

**The University of Alabama at Birmingham School of Medicine
and UAB Health System
Guidelines for Relationships with Industry
March 2009**

Background

Relationships between academic communities and industry, particularly pharmaceutical firms, have come under increasing scrutiny in large part because of both real and perceived conflict of interest. While this perception is true in some instances, it is not so for all medical care providers. The perception of conflict is a result of a common practice in which some physicians receive gifts, travel, and/or financial support from industry that, in turn, stands to receive financial gain from the physicians' medical care practices, particularly those related to major illnesses. The consequences of this perception have resulted in increased oversight of the activities of employees of industry and medical centers by the government, academic institutions and public.

The current interface between academic medical centers (AMC) and health care industry has resulted in standards of conduct issued by both the AAMC, the pharmaceutical industry and the medical device industry. The pharmaceutical industry standards are effective beginning January 1, 2009. The AAMC and medical device industry guidelines will be enforced by July 1, 2009. Toward this end, the UAB School of Medicine and UAB Health System (collectively "UAB AMC") have developed a set of standards expected of the UAB AMC faculty and staff.

The Relationship between the UAB AMC and Industry

At the outset, it should be recognized that the UAB AMC and industry have a relationship that is mutually interdependent. Many UAB AMC investigators receive grant support for the conduct of clinical trials that enhance the well being of patients receiving clinical care. These clinical trials not only provide monetary support for the institution, but also intellectual insight into improved medical care whether through the development of new therapeutics or interventions. In some circumstances, the knowledge derived from these trials provides data for new research applications.

A primary goal of the UAB AMC is to provide outstanding, state-of-the-art medical care. This care must be as free as possible of both real and perceived conflict of interest and competing interests. As conflicts are identified, they must be managed in a transparent fashion. Public perception is of the utmost importance and mandates transparency between the institution and the community. Only in a transparent environment will the trust that is required for outstanding medical care be generated. Toward this end, the guiding principles for the following document define a relationship with industry for all employees of the UAB AMC that manages 'competing interests' while being totally transparent. These principles are in accord with our goal of continuing to provide patient care of the highest quality.

Recommended Guidelines

The following guidelines are set forth to consciously and actively insulate clinical care decisions from any perceived or actual benefits accrued or expected from industry. They will need to be reviewed regularly and revised appropriately as the law and the expectations of the public and the medical profession evolve.

For the purpose of this document, the following definitions apply:

“UAB AMC employee or trainee” refers to any physician, faculty member, staff member, or other individual who is employed by the UAB School of Medicine (“SOM”), the UAB Health System, University Hospital, UAB Highlands, University of Alabama Health Services Foundation (“HSF”), Ophthalmology Services Foundation, UAB Family Medicine, The Valley Foundation, The Kirklin Clinic, The Kirklin Clinic at Acton Road, UAB Health Centers, the Huntsville, Montgomery and Selma residency program clinics, and any other clinical entity managed by UAB Health System that is exclusively staffed by SOM physicians. The term includes those individuals with either full-time or part-time employee status and those with regular, adjunct, voluntary, visiting, or emeritus status. Trainee includes any individual who is receiving formal education from the SOM, including medical residents employed by University Hospital, medical students, graduate students, post-doctoral scholars, visiting scholars and fellows.

“Industry” refers to pharmaceutical, device, equipment, supply and service providers.

“UAB AMC campus” refers to UAB AMC-owned or UAB AMC-leased buildings and property, including University Hospital, School of Medicine and other UAB-owned/leased clinical facilities. In addition, for purposes of this document, UAB AMC campus includes all clinical facilities owned or leased by HSF, including, but not limited to, The Kirklin Clinic, The Kirklin Clinic at Acton Road and UAB Health Centers.

These guidelines are operable in any clinical facilities in which “UAB AMC employees and trainees” practice and/or work, including, but not limited to, Children’s Hospital, Cooper Green Hospital, and the VA Hospital, among other facilities.

