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| <b>UT Health Science Center:</b>  |                                     |
| <b>FI0126-H Conflict of Interests (Interactions Between Health Care Professionals and Industry)</b> |                                     |
| <b>Version 1</b>  | <b>Publication Date: 05/26/2022</b> |

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| <b>No./Title:</b> F126 – Conflict of Interests (Interactions Between Health Care Professionals and Industry) | <b>Resp. Office:</b> FINANCE   | <b>Effective Date:</b> 07/01/2016   |
| <b>Category:</b> Compliance  | <b>Last Review:</b> 10/01/2019   | <b>Next Review:</b> 10/01/2021  |
| <b>Contact:</b> Melanie Burlison, Assistant Vice Chancellor<br>Institutional Compliance Office               |  901.448.8030 |  mburlison@uthsc.edu |
| <b>Forms:</b> <a href="#">Outside Interests Disclosure Form - UTHSC</a>                                      |  |   |
| <b>Related Policies:</b> <a href="#">F125 - Conflict of Interests</a>  |  |   |

## PURPOSE

This policy is to establish guidelines for University faculty, staff, students, and residents (including dependents) interactions with external agencies.

## BACKGROUND

UTHSC Fiscal Procedure **F125 - Conflict of Interests** provides guidance for training, reporting, and managing issues related to conflicts of interest. Full time faculty, staff, students, and residents are covered by this policy 24 hours/day, on or off campus. Part time faculty are covered while in University roles, or representing the University (including simple reference to University appointment). All faculty, both full and part time, are covered by ethics rules against overt conflicts of interest at all times, as covered in other policies and procedures.

## PROHIBITION OF GIFTS AND COMPENSATION

- Soliciting or accepting personal gifts or the use of gifts, gratuities, and favors from industry representatives is not allowed, as it creates the possibility of (or appearance of) favored treatment or an unfair influence for the outside entity.
- UTHSC personnel may not accept gifts or compensation for listening to sales talks by industry representatives or prescribing medications.
- UTHSC personnel may not accept meals or other gratuities supplied directly by industry.
- Grants and gifts provided to the University to support education and development activities are permissible. However, industry officials cannot exhibit industry products, service, devices, or promotional materials directly within the education or development activity site. Such displays are permitted, however, at general vendor designated areas.

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- “In service” training and new product/technique instruction, may be allowed, subject to the following:
  - Industry access to learners shall be in controlled environments, away from patient care areas, and supervised by faculty.
  - Activities covered as accredited CME, or other accredited continuing education, are allowed, though faculty should be prudent in choice and level of participation. Gifts are not allowed here, either, although faculty may accept reduced tuition, and supported activities (including food) from the sponsoring institution (not directly from industry).
- UTHSC personnel may not accept compensation or defrayment of cost from industry sources simply for attending a continuing education event or other activity if the individual is not speaking or a course participant.
- The appropriate handling for pharmaceutical samples should be managed according to medical / dental practice plan policy.
- UTHSC personnel cannot accept authorship of material ghost written by industry (or other source), or deliver materials prepared by industry.
- Consulting agreements which provide remuneration without associated duties are prohibited.
- A faculty member/staff/student may not participate in a sponsored program if he, she, or a family member has a significant interest in the sponsoring organization. Note: This prohibition applies to any family member (not just spouse, dependent children, parents, and non-dependent children).
- UTHSC may not participate in a sponsored program if the dean, department chair, or other supervisor has a significant financial interest in the sponsoring organization.

**Appendix A:** Industry Support Sponsorship Policy Guidelines at the end of this procedure is intended to provide examples and additional guidance.

## **DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

Given that the University encourages its faculty to develop entrepreneurship and translate new discoveries/scholarship into products for public good, the following guidelines are designed to

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allow and encourage a balance between fulfilling academic responsibilities and pursuing individual interests in translational activities that may reach outside the institution and that may provide financial reward to the researcher/scholar. Faculty are required to disclose significant financial interests, including but not limited to:

- Salary for services from a single source when aggregated over 12 months expected to exceed \$5,000.
- Equity interests including gifted stock in faculty/staff/student owned companies or a company proposing to sponsor research at UTHSC.
- Intellectual property rights (patents, copyrights, and royalties)

**NOTE:** This disclosure requirement applies not only to the interests of UTHSC faculty, but also to the interests of a spouse and dependent children and in some circumstances to the interests of non-dependent children and parents. Faculty should err on the side of full disclosure of significant financial interests of non-dependent children and parents that might present an appearance of a conflict of interest.

