

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 10	Ethics, Standards of Conduct, and Relationships with External Entities	Effective:	January 2008
Section 10.1	Ethics, Standards of Conduct and Relationships with External Entities	Revised:	November 2015
Policy 10.1.11	Guidelines for Interactions Between Clinicians and Researchers With Industry	Responsible Party:	Vice President for Research

GUIDELINES FOR INTERACTIONS BETWEEN CLINICIANS AND RESEARCHERS WITH INDUSTRY

Overview

The overriding goal of these guidelines is to ensure to the fullest extent possible that the integrity of clinical and research decision making is not compromised by financial or other personal relationships with industry. The guidelines are intended to meet this goal by setting standards for the interactions of Health Science Center clinicians and researchers with representatives of industry, primarily the pharmaceutical clinical device, laboratory equipment, and supplies sectors. The guidelines apply to all Health Science Center clinicians and researchers at both faculty and training levels.

Industry plays a vital role in drug discovery, technology development, and improving the public health. The Health Science Center is eager to promote a mutually beneficial relationship with industry, one that facilitates discovery and evidence-based use of medications and devices and is characterized by the highest professional standards of ethics and integrity. These guidelines specifically seek to preserve and fortify the autonomy of our faculty and trainees, ensure that we incorporate the most objective information in the care of our patients, and the performance of research, reduce the potential for real or perceived bias in our programs of clinical care, research and education, and ensure compliance with the law. The complexities of relationships with industry preclude the identification of all specific circumstances in which a conflict of interest or commitment may arise or in which an interaction may be inappropriate. It is clear, however, that the guiding principles in unclear situations should be to protect the interests of our patients and the independence of our faculty.

Adherence to all provisions of the guidelines is strongly encouraged and expected in order to avoid conflicts of interest in clinical practice and research, the appearance of such conflicts, and statutory violations.

Clinical Practice Sites

Health Science Center clinicians carry out their clinical and academic activities in multiple venues. The interpretation of the guidelines may be

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specific by site. All guidelines apply fully and precisely as stated when the clinician is present in the facilities of the Health Science Center, including leased space and facilities operated by UT Medicine. When faculty are present in the facilities of a Health Science Center affiliate (e.g. University Health System, South Texas Veterans Health Care System, Christus Santa Rosa Health Care), they should abide by the guidelines of either the Health Science Center or the affiliated organization, whichever is more strict with respect to the particular action in question. For example, an action that is permitted by the Health Science Center, but restricted by the affiliated organization would be restricted when the Health Science Center clinician is practicing in the affiliated organization. Analogous considerations apply to Health Science Center researchers, who may occasionally carry out their studies at outside venues.

Definitions

CLINICIANS: Means faculty members and trainees at all levels (students, interns, residents, fellows, post-doctoral trainees) in any patient care discipline, including specialties of medicine, dentistry, nursing, and allied health sciences.

CONTINUING PROFESSIONAL EDUCATION (CPE): Means educational activities intended for practicing clinicians, including those in medical, dental, nursing, and allied health specialties.

GIFT: Means anything of value given to a clinician or researcher directly from a representative of industry. Examples of gifts include meals, trips, event tickets, textbooks, electronic devices, flashlights, pens, and notepads. Not included are items such as product brochures, fact sheets, article reprints, and bibliographies. These lists are provided as examples only and are not intended to be comprehensive.

INDUSTRY: Means any for-profit entity or representative of such entity that develops, produces, markets, sells, or distributes drugs, biomaterials, herbal/nutritional products, devices, laboratory supplies, services, or equipment intended for use in the practice of clinical specialties or the performance of biomedical research.

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RESEARCHER(S): Means any faculty member and all others, including trainees at all levels, who are engaged in any area of basic, translational, clinical, epidemiologic, health services, or community-based research.

Policy

Specific Prohibited or Regulated Activities

1. Provision of compensation or gifts from industry to Health Science Center clinicians or researchers
 - a. Health Science Center clinicians or researchers may not accept any form of personal gift from industry or its representatives;
 - b. Meals funded directly by industry should not be provided on the Health Science Center campus, nor at Health Science Center sponsored events held in off-campus locations. In addition, Health Science Center faculty and trainees are advised to avoid participating in industry-sponsored meals off-campus. However, schools, departments, divisions, CPE offices, may receive unrestricted educational grants from industry donors in support of educational programs that are planned and carried out by these institutional components, and in such cases, a reasonable portion of the grant may be used for meals, to the extent that this is required by the timing or nature of the educational program. The use of industry funds should be disclosed to participants. Academic department Chairs and Directors should report all such industry-donated educational funds annually to the Assistant Vice President for Research and Sponsored Programs on behalf of the Vice President for Research through the appropriate Dean’s office.
 - c. A Health Science Center clinician or researcher may accept only fair market compensation for specific, legitimate services provided by him or her to industry. Payment must commensurate with time and effort. The terms of the arrangements, services provided, and compensation must be set forth in writing;