1. PROVISION OF COMPENSATION OR GIFTS FROM INDUSTRY TO UAB AMC EMPLOYEES OR TRAINEES

- a. UAB AMC employees and trainees shall not accept any form of personal gift from industry or its representatives, regardless of the value or nature of the gift,
- b. With the exception of food provided in connection with an ACCME-accredited program and in compliance with ACCME guidelines**, meals directly funded by industry shall not be provided on the UAB AMC campus. Industry-supplied food and meals are considered personal gifts and thus shall not be permitted or accepted on the UAB AMC campus. Similarly, UAB AMC employees and trainees are strongly discouraged from participating in non-ACCME accredited industry-sponsored meals off-campus.
- c. UAB AMC employees and trainees shall not use or display industry paraphernalia in patient care areas (i.e., pens, notepads, clipboards, etc), with the single exception of educational materials. These materials may be used at the discretion of the UAB AMC employee or trainee as needed within the clinical setting, but should not be on general display.
- d. With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers where there is opportunity for critical exchange of ideas, UAB AMC employees and trainees are strongly discouraged from participating in industry-sponsored Speakers’ Bureaus. If a UAB AMC faculty member chooses to participate in an industry-sponsored, FDA-regulated program, this participation is considered external consulting and is governed by the [UAB Faculty Handbook and Policies external consulting policy \(3.5.1\)](#).

More than one presentation or seminar to a for-profit business per year requires the faculty member to seek approval for this activity.

- External consulting is allowed if it
 - a) does not interfere with faculty member responsibilities,
 - b) is limited in time,
 - c) is compatible with UAB interests, and
 - d) requires no significant use of UAB resources or facilities.

Prior approval must be received before external consulting services for a non-UAB entity may be performed. Faculty should complete the Faculty/Staff Disclosure for External or Internal Activity/Sponsored Research Submission that can be accessed through the UAB CIRB website (www.uab.edu/cirb). Faculty also are responsible for ensuring that consulting activities are conducted in accordance with UAB policies on conflicts of commitment and conflicts of interest, as well as UAB policies on disclosure of discoveries and inventions, patents, and computer software. When participating in consulting activities outside of UAB, the faculty member should not allow the name of the University of Alabama at Birmingham or UAB Health System to appear in any such manner as to indicate that UAB is participating in, or in any way is sponsoring, the activity or the project.

- The [Conflicts of Commitment Policy](#) requires written disclosure of the conflict to the appropriate UAB administrative officials, resolution of the conflict, and management of the conflict if permission to participate in the activity is granted.
- The [Conflicts of Interest Policy](#) requires written disclosure of the conflict to the appropriate UAB administrative officials, a determination of the conflict, resolution of the conflict, and a management plan.

e. UAB AMC employees or trainees who are simply attending a CME or other instructional activity and are not speaking or otherwise actively participating or presenting at the meeting may not accept compensation for attending the event; may not accept compensation for defraying costs related to attending the event; and may not accept personal gifts from industry at such events.

Relevant References and Policies

- [UAB Conflicts of Interest Policy](#)
- [UAB Conflicts of Commitment Policy](#)
- [FDA Guidance for Industry: Industry Supported Scientific and Educational Activities](#)
- [UAB Hospital Interdisciplinary Standard: Gifts and Gratuities](#)
- [UAB Health System Administrative Standard: Interaction with Vendors](#)
- [UAB Health System Administrative Standard: Conflict of Interest](#)

2. INVOLVEMENT IN PURCHASING DECISIONS

UAB AMC believes the management of potential conflicts of interest in purchasing decisions is best managed on a case-by-case basis. Therefore, to facilitate individual review of these cases, UAB AMC employees and trainees will: 1) complete annual disclosure statements listing their financial interests (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of a compensated relationship) with industry, and 2) when involved in evaluating or recommending the purchase of products or services to a UAB AMC entity, affirmatively disclose their financial interests with all potential vendors in the manner set forth by that UAB AMC entity. For purposes of this provision, financial relationship does not include the indirect ownership, through mutual funds or other investment vehicles, of equities in publicly

