

Vendors

Scope

The policy applies to all residency and fellowship programs at CCHS.

Purpose:

The Sponsoring Institution must maintain a policy that addresses interactions between vendor representatives/corporations and residents/fellows and ACGME-accredited programs.

Policy and Guidelines

Background

Relationships between academic communities and industry, particularly pharmaceutical firms, have come under increasing scrutiny, in large part because of both real and perceived conflicts of interest. While this perception is true in some instances, it is not so for all medical care providers. The perception of conflict results from a common practice in which some physicians receive gifts, travel and/or financial support from companies that, in turn, stand to benefit financially 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 industry employees and medical centers by government, academic institutions, and the public.

The current interface between academic medical centers (AMC) and the health care industry has resulted in standards of conduct issued by the Association of American Medical Colleges (AAMC), the pharmaceutical industry, and the medical device industry. Pharmaceutical industry standards took effect in January 2009. The AAMC and medical device industry guidelines were implemented in July 2009. Toward this end, The University of Alabama College of Community Health Sciences, which also functions as a regional campus of the University of Alabama, School of Medicine (collectively CCHS) has developed a set of standards expected of its faculty, residents/fellows and staff.

The Relationship between CCHS and Industry

At the outset, it should be recognized that CCHS and industry have a relationship that is mutually interdependent. Many CCHS investigators receive grant support for the conduct of clinical trials that enhance the wellbeing 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 CCHS is to provide outstanding, patient-centered medical care. This care must be as free as possible of both real and perceived conflicts 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. Therefore, the guiding principles for this document define a relationship with industry for all CCHS employees 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 were established to consciously and actively insulate clinical care decisions from perceived or actual benefits accrued or expected from industry. These guidelines need to be reviewed regularly and revised appropriately as the law and expectations of the public and the medical profession evolve.

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

CCHS employee or trainee refers to a physician, faculty member, resident/fellow, staff member, or other individual employed by CCHS, Capstone Health Services Foundation, and the University Medical Center. The term employee includes individuals with either full-time or part-time status and those with regular, adjunct, voluntary, visiting, or emeritus status. Trainee includes an individual who is receiving formal education from CCHS, including resident physicians, fellows, medical students, graduate students, post-doctoral scholars, “shadowing” undergraduate students, and visiting scholars and fellows.

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

CCHS campus refers to CCHS owned or leased buildings and property, including University Medical Center, UMC-Northport and Nott Hall. These guidelines are operable in clinical facilities in which “CCHS employees and trainees” practice and/or work.

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

- a. CCHS 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 are not allowed on the CCHS campus. Industry-supplied food and meals are considered personal gifts and, thus, not permitted or accepted on the CCHS campus. Similarly, CCHS employees and trainees are strongly discouraged from participating in non-ACCME accredited industry-sponsored meals off-campus.

- c. CCHS 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 within the clinical setting at the discretion of CCHS employees or trainees as needed but should not be on general display.
- d. With the exception of settings in which academic investigators present results of their industry-sponsored studies to peers, with the opportunity for critical exchange of ideas, CCHS employees and trainees are strongly discouraged from participating in industry-sponsored Speakers' Bureaus[ZL4]. If a CCHS faculty member chooses to participate in an industry-sponsored, FDA-regulated program, participation is considered external consulting.
 1. External consulting is allowed if it
 - a. does not interfere with faculty responsibilities,
 - b. is limited in time,
 - c. is compatible with CCHS interests,
 - d. requires no significant use of CCHS resources or facilities, and
 - e. otherwise complies with Faculty Handbook[ZL5] guidelines, including those on supplemental compensation, if applicable.
 2. Prior approval of the department chair and dean must be received before external consulting services for a non-CCHS entity may be performed. Faculty also are responsible for ensuring that consulting activities are conducted in accordance with CCHS and/or University of Alabama policies on supplemental compensation, conflicts of interest, financial disclosure in research, and other sponsored programs, as well as CCHS and/or University or Board of Trustees policies on disclosure of discoveries and inventions, patents, and computer software. When participating in consulting activities outside of CCHS, faculty members should not allow the name of The University of Alabama or CCHS to appear in any such manner as to indicate that CCHS is participating in, or in any way is sponsoring, the activity or project.
- e. CCHS employees and/or trainees who are simply attending a CME or other instructional activity and are not speaking or otherwise actively participating in 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.

