

Section 6 Subject 6.1	Compliance Policies General Compliance	03/28/08 – Originated 02/19/14 – Reviewed w/ changes - Reviewed w/o changes 02/01/14 - Effective Office of Institutional Compliance - Author
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Policy 6.5.2 Ethical Interactions with Industry

Ethical Interactions with Industry

Definitions

Clinician: includes faculty members, employees, 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.

Compensation: any form of benefit, including but not limited to salary, retainer, honoraria, intellectual property rights or royalties, or promised, deferred, or contingent interest. It also includes sponsored travel or reimbursement unless paid for by a Federal, state, or local agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Conflict of Commitment (COC): a state in which the time or effort that a UTMB employee devotes to an outside activity directly or significantly interferes with the employee’s fulfillment of his or her institutional responsibilities or when the employee uses State property without authority in connection with the employee’s outside employment, board service, or other activity. Exceeding the amount of total time permitted by U.T. System or UTMB policy for outside activities creates the appearance of a conflict of commitment.

Conflict of Interest (COI): a significant outside interest of a UTMB employee or one of the employee’s immediate family members that could directly or significantly affect the employee’s performance of his or her institutional responsibilities. The proper discharge of an employee’s institutional responsibilities could be directly or significantly affected if the employment, service, activity, or interest: (1) might tend to influence the employee’s conduct or decisions; (2) could reasonably be expected to impair the employee’s judgment in performing his or her institutional responsibilities; or (3) might require or induce the employee to disclose confidential or proprietary information acquired through the performance of institutional responsibilities.

Continuing Professional Education (CPE): educational activities intended for practicing clinicians, including those in medical, dental, nursing, and allied health specialties.

Exempt Employee: an employee who has been determined to be exempt from the Fair Labor Standards Act and is, therefore, not entitled to overtime pay.

Full-Time Faculty Member: an employee who has a nine (9) or 12 (twelve) month faculty appointment and receives any compensation or benefits from UTMB regardless of the source of funds or assignment during the year.

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**Definitions,
continued**

Gift: anything of value, including, but not limited to cash, securities, bequest/trust distributions, life insurance, real estate, loans, gift cards, tickets to entertainment or sporting events, and food given to UTMB, a department/institute, and/or a UTMB employee by a third party. NOTE: salary, honoraria, expense reimbursements, and other such payments for services are not considered gifts. These payments are considered compensation for disclosure purposes.

Honoraria: a payment provided to a UTMB employee from an academic entity, professional service organization, non-profit organization, federal or state agency, foundation, or other similar entity outside UTMB for service provided to the entity, speaking engagement or other public appearance that is beyond the employee’s normal responsibilities to UTMB. Payments from private, for-profit, health-care related Industry shall not be considered honoraria.

Immediate Family Members: Include:

- a) a spouse;
- b) a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and
- c) a related or non-related, unmarried adult who resides in the same household as the individual and with whom the individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

Industry: includes any for-profit entity or representative of such entity that develops, produces, markets, sells, or distributes drugs, biomaterials, herbal/nutritional products, devices (including durable medical devices), services (including home health care services), hospice care, or equipment intended for use in the practice of clinical specialties.

Industry Vendor: any sales representative or account executive and includes, but is not limited to, any sales representative, pharmaceutical representative, clinical educator, scientific liaison, or equipment or device manufacturer representative.

Institutional Responsibilities: any professional responsibility performed by an Institutional Official on behalf of UTMB.

Researcher(s): includes 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.

Vendor: any individual or company that has sold, currently sells, or may sell goods and/or services to UTMB.

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Policy

This policy applies to all UTMB employees and must be followed in addition to IHOP 6.5.1 – *Research Conflicts of Interest*; IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*, IHOP 6.5.4 – *Institutional Conflicts of Interest*, and other IHOP policies where applicable.

Appropriate ethical behavior requires adherence to well-defined policies to guide interactions between UTMB faculty, trainees, and staff and those who provide items and services necessary for the University to carry out its professional duties. Furthermore, it is important for our relationships with our patients, students, and the public that we be free of conflicts of interest, conflicts of commitment, and to the extent possible, perceptions of such conflicts. This policy is intended to guide interactions of all members of the UTMB community with employees of companies that promote and sell biomedical, scientific, or pharmaceutical products or services. This policy is not intended to address employers (including vendors) that are invited onto the UTMB campus for the purpose of providing UTMB students with potential employment information (*i.e.*, job fairs). Such on-campus activity will require institutional approval by the appropriate dean or the Purchasing Department.