traded companies. UAB AMC purchasing entities will have access to the annual disclosure statements for purposes of working with the UAB AMC employee and trainee involved to review each case and take appropriate action with respect to evaluations or recommendations for the purchase of products or services from industry that involve potential conflicts of interest. The actions may range from recusal of the UAB AMC employee and/or trainee from the procurement decision altogether to a request for additional opinions from physicians who do not have a financial interest in the vendor. Participation in UAB AMC committees, such as the UAB Health System Infection Control Committee, and the UAB Health System Pharmacy and Therapeutics Committee, which recommends specific vendor products, will also be subject to annual disclosure statements and case-by-case review for potential conflicts of interest.

Relevant References and Policies

- [UAB Health Administrative Standard: Conflict of Interest](#)
- [UAB Conflicts of Interest Policy](#)
- [UAB Conflicts of Commitment Policy](#)

3. ACCESS TO CLINICAL FACILITIES BY VENDORS

UAB AMC employees and trainees shall request vendors to comply with the [UAB Health System clinical facility standards for vendor access to the clinical facilities](#), which include registration and issuance of a UABHS ID badge. Vendor representatives should come to the clinical facilities only by appointment with a physician and no trainee should meet with a vendor representative unless a faculty representative is also present. Vendor representatives should not be present in patient care areas except that vendor representatives, such as device manufacturer representatives, who are appropriately credentialed by the UAB Health System clinical facility, may be present in patient care areas to provide in-service training or assistance on devices and equipment.

Relevant References and Policies

- [UAB Health System Administrative Standard – Interactions with Vendors](#)
- [UAB Hospital Interdisciplinary Standard – Vendor Representatives](#)
- [UAB Hospital Interdisciplinary Standard – Vendor Representatives in the Perioperative Division](#)
- [UAB Hospital Laboratory Standard – Outside Vendors](#)
- [UAB Hospital Interdisciplinary Standard – Activities of Pharmaceutical Vendor Representatives](#)
- [The Kirklin Clinic/Affiliated Clinics: Vendor Regulations](#)

4. PROVISION OF FREE DRUG SAMPLES TO UAB AMC EMPLOYEES AND TRAINEES FOR PERSONAL USE

- a. Free drug samples or vouchers for free drug samples shall be considered personal gifts, and shall not be accepted or used by individual UAB AMC employees and trainees or their family members. However, free drug samples for patients may be accepted and distributed in accordance with policies (see below) of the UAB Health System clinical entities.
- b. UAB AMC employees and trainees shall not sell or bill drug samples to patients or third-party payers.

Relevant References and Policies

- [The Kirklín Clinic / Affiliated Clinics Interdisciplinary Standard: Medication Samples](#)
- [UAB Hospital Interdisciplinary Standard: Medication Samples](#)

5. INDUSTRY SUPPORT FOR EDUCATIONAL EVENTS ON THE UAB AMC CAMPUS

UAB AMC employees and trainees should be aware of the [Standards for Commercial Support established by the Accreditation Council for Continuing Medical Education \(ACCME\)](#). The UAB Division of Continuing Medical Education (CME) has established policies and procedures that address educational programs for practicing clinicians, including residents and fellows. These policies are available at <http://www.cme.uab.edu>.

All educational events sponsored by industry on the UAB AMC campus must be fully compliant with ACCME guidelines, regardless of whether formal CME credit is awarded or not. In addition, all events sponsored by UAB AMC, including those in an off-campus setting, must comply with ACCME guidelines and policy established by the UAB Division of CME. The ACCME guidelines now require that, if an event is to qualify for CME credit, its provider must ensure the following:

