conversation at a sporting event. In addition, the educational offerings must be science based, supporting the free exchange of information with knowledgeable parties presenting and participating. The following support this general policy and are irrespective of location (e.g. off-site versus on-campus).

- A. General. ACCME *Standards for Commercial Support* (the “Standards”) must be followed for all Industry support for educational activities. These activities must be coordinated with The University of Chicago Clinical Medical Education (“CME”) office regardless of whether the educational session is provided for CME credit. The *Standards* provide guidelines for evaluating all forms of Industry interaction, both on and off campus and including both Enterprise-sponsored and other events. The *Standards* may be found at <http://www.accme.org>. This Section is not intended to prohibit Industry from providing financial support for departments, section, and programs of the Enterprise when such support is provided in a manner that is consistent with this Policy (including Section IV) and the *Standards*. Such financial support must be unrestricted and the department, section, or program is free to utilize such support in the manner it sees fit, subject to the limitations noted in section V(C) below.

- B. Medical Center Enterprise Sponsored Education. Industry financial support may be provided to the Medical Center Enterprise on behalf of any department, section, or program within the Enterprise. The funds are provided to a central administrative department identified by the Dean of the Biological Sciences Division of the University of Chicago, and not to a department, program, section, or physician. Leadership within the department, section, or program may request the distribution of monies from the fund, which the designee of the Dean will grant or deny in its sole discretion and consistent with all applicable Medical Center Enterprise and University policies. Industry personnel must not restrict but may request, how such monies are

spent within the Medical Center Enterprise, department, section, or program.  
However,  
Industry financial support provided for educational purposes must be used solely to  
support educational purposes. To ensure compliance with the *Standards*, among other  
things the CME office will independently examine proposed programs and  
periodically  
audit the content and quality of offerings that have taken place.

C. Identification of the Sponsor. Industry contributors must be recognized in an appropriate manner as outlined in the *ACCME Guidelines*.

D. Food. Industry must not directly fund meals or other types of beverage and/or food offerings at Medical Center Enterprise meetings, luncheons, case conferences, etc.

E. Attendance. Because of the high potential for a perceived or real conflict of interest,  
individuals—especially faculty and other academic personnel—must carefully assess  
their own participation in meetings and conferences that are fully or partially sponsored  
or run by Industry.

F. Active Participation. Individuals who actively participate in meetings and conferences supported in part or in whole by Industry (e.g., by giving a lecture, organizing the meeting) whether on-site or off-site must follow these guidelines:

1. The meeting sponsor must fully disclose the financial support by industry.
2. The meeting or lecture content and materials must be determined and created by the speaker and not the Industry sponsor.
3. The Individual must provide a fair and balanced assessment of therapeutic options to promote objective scientific and educational activities and discourse.
4. An industry sponsor must not require the Individual to accept advice or services concerning speakers, content, etc., as a condition of the sponsor's contribution



of funds or services.

5. The Individual must make clear that content reflects individual views and not the views of any institution within the Medical Center Enterprise.
6. The use of the “The University of Chicago” or “The University of Chicago Medical Center” name and logo in non-University of Chicago events is limited to the identification of the individual by his or her title and affiliation.

*NOTE:* This Section does not apply to meetings of professional societies that may receive partial Industry support or meetings governed by the *Standards*.

G. Off-Site Activities. Individuals must not attend sales or marketing sessions. A sales or marketing session is any non-CME event that is sponsored by industry whether or not the topic is focused directly or indirectly on the sponsor’s product. For example, a breakfast, lunch, or dinner talk at a restaurant that is given by a physician thought leader hired by the sponsor for the event is a marketing session. This is true even if the agenda or topic for discussion is advertised as a topic of general medical or scientific interest. Individuals must comply with the *ACCME Standards* in the same manner as if the education was organized by the Medical Center Enterprise. Additionally, as stated above, individuals must not accept personal gifts or payments from industry regardless of site or circumstance. Individuals may only accept items of value as permitted in this policy.

H. Speakers’ Bureaus, Consulting Arrangements, and Other Services

1. Individual participation in speakers’ bureaus poses special concerns, including damage to the Individual’s credibility and the real potential for misuse of the Enterprise’s reputation as a consequence of the individual’s academic affiliation. Be wary of invitations to any event, including panel discussions, to which you are invited to participate with payment in cash or in kind and for which the sponsor provides you with talking points or other materials to discuss or present.
2. Participation in speakers’ bureaus or other consulting engagements is subject to timely disclosure under and in compliance with the University’s Staff Policy on Conflicts of Interest.

I. Individuals may receive compensation from Industry if the compensation is for services rendered. Both the services rendered and compensation must be set forth in a written agreement signed by both parties and the compensation is fair market

value. Such compensation agreement must be disclosed by the individual according to Faculty and Staff Policies.

