

POLICY AND GUIDELINES FOR INDUSTRY RELATIONSHIPS
UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE

I. Purpose

This policy establishes guidelines for interactions with companies engaged in the manufacture or sale of diagnostic or therapeutic drugs, devices or services for research, education or clinical care. It applies to all personnel, which includes faculty, staff, students, and trainees of the University of Cincinnati College Of Medicine as defined subsequently (see IV.A.). Interactions with industry occur in a variety of contexts. These interactions can be positive and important for promoting the educational, clinical and research missions of the College of Medicine. These interactions must adhere to the highest ethical standards and must not create conflicts of interest that could endanger patient safety, research integrity, the integrity of our education and training programs, and the reputation of the College of Medicine or its personnel.

II. Statement of Policy

It is the policy of the University of Cincinnati College of Medicine that interactions with industry should be conducted in such a manner so as to identify and address conflicts of interest and to comply with relevant provisions of University Policy and applicable law.

III. Scope of Policy

This policy applies to all academic and administrative units of the College of Medicine, and to all College of Medicine personnel. This policy is divided into three sections 1) Industry Interactions Occurring in the Context of Research and Scholarly Activity; 2) Industry Interactions Occurring in the Context of Clinical Training and Patient Care; and 3) Industry Interactions in the Form of Consulting, Collateral Employment and Entrepreneurial Affairs/Technology Transfer. This policy is intended to supplement the requirements of the applicable University of Cincinnati Board Rules, including Rule 10-17-03 (“Employee Responsibilities”); 10-17-08 (“Policy on Conflicts of Interest in the Conduct of Research at the University of Cincinnati”); 30-21-02 (“Policy on Collateral Employment for Faculty Members and Librarians”); 30-21-03 (“Collateral Employment Policy for All Employees (Excluding Faculty Members and Librarians”); and 10-17-09 (“Employee Financial Interests in Companies That are Commercializing University Discoveries, Inventions or Patents”).

IV. Definitions

As used herein, the following terms have the indicated meaning:

- A. “Personnel” refers to all faculty, staff, and trainees of the University of Cincinnati College of Medicine. “Trainees” include students, residents, and fellows.
- B. “Industry” refers to firms or vendors engaged in the manufacture or sale of diagnostic or therapeutic drugs, devices, supplies, or services for research, education or clinical care.
- C. “Gifts” or “Compensation” refers to anything of value provided by or on behalf of Industry, including but not limited to food, beverages, pharmaceutical or device samples, or travel related expenses. “Gifts” and “Compensation” shall not include pharmaceutical samples which are provided in keeping with a written Departmental Policy which ensure the absence of inappropriate influence by Industry in connection with such distribution.

V. Industry Interactions Occurring in the Context of Research and Scholarly Activity

A. Conflict of Interest Disclosures for Research

- 1. All Personnel who participate in the design, conduct, analysis or reporting of research shall comply with the provisions of University Rule 10-17-08, entitled “Policy on Conflicts of Interest in the Conduct of Research at the University of Cincinnati.”
- 2. All Personnel who participate in the design, conduct, analysis or reporting of human subjects research shall also comply with University Institutional Review Board Policy IV.02 “Investigator Conflict of Interest in Human Subjects Research”

B. Professional Publications and Presentations

- 1. Publications which are supported by and/or include contributions from industry author(s) shall strictly comply with “Authorship Guidelines – Faculty University of Cincinnati College of Medicine” (May 13, 2004) as amended from time to time.
- 2. In professional presentations and publications, individuals must disclose their personal financial interests and financial support from industry in accordance with policies promulgated by the International Committee of Medical Journal Editors (<http://www.icmje.org/>).

VI. Industry Interactions Occurring in the Context of Clinical Training and Patient Care

A. Site Access by Industry Representatives

Industry representatives other than service personnel are not permitted on the premises of the College of Medicine except for specific appointments with faculty or authorized staff members. Presence at other times must be approved. Approvals may be granted on a per visit basis or as a standing appointment for a specified period of time at the discretion of the faculty member, his or her division or department.

B. Affiliated Training Sites' Policies

Policies established by affiliated training sites which regulate access of Industry to such sites shall be honored to the extent that such policies may impose additional restrictions or limitations on site access by sales and marketing representatives.

C. Gifts or Compensation

It is expected that no form of Gift or Compensation from Industry will be accepted by Personnel of the University of Cincinnati College of Medicine under any circumstances, except as reasonable compensation for *bona fide* services. Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from Industry. It is unacceptable and unlawful for patient care decisions to be influenced by the possibility of personal financial gain.