- a. All decisions concerning educational needs, objectives, content, methods, evaluation and speaker are made free of a commercial interest (ACCME Standard 1.1);
- b. A commercial interest is not taking the role of non-accredited partner in a joint sponsorship relationship (ACCME Standard 1.2);
- c. All persons in a position to control the content of an educational activity have disclosed all relevant financial relationships to the provider of the CME. A relevant financial relationship is defined as one which an individual (or spouse or partner) has with a commercial interest that benefits the individual in any financial amount that has occurred within the past 12 months; and the opportunity to affect the content of CME about the products or services of the commercial interest. Failure to disclose these relationships will result in disqualification of the individual from participating in the CME activity or its planning or evaluation (ACCME Standards 1.1, 1.2);
- d. The lecturer explicitly describes all his or her related financial relationships to the audience at the beginning of the educational activity in accordance with national ACCME standards. If an individual has no relevant financial relationship, the learners should be informed that no relevant financial relationship exists (ACCME Standard 6.1, 6.2);
- e. All conflicts of interest should be identified and resolved prior to the educational activity being delivered to learners (ACCME Standard 2.3). Examples of strategies to resolve conflicts of interest include severing the financial ties with the commercial entity that gives rise to the conflict, having a third party without a conflict conduct the educational event, or having the content of the educational materials reviewed and endorsed by a peer expert who does not have a conflict of interest;
- f. Written policies and procedures that govern honoraria and reimbursement of out of pocket expenses for planners, teachers, and authors are in place (ACCME Standard 3.7);
- g. Product-promotion material or product-specific advertisements of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same

products or subjects must be avoided. Live (staffed exhibits, presentation) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME (ACCME Standard 4.2);

h. A commercial interest is not used as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities (ACCME Standard 4.5);

i. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest (ACCME Standard 5.1);

j. Attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, lodging, honoraria, or personal expenses) (ACCME Standard 3.12);

In addition to the aforementioned ACCME Standards and consistent with Guideline 1 of this policy, educational events sponsored by industry on UAB AMC campus shall comply with the following provisions:

a. Personal gifts of any type shall not be distributed to attendees or participants before, during, or after the meeting or lecture, other than educational materials as set forth in #1;

b. Funds for educational activities shall be provided to a central fund managed by a department or division administrative office and not to individuals for specific educational activities.

Relevant Policies and References

- [ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities](#)
- [UAB Continuing Medical Education](#)

6. GUIDELINES FOR DELIVERING AND PARTICIPATING IN INDUSTRY-SPONSORED LECTURES AND CONFERENCES AND MEETINGS OF UAB AMC EMPLOYEES AND TRAINEES OFF OF THE UAB AMC CAMPUS

Clinical meetings and scientific meetings sponsored by professional societies frequently derive a portion of their support from industry. Such sponsorship may give rise to inappropriate industry influence on the content of the conference or its attendees. Grants for meetings and conferences that originate from the company's marketing division may be particularly problematic. UAB AMC employees or trainees should actively participate (e.g., as a lecturer or organizer) only if:

a. Financial support by industry is fully disclosed at the meeting by the sponsor;

b. The meeting or lecture's content, including slides and written materials, are directly created by and/or approved by the UAB AMC employee or trainee;

c. The lecturer is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse;

- d. The UAB AMC employee or trainee is not required by the company sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor's contribution of funds or services;
- e. The UAB AMC employee or trainee receives compensation only for the services provided and the compensation is at a reasonable rate.
- f. The lecturer explicitly describes all his or her related financial interests (past, existing, or planned) to the audience;
- g. The UAB AMC employee should not facilitate the participation of UAB AMC trainees in industry-sponsored events that fail to comply with these standards.

7. DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

- a. UAB AMC employees and trainees must disclose all of their related financial interests, including past (prior year), existing or expected interests (e.g., grants and sponsored research, compensation from consulting, advisory boards; investments and ownership interests) to journal editors in manuscripts submitted for publication, and audiences at lectures or presentations;
- b. UAB AMC employees and trainees must provide specific written information on financial interests with industry in accordance with all UAB policies, including, but not limited to, the outside consulting policy, and Conflict of Interest Review Board policies.
- c. UAB AMC employees with supervisory responsibilities for trainees or staff must ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the activities or responsibilities of the trainee or staff member.

