

TEMPLE UNIVERSITY



POLICY AND PROCEDURE

Title:	Conflict of Interest and Conflict of Commitment
Category:	Administrative
Policy Number:	LKSOM 01.03.01
Issuing Authority:	Dean of the Lewis Katz School of Medicine
Policy Administrator:	Senior Associate Dean, Faculty Affairs
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Reviewing Office/Committee:	Office of Faculty Affairs; Conflict of Interest Committee

Policy

All employees are governed by Temple University's policies on Conflict of Interest – All Employees as published online. These policies apply generally to financial relationships and personal relationships between employees and their respective families, and non-Temple University entities and persons and other circumstances that might give the appearance that an individual's judgment could be impaired. Employees holding primary appointments in LKSOM may encounter potential conflicts of interest that are less well defined than those described in the general University policy. Therefore there is a need to describe in detail the responsibilities of employees regarding possible interactions with industry or other private entities and to provide direction for appropriate types and levels of external activities as described herein. To the extent an employee's action does not fall under the oversight of these procedures, the employee must ensure compliance with the appropriate Temple University policies on Conflict of Interest and conflict of commitment, as referenced above, for disclosure and approval. All employees working within LKSOM are also covered by LKSOM Conflict of Commitment policies as they are amended from time to time.

A commitment to engage in services or other activity outside the university or that involves an external institution, agency or company should be made by an employee only after serious consideration of whether the activity will compromise the amount of time available for fulfillment of the employee's primary commitment to LKSOM and whether the nature of the proposed activity is commensurate or consistent with the employee's responsibilities to Temple University. An employee must additionally consider carefully whether a possible external obligation might constitute a conflict, or the appearance of a conflict, with the interests of LKSOM or of the University.

These procedures provide examples of such conflicts, list specific circumstances where employees are prohibited from engaging in an activity and list where employees are required to obtain prior approval of a proposed activity as required by either the LKSOM Faculty Handbook or the Temple University

Faculty Handbook. Employees' activities are also governed by relevant policies of Temple University Physicians, Temple Faculty Practice Plan and of the Temple University Health System.

These procedures replace all prior LKSOM policies and procedures regarding the subject matter contained herein and supplement existing university policies and procedures.

Scope

This policy and procedure applies to all LKSOM employees (faculty and staff).

Procedure

Disclosure: Because extramural activities available to LKSOM faculty are many and varied, no policy statement or procedures document can address all possibilities. It is therefore the obligation of each faculty member to (1) carefully consider 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 including all extramural and consulting activities, before undertaking the questionable activities, to his/her department chairperson, section chief or center director as discussed herein, and (3), if there are questions about the appropriateness of a potential activity and whether or not it qualifies for disclosure to the faculty member's department chairperson, section chief or center director, and/or review by the Conflict of Interest Committee, to discuss the activity with the Senior Associate Dean for Faculty Affairs.

All conflicts of interest shall be submitted for review to the LKSOM Conflict of Interest Committee. No faculty member may proceed with a proposed activity for which there is a potential or actual conflict of interest until that faculty member has received notice of approval from the Conflict of Interest Committee, as reviewed and approved by the Dean of LKSOM, Provost, and University Counsel, where appropriate.

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 LKSOM administration as required herein. It is the obligation of the faculty member to report, in accordance with these procedures, to his/her department chairperson, section chief or center director any situation that could potentially present a conflict of interest or conflict of commitment.

Prior Approval: Excluding the first 5 days of continuing medical education (CME) per fiscal year, prior approval of proposed activities by the faculty member's department chairperson/section chief/center director (or by the Dean or the Dean's designee if the department chairperson or center director is the faculty member seeking approval) is required when the following circumstances apply:

- The activity will require the faculty member to be absent from his/her duties at LKSOM for more than three consecutive working days or when the faculty member's non-vacation time will exceed 10 days per calendar year.
- The faculty member will be compensated \$5,000 or more per fiscal year in the aggregate by a non-Temple University entity.
- A proposed external activity conflicts with the fulfillment of regularly scheduled commitments of the faculty member at LKSOM (e.g., teaching, patient care).