This policy is divided into the following nine (9) sections:

1. [Conflict of Interest Official and Conflict of Interest Committee;](#)
2. [Request for Prior Approval to Engage in Outside Activities;](#)
3. [Disclosure of Relationships with Industry and Industry Vendors;](#)
4. [Gifts, Meals, and Compensation;](#)
5. [Industry Access to UTMB, Industry Interactions with Patients and UTMB Trainees, and Provision of Free Drug, Device and Other Product Samples;](#)
6. [Industry Support for Educational Events on the UTMB Campus;](#)
7. [Guidelines for Delivering Industry-Sponsored Lectures or Participating in Legitimate Conferences and Meetings of UTMB Employees in Locations Other than UTMB Facilities;](#)
8. [Enforcement and Compliance;](#)
9. [Audits.](#)

Section 1:
Conflict of Interest Official (COIO) and Conflict of Interest Committee (COIC)

Conflict of Interest Official:

The President of UTMB is responsible for overseeing implementation of this policy and may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable federal and state regulations and policies.

The UTMB President shall appoint a Conflict of Interest Official (COIO), who shall report to the UTMB President regarding all conflicts of interest activities. The COIO shall perform the duties required by this policy and other duties as assigned by the President. Additionally, the UTMB President shall establish

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**Section 1:
Conflict of
Interest Official
(COIO) and
Conflict of
Interest
Committee
(COIC),
continued**

processes for the review of conflict of interest disclosure statements, for managing, reducing, or eliminating conflicts of interest, and for resolving disputes related to managing, reducing, or eliminating conflicts of interest.

Conflict of Interest Committee:

Upon recommendation of the COIO, the UTMB President shall appoint a Conflict of Interest Committee (COIC) to fulfill the duties prescribed in this policy. The COIC shall consist of: faculty members and administrators from academic, clinical, and basic science departments; representative from various university areas such as Research Services, UTMB’s Human Research Protection Program, Purchasing, Office of Institutional Compliance, and Legal Affairs, as well as representatives from the local Galveston County community.

The COIC shall meet as necessary to review disclosures and other related issues brought to the attention of the Committee. The COIC shall make recommendations as needed including the design of management plans in order to manage, reduce, or eliminate identified conflicts of interest.

**Section 2:
Request for Prior
Approval to
Engage in
Outside Activities**

Please see Section 2 of IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* for prior approval requirements.

**Section 3:
Disclosure of
Relationships
with Industry
and Industry
Vendors**

Please see Section 3 of IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities* for disclosure requirements.

NOTE: If you are engaged in organized research activities or responsible for the design, conduct or reporting of research, including a principal investigator, co-investigator, faculty agent, research tech, research nurse, staff, fellow or administrator who participates in research, please see Section 4 of IHOP 6.5.1 – *Research Conflicts of Interest* for annual disclosure requirements.

**Section 4:
Gifts, Meals, and
Compensation**

Unsolicited gifts from patients and/or patients’ family members may be accepted so long as they are of reasonable value, e.g., small gift baskets, and are not given to influence or with the intent to influence care or secure preferential treatment. Gifts of cash or cash equivalents from patients and/or patients’ families provided in the context of patient-care activities must be fully assigned to the Institutional Trust Fund as required by UTMB’s MSRDP Faculty Practice Plan Bylaws.

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**Section 4:
Gifts, Meals, and
Compensation,
continued**

Provision of compensation or gifts from industry to UTMB clinicians or researchers:

1. UTMB clinicians or researchers may not accept any form of personal gift from industry or its representatives except if provided as an exception in the examples of prohibited gifts below;
 - a. Prohibited gifts include meals, services, and entertainment that are not provided as part of appropriately sanctioned educational activities (*e.g.*, scientific or educational meetings);
 - b. Meals funded directly by industry should not be provided on the UTMB campus, nor at UTMB-sponsored events held in off-campus locations that are not provided as part of appropriately sanctioned educational activities (*e.g.*, scientific or educational meetings);
 - c. Unrestricted educational grants may be accepted from industry donors in support of both Continuing Professional Education (CPE) (such as CME) and non-CPE educational programs that are planned and carried out by these institutional components. Only department chairs, training program directors, deans, or their designees may apply for such grants. In such cases, a reasonable portion of the grant may be used for meals, to the extent that it is required by the timing or nature of the educational program. The use of industry funds should be disclosed to participants. Documentation for all such educational grants should be provided to the Provost’s Office;
 - d. A UTMB employee 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. The UTMB employee must adhere to the requirements of IHOP 6.5.3 to request and obtain approval for the outside activity. (*See IHOP 6.5.3 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*);
 - e. UTMB clinicians or researchers may not accept compensation for listening to a sales pitch (*e.g.*, detailing) by an industry representative;
 - f. UTMB clinicians or researchers may not participate in or receive compensation for papers or speeches that were ghostwritten by individuals employed or retained by industry;
 - g. UTMB 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