## **EMPLOYEE REPORTING REQUIREMENTS**

Employees are notified annually to disclose outside interests on the form required by the University. This form requires the disclosure of specific outside interests that may or may not represent conflicts. New employees are required to complete and file new disclosure forms within 30 days of employment. All employees are required to take the initiative and report in writing to their immediate supervisor any conflict or potential conflict of interests involving their University duties and an outside interest as soon as it develops.

## **UTHSC ENFORCEMENT RESPONSIBILITIES**

The UTHSC Finance and Operations office has responsibility for review of potential conflict of interests and the development of oversight procedures to manage potential conflict of interests. Responsibilities include:

- a. Presenting and discussing this policy with new employees during orientation;
- b. Requiring all faculty and exempt staff to have outside interest disclosure forms on file;
- c. Notifying employees annually of their obligation to disclose in writing outside interests and activities;
- d. Instructing department heads and supervisors to ensure they understand their responsibility in identifying and reporting conflict of interests;

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- e. Establishing a committee(s) to review information disclosed by employees and determine whether conflict of interests exist;
- f. Working with employees to prevent or resolve conflicts and documenting the review of information disclosed and conflicts resolved.

## **FAILURE TO COMPLY**

Failure to comply with this policy may result in disciplinary action up to and including termination of employment.

## **APPENDIX A: INDUSTRY SUPPORT SPONSORSHIP POLICY GUIDELINES**

### **BACKGROUND**

The University should maintain clinical, educational, and research relationships with business and industry, but these should be above reproach, in order to maintain public trust. This applies in three general areas:

- For our professions as health care providers,
- For our profession as teachers and role models for our students,
- For our positions as publicly-funded and publicly-missioned individuals,

In each of these areas we have individual responsibility not only to avoid conflict of interest with our professional and salaried duties, but further to minimize even the potential appearance of conflict of interest. Avoidance of conflict of interest, both actual and perceived, is necessary to honor and protect the public trust, so that none of our University actions are swayed, or appear to be swayed, by inappropriate external influences. While more egregious violations of state and University rules are indeed criminal, the focus here is not to question motivational intent of individuals, but to affirm the integrity of the University and Professional missions.

These rules have been adopted in accord with state and university regulations, and standards laid out by various professional organizations (notably the AAMC). Regulations on financial disclosure, ethics, and procedures pertaining to research, as well as potential legal actions for infractions, are also covered by separate policy.

A legal situation is *quid pro quo*, something for something – a gift for influence, or access for potential influence. Whether access or involvement leads to actual influence may determine whether civil or criminal statutes are violated, but the professional issue remains wherever the potential is evident. That is injurious to the public trust.

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This is not policy governed for or by an individual's personal ethics, but professional and government ethics (the two may and should overlap, but are not identical). No imputations against any past actions are implied. Questions rephrasing the professional and public trust might be:

- a. In the role as a medical professional, could a patient, a peer, or a jury assume a gift, honoraria, etc. might have influenced action, even subtly?
- b. In the role as a public employee, could a reasonable citizen perceive that position was used to gain influence?
- c. In the role as educator, could a parent wonder whether curricular message has been influenced by extracurricular activities?
- d. In the role as a researcher, can peers question validity of interpretations based on external commitments?

All of these questions are phrased as potential interpretations of UT personnel action; none are phrased as intent. Intent may be weighed in disciplinary actions, but not in this policy. This policy is not personal, but professional. No individual assertions of personal integrity remove public appearance.

### **COVERED AND UNCOVERED ELEMENTS**

What is prohibited is acceptance of cash or substance from external sources (e.g., private industry, external institutions, or individuals) for either action/decision or influence; influence may be defined as simply as access, or audience, which is seen as favored treatment. This is particularly egregious when payment is to an individual.

Access to industry, even salesmen, is not prohibited. Favored access to select individuals, however, is prohibited, most especially if tied to inducement. Any transaction that is seen as a direct 1:1 exchange of some benefit for some service, such as meal payment in exchange for captive marketing access, is disallowed.

Unrestricted, or even targeted, educational or research grants are encouraged, especially in support of continuing educational activities. Indeed, activities accredited as continuing education typically have enough formal requirements to minimize conflicts, or at least to allow oversight and correction of excesses.

So, generally speaking, grants and awards are allowed, and continuing education oversight is strongly encouraged. Similar situations arise in research and development, and clinical care.

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Research grants and studies, formal contracts, formal research and business planning, such as for joint venturing, are not covered by this policy. Contracts to individuals and an individual's personal business affairs are covered by separate University policy and procedures.

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## SPECIFICS

### **A. GIFTS TO INDIVIDUALS**

The University prohibits the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees.

