

# TEMPLE UNIVERSITY SCHOOL OF MEDICINE

## POLICY ON CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST

**Introduction:** The primary responsibility of full-time faculty members at Temple University School of Medicine (TUSM) is to direct their entire professional effort and energy to furthering the missions of the School. As part of this responsibility, faculty members who participate in academic activities outside of TUSM must ensure that these activities are consistent with their primary professional commitment to the University and to the School. These include activities in professional or scientific organizations, service on reviewing bodies for government and private entities, and any other external activities that enhance and develop the faculty member's professional skill and reputation and that benefit TUSM.

All faculty members at TUSM are governed by Temple University's Policy on Conflict of Interest and Conflict of Commitment as published online at <http://www.temple.edu/ovpr/ovpr/tuconflictpolicy.html>. That policy applies generally to financial relationships between faculty members and their families and non-Temple entities and persons. Temple faculty holding primary appointments in TUSM may encounter potential conflicts of interest that are less well defined than those described in the general University policy. Thus, there is a need to describe in detail the responsibilities of TUSM faculty members regarding possible interactions with industry or other private entities and to provide policy direction for appropriate types and levels of external activities.

This TUSM policy will first define and address the issue of conflict of commitment, and then address situations encountered by TUSM faculty members where there is the potential for conflict of interest. A commitment to engage in any activity which involves an external institution, agency or company should be made by a faculty member only after serious consideration of whether the activity will compromise the amount of time available for fulfillment of the faculty member's primary commitment to TUSM and whether the nature of the proposed activity is commensurate or consistent with the faculty member's responsibilities to Temple. A faculty member must additionally consider carefully whether a possible external obligation might constitute a conflict, or the appearance of a conflict, with the interests of TUSM or of the University. This policy defines such conflicts and lists specific circumstances where faculty members will be required to obtain prior approval of a proposed activity. TUSM faculty members' activities are also governed by relevant policies of Temple University Physicians and of the Temple University Health System.

### **Definitions:**

*Conflict of Commitment:* A conflict of commitment occurs when any outside activity, or the sum of all outside activities on an annual basis, burdens or interferes with the ability of a faculty member to fulfill his/her obligations to TUSM. An outside activity is defined as any activity which takes place at a location other than TUSM or its affiliates, or an activity exclusive of grant-funded research which takes place at a Temple site but is sponsored or supported by a non-Temple entity. All faculty have an obligation to conduct the affairs of TUSM in a manner that promotes the best interests of TUSM.

*Conflict of Interest:* A conflict of interest occurs when a faculty member's obligations to TUSM are, could, or appear to be compromised by the external activities or agreements undertaken by himself/herself, or those undertaken by a family member. Actual or potential conflicts of interest may take many forms, but frequently involve a tangible

benefit to the faculty member from an outside source, financial or otherwise, which may, or may appear to, influence the faculty member's professional actions. A conflict may also arise if a faculty member engages in activities with another organization that may compete with similar activities at TUSM.

**Policy:**

*Disclosure:* It is the responsibility of each faculty member to keep detailed records of all extramural activities, including the amount of time involved, the amount and source of any financial or other benefit or any reimbursements, and all other relevant details, and to disclose this information to TUSM administration as required, but at least annually.

*Prior Approval:* Because extramural activities available to TUSM faculty are many and varied, no policy statement can address all possibilities. It is therefore the obligation of the faculty member to (1) consider carefully whether a particular activity might constitute an actual or apparent conflict of interest or a conflict of commitment, (2) disclose activities that pose actual or potential conflicts, or what may appear to be conflicts, before undertaking the questionable activities to his/her Chairperson, Section Chief or Center Director, and (3), if there are questions about the appropriateness of a potential activity, to discuss the activity with the Dean or Dean's designee and with University Counsel.

Excluding the first 5 days of Continuing Medical Education (CME) per fiscal year, prior approval of proposed activities by the faculty member's Chairperson/Section Chief/Center Director (or by the Dean in the case of a faculty member who reports directly to the Dean) is required when the following circumstances apply to that activity:

- when the activity will require the faculty member to be absent from his/her duties at TUSM for more than three consecutive working days or when the faculty member's non-vacation time will exceed 10 days per fiscal year devoted to an activity for or sponsored by a single external institution.
- when the faculty member will be compensated \$5,000 or more per fiscal year by a non-Temple entity. See also, the University's policy and procedures for approval of outside compensation in the Faculty Handbook and Temple University Policy No. 02.78.11: Presidential Policy Implementing Temple University's Regulations on Extra Compensation, requiring, among other things, prior approval of the Dean and limiting such activities to an average of one day per calendar week.
- when a proposed external activity conflicts with the fulfillment of regularly scheduled commitments of the faculty member at TUSM (e.g., teaching, patient care).
- in cases in which the faculty member is compensated for professional services that are the same as those provided for TUSM (e.g., teaching, clinical service, research). The Dean or his/her designee will determine whether such compensation should be paid to Temple or whether such compensation may be retained by the faculty member.

