

2016 Medical School Online Submission Form

Policy Assessment:

General Statement: The University of Chicago's and The University of Chicago Medical Center's policies do not prohibit interactions with industry. These interactions can lead to collaborative work and discoveries that benefit science and health care. Rather, relationships are acknowledged and managed. For example, the Chair of the Pharmacy & Therapeutics Committee calls for conflicts at each meeting when vendor interests are implicated by a decision, medical center leadership recuse themselves when conflicts, actual or potential, are present, faculty function under management plans, and firewalls are created for endowment decisions and management.

1. & 2. Gifts from industry & Meals from industry

A. Gifts (including meals)

Response: All gifts and on-site meals funded by industry are prohibited, regardless of nature or value.

Support: The medical center policy applicable to relationships with industry that applies to medical students, residents and faculty does not permit gifts, including meals. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3; "Policy Principles and Summary," pages 3-4, Part I, "Gifts and Payments"; *Vendor Relations Policy*, page 6 (Gifts and Compensation). One policy that allows modest gifts is a hospital policy. It does not apply to medical students, residents, fellows, or faculty to the extent it conflicts with the Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries, page 3; "Policy Principles and Summary," pages 3-4, Part I, "Gifts and Payments"; the more stringent policy applies.

The University's COI policy applicable to staff employees (not faculty/OAA physicians and not students) discourages gifts.

See <http://humanresources.uchicago.edu/fpg/policies/600/p600.shtml>, paragraph 9. The COI policy applicable to faculty/OAAs including BSD physicians has a zero dollar threshold for financial interests, therefore a gift from industry would be a disclosable financial interest under the COI policy, if it "could reasonably appear to affect the design, conduct or reporting of their research or their performance of other Institutional Responsibilities." Institutional responsibilities include patient care and teaching and mentoring of students.

B. Disclosure

Response: School of Medicine faculty are required to disclose past and present financial ties with industry to University Research Administration and faculty who are influential at the medical center must disclose the same to the Office of Legal Affairs and the Office of Corporate Compliance.

Support: URA's requirements are consistent with those required by research regulations—disclosures are to be made within thirty (30) days of the arrangement and annually. The medical center's requirements are based upon the role of the individual—reporting is expected as the arrangement occurs, as topics arise during committee activities (e.g. Pharmacy & Therapeutics Committee upon the call for a formulary addition or removal), and annually, concurrent with the URA annual reporting. University officials must report conflicts within the department, which ultimately can be referred to the Standing Committee on Institutional Conflicts of Interest. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 10, Part VI; *The University of Chicago Medical Center Conflict of Interest Policy*, A00-12, page 2; "Identification and Resolution of Conflicts of Interest, pages 4-5; "Disclosure Obligations." Relationships must also be reported during educational activities and in scholarly publications and other articles. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, pages 7, 8 & 10, Part V(A), V(C), VI. See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012), Part VI and X, and *The University of Chicago Institutional Conflicts of Interest in Research policy*, page 3.

3. Industry-sponsored promotional speaking relationships

Response: Industry-funded speaking relationships are regulated. The policy explicitly cautions the professionals who perform these services regarding speaking arrangements, including speaker's bureaus and talking points.

Support: The medical center policy applicable to relationships with industry that applies to medical students, residents and faculty contains strict cautions about speaking relationships, noting that they pose "special concerns," guiding the reader to "be wary" of those that involve the sponsor providing "talking points or other materials to discuss or present." In addition, individuals who give lectures or participate in meetings and conferences must follow specified guidelines, including without limitation, that (a) the contents are created and determined by the speaker and not the industry sponsor, and (b) the individual provides a fair and balanced assessment of therapeutic options to promote the objective scientific and educational activities and discourse. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 9, Part V(F) and (H). See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012).

4. Industry support of ACCME-accredited CME

Response: Our policy states that industry funding is not accepted for the support of accredited CME courses except in certain clearly defined circumstances. It is the policy of the University of Chicago to ensure balance, independence, objectivity, and scientific rigor in all its individually sponsored or jointly sponsored educational activities. Individuals who are in a position to control the content of any educational activity are required to disclose all relevant financial relationships with any commercial interest related to the subject matter of the educational activity. Faculty will also disclose any off-label and/or investigational use of pharmaceuticals or instruments discussed in their presentation. Mechanisms to ensure that presentations are free from any commercial bias are in place and fully implemented by the CME office before any accredited CME event. In fact, every presentation is fully reviewed including slides and disclosures by the CME office before approval of any CME accredited event.

The University of Chicago Continuing Medical Education abides by all requirements of the *ACCME Standards for Commercial Support of Continuing Medical Education* (submitted to AMSA), in order to ensure that all educational decisions are made free of the control of any commercial interest.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3; “Policy Principles and Summary,” pages 6-10, Parts IV and V.

5. Attendance of industry-sponsored promotional events

Response: Industry-sponsored promotional events are discouraged and therefore attendance to these events is not encouraged. The policy explicitly cautions professionals about these services.