- The faculty member engages in any extramural or consulting relationship with any non-Temple University entity, as further elaborated below and in the Policy Statements attached to these procedures.
- All non-Temple University compensated travel requires full disclosure of all details to the applicable department chairperson, section chief or center director for prior review and approval (and to the Dean or the Dean's designee if the department chairperson or center director is the faculty member seeking approval). The department chairperson, section chief or center director may bring the issue to the Institutional Official for further clarification and guidance, which may include submission of the activity to the Conflict of Interest Committee for prior review and approval.

Annual Disclosure: All faculty members shall be required to complete a Conflict of Interest Disclosure Form at the time of appointment and at least annually.

REMINDER: Per the applicable Temple University Conflict of Interest Policy referenced above for employees, each employee must seek prior approval in all instances when the employee or the employee's family is an officer, director, trustee, partner or agent of, or has a 5% or greater interest in an entity involved in a transaction with or affecting the University. Such prior recommendation of approval must be made to the employee's department chairperson/section chief/center director (or to the Dean or the Dean's designee if the department chairperson or center director is the employee seeking approval). All conflicts of interest shall be submitted for review to the LKSOM Conflict of Interest Committee. No employee may proceed with a proposed activity for which there is a potential or actual conflict of interest until that employee has received notice of approval from the Conflict of Interest Committee.

Relationships between Employees and External or Industry Entities:

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 employees. 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 an employee. The following directives apply to all relationships between employees and external or industrial entities, including but not limited to pharmaceutical companies and manufacturers of medical devices or scientific equipment/supplies, as well as governmental entities for the purpose of research.

Policy Statement A:	Gifts to Employees
Policy Statement B:	Gifts to LKSOM
Policy Statement C:	Site Access by Manufacture Representatives
Policy Statement D:	Participation in Industry Sponsored Programs
Policy Statement E:	Faculty Consulting and Research Relationships
Policy Statement F:	Faculty Expert Witness Services
Policy Statement G:	Faculty Ghostwriting Services
Policy Statement H:	Purchasing Decisions
Policy Statement I:	Financial Conflicts of Interest in Research

For the Policy Statements listed above, E, F and G apply to faculty only. The balance of the Policy Statements apply to all employees.

Responsibility for the oversight of this policy and procedure resides with the Conflict of Interest

Committee of LKSOM. The Committee's purpose, membership, and responsibilities are detailed below.

Conflict of Interest Committee:

LKSOM and the University have long valued the relationships that it and its employees have with outside entities including industry sponsors. Many of these relationships are critical in allowing LKSOM to follow its mission of education, research and health care. In order to ensure the integrity of research and those relationships with outside entities and industry, employees must disclose such relationships as elaborated in these procedures, and through the mechanisms that LKSOM and Temple University have in place to capture such disclosures. The Conflict of Interest Committee is a key step in the disclosure process as it is best positioned to thoughtfully examine potential conflicts and create management plans which reduce or eliminate conflicts or bias. Employee non-compliance and failure to follow this procedures document and the Conflict of Interest Committee's decision(s) can result in significant harm not just to the employee, but also to LKSOM, the University and LKSOM affiliates. It is the policy and position of LKSOM and the University that each employee conducts his/her behavior in a way that promotes objectivity and reduces all instances of potential bias or conflict.

- A. Powers and Authority. The Conflict of Interest Committee (the "Committee") is advisory to the LKSOM Dean, or his/her designee, and shall perform the duties described in this procedures document and such other duties as the Dean may assign. The Committee shall report regularly to the Dean or his/her designee on all such matters.
- B. Establishment. The Committee is established to review and recommend whether or not approval is appropriate for those activities disclosed under LKSOM and University, if applicable, conflict of interest policies. The Committee is charged with the protection of the integrity of LKSOM's research and educational missions, as well as those of the employee.