- J. Procurement: Individuals may evaluate products or services offsite as part of purchasing decision only when UCMC pays for site visit.

## **VI. Disclosure of Relationships with and Interests in Industry**

- A. An individual must not publish an article solely or primarily under his or her own name if the article was in fact written in whole or material part by an Industry employee or employees without attribution. Individuals must retain the discretion to review or edit published material.
- B. In scholarly publications, Individuals must disclose their related financial interests in accordance with the requirements of the journal or publication.
- C. Individuals who have a role in Enterprise decisions or recommendations related to supply, equipment, services, or drug procurement or the hospital's formulary decisions must disclose to the purchasing unit or committee—prior to making any discussion on the matter—any interest (financial or otherwise) they or their immediate family have in entities that might benefit from the decision or recommendation. Such interests include but are not limited to equity ownership, options, compensated or uncompensated positions on advisory boards, a paid consultancy, fiduciary roles, or other forms of remunerated relationship. This disclosure obligation excludes indirect ownership such as stock held through mutual funds. Individuals must also disclose any research or educational interest they or their department or section has that might substantially benefit from the decision. The purchasing unit or committee chair will decide whether the Individual must recuse him/herself from the purchasing decision.
- D. The reporting outlined in this Section does not modify the disclosure requirements set forth in the University Faculty and Staff Policies or The University of Chicago Medical Center Conflict of Interest Policy (A00-12). Each entity within the Medical Center Enterprise will share conflict and other germane information to facilitate compliance with applicable law, reporting obligations, and institutional policies.
- E. For disclosure requirements related to educational activities, see the *Standards*.

## **VII. Training of Students, Residents, Fellows, and Faculty Regarding Potential Conflict of Interest in Interactions with Industry**

Individuals must receive information and training regarding this Policy and potential conflicts of interest associated with interactions with Industry.

## **VIII. Enforcement and Questions**

Questions regarding this policy must be directed to the Medical Center Compliance Office or the Office of Legal Affairs of the University or Medical Center.

This policy will be enforced by the Office of the Dean for the Biological Sciences Division.

## **IX. References**

- A. Accrediting Council for Continuing Medical Education (ACCME) Standards for Commercial Support (<http://www.accme.org/>)
- B. *University of Chicago Medical Center Conflict of Interest Policy* (A00-12) ([http://frontline.mcis.uchicago.edu/admin/hsp\\_pp.nsf/110c44d662f7a775862565ad005de7b7/4ddc16e89f02e4ab862568eb006f1116?OpenDocument](http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de7b7/4ddc16e89f02e4ab862568eb006f1116?OpenDocument))
- C. *University of Chicago Medical Center Vendor Relations Policy* (A05-08) ([http://frontline.mcis.uchicago.edu/admin/hsp\\_pp.nsf/110c44d662f7a775862565ad005de77/57a725fe832c0340862568ef00577d0a/\\$FILE/A05-08%20Vendor%20Relations%20Policy\(10.2007\).doc](http://frontline.mcis.uchicago.edu/admin/hsp_pp.nsf/110c44d662f7a775862565ad005de77/57a725fe832c0340862568ef00577d0a/$FILE/A05-08%20Vendor%20Relations%20Policy(10.2007).doc))
- D. *University Staff Policy on Conflicts of Interest* (U600) (<http://hr.uchicago.edu/policy/p600.html>)
- E. *Outside Professional and Commercial Activities of Faculty and Conflict of Interest*  
(prepared by the Council on Research and approved by the Council of the University Senate on July 27, 2007)  
(<http://researchadmin.uchicago.edu/regulations/coi.shtml>)
- F. *The Report of the Standing Committee on Conflict of Interest* (dated January 16, 2004 and setting forth recommendations to clarify, streamline, and strengthen the University Policy) (<http://researchadmin.uchicago.edu/regulations/coi.shtml>)
- G. *Industry Funding of Medical Education Report*, AAMC Task Force, June 2008 ([https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd\\_id=232&prv\\_id=281&pdf\\_id=114](https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114)).

- H. *Protecting Patients, Preserving Integrity Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC/AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008  
([https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd\\_id=220&prv\\_id=268&pdf\\_id=107](https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107)).
- I. *The Scientific Basis of Influence and Reciprocity: A Symposium*, June 12, 2007  
([https://services.aamc.org/Publications/showfile.cfm?file=version106.pdf&prd\\_id=215&prv\\_id=262&pdf\\_id=106](https://services.aamc.org/Publications/showfile.cfm?file=version106.pdf&prd_id=215&prv_id=262&pdf_id=106))

## Frequently Asked Questions

### **Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies & Services Industries**

#### **1. Conferences – Attendance at conferences and related receptions that are sponsored by industry.**

**Situation:** I am attending a conference that is hosted by a professional association. I/my department or section am/is paying a registration fee to the professional association to cover attendance at the meeting. I/my department or section am/is paying for airfare, hotel, and meals.