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- d. Health Science Center clinicians or researchers may not accept compensation for listening to a sales pitch (e.g., detailing) by an industry representative;
 - e. Health Science Center clinicians or researchers may not participate in or receive compensation for papers or speeches that were ghostwritten by individuals employed or retained by industry;
 - f. Health Science Center clinicians or researchers who are simply attending a CPE or other instructional activity and are not speaking or otherwise actively participating or presenting at the meeting, should not accept compensation from companies for either attending or defraying costs related to attending the meeting;
 - g. Health Science Center clinicians must consciously and actively divorce clinical care decisions (including referrals and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from any company (including but not limited to personal gifts, research funding, scholarships for CPE attendance, consulting agreements, and the like);
 - h. Health Science Center clinicians or researchers who are involved in institutional decision making concerning the approval or purchase of medications, devices, or equipment, or the negotiation of other contractual relationships with industry, must not have any financial or personal interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in companies or their employees that might benefit from the institutional decision. This provision is not intended to preclude the indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded companies by Health Science Center faculty;
 - i. Health Science Center clinicians may not receive any form of compensation for issuing or changing a patient's prescription;
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- j. Health Science Center clinicians may not receive compensation for “shadowing” or preceptor services, whereby industry representatives observe clinicians treating patients;
 - k. Industry representatives are not allowed in patient care areas. Therefore, Health Science Center clinicians should meet with industry representatives only in non-patient care areas. Exceptions are permitted when there is a clear educational or patient care benefit, for example demonstration of a patient procedure requiring technical support by industry personnel. However, access to patient care areas should be permitted only when the industry representative has been appropriately credentialed by the Health Science Center and/or the relevant clinical/hospital partner and is accompanied by a Health Science Center clinician. Moreover, representatives should not be allowed to be present during any patient care interactions, unless there has been prior disclosure to and consent by the patient.

2. Industry interactions with Health Science Center trainees

Faculty should be sensitive to potential abuses arising from direct interaction between trainees and industry representatives and should provide guidance to trainees in these matters. Health Science Center clinicians and researchers should ensure that support of either clinicians or research trainees by industry through funding mechanisms such as scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training are free of any actual or perceived conflict of interest. Industry funding of trainees is permitted only if all of the following stipulations are met:

- a. The trainee is selected by the Health Science Center school, department, division, or program;
- b. The funds are provided to the department or other appropriate institutional entity, rather than directly to the trainee;

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- c. The school, department, division, or program has determined that the conference or training experience has educational merit;
 - d. The recipient of the funds is not subject to any implicit or explicit quid pro quo (i.e., “no strings are attached”).
3. Provision of free drug, device, and other product samples to clinicians
- a. Health Science Center clinicians may accept free drug, device, or other product samples from industry only for distribution to patients;
 - b. Health Science Center clinicians should use discretion in the distribution of non-formulary drugs to patients, balancing the potential benefits (particularly for indigent patients) against the possible encouragement of the use of costlier medications;
 - c. Free drug, device, or other product samples must not be sold;
 - d. Free drug, device, or other product samples should not be used by Health Science Center clinicians or researchers for themselves or family members;
 - e. Free device samples intended for student skills practice sessions (e.g., suturing kits) should not be provided directly to trainees. Acceptance of donations of such materials from representatives of industry should be considered and managed by appropriate Dean’s office officials on a case-by-case basis, taking into account the potential for conflict of interest and professionalism risks vs. the potential benefits.
4. Industry support for educational events on the Health Science Center campus

Health Science Center clinicians and researchers should be aware of the “Standards for Commercial Support” established by

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accrediting organizations, for example the Accreditation Council for Continuing Medical Education. All educational events sponsored by industry on the Health Science Center campus must be fully compliant with the guidelines of the appropriate accrediting organization, regardless of whether formal CPE credit is awarded or not. The elements of these guidelines require that if an event is to qualify for CPE 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;
- b. A commercial interest is not taking the role of non-accredited partner (ghost sponsor) in a joint sponsor relationship;
- 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 CPE. A relevant financial relationship is defined as one in which an individual (or a family member) has received compensation of any kind within the past 12 months from an industry that offers products or services that relate to the subject of the educational activity. Failure to disclose these relationships will result in disqualification of the individual from participating in the CPE activity or its planning or evaluation;
- d. The lecturer explicitly describes all of his or her related financial relationships to the audience at the beginning of the educational activity. If an individual has no relevant financial relationship, the learners should be informed that no relevant financial relationship exists;
- e. All conflicts of interest should be identified and resolved prior to the educational activity being delivered to learners. 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;