The Committee is also charged with (1) reviewing the LKSOM conflict of interest policies, (2) reviewing individual cases where an employee is required to disclose an actual or potential conflict of interest and (3) serve as a sanctioning body in individual cases where an employee fails to comply with a conflict of interest management plan.

C. Membership.

1. Committee Composition.
 - a. The Committee will consist of seven (7) employees with representation from clinical and basic science departments, including at least two members who serve as principal investigators on research grants or trials. These members shall have voting rights.
 - b. Additionally, the Committee will include an ex officio voting member from each of the following administrative offices: Office of Research and Office of Faculty Affairs. The Senior Associate Dean for Faculty Affairs may attend any meeting but shall not be permitted to vote. A representative from the Office of Counsel shall be present at the meetings.
 - c. Quorum will consist of five (5) Committee members present.
 - d. The Committee will be chaired by the LKSOM Institutional Official.
 - e. Office of University Counsel shall provide counsel to the Committee.
2. Selection of Members. The Chair will solicit recommendations for membership of new members from current Committee members and department chairs.
3. Term of Service. Appointments to the Committee will be for three years. There are

no term limits for these positions.

D. Meetings.

1. Meeting Frequency. The Committee meeting frequency will be commensurate with the volume and complexity of the issues requiring Committee review. The Committee shall meet at least quarterly.
2. The Chair is empowered to call a meeting at any time, and may delegate this to another voting member in the case the Chair is unavailable. The Dean of LKSOM and/or the Senior Associate Dean of Faculty Affairs may also call a meeting if necessary.

E. Responsibilities.

1. Review of Conflicts. The Committee is tasked with reviewing actual or potential conflicts as enumerated in these procedures. The Committee shall examine whether or not a conflict exists, and if appropriate, create and implement an appropriate management plan, under which the employee is required to follow. The Committee shall establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure compliance with any Committee determinations or management plans in accordance with all applicable Temple University and LKSOM policies and procedures.
2. Use of Consultants. The Committee may use consultants when necessary. Consultants do not have voting privileges.

Committee member conflicts of interest. Committee members must declare any potential conflicts of interest they have with items brought before the Committee. Those Committee members with actual or potential conflicts of interest may participate only to provide information to the Committee as requested. Conflicted Committee members must recuse themselves during the discussion and voting on items in which they have an actual or potential conflict.

3. Policy and Procedure Review. The Committee may recommend changes to LKSOM or University policies and procedures that have a potential impact on conflicts of interest, the general integrity of LKSOM's research program or any policy or procedure involving employee relationships with external entities.
4. Subcommittees. The Committee may establish subcommittees to further investigate specific issues. Such subcommittees shall report to the Committee and may include Faculty from the Committee and at large, as well as non-Faculty.
5. Confidentiality. Information concerning employee relationships with industry and external entities, conflicts of interest, management plans, financial interests and non-compliance is of a highly sensitive nature and is not to be discussed with any members outside of the Committee, except those persons for which discussion is required in furtherance of an inquiry. All Committee members understand the importance of such confidentiality and agree to maintain confidentiality at all times.

Definitions

- Affiliate: Includes Temple University – Of The Commonwealth System of Higher Education, including its schools and colleges, as well as Temple University Health System, Inc. and its member hospitals and organizations.
- 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 an employee

to fulfill his/her obligations to LKSOM. An outside activity is defined as any activity that takes place at a location other than LKSOM or its Affiliates, or an activity exclusive of grant-funded research which takes place at a Temple University site but is sponsored or supported by a non-Temple University entity. All employees have an obligation to conduct the affairs of LKSOM in a manner that promotes the best interests of LKSOM.