Support: The medical center policy applicable to relationships with industry that applies to medical students, residents and faculty contains strict cautions about relationships with the industry, noting that they pose “special concerns,” guiding the reader to “be wary” of those that are involved. In addition, individuals who give lectures or participate in meetings and conferences must follow specified guidelines, including without limitation, that (a) the contents are created and determined by the speaker and not the industry sponsor, and (b) the individual provides a fair and balanced assessment of therapeutic options to promote the objective scientific and educational activities and discourse. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 9, Part V(F) and (H). See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012).

5B. Compensation for Travel or Attendance at Off-site Lectures & Meetings

Response: Industry support of educational activities is limited to ensure independence of educational content; standards include Biological Sciences Division leadership approval of the conference or program, and acknowledgement of the vendor support to ensure transparency. On-site and off-site support must adhere to ACCME standards.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3; “Policy Principles and Summary,” pages 6-10, Parts IV and V.

6. Industry-funded Scholarships & Awards

Response: The policy imposes limitations on industry support of educational activities to ensure independence of educational content and prevents industry from earmarking or awarding funds to support the training of a particular individual. Standards include Biological Sciences Division leadership approval of the conference or program and a prohibition on any quid pro quo in return for the support.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3; “Policy Principles and Summary,” pages 6-7, Part IV. See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012).

7. Ghostwriting and honorary authorship

Response: The University strictly prohibits all instances of academic fraud, which is defined as “plagiarism; fabrication or falsification of evidence, data or results; fabrication or falsification of evidence, data, or results; the suppression of relevant evidence or data; the conscious misrepresentation of sources; the theft of ideas; or the intentional misappropriation of the research work or data of others.” The policy defines fraud as involving a deliberate effort to deceive. Activities such as industry-funded ghostwriting and honorary authorships would likely fall squarely within the kinds of activities that would be strictly prohibited under the academic fraud policy. Further, UCMC’s policy on interactions with industry states that interactions with industry for legitimate medical and scientific collaboration “must not be tarnished by low level interactions such as...involvement with ghost writing...” The policy specifically prohibits an individual from publishing an article under his or her own name if it was written in whole or in part by an industry representative without attribution. In addition, individuals are required to retain the ability to review or edit published material.

Support: See, *Policy on Academic Fraud; Report of the Provost’s Committee on Academic Fraud*. See, also, *Policy and Guidelines for Interactions with the Pharmaceutical,*

Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries, page 1, Prologue, pages 7-10, Parts V and VI(A).

8. Consulting and advising relationships

Response: Interactions with industry for commercial, entertainment or marketing purposes are prohibited. Consulting or advising relationships for research and scientific activities are encouraged as they are viewed as crucial in drug and device discovery and refinement. Such consulting relationships with industry must be described in a formal contract and payment for services must be at fair market value.

Support: The medical center policy applicable to relationships with industry that applies to medical students, residents and faculty requires consulting relationships to be in writing with compensation set at fair market value. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, pages 9-10, Parts V(H) & V(I). See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012). A documented fair market value analysis conducted by the department offering the services is submitted to the Office of Legal Affairs.

9. Access of pharmaceutical sales representatives

Response: Sales and marketing representatives are only permitted in certain areas of the medical center, and subject to limitations. They are not permitted at the School of Medicine.

Support: Sales and marketing representatives are excluded from patient care areas. Representatives from vendors who are experts in a particular product or needed for training or support of the providers are permitted in patient care areas to provide the training and support. Vendor representatives involved in clinical research with School of Medicine faculty are subject to these same rules. Sales and marketing representatives may only meet with medical students at the request of clinical staff and only at the medical center. The vendor policy sets forth the areas and process for representative visits; all other visits are prohibited. The policy does not permit vendor representatives at the School of Medicine. Pharmaceutical representatives may only meet with medical, nursing and pharmacy staff, and then subject to restrictions, including appointments and registration. Visits are to be by appointment and upon the request of a UCMC representative. Students, residents and fellows are under more stringent requirements. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, pages 5-6, Part III; *The University of Chicago Medical Center Vendor Relations Policy, A05-08*.

9A. Pharmaceutical Samples

Response: While samples or vouchers for medications may be accepted, significant limitations apply.

Support: Individuals are cautioned about the risks of accepting samples, and are directed to use a centralized Pharmacy-Department run outpatient pharmacy. Samples are not permitted in inpatient areas, and outpatient storage and use is through the Pharmacy unless an exception is granted. The use of samples must follow strict requirements, including logging, and samples must be approved consistent with the formulary review through the Pharmacy & Therapeutics Committee. See *Sample Medication Policy*, (June 2013); *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, pages 4-5, Part II.