*Relationships between TUSM Faculty and Industry:* Academic medicine and health-related industries share the goal of improving the health of the public. This goal by its nature has given rise to many different interactions between industry and TUSM faculty. These interactions must be transparent in all aspects. They should support unrestricted exchange of information, should be free of bias and should not in any way influence the professional behavior of the faculty member. The following directives apply to all relationships between TUSM faculty and industrial entities, including pharmaceutical companies and manufacturers of medical devices or scientific equipment/supplies:

- A. Gifts to individuals: It is very important to avoid even the appearance that professional decisions of TUSM faculty members might be influenced by any perceived or actual benefits from a company or an individual not affiliated with Temple. Accordingly, no TUSM faculty member may accept any personal gifts from such companies or individuals under any circumstances. A gift is defined as anything of value that is given directly to a faculty member or to his/her family member by a business or person that does or seeks to do business with TUSM or any Temple affiliate. A gift includes but is not limited to supplies, equipment, meals, travel, hospitality in the form of tickets to events, payment or reimbursement of expenses for attending a meeting or other event at which the faculty member is not a speaker or presenter, or payment for recommending or prescribing a specific medication or medical device.
- B. Gifts to TUSM. Under circumstances in which a potential gift may support the mission of TUSM, (e.g., samples for evaluation, contributions towards seminars or other internal conferences, items of educational value such as books), such gifts may not be donated directly to an individual faculty member under any circumstances. These gifts may be made to TUSM, subject to the following:
1. Continuing Medical Education (CME) Programs: Where support from an external source is intended for educational programs which will issue CME credits, this support must be organized through the TUSM Office for CME, which will manage these funds and insure that all relevant guidelines of the Food and Drug Administration and standards of the Accreditation Council for CME will be met. A faculty member who presents at such a conference or meeting may accept an honorarium from the TUSM CME Office, as discussed below in section D. Extensive information regarding regulation of CME-related interactions between private entities and TUSM is available online at [http://www.temple.edu/medicine/cme/regulatory\\_guidance.html](http://www.temple.edu/medicine/cme/regulatory_guidance.html).
  2. Pharmaceutical samples: Free samples of medications or devices may not be accepted by faculty members for their own use or that of family members or other employees, and free samples may never be sold. Vendors may donate their products to a clinical department and they may be distributed to patients when their use facilitates patient care, but they may not be distributed solely because of encouragement by company representatives. Receipt of drug samples must be the responsibility of designated individual(s) in each clinical department who will insure that samples are stored in locations available only to appropriate TUSM personnel. TUSM faculty are also subject to any additional regulations regarding the handling of pharmaceutical samples which are established by Temple University Health System.
  3. Other gifts to TUSM. Other gifts not described in the two preceding paragraphs (e.g., support for non-CME educational events, cash donations for other purposes, donations of books, equipment, supplies, etc.) which are provided by an external source must be managed through the TUSM Office of Institutional Advancement. (Unrestricted grants may be managed as appropriate through the Office of Sponsored Projects.)