2. INVOLVEMENT IN PURCHASING DECISIONS

CCHS 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, CCHS employees and trainees will: 1) complete annual disclosure statements listing their financial interests with industry (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of a compensated relationship), and 2) when involved in evaluating or recommending the purchase of products or services to a CCHS entity, affirmatively disclose their financial interests with all potential vendors in the manner set forth by that CCHS 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. CCHS purchasing entities will have access to the annual disclosure statements for purposes of working with CCHS employees and trainees involved to review each case and take appropriate action with respect to evaluations or recommendations for the purchase of industry products or services that involve potential conflicts of interest. Actions may range from recusal of a CCHS employee and/or trainee from the procurement decision to a request for additional opinions from physicians who do not have a financial interest with the vendor. In all circumstances, employees and trainees are required to comply with Alabama ethics laws.

3. ACCESS TO CLINICAL FACILITIES BY VENDORS

CCHS employees and trainees shall request that vendors comply with the Industry Representative Guidelines, which include registration and issuance of a CCHS visitor's pass. Vendor representatives should come to the clinical facilities only by appointment with a physician, and no trainee should meet with a vendor representative unless the meeting is for educational purposes and only if a supervising faculty representative is also present. Vendor representatives should not be present in patient care areas, with the exception of device manufacturer vendor representatives who are appropriately credentialed by CCHS and when patient consent has been received, and then only to provide in-service training or assistance with devices and equipment.

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

- a. Free drug samples or vouchers for free drug samples shall be considered personal gifts, and, therefore, cannot be accepted or used by CCHS employees and trainees or their family members. Drug vouchers may be accepted and distributed to patients.
- b. CCHS employees and trainees shall not sell or bill drug samples to patients or third-party payers.

5. INDUSTRY SUPPORT FOR EDUCATIONAL EVENTS ON THE CCHS CAMPUS

CCHS employees and trainees should be aware of the Standards for Commercial Support established by the Accreditation Council for Continuing Medical Education (ACCME).

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

- a. All decisions about educational needs, objectives, content, methods, evaluation, and speakers are made free of a commercial interest (ACCME Standard 1.1);
- b. A commercial interest is not taking the role of a 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 in which: an individual (or spouse, or partner) has with a commercial interest that has benefited the individual in any financial amount within the past 12 months; and an opportunity exists to affect CME content with products and/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 of 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); (slide at the beginning of presentation is acceptable)
- 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 are 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, presentations) 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 of quality in health care 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 the CCHS 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 Guideline 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

6. GUIDELINES FOR CCHS EMPLOYEES AND TRAINEES DELIVERING AND PARTICIPATING IN INDUSTRY-SPONSORED LECTURES, CONFERENCES, AND MEETINGS OFF OF THE CCHS CAMPUS (ALL FACULTY, STAFF, AND TRAINEES SHOULD ADHERE TO THESE STANDARDS):

Clinical 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 a company's marketing division may be particularly

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

7. DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY (Include general disclosure form with contracts each year)

- a. CCHS employees and trainees must disclose all 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 to audiences at lectures or presentations.
- b. CCHS employees and trainees must provide specific written information on financial interests with industry in accordance with all CCHS and University policies, including, but not limited to, the Faculty Handbook Supplemental Compensation Policy, and The University of Alabama Policy on Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs.
- c. CCHS employees with supervisory responsibilities for staff or trainees 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 CCHS 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 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.
 1. Medical students have multiple opportunities to work with the clinical faculty during their clinical training, especially in outpatient settings. While engaged in teaching medical students, clinicians should be given copies of these guidelines so that they understand and respect the conduct expected of medical students.
 2. Individual departments are responsible for educating their respective clinical faculty about these policies, and reminding them that when medical students are working with them, clinical faculty should adhere to these guidelines.
 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.
 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 CCHS 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 CCHS.

9. GHOSTWRITING

CCHS employees and trainees may not allow their professional presentations to be ghostwritten by any party. CCHS 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. [ZL6]

10. ENFORCEMENT

Violation of these guidelines 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/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/ceja-reports.page>.
2. Department of Health and Human Services, Office of Inspector General. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Fed Regist2003;68:23731-43. Page
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/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>.
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)

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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

The policy can also be viewed at <https://intranet.cchs.ua.edu/administrative-resources/cchs-policies/guidelines-for-relationships-with-industry/>.