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- f. Product promotion material and product-specific advertisements of any type are prohibited in or during CPE 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 CPE;
 - g. A commercial interest is not used as the agent providing a CPE activity to learners, e.g., distribution of self-study CPE activities or arranging for electronic access to CPE activities;
 - h. The content or format of a CPE activity or its related materials must promote improvements of quality in health care and not a specific proprietary business purpose of a commercial interest;
 - i. 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);
 - j. No gifts of any type are distributed to attendees or participants before, during, or after the meeting or lecture;
 - k. Funds to pay for the specific educational activity are provided to the school, department, division, or program and not to an individual clinician;
 - l. The CPE Office of the appropriate Health Science Center School maintains oversight of the event to assure implementation of the established standards of the appropriate accrediting organization.
5. Guidelines for delivering industry-sponsored lectures or participating in legitimate conferences and meetings of clinicians or researchers in locations other than Health Science Center facilities

Clinical meetings and scientific conferences 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.

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Grants for meetings and conferences that originate from the company's marketing division may be particularly problematic. Industry sponsorship takes one of two general forms and different standards apply in each case:

- a. Professional society meetings partially sponsored by industry – Health Science Center clinicians and researchers are expected to participate in meetings of professional societies as part of their CPE and professional obligations. Nonetheless, faculty should be aware of the potential influence of industry on these meetings and attentive to the guidelines set forth below in evaluating whether and how to attend or participate in these meetings.
- b. Meetings fully sponsored by industry – The guidelines apply to all lectures, meetings, and related publications sponsored directly by industry or by intermediate educational companies subsidized by industry. Health Science Center clinicians and researchers may actively participate (e.g., by giving a lecture, organizing the meeting) in such meetings or lectures only if:
 - i. Financial support by industry is fully disclosed at the meeting by the sponsor;
 - ii. The meeting or lecture content, including slides and written materials, is determined independently by the Health Science Center faculty member;
 - iii. The lecturer is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse;
 - iv. The Health Science Center faculty member 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;

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- v. The lecturer explicitly describes all of his or her relevant financial interests (past, existing, or planned) to the audience;
 - vi. Attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses or provision of gifts);
 - vii. No gifts of any type are distributed to attendees or participants before, during, or after the meeting or lecture;
 - viii. The Health Science Center faculty member receives compensation and expense reimbursement only for the services provided and the compensation is reasonable;
 - ix. Time spent in preparing and delivering the lectures does not impair the Health Science Center faculty member's ability to fulfill institutional responsibilities;
 - x. The lecturer makes clear to the audience that the content of the lecture reflects the views of the lecturer and not the Health Science Center;
 - xi. Health Science Center faculty members must not facilitate the participation of Health Science Center trainees in industry-sponsored events that fail to comply with these standards.

6. Disclosure of relationships with industry

As required by [Section 10.1.6](#), "Conflicts of Interest in Research and Disclosure" and [Section 10.1.9](#), "Conflict of Interest, Conflict of Commitment and Outside Activities" of the *Handbook of Operating Procedures* (HOP), all Health Science Center faculty members must make an annual report of their financial interests as defined by the policy. In addition, Health Science Center faculty shall:

- a. Disclose as part of their annual financial interests report, all of their relevant financial interest, including recent past (one year), existing, and expected interests (e.g., grants and sponsored

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research, compensation from consulting, speakers' bureaus, advisory boards, investments and ownership interests) to journal editors in manuscripts submitted for publication and to audiences at lectures and presentations;

- b. Consistent with Health Science Center policy, disclose their real, perceived, and potential conflicts of interest related to any institutional deliberations and generally refrain from participating in deliberations in which he or she has a real, perceived, or potential conflict of interest;
- c. Ensure that their real, perceived, and potential conflicts of interest do not affect or appear to affect the supervision of the activities or responsibilities of any trainee or staff member.

Disclosure to Patients

In addition to the disclosure requirements of this policy and those of [Section 10.1.6](#) "Conflicts of Interest in Research and Disclosure" and [Section 10.1.9](#), "Conflict of Interest, Conflict of Commitment and Outside Activities" of the HOP, a Health Science Center physician or other health professional who has a Significant Financial Relationships with a commercial health care company that manufactures implantable medical devices (including but not limited to joint prosthesis, dental implants, cardiac pacemaker, automated implantable cardioverter-defibrillator), must disclose to their patient this financial relationship as an integral element of obtaining the patient's consent to implant the device. Such disclosure must be documented in the patient's medical record.

It is also expected that Significant Financial Relationships with commercial companies, other than those specifically listed above, will warrant patient disclosure when a Health Science Center physician or other health professional recommends, prescribes, or uses that company's medical device, pharmaceutical, or medical care-related product in their patients. Prudent record-keeping practices under these circumstances should include written documentation of these discussions by the practitioner.

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Disciplinary Action

Violations of these guidelines are subject to disciplinary action as described in [Section 2.1.2](#) of the HOP or in the Graduate Medical Education [Policy 2.1.1](#), "GME General Policies".