- **Conflict of Interest**: A conflict of interest occurs when an employee's obligation(s) to LKSOM are, could be, or appear to be compromised by the external activities or agreements undertaken by the employee, or those undertaken by an immediate family member. Actual or potential conflicts of interest may take many forms, but frequently involve a tangible benefit to the employee from an outside source, financial or otherwise, including but not limited to ownership of equity in a for-profit company, which may, or may appear to, influence the employee's professional actions. A conflict may also arise if an employee engages in activities with another organization that may compete with similar activities at LKSOM.
- **Conflict of Interest Committee**: The LKSOM committee charged with examining and making recommendations on conflicts of interest and commitment, and drafting management plans for recommendation for the Dean of LKSOM and/or his/her designee.
- **Employee**: Any Temple University W-2 employee who primarily performs work for LKSOM.
- **Faculty (sometimes also referred to as Faculty Member)**: Any employee who holds an appointment from the Dean of LKSOM or the President of Temple University.
- **Family**: The employee's spouse or spousal equivalent, and any of their parents, children (whether natural or adopted and the spouses of children), or brothers or sisters (whether whole or half-blood and the spouses of brothers and sisters).
- **Immediate Family**: The employee's spouse or spousal equivalent and dependent children.
- **Institutional Official**: For the purposes of these procedures, the Institutional Official resides in the Office of Faculty Affairs.
- **LKSOM**: Temple University – Of The Commonwealth System of Higher Education, Lewis Katz School of Medicine.

Attachments

Policy Statements A – I.

History

The August 24, 2012 amendment changed policy statements and procedures to reflect best practices and changes in regulation. The **XX XX** March, 2024 revision changed policy statements and procedures to reflect best practices.

Cross Reference(s) To other Policy(s)

- Conflict of Interest - All Employees:
<https://secretary.temple.edu/sites/secretary/files/policies/04.16.01.pdf>Gifts and Conflicts of Interest – All Employees: <https://secretary.temple.edu/sites/secretary/files/policies/04.16.03.pdf>
- Conflict of Interest - Faculty:
<https://secretary.temple.edu/sites/secretary/files/policies/04.16.02.pdf>
- Financial Conflict of Interests in Research:
<https://secretary.temple.edu/sites/secretary/files/policies/02.52.12.pdf>
- Conflict of Commitment and Conflict of Interest, LKSOM:
https://research.temple.edu/sites/research/files/documents/lksom_policy.pdf

Policy Statements

A. Gifts to Employees

Employees must avoid even the appearance that their professional decisions might be influenced by any perceived or actual benefits from a company or an individual not affiliated with LKSOM or a LKSOM affiliate. Accordingly, no employee may accept any personal gifts from such companies or non-Temple University individuals under any circumstances. A gift is defined as anything of any value that is given directly to an employee or to his/her Family by a business or person that does or seeks to do business with LKSOM or any Temple University affiliate. A gift includes but is not limited to:

- supplies,
- books
- equipment,
- food and beverage,
- travel (not otherwise covered in Policy Statements D and E of these procedures),
- hospitality in the form of tickets to events,
- payment or reimbursement of expenses for attending a meeting or other event at which the employee is not a speaker or presenter,
- payment for recommending or prescribing a specific medication or medical device, or
- industry marketing materials such as pens, paper pads and bags.

Policy Statements (cont.)

B. Gifts to LKSOM

Under circumstances in which a potential gift may support the mission of LKSOM, (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 employee under any circumstances. These gifts may be made to LKSOM, subject to the following:

1. Continuing Medical Education (CME) Programs: Where support from an external source is intended for educational programs that will issue CME credits, this support must be organized through the LKSOM Office for CME, which will manage these funds and ensure that all relevant guidelines of the Food and Drug Administration and standards of the Accreditation Council for CME are met. An employee who presents at such a conference or meeting may accept an honorarium from the LKSOM CME Office, as discussed below in Policy Statement D (employee participation in industry sponsored programs) of these procedures. Extensive information regarding regulation of CME- related interactions between private entities and LKSOM is available online at http://www.temple.edu/medicine/cme/regulatory_guidance.html.
2. Pharmaceutical samples: Free samples of medications or devices may not be accepted by employees for use at LKSOM, any Temple University Physicians practice, an employee's own use or that of the employee's Family or other Temple University employees. Employees are also subject to any additional regulations regarding the handling of pharmaceutical samples that are established by Temple University Health System. Pharmaceutical samples may not be kept in outpatient areas and may not be distributed to patients.
3. Other gifts to LKSOM. 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.) that are provided by an external source must be managed through the LKSOM Office of Institutional Advancement. (Unrestricted grants may be managed as appropriate through the Office of Sponsored Projects.)

Policy Statements (cont.)

C. Site Access by Manufacturer Representatives

Industry access to LKSOM premises and to physicians, scientists, trainees and students may occur for legitimate, educational reasons or to discuss or demonstrate new products or devices. However, to protect patient privacy, to protect certain LKSOM proprietary interests, to guard against access to restricted areas and to ensure that any possibility of inappropriate marketing activities is avoided, sales and marketing representatives are not permitted in any patient-care areas at LKSOM.

An exception to these procedures may be made for provision of in-service training on devices or other equipment already at LKSOM or being demonstrated for consideration of potential purchase. Under this exception, representatives are permitted in 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, Department Chairperson, or other designated officials of LKSOM. While on site, representatives may not use the resources of educational or administrative offices of LKSOM to promote products or to support industry-sponsored events.

Industry representatives may not bring onto campus or pay for any food or beverage that is intended for consumption by employees. If an industry representative is noncompliant, then LKSOM personnel may (1) ask the representative to leave the campus, and/or (2) notify the industry representative's supervisor, and may ask that the representative not be allowed back on campus. Employees may not participate in industry-sponsored, online marketing activities. Overall activity of sales representatives must be monitored by Section Chiefs and Department Chairpersons, and these activities are also subject to oversight by other designated officials of LKSOM.

Policy Statements (cont.)

D. Participation in Industry-Sponsored Programs

Transfer of information between industry and employees and trainees should occur for the most part at ACCME-accredited CME events, which are managed by the LKSOM Office of CME. For CME-certified activities, any reimbursement of expenses for employee participants will be administered by the LKSOM Office of CME and may not be paid directly from industry representatives to participating employees. In addition, CME- certified activities should not involve direct interaction between industry representatives and the participating employee.

1. Faculty may not give compensated presentations or accept honorarium, food, lodging or transportation for participation in non-CME events directed at physicians or other health care professionals, such as restaurant talks. It is acknowledged that consultation for industry may require presentations. Such presentations are subject to Policy Statement E.
2. Faculty may not accept compensation for membership on a speakers list (speakers bureau), nor 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.
3. Industry sponsored, non-CME events cannot be advertised using LKSOM or a LKSOM affiliate's resources such as email, bulletin boards or flyers.
4. Employees may accept reasonable travel, food and lodging for industry site visits in such limited cases as when it is necessary to assess equipment, software or vendor services; however such travel is only permitted upon prior approval from the employee's Department Chairperson, Section Chief or Center Director (or the Dean or the Dean's designee if the Department Chairperson or Center Director is the employee seeking approval).
5. Employees may not accept any form of compensation in exchange for referring or recruiting prospective subjects in clinical research (i.e. "finders fees").

Policy Statements (cont.)

E. Faculty Consulting and Research Relationships

It is recognized that exchange of scientific information between Faculty and industry is of vital importance. LKSOM also understands the essential value of service of Faculty on governmental, academic and industry scientific advisory boards, data safety monitoring boards, other clinical research advisory panels, and investigator meetings for industry funded research. Subject to the restrictions otherwise found in these procedures or Policy Statements, Faculty may engage in compensated consulting arrangements with industry or other external entities provided such relationships are fully disclosed to the Faculty Member's Department Chairperson, Section Chief or Center Director for prior review and approval (and to the Dean or the Dean's designee if the Department Chairperson or the Center Director is the Faculty Member seeking approval). The Department Chairperson, Section Chief or Center Director may bring the issue to the Institutional Official for further clarification and guidance, which may include submission of the activity to the Conflict of Interest Committee for review. All Conflicts of Interest shall be submitted for review to the LKSOM Conflict of Interest Committee. No Faculty Member may proceed with a proposed activity for which there is a potential or actual Conflict of Interest until that Faculty Member has received notice of approval from the Conflict of Interest Committee.