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- compensation from companies for either attending or defraying costs related to attending the meeting;
- h. Although discouraged, this policy is not intended to prohibit UTMB personnel attending a conference or other event at an off-campus site from accepting Industry gifts offered for free to all conference attendees (*e.g.*, pens);
 - i. This policy is not intended to prohibit industry support of post-purchase training or product support. Such industry support should be provided for by contract and adhere to the requirements of IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*;
 - j. UTMB 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);
 - k. UTMB clinicians, researchers, or other employees 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 UTMB faculty (*See* IHOP 6.5.4 – *Institutional Conflicts of Interest*);
 - l. UTMB clinicians may not receive any form of compensation for issuing or changing a patient’s prescription;
 - m. UTMB clinicians may not receive compensation for “shadowing” or preceptor services, whereby industry representatives observe clinicians treating patients

NOTE: For more information regarding what gifts or benefits a UTMB employee may or may not receive, please consult IHOP 6.5.5 – *Gifts, Honoraria, Fundraising, and Other Activities*.

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Section 5:
Industry Access to UTMB, Industry Interactions with Patients and UTMB Trainees, and Provision of Free Drug, Device and Other Product Samples

(6) Industry Access to UTMB and Patients:

- a. Industry representatives are not allowed in patient care areas except as detailed in sub-sections (e) and (f) below. UTMB clinicians should meet with industry representatives only in non-patient areas. Industry vendors must make an appointment to meet with clinicians in offices or laboratories on a per-visit basis or as a standing appointment, subject to verification. Vendor access procedures are discussed in IHOP 9.7.2 – *Vendor Visitation: UTMB Clinical Enterprise* and UTMB’s Vendor Code of Conduct, and must be followed by all vendors;
- b. Industry vendors may not demonstrate or promote products in public areas, including but not limited to, inpatient or outpatient care units, clinics, and common areas;
- c. Industry vendors are specifically prohibited from directly contacting students, residents, and postdoctoral fellows for the purpose of promoting professional products or for distributing materials of any type. This policy specifically prohibits the provision of free beverages or meals, tickets to entertainment and sporting events, or other types of social functions;
- d. Industry vendors who desire to provide educational material to members of the aforementioned groups in sub-section (c) must contact the appropriate training director. The training director will review all material for the accuracy and appropriateness of the educational content and will then make decisions about the proper forum for making the information available to the trainees;
- e. Industry vendors are prohibited from entering patient care areas within the medical center for promotional purposes. This policy does not preclude vendors from working with clinicians in patient care areas for the purpose of evaluating or testing new technologies or services, setting up new equipment or devices already purchased or approved for purchase, or similar activities associated with a contractually agreed to business purpose. Such services must be provided by appointment;
- f. Industry vendors are not permitted to touch or treat patients or undertake any activities that could be construed as patient care unless:
 - (1) The industry vendor is a Physician, Nurse Practitioner or Physician Assistant and has been credentialed by Medical Staff Services; or
 - (2) The industry vendor is a technician or individual with unique skills that will aid in the care of UTMB patients and this

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individual’s qualifications have been reviewed by Human Resources through the vendor competency process. For individuals who qualify under this provision, they may not touch or treat patients but may advise UTMB providers on customized care associated with their products or services when the individual has the required expertise and experience. Clinicians involved in such evaluations or testing are advised to seek clarification from the UTMB Institutional Review Board (IRB) regarding whether the activity qualifies as human subject research;

- g. Industry vendors shall not attend programs in which specific patients are identified or when quality assurance or risk management issues are presented;
- h. Events such as vendor shows may occur on campus under limited circumstances and only through written approval by the Purchasing Department;
- i. Information on the formulary status of new medications can be obtained by appointment in the hospital pharmacy

2. Industry Interactions with UTMB trainees

- a. UTMB 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. UTMB 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.
- b. Industry funding of trainees is permitted only if all of the following stipulations are met:
 - (1) The trainee is selected by the UTMB school, department, division, or program;
 - (2) The funds are provided to the department or other appropriate institutional entity, rather than directly to the trainee;
 - (3) The school, department, division, or program has determined that the conference or training experience has educational merit;
 - (4) The recipient of the funds is not subject to any implicit or explicit quid pro quo (i.e., “no strings are attached”).

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- 3. Provision of Free Drugs, Device, and Other Product Samples to Clinicians**
- a. With rare exceptions, product samples may not be left by vendor representatives in any inpatient or outpatient clinical area. Rare exceptions to this prohibition (e.g., some injectable drugs, HIV drugs) may be authorized under limited circumstances for good cause.
 - b. Authorization to receive and distribute samples in inpatient and outpatient clinical areas must be obtained from the Chief Medical Officer for the UTMB Health System. This authorization requirement is not intended to apply to University-approved patient assistance programs.
 - c. Product samples may not be evaluated for institutional purchase for patient use without going through the Value Analysis Process and being presented to the appropriate Cost Management Team.
 - d. UTMB 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.