Financially substantive gifts, at some lower limit (e.g., \$50 or \$500), will be variably tracked and reported by industry and publicly accessible. These are inappropriate for University personnel, whether in cash or in kind (travel, equipment, services).

Trinket level gifts (pens, pocket protectors, mugs, etc.), while not financially flagrant as a gift, are not worth the potential misunderstanding of the general public, and there is also substantial business, psychological, and medical practice data that they do, in fact, influence practice, whether the practitioner is aware of the influence or not. As well, they are often obtained in that 1:1 interaction, so that appearance alone suggests exchange of individual access and potential influence for a rather cheap purchase price.

### **B. PHARMACEUTICAL SAMPLES**

In this social and medical environment, the University appreciates the generosity of support for pharmaceuticals and medical devices from industry for those patients who cannot afford them, or need a brief starter trial. In these circumstances, the most appropriate routing is to be sure the samples are directed to a common location, preferably with pharmacy oversight and dispensing, but in all cases prescriptions must be given in accordance with state law (requiring medical record keeping, provider authorization, etc.). Unfettered access by office personnel is not allowed, by this policy or state prescribing law.

Direct access to these samples (from the industry representative to University personnel) represents a prohibited acceptance of a gift, sometimes of significant value. Distribution of a sample (as in a starter kit) by another licensed provider to UT personnel (as patients) is acceptable, within medical practice standards.

### **C. SITE ACCESS BY PHARMACEUTICAL REPRESENTATIVES**

Access to faculty is not prohibited. Access to learners (students, residents, etc.) should only be in the general presence of faculty, and the faculty member should accept the responsibility to be primarily in charge of that educational encounter, both on subject matter and on the process of the interaction itself. That may entail clarification, interruption, or termination of the interaction.

Such interactions should not be in public areas, as such may be taken as obvious influence. They should be at the discretion and schedule of the practitioner, and should not interfere with schedules or patient care.

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Recognizing that new information and techniques may be appropriately communicated by industry contact, access to educational venues may be offered:

- a. Legitimate and qualified continuing education activities, generally presented by advanced degree professionals, with full disclosure of interests.
- b. Common access displays – as long as they are generally available to competitors, and as long as there is no compulsion for faculty or learners to participate, nor obligate connection to an educational activity. Such access could be set up by Department or Division, by its own rules, and in accord with all aspects of this policy.

Should a College, Department, or Division, elect to offer such site access, the Dean/Chairman/Chief may collect a fee into a restricted educational or research fund, as long as all the concerned companies have similar opportunity, and that interaction gives no special benefits for the giving company. That disallows direct support of a specific conference (except as covered below as CME activities). Acknowledgement of the gift may be appropriate.

#### **D. SITE ACCESS BY DEVICE MANUFACTURER REPRESENTATIVES**

Interactions with device manufacturer representatives are covered by the same considerations as those with pharmaceutical representatives, but additionally they must be duly credentialed for any patient care activities for which they are present, and that credentialing is site specific (e.g., each hospital or clinic). Their presence is for in-service/ education, not supervision of patient care or unilateral selection of device. Generally, the patient must concur with their presence, and the provider must be the agent providing actual care.

The University has faculty practicing in multiple practice sites and hospitals. Each clinical site has its own explicit rules, and, in general, those supersede this policy, since the University is not the practice site.

#### **E. CONTINUING MEDICAL EDUCATION**

Continuing education should be conducted under the auspices of national discipline specific guidelines. For instance, in the University Of Tennessee College Of Medicine (UT COM), CME programs are under the guidance and approval of the UTHSC CME program ([www.uthsc.edu/cme](http://www.uthsc.edu/cme)), which is, in turn, accredited by the ACCME. ACCME accredited programs may also be offered by local hospitals or other agencies. Other national oversight approval agencies (or other nationally approved continuing education) exist for other college disciplines, Nursing, Pharmacy, Allied Health, etc. (For purposes of this University policy, the term “CME” covers all such Health Care professional disciplines). In this context of UT COM CME activity:



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- a. Fees are expected of participants, but may be waived (with approval) for UT personnel. That is inclusive of food. However, the oversight from the CME office must approve such waivers on the suggestion of Program Directors or Chairmen. That implies prospective approval.
- b. Regular conferences, such as Grand Rounds or Journal Club, should be approved and then reviewed annually; initial application is expected by June. Approval is for the general content, and is not general approval for industry support of single sessions. Outside speakers may be brought in conjunction with these CME activities (or special events); payment through UT is governed by above policy.
- c. The interpretation of this would allow grand rounds to be a CME activity, and fees can be waived. Approved UT funds (such as unrestricted educational grants) may be used, with oversight from the CME process. However, direct external support of food and entertainment in association with a particular session is not, in general, approved.
- d. Industry support of activity is, at most, a joint participation in CME activity; examples would be scheduled and approved symposia, etc. By extension, unapproved activities cannot receive industry gifts, including food.