10. Access of medical device representatives

Response: Medical device and equipment representatives are permitted in patient care areas by appointment and only when their presence has been requested by an attending physician, unit/clinic director or division chief *and* only when access to the patient care area is required to provide in-service training, technical support, and maintenance of devices and other equipment. Medical device and equipment representatives are not permitted in patient care areas for marketing purposes.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 5, Part III; *The University of Chicago Medical Center Vendor Relations Policy*, A05-08.

10A. Purchasing & Formularies

Response: Formulary committees and committees overseeing purchases of medical devices require disclosure and, if appropriate, recusal, of those who have financial relationships with the drug or device manufacturer that sells or manufactures the product.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3, & page 10, Part VI(C), *The University of Chicago Medical Center Conflict of Interest Policy*, A00-12, page 1; "Purpose," page 2; "Identification and Resolution of Conflicts of Interest, pages 4-5; "Disclosure Obligations."

11. Conflict of interest disclosure

Response: School of Medicine faculty are required to disclose past and present financial ties with industry to University Research Administration (URA) and faculty who are influential at the

medical center must disclose the same to the Office of Legal Affairs and the Office of Corporate Compliance. Relationships must also be disclosed to trainees and audiences during educational activities and in scholarly publications and other articles.

Support: URA's requirements are consistent with those required by research regulations—disclosures are to be made within thirty (30) days of the arrangement and annually. The medical center's requirements are based upon the role of the individual—reporting is expected as the arrangement occurs, as topics arise during committee activities (e.g. Pharmacy & Therapeutics Committee upon the call for a formulary addition or removal), and annually, concurrent with the URA annual reporting. University officials must report conflicts within the department, which ultimately can be referred to the Standing Committee on Institutional Conflicts of Interest. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 10, Part VI; *The University of Chicago Medical Center Conflict of Interest Policy*, A00-12, page 2; "Identification and Resolution of Conflicts of Interest, pages 4-5; "Disclosure Obligations." Relationships must also be reported during educational activities and in scholarly publications and other articles. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, pages 7, 8 & 10, Part V(A), V(C), VI. See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012), Part VI and X, and *The University of Chicago Institutional Conflicts of Interest in Research policy*, page 3.

12. Existence of an adequate conflict-of-interest medical school curriculum

Response: Students, residents, fellows, faculty and staff are offered training about the policies as well as potential and actual conflicts of interest associated with industry and vendors.

Support: Several required pre-clinical courses and core clerkships of Pritzker's undergraduate medical education address the topic of *conflict of interest*. Students attend class sessions that address the effects of industry marketing on physician education and practice, and its relationship to medical professionalism and the effects of industry influence on how the efficacy and safety of drugs and devices are demonstrated, regulated, and/or marketed.

The Office of Legal Affairs and the Office of Corporate Compliance offer live sessions about conflicts in general as well as the policies for any department. (Questions and answers with specific examples are attached to the policy). Articles demonstrating the influence of vendors are included in the discussions and training. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 11, Part VII. See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012).

13. Extension of COI policies to adjunct/courtesy faculty and affiliated hospitals/clinics

Response: Conflicts of interest policies apply to University staff, full-time and part-time faculty and other academic appointees. In addition, the medical center's COI policy applicable to relationships with industry applies to all UCMC employees and independent contractors, and all UCMC medical staff members and others with UCMC clinical privileges under the UCMC Medical Staff Bylaws as well as medical students, residents and fellows. These policies are not limited to the University or medical center campus and apply to all an individual's activities, whether they occur locally or abroad, including off-site clinics, community hospitals and affiliated institutions.

Support: See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 1-2, Part VI; *The University of Chicago Medical Center Conflict of Interest Policy*, A00-12, pages 1, 3, 7-8; *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees* (August 24, 2012); *The University of Chicago Conflict of Interest Policy*, U600 <http://humanresources.uchicago.edu/fpg/policies/600/p600.shtml>

14. Enforcement and sanctions of policies

Response: Violations are to be reported. Disciplinary action for violations include training, counseling, and termination.

Support: Enforcement is with the Office of Legal Affairs, Office of Corporate Compliance and the Dean of the Biological Sciences Division, together with the medical center's human resources departments. In addition, as part of the University's global policy, faculty function under management plans with specific direction for the appropriate management of conflicts. See *Policy and Guidelines for Interactions with the Pharmaceutical, Biotechnology, Medical Device, and Research Equipment and Supplies and Services Industries*, page 3; "Policy Principles and Summary," page 11, Part VIII; *University of Chicago Medical Center Vendor Relations Policy*, A05-08, page 7; "Possible Violations by Others" & "Disciplinary Actions." See also *The University Of Chicago Conflict Of Interest And Conflict Of Commitment Policy For Faculty And Other Academic Appointees*, Part XII (August 24, 2012).

Regarding students, if a student's conduct violated a policy or other standard of conduct applicable to the student, the student could be subject to the University's disciplinary processes. The School of Medicine has its own area disciplinary processes. See this excerpt from the Student Manual describing the area disciplinary process and how it works: <https://studentmanual.uchicago.edu/area>. The discussion includes a discussion of sanctions available for misconduct.