**Section 6:
Industry Support
for Educational
Events on the
UTMB Campus**

UTMB clinicians should be aware of the Standards for Commercial Support established by accrediting organizations such as the [Accreditation Council for Continuing Medical Education](#). All educational events sponsored by Industry on the UTMB 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 all of 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.

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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;
- 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, 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 UTMB School maintains oversight of the event to assure implementation of the established standards of the appropriate accrediting organization.

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**Section 7:
Guidelines for
Delivering
Industry-
Sponsored
Lectures or
Participating in
Legitimate
Conferences and
Meetings of
UTMB
Employees in
Locations Other
than UTMB
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. 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:** UTMB 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. UTMB clinicians and researchers may actively participate (*e.g.*, by giving a lecture, organizing the meeting) in such meetings or lectures only if:
 - (1) The activity is designed to promote evidence-based clinical care and/or advance scientific research and is not promotional in nature;
 - (2) Financial support by industry is fully disclosed at the meeting by the sponsor;
 - (3) The meeting or lecture content, including slides and written materials, is determined independently by the UTMB faculty member without prior approval requirements by the Industry sponsor (this restriction does not apply to input provided by government regulators);
 - (4) The lecturer is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse;
 - (5) The UTMB employee 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;
 - (6) The lecturer explicitly describes all of his or her relevant financial interests (past, existing, or planned) to the audience;

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- (7) Attendees in the audience are not compensated or otherwise materially rewarded for attendance (*e.g.*, through payment of travel expenses or provision of gifts);
- (8) No gifts of any type are distributed to attendees or participants before, during, or after the meeting or lecture **unless they are a** part of the program (*i.e.*, this is not meant to disqualify meals that are provided as part of a conference, nor those off-campus events where vendors hand out gifts of *de minimis* value such as pens, cups, markers, etc.);
- (9) The UTMB employee receives compensation and expense reimbursement only for the services provided and the compensation is reasonable with regard to fair market value.
- (10) The lecturer makes clear to the audience that the content of the lecture reflects the views of the lecturer and not UTMB;
- (11) UTMB faculty members must not facilitate the participation of UTMB trainees in industry-sponsored events that fail to comply with these standards.
- (12) These activities do not represent an unmanageable COI or COC and receive prior approval and are disclosed using the procedures outlined in IHOP 6.5.3 – *Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities*.

Participation in the following activity is not permitted:

- (a) Marketing and training programs designed solely or predominantly for sales, marketing, or promotional purposes.
 - 1. This includes Industry-sponsored speaking engagements typically referred to as "speakers bureaus" (*i.e.*, contractual relationships to give talks in which the topic(s) and/or content are provided by the company) that are solely or predominately promotional in nature. Faculty members must retain full control and authority over professional material the faculty member presents. Such communications or presentations may not be subject to approval by any commercial interest other than approval for the use of proprietary information.

NOTE: If the speaking engagement is scholarly, scientific, or academic in nature (e.g. health-related presentation to AHA), it is permissible even if it is contractually referred to as a "speakers bureau".

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Section 8:
Enforcement and Compliance

State Laws and Regulations and Institutional and UT System Policies:

This policy supplements, and employees are required to adhere to, federal and state laws and regulations as well as other UTMB policies, including but not limited to the Rules and Regulations of the University of Texas System Board of Regents, University of Texas System Business Procedure Memoranda, the UTMB Institutional Handbook of Operating Procedures (IHOP), and UTMB’s *Standard of Conduct Guide*.

Section 9:
Audits

The institution will provide for regular audits of financial interest disclosure statements to determine individual and institutional compliance with this policy.

Contacts

Conflicts of Interest Office
Office of Institutional Compliance
(409) 266-9435
<http://www.utmb.edu/coi>

References

[UT System Regents’ Rules and Regulations](#)

- [UT System Regents’ Rules and Regulations](#) - <http://www.utsystem.edu/BOR/rules/>
- [UTMB Standards of Conduct Guide](#) - <http://www.utmb.edu/compliance/standardsofconduct.htm>
- [UT Regents’ Rules and Regulations](#)
- UT System Rule 180
- UT System Rule 175
- IHOP 6.5.1 – Research Conflicts of Interest
- IHOP 6.5.3 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities
- IHOP 6.5.4 – Institutional Conflicts of Interest
- IHOP 6.5.5 – Gifts, Honoraria, Fundraising, and Other Activities