I noticed while reading the meeting brochure that industry is sponsoring some portion of the conference and in particular the evening reception that occurs at the end of each day of meetings.

***Q:** Is it a violation of the Medical Center's conflict of interest policy to attend the conference?*

**A.** It is not a violation of the Medical Center's conflict of interest policy for a member of the faculty or a resident to attend a professional association meeting that is sponsored in part by industry so long as you or your department or section pays for the registration fee. In addition, a department may accept scholarship money to allow residents or fellows to attend. This (applying for a grant to attend a conference) is something that would be handled in a centralized manner and absolutely not on a personal level. Do not personally accept "comp" offers from the meeting planners or industry to attend any meeting free of charge.

***Q.** Is it a violation of the Medical Center's conflict of interest policy to attend the evening reception?*

- A.** a. It is not a violation of the Medical Center's conflict of interest policy for a member of the faculty or a resident to attend a post-conference reception that is sponsored by industry so long as the reception is open to all conference participants and covered under the basic registration fee.
- b. It is a violation of the Medical Center's conflict of interest policy to attend at the sponsor's expense a private reception or dinner whether on the conference premises or at a nearby location. These are generally invitation only events through which you are notified

in writing, via e-mail or text-page, by a phone call, or in-person invitation. If you wish to attend, you must pay your own way. Sponsors understand that most invitees will be subject to a conflict of interest policy that require the attendee to pay and will be prepared to quote you a price when you call to inquire.

## **2. Conferences – Scholarships for residents and fellows to attend professional association meetings.**

***Q:** Does the conflict of interest policy prohibit us from accepting scholarship funds from industry that would permit us to send a resident or fellow to a professional conference.*

**A:** The conflict of interest policy does not prohibit a department or section from accepting scholarship funds from industry for the purpose of sending a resident or fellow to a professional conference so long as these funds are secured in accordance with CME protocol. Section IV of the Medical Center's conflict of interest policy addresses this issue and sets forth the requirements for managing these scholarships.

## **3. Breakfast, Brunch, Lunch, and Dinner**

***Q:** I occasionally have dinner with sales (drug or device) representatives and/or scientists of industry. Is it permissible under the conflict of interest policy to allow the industry representative to pay for my meal?*

**A:** It is never acceptable under the policy to allow an industry representative to pay for your meal. Please pay for your own meal whether it is breakfast, brunch, lunch, or dinner. See Section I and V of the policy for more information.

## **4. Educational Materials for Patients**

***Q:** Several pharmaceutical and device companies provide written materials and other education tools that we distribute to patients. The company logo is printed on each document. Are we permitted under the conflict of interest policy to continue to accept these materials and give them to our patients?*

**A:** We are not permitted to accept these educational materials from industry whether or not the materials are branded with the company logo. Industry is welcome to contribute to a central fund that is managed by your department. The department may then distribute funds to be used to produce educational materials for patients. The Medical Center recognizes that it may take certain departments and sections time to transition away from educational materials that display Industry logos and will allow six to twelve months for implementation.

***Q:** May we accept a grant from a pharmaceutical company to create and film an educational video for patients?*

**A:** Yes -- so long as your section and department follow the pharmaceutical company's formal award process, meaning that an application is completed and sales representatives or other company representatives are not solicited for funds.

***Q:** May we accept a grant from a pharmaceutical company to cover the costs of creating and printing educational brochures for patients?*

**A:** Yes -- so long as your section and department follow the pharmaceutical company's formal award process, meaning that an application is completed and sales representatives or other company representatives are not solicited for funds.

## **5. Industry Support - General**

***Q:** I have heard that it is against policy to request funds from industry to sponsor educational events or to support conference scholarships for residents or educational materials for patients. Yet at the same time the policy talks about managing funds centrally. Please clarify.*

**A:** Industry has a mechanism for contributing support that should be followed carefully. Do not request or solicit funding from individual sales or other company representatives. Instead, ask for the contact information of the person or department in the company that accepts applications for support. Most pharmaceutical and device companies have this information posted on their websites. Follow this transparent application process. If funds are awarded, then they should be managed centrally in the department or section. Funds should not be delivered to an individual faculty member, fellow, resident, or staff.

## **6. Evaluating Equipment and Services**

***Q:** Does the policy prohibit the practice of allowing industry to pay for travel to off-site locations to evaluate equipment or other services?*

**A:** Unless provision has been made for payment through the request for proposal process, it is not permissible to allow industry to pay for travel and other expenses associated with a trip to evaluate equipment or services.