Examples of circumstances involving Gifts and Compensation that are unacceptable under this Policy include, but are not limited to, the following:
Individuals may not accept Gifts or Compensation

1. for prescribing or for changing a patient's prescription to a specific medication.
2. for recommending or utilizing a specific diagnostic or therapeutic device.
3. for listening to a sales talk by an Industry representative.
4. while attending a CME or other activity or conference (that is, if the individual is not providing *bona fide* services at the event).
5. provision of scholarships and other educational funds directly to students and trainees

D. Industry Support for Unique Educational or Training Opportunities

Industry support for Unique Educational or Training Opportunities must be specifically for the purpose of education and must comply with all of the following provisions:

1. The student or trainee to receive such support must not be selected by the industry providing the support.
2. The funds are approved by the department, program, or division responsible for the student or trainee;
3. The department, program or division has determined that the funded conference or program has educational merit; and
4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "*quid pro quo*."
5. The name of the College of Medicine or the attendee's affiliation with the College of Medicine may not be used to imply endorsement of a product or service by the College.

E. Support for Educational Activities

1. All continuing medical education events sponsored by or accredited by the University of Cincinnati College of Medicine must be compliant with ACCME Standards for Commercial Support whether or not CME credit is awarded. The Standards may be found at www.accme.org.
2. Educational grants that are compliant with the ACCME Standards may be received from Industry but must be administered by departments or divisions of the College of Medicine and not by individual faculty.
3. Meals or other types of food and beverages directly funded by Industry may not be provided at educational events sponsored by or accredited by the University of Cincinnati College of Medicine.
4. Gifts other than educational material approved by the faculty director of the educational event may not be provided at educational events sponsored or accredited by the University of Cincinnati College of Medicine.
5. Faculty and medical staff should evaluate carefully their own participation in or attendance at meetings and conferences that are fully or partially sponsored or run by Industry because of the potential for conflict of interest. Meetings and conferences supported in part or in whole by Industry should follow these guidelines:
 - a. Financial support by Industry is fully disclosed by the meeting sponsor.
 - b. The educational content promotes scientific and educational activities and discourse.

6. The name of the University of Cincinnati or its College of Medicine may not be used in a way which suggests commercial endorsement. The use of the name of the University or the College of Medicine in connection with non-University of Cincinnati-Sponsored events is limited to the identification of the participating University of Cincinnati individual by his or her title and affiliation.
7. It is recognized that industry sponsored literature and models are utilized for teaching purposes in our clinical and education programs because of their benefit to patients. Information provided by unbiased sources is preferred. However, industry sponsored literature and models may be utilized with the following provisions intended to minimize marketing and advertising influence:
 - a. The materials are used solely for education.
 - b. The clinician decides when they are utilized, not the industry representative.
 - c. The materials are not overtly promotional in nature.
 - d. The educational literature and models must not be displayed publicly in a manner intended for the purpose of product promotion.

F. Training of Students, Trainees, and Staff Regarding Potential Conflict of Interest in Interactions with Industry

The University of Cincinnati of College of Medicine shall make available training regarding potential conflicts of interest in interactions with Industry to all faculty, students, residents, trainees and staff.

VII. Industry Interactions in the Form of Consulting, Collateral Employment and Entrepreneurial Affairs/Technology Transfer

- A. Faculty members and staff of the College of Medicine may engage in collateral employment with Industry, including work of a consulting nature, provided information regarding such employment is made known in advance to the individual's department head and the Dean of the College of Medicine and provided said department head and Dean agree that the collateral employment:
 1. Does not interfere with nor is inconsistent with the performance of the individual's university duties; and
 2. Does not raise questions of conflict of interest in connection with other interests or work in which the individual or the College is involved.

- B.** Reporting of collateral employment shall be made in accordance with University Rule 30-21-02 (“Policy on Collateral Employment for Faculty Members and Librarians”) and 30-21-03 (“Collateral Employment Policy for All Employees (Excluding Faculty Members and Librarians”) on University of Cincinnati forms provided for that purpose. Any proposed collateral employment may be subject to the development of an acceptable conflict management plan or other mechanism designed to ensure that such collateral employment will comport with the requirements of this Policy.
- C.** Any College of Medicine employee who intends to become involved with a “Technology Development Company” as that term is defined in University Board Rule 10-17-09, entitled “Employee Financial Interests in Private Companies that are Commercializing University Discoveries, Inventions or Patents” is expected to comply with the provisions of that Rule, including the development and approval of a conflict management plan for approval by the Office of Research.

VIII. Monitoring and Enforcement

- A.** Enforcement of this policy shall be the responsibility of the academic unit head and dean or staff supervisor, as the case may be. Violations of the policy may subject the individual in violation of the Policy to discipline in accordance with standard policies of the University of Cincinnati and the College of Medicine.
- B.** The College of Medicine shall establish an Industry Interactions Committee which shall be charged with oversight of this policy, coordinating training and education under the policy, communicating with outside entities as required by the policy, and providing support to the College of Medicine for interpretation of the policy. The Committee shall report to the Dean, College of Medicine not less than annually.

Date Adopted January 10, 2008

Date Revision Adopted May 14, 2008

Signature David M. Stein