8. EDUCATION OF UAB AMC EMPLOYEES AND TRAINEES REGARDING INDUSTRY RELATIONSHIPS

The policies outlined in this document apply to the full spectrum of education, beginning with students and continuing into the post-graduate years, residency, and beyond.

- a. Individual departments must provide education to trainees and appropriate staff regarding potential conflicts of interest inherent in industry interactions. This education should include data interpretation techniques as well as an emphasis on evidence-based medicine. Appropriate venues for such education include departmental grand rounds, regularly occurring clinical teaching conferences.
- b. Medical student education must include techniques to minimize conflict of interest and bias in clinical decision making when interacting with industry representatives. Appropriate venues for such education include courses and special topics such as, Doctor Patient and Society, Introduction to Clinical Medicine, and Evidence-Based Medicine. In addition, such education should be formally incorporated into the didactic portion of the clinical clerkships.
 - b.1. Medical students have multiple opportunities to work with the clinical (formally "voluntary") faculty during their clinical training, especially in outpatient settings. While engaged in teaching medical students, these clinicians should be given copies of these Guidelines so that they understand and respect the conduct expected of the medical students.

b.2. Individual departments are responsible for educating their respective clinical faculty on these policies, and reminding them that when medical students are working with them, they should be adhering to these guidelines.

b.3. At the end of each rotation, students should evaluate compliance with these guidelines by their clinical faculty preceptors; this will require the addition of an additional item to their current evaluation screen online.

b.4. Department chairs should be provided with the above feedback and given pooled data for consideration during the process of periodic reappointment of clinical faculty in their respective departments.

c. Any scholarships or other educational funds from industry or professional societies must be managed by the UAB AMC and not by the recipient of the award. These funds will only be accepted if there are not conditions or requirements for the use of these funds other than to support the work of the trainee or faculty member scientifically and educationally. The management of these funds will be at the discretion of the UAB AMC.

9. GHOSTWRITING

UAB AMC employees and trainees may not allow their professional presentations of any kind, to be ghostwritten by any party. UAB AMC employees and trainees who serve as authors should comply with the standards listed in the [Uniform Requirements](#) for the conduct and reporting of research.

Relevant Policies and References

- [Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, Updated October 2007.](#)

10. ENFORCEMENT

As clearly stated in the UAB Faculty Handbook “a key strategic goal of UAB is to create and maintain a positive, supportive, and diverse work/study environment where faculty, staff, and students can excel.” To fulfill this goal, UAB expects that faculty, staff, and administrators will display professionalism as applicable to teaching, research and institutional service. Violation of the “The University of Alabama at Birmingham School of Medicine and UAB Health System Guidelines for Relationships with Industry” is a violation of professional behavior and may result in the taking of disciplinary action up to, and including, discharge.

References:

The following references were utilized in the compilation of these Guidelines:

1. American Medical Association. Opinion of the Council on Ethical and Judicial Affairs, E-8.061 <<http://www.ama-assn.org/ama/pub/category/4001.html>> Accessed January 20, 2005.
2. Department of Health and Human Services, Office of Inspector General. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Fed Regist2003;68:23731-43. Page 25

3. Pharmaceutical Research and Manufacturers of America. PhRMA Code on Interactions with Healthcare Professionals. Wash D.C., PhRMA, 2002.
4. Accreditation Council for Continuing Medical Education Report on Standards for Commercial Support accessed March 12, 2005 at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
5. Moses, H, et.al. Collaborating with Industry-Choices for the Academic Medical Center. N Engl J Med 347:1371-5, 2002.
6. Yale University Faculty Handbook, Section X. University Policies Concerning Teaching and Research (http://www.yale.edu/provost/handbook/handbook_x_university_policies_concerni.html)
7. Yale University Policy on Conflict of Interest and Conflict of Commitment (<http://www.yale.edu/provost/html/coi.html>)
8. Yale-New Haven Hospital and Yale-New Haven Health System Policies on Interactions with Pharmaceutical Representatives.
9. Association of American Medical Colleges. [Industry Funding of Medical Education, Report of an AAMC Task Force, June, 2008](#)

**Appendix A
Task Force Members**

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