It is expected that such consulting will not interfere with the Faculty Member's full commitment to his/her primary responsibilities to LKSOM and that there will be no use of LKSOM 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 Policy A (Gifts to Employees).

Policy Statements (cont.)

F. Faculty Expert Witness Services

Faculty may serve as expert witnesses in litigation, except when any Temple University entity, physician or a LKSOM Affiliate is a party to the litigation. It is also expected that serving as such expert witness will not interfere with the Faculty Member's full commitment to his/her primary responsibilities to LKSOM and that there will be no use of LKSOM facilities or staff in such expert witness activities. Finally, it is strongly recommended that Faculty not engage in expert witness activity adverse to physicians or hospitals in the five counties of southeast Pennsylvania (Philadelphia, Montgomery, Bucks, Delaware and Chester).

Expert witness testimony is expected to benefit one party to litigation at the expense of the other. Accordingly, serving as an expert witness may place the Faculty Member in a position adverse to LKSOM or to another Faculty Member. Such conflicts may arise from ongoing research, projects, contracts or relationships that LKSOM may have with or to the parties in litigation. For this reason, prior to accepting or engaging in any expert witness activities, the Faculty Member must submit the proposed activity to the Faculty Member's Department Chairperson, Section Chief or Center Director for prior review and approval (and to the Dean or the Dean's designee if the Department Chairperson or Center Director is the employee seeking approval). The Department Chairperson, Section Chief or Center Director may bring the issue to the Institutional Official for further clarification and guidance, which may include submission of the activity to the Conflict of Interest Committee for review. All Conflicts of Interest shall be submitted for review to the LKSOM Conflict of Interest Committee. No Faculty Member may proceed with a proposed activity for which there is a potential or actual Conflict of Interest until that Faculty Member has received notice of approval from the Conflict of Interest Committee.

Policy Statements (cont.)

G. Faculty Ghostwriting Services

Interaction between 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 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 a Faculty member be listed as an author 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 by the Faculty Member and not by industry representatives.

Policy Statements (cont.)

H. Purchasing Decisions

Employees 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, employment relationship) between the employee, including the employee's Family, with a company that provides a potential product or service must be disclosed to the employee's Department Chairperson, Section Chief or Center Director for prior review and approval (and to the Dean or the Dean's designee if the Department Chairperson or Center Director is the employee seeking approval). The Department Chairperson, Section Chief or Center Director may bring the issue to the Institutional Official for further clarification and guidance, which may include submission of the activity to the Conflict of Interest Committee for review. Such review and approval must occur prior to the employee's involvement in the selection process. All Conflicts of Interest shall be submitted for review to the LKSOM Conflict of Interest Committee. No employee may proceed with a proposed activity for which there is a potential or actual Conflict of Interest until that employee has received notice of approval from the Conflict of Interest Committee.

Policy Statements (cont.)

I. Financial Conflict of Interest in Research

The Temple University policy for Financial Conflicts of Interest in Research is found in the online Temple University Policy and Procedure Manual (Policy #02.52.12). It is also located on the Temple University website under Senior Vice Provost for Research and Graduate Education.

For the purposes of the Temple University Financial Conflicts of Interest in Research Policy, the LKSOM Institutional Official resides in the LKSOM Office of Faculty Affairs.

For the purposes of the Temple University Financial Conflicts of Interest in Research Policy as it applies to LKSOM employees, this Policy shall pertain to all research regardless of funding source.