External to UT COM, accredited CME programs are permissible for UT participants (see below for paid or speaker participation). However, in all cases UT personnel are still governed by these ethics guidelines, and minor gifts, including food, should not be accepted in exchange for industry access or influence. In general, an accredited CME program (such as through a hospital), may be assumed more likely free of conflict, but it remains the individual’s responsibility to exercise judgment.

## **F. PARTICIPATION IN INDUSTRY-SPONSORED PROGRAMS**

UT does not, at this time, disallow faculty from participating in industry “speaker’s bureaus” or otherwise being paid honoraria to deliver talks, with caveats.

The legitimate purpose of faculty in academia and medical education is not product endorsement, but rather dissemination of critical information, often new or newly interpreted information, so the basis of participation should first be presentation for critical exchange of information. UT strongly discourages participation by their faculty in industry sponsored and controlled speaker’s bureaus, often direct marketing. Further, UT explicitly prohibits faculty delivering industry written or rote presentations; presentations should reflect academically independent analysis and interpretation. In such a case, it is entirely inappropriate to present oneself as anything but an agent of the company, but not as faculty, or as independent

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professional; such a distinction is incompatible with UT appointment. “Disclosure” does not mitigate this. Academic use of components of industry material (e.g., specific slides), may be appropriate (if approved by the copyright owner), but interpretation of such material must not be proscribed by industry (be aware there may be applicable FDA rules governing what may be said, as well). When uncertain, do not use.

Faculty may participate in accredited FDA or CME programs, regardless of industry sponsorship. In addition to the requirement of the nature of the content mentioned above. UT requires faculty (or trainees so involved):

- a. Faculty and personnel must have full transparency and disclosure to the centers and audience and when participating in such programs.
- b. Payments to academic personnel (from whatever source) may be only at fair market value (see UT CME policy for UT guidelines; most accredited program will have similar rules). The riskier behavior is most likely from unaccredited activities.
- c. For attendance only, UT faculty should not accept honoraria, travel, per diem, or other significant gifts from industry. Again, UT CME policy allows tuition reduction from the formal sponsor. Non accredited programs represent a particular problem for conflicts, even when marketed as “continuing medical education”. Generally faculty and trainees should not attend, and should never receive personal payment (however labeled, or in kind, cash or gifts).

## **G. INDUSTRY-SPONSORED SCHOLARSHIPS & OTHER EDUCATIONAL FUNDS FOR TRAINEES**

Industry may not provide grants or awards directly to trainees. Industry may award money to the University for such an award, but the selection of the trainee remains a UT and Departmental function. With Departmental and/or College approval (e.g., Chairman or Dean), certain well established and known non-profit entities may directly award trainees. However, awards of any description cannot be *quid pro quo* for any future external expectations or performance.

## **H. FOOD**

To reiterate the policy above, food and other small gifts are disallowed except in the context of accredited CME activity, or legitimate UT approved and UT supported activity; this is applicable whether the activity is on or off site. Each Department may have funds available through any

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legal avenue, including unrestricted grants. A direct quid pro quo avenue may not exist between any such gifts and industry's access or influence.

### **I. PROFESSIONAL TRAVEL**

UT faculty and learners may not accept travel funds from industry, other than for legitimate reimbursement or contractual services.

### **J. GHOSTWRITING**

The validity of formally committed words of faculty – whether in print, electronic, or recorded – is essential to the integrity of the professions of health care and education. No faculty should ever accept authorship of material ghost written by industry (or other source), or deliver “canned” material prepared by industry. Joint authorship, committee authorship, etc. are all legitimate collaborative academic activities (whether between Universities, or academia and industry), but authors must be able to accept responsibility for the words ascribed to them.

### **K. PURCHASING**

For purposes of this policy, purchasing responsibilities (e.g., P&T committee, equipment committees, OR committees, etc.) that recommend or decide purchases, are covered separately by other UT policy and required annual disclosures. Faculty should be aware that conflicts of interest involving expenditure of funds may also have civil and criminal penalties.

Suffice it to say, decisions favoring purchase should not be conflicted by industry relations. Any such conflict, real or potential, should be disclosed and the individual possibly recused from the decision. Of course, faculty may be called upon for content expertise (especially on therapeutic advantages); committees should simply be aware of potential biases.