- C. Site Access by Manufacturer Representatives: Industry access to TUSM premises and to physicians, trainees and students may occur for legitimate, educational reasons or to discuss or demonstrate new products or devices. However, to protect patient privacy, to guard against access to restricted areas and to insure that any possibility of inappropriate marketing activities is avoided, sales and marketing representatives are not permitted in any patient-care areas at TUSM. An exception to this policy may be made for provision of in-service training on devices or other equipment already at TUSM. Under this exception, representatives are permitted in *non-patient* areas by prior appointment only, which may be made at the discretion of any faculty member, but which must be reported to an appropriate Section Chief, Chairperson, or other designated officials of TUSM. While on site, representatives may not use the resources of educational or administrative offices of TUSM to promote products or to support industry-sponsored events. TUSM faculty members may not participate in industry-sponsored, online marketing activities. Overall activity of sales representatives must be monitored by Section Chiefs and Chairpersons, and these activities are also subject to oversight by other designated officials of TUSM.
- D. Participation of TUSM faculty members in industry-sponsored programs: Transfer of information between industry and TUSM faculty and trainees should occur for the most part at ACCME-accredited CME events, which are managed by the TUSM Office of CME. For CME-certified activities, any reimbursement of expenses for faculty participants will be administered by the TUSM Office of CME and should not involve direct interaction between industry representatives and the participating faculty member. TUSM faculty may also be invited by industry to act as clinical experts speaking or consulting at industry-sponsored, non-CME events. Participation in these events may enhance the reputation of the faculty member and of TUSM. Nonetheless, full disclosure of all details is required and participation is subject to the following guidelines.
1. A TUSM faculty member may not accept compensation for membership on a speakers list (speakers bureau), nor may he/she accept any compensation from industry for attending any industry-sponsored event at which he/she is not a speaker. This includes industry support to defray costs of attending such meetings, e.g., travel, hotel, and meals.
  2. TUSM faculty members may accept a “fair-market” honorarium and reimbursement for reasonable travel, lodging and meals from an industrial sponsor for making a presentation at a non-CME conference or meeting, providing the following conditions are met:
    - a. Financial support by industry is disclosed in full by the sponsor of the conference or meeting.
    - b. The content of the presentation is chosen at least in part by the faculty member, and is presented as part of a fair and balanced consideration of clinical options or scientific interpretation, including an unbiased discussion of the relevant topics based on the best current scientific evidence. The content of the presentation may not be subject to prior approval by the industrial sponsor.

- c. The speaker in no way indicates that, by virtue of his/her participation in the event, TUSM endorses or promotes any product of the industrial sponsor. The use of the TUSM name should be limited to identification of the faculty member by his/her title and affiliation.
  - d. If industry-sponsored literature or models are used during the conference or meeting, they must be provided solely for their educational value and not for any promotional reason. No samples or other gifts of any kind may be distributed by industrial representatives at the meeting.
- E. Consulting relationships: TUSM faculty members may engage in compensated consulting arrangements with industry provided such relationships are fully disclosed and are (1) either pursued exclusively during personal, non-work time or (2), are pre-approved by the Section Chief or Chairperson and the Dean if required by conditions specified in the “Prior Approval” section of this policy, above. It is also expected that such consulting will not interfere with the faculty member’s full commitment to his/her primary responsibilities to TUSM and that there will be no use of TUSM facilities or staff in such consulting activities. The compensation paid must be reasonable and reflect fair market value for time/services, and under no circumstances may compensation be accepted without provision of specific services. Such a payment without associated duties would be considered a gift prohibited under section A, above. In addition, if a consulting relationship with a single entity is likely to compensate a faculty member in excess of \$5,000 in a single fiscal year, prior approval is required, in accordance with the “Prior Approval” section of this policy, above.
- F. Ghostwriting services: Interaction between TUSM faculty and industry in the pursuit of scientific knowledge is appropriate and may lead to development of important new concepts. It is expected, however, that faculty members who publish papers with members of industry will participate in development of the study in a meaningful way, including interpretation of data and the preparation of the final manuscript. Under no circumstances may TUSM faculty members be listed as authors on publications that have been ghost-written by industry representatives. This prohibition also applies to other forms of spoken and/or visual presentations whose content should always be developed at least partly by the faculty member and not solely by industry representatives.
- G. Purchasing decisions: TUSM faculty members who participate in making purchasing decisions for pharmaceuticals, supplies or equipment must have no conflicts of interest in making such recommendations. Therefore, any financial relationship (equity ownership, paid consultation, compensated membership on boards, etc.) with a company which provides a potential product or service must be disclosed to TUSM prior to the faculty member’s involvement in the selection process, and no gift or other compensation may be solicited or accepted personally or for TUSM by the person involved in the purchasing decision.

**Disclosure of extramural relationships**: To ensure that all situations that present the potential for conflict of either commitment or interest are addressed carefully and fairly, TUSM faculty members are required to disclose possible conflicts on a regular basis and, in those instances specified in the “Prior Approval” section, above, prior to the beginning of such a commitment. Such disclosure will protect the individual faculty member, TUSM and the University, and should be made to the Section Chief/Center Director or

Chairperson of the faculty member's department and the Dean via mechanisms developed by TUSM administration.