## **7. Collaboration with Industry on Scientific Papers**

***Q:** Does the policy prohibit me from collaborating with a colleague in industry on a paper for publication in a scientific or medical journal?*

**A:** No. The policy does not prohibit legitimate collaboration that occurs in accordance with established professional authorship standards. What the policy

does absolutely prohibit is ghost writing, or the practice of allowing industry to write a paper that a faculty member would then publish under his or her name.

## **8. Consulting Arrangements**

*Q: Does the policy prohibit a legitimate consulting arrangement, which is an arrangement that is set forth in writing for which compensation is commensurate with work performed?*

**A:** The policy does not prohibit legitimate consulting arrangements. You should consider carefully, however, the number of such arrangements in which you participate and be certain that such commitments do not violate that time granted to you by the University (11 days per quarter) for participation in such activities. Keep in mind that any arrangement, consulting or otherwise, that you have with a pharmaceutical or device manufacturing company will be published by these companies on their websites. In most cases this is, at present, voluntary. Soon it will be required by law.

## **9. Speaker's Bureaus**

*Q. Does the policy prohibit participation in speaker's bureaus?*

**A.** While the policy does not expressly prohibit participation in speaker's bureaus or discussion panels, approach this activity with caution. Never participate in branded speaker's bureaus activities. This would include events for which the sponsor proposes that you speak about the sponsor's drug or device. This also includes events that are unbranded but for which the sponsor wishes to provide the speaker with a script of statements to be made during the course of the talk. It is a good idea to protect yourself by negotiating a clause in your contract with the sponsor that clearly states that you are under no obligation to mention or advocate for the sponsor's products.

In order to avoid putting themselves at risk, residents and faculty should carefully evaluate activities that Industry sponsors propose to avoid becoming unwittingly involved in something that is intended, designed, or likely to be perceived as a marketing event.

## **10. Off-site CME Events**

*Q: Our residents and faculty are often invited to attend citywide evening educational lectures accompanied by a dinner. These are often but not always ACCME-approved events. There is typically not a registration fee at an event like this. The educational presentations are given by academic local, regional, or national faculty. May our residents and faculty continue to attend such events?*



**A:** Residents and faculty may attend these events so long as 1) the event is unbranded and 2) the resident or faculty pays for his food and drink. If these two conditions are met, residents and faculty may attend, whether or not the event is CME. Keep your receipts. Consider carefully the appearance of impropriety factor and the likelihood that your name will be listed on the sponsor's records. Federal investigations of sponsors (drug and device companies) are occurring at increasing frequency. Information gathered through these investigations is being used to identify physicians who are frequent attendees at these events. These physicians may themselves become the subject of an investigation.

***Q:** Sometimes a member of the faculty gives a presentation at the kind of events described in above. If the faculty is compensated for participation through a legitimate consulting or speaker's bureau arrangement (both of which would need to be fully disclosed to UC, UCMC, and at the speaking site) may our faculty continue to participate in this kind of activity?*

**A:** Yes, so long as the talk is not a branded talk meaning that neither the written content nor spoken comments are scripted by the sponsor. See our cautions above about attendance at these events and the appearance of impropriety.

## **11. Conferences – Investigator Meeting prior to the conduct of an Industry Sponsored Clinical Trial**

***Q:** Does the conflict of interest policy prohibit us from attending the Industry sponsored "Investigator Meetings" held prior to the initiation of a clinical trial?*

**A:** Attendance at the national study initiation meetings ("Investigator Meetings") when the clinical trial agreement with the University is either pending or finalized and for which attendance is an expectation of participation, is acceptable. The conflict of interest policy does not prohibit faculty or staff from attending these national study initiation meetings and it is acceptable for the Industry sponsor to pay for the associated costs, if it is contractually that the principal investigator attends the meeting. Participation in an Industry sponsored Clinical Trial is governed formally by the clinical trial agreement between Industry and the University.

## **12. Patient Holiday Parties**

***Q:** Is it okay for Industry to sponsor our annual Christmas party?*

**A:** No. Industry sponsorship of patient holiday parties is not permitted.

## **13. Employee Holiday Parties**

***Q:** Is it okay for Industry to sponsor holiday parties for faculty, staff, or residents?*

**A:** No. Industry sponsorship of faculty, staff, or resident holiday parties is not permitted.

#### **14. International Activities**

***Q:** Do these rules apply to my interactions with Industry that occur outside of the United States? Do these rules apply to interactions that occur in the United States with an Industry company that is headquartered outside of the United States?*

**A:** In both cases the answer is yes. These rules apply to all of your activities, whether on campus or off, in the United States or abroad, regardless of where the Industry entity is headquartered.