

Frequently Asked Questions

COI Policy and Process:

1) To whom does the TUSM policy apply?

The TUSM Policy on Industry Conflicts of Interest applies to all faculty and administrators who hold appointments at TUSM and all students enrolled at TUSM.

2) Does the TUSM COI policy apply to those who work primarily or exclusively at a TUSM-affiliated hospital, but not on the Tufts campus?

Yes.

3) What if I work at a TUSM-affiliated hospital that has its own COI policy that is not consistent with TUSM's policy?

The TUSM policy should not conflict with the COI policies of any of its affiliates. If you feel there is an ambiguity or conflict that pertains to you, contact one of the COI administrators at med-coi@tufts.edu

4) Is it necessary to fill out the TUSM disclosure form in addition to the one submitting for research grants through Tufts?

Yes, if the TUSM policy applies to you.

5) Who has access to the information I disclose for this purpose?

The COI administrators will have access to the information disclosed, as will key TUSM administrators who are responsible for collection and management of COI data. In addition, if industry relationships are reported that require additional management, department chairs, chiefs, deans and other key administrative personnel will have access to this information.

6) Is the TUSK Online Reporting System a secure database?

It is reasonably secure consistent with state of the art technology for online data collection.

7) How will failure to disclose or inaccurate disclosure affect my employment or faculty appointment?

TUSM reserves the right to terminate the employment or faculty appointment of any faculty or administrator who fails to comply with its Conflict of Interest reporting requirements.

8) If it is determined that I have a Conflict of Interest, what are the consequences?

If a COI is revealed, the COI administrators or COI Advisory Committee will work with you to manage, reduce or eliminate the conflict.

10) Are conflicts of interest analyzed on an individual basis or by certain pre-determined categories?

Both. There are some activities such as the receipt of gifts or participation in speakers' bureaus that are not permitted at TUSM. Other activities, such as consulting arrangements, advisory boards or industry-sponsored research only pose a conflict based upon aggregate influence or relationship to one another.

11) How often must I submit or update a COI disclosure form to TUSM?

Once annually. More frequent updates as new relationships are established is not required at this time. This also does not affect additional reporting required by Tufts University Office of Research Integrity.

12) What responsibility do managers (Department Chairs, Chiefs, Deans) have in ensuring that faculty and employees submit a disclosure form?

If called upon by the COI Administrators to assist in data collection, managers will be requested to contact faculty and employees and urge them to submit disclosure forms.

13) Is there an approved format or form available for complying with the reporting requirement? To whom should the report be sent?

The 2009 and 2010 reporting format and requirement will be sent to you via email in late April and May. You will be prompted to go to the reporting site, fill in the information and submit it.

14) Why is TUSM requiring this procedure in addition to the COI reporting conducted by the Office of Research Administration?

It is a requirement of the Medical School's accreditation body, LCME.

15) Will sanctions be administered by direct supervisors or by another independent body?

The Office of the Dean is responsible for administering and enforcing the TUSM COI policy.

Questions Received Concerning Managing Conflicts of Interest:

1) Are there any conditions in which participation in an informational posting on a drug company website is consistent with the TUSM COI policy?

This suggests that the intent is to market an industry product, which is an inappropriate industry relationship.

2) I have industry support for approved clinical studies. None of the money goes directly to me but rather it goes to support the research costs e.g. study coordinators. The amount of support is based upon the number of patients enrolled. While the total study budget for the year was greater than \$10,000 we only enrolled a few patients and thus we received less than that amount. Should I check "more" or "less" than \$10,000?

Less than \$10,000 since that was the amount received.

3) Almost all of the industry-funded income earned from my research and consulting contracts goes to the hospital; it does not go to me personally. How do I report this on the form?

Although your income does not go to you personally, it is still important to list all income received and to do so in the category where it best fits in e.g. for any research in which you are an investigator, you would list that as industry-sponsored research and identify the company, the amount, etc.

4) I am the Director of a summer research program for undergraduates. This program brings students from all over the country to TUSM for the summer to participate in research. One of our activities is going to a local pharmaceutical or biotech company for a tour and to meet with their scientists. Often the company provides an informal lunch for students where they also discuss career opportunities with the scientists. Does the TUSM COI policy concerning interactions with industry allow the students and/or me to eat lunch at these outings? Is there a place for me to declare this activity?

Since these students are not TUSM students, the TUSM COI policy does not apply to them but it does apply to you. Similarly, if an industry representative came to TUSM and wished to serve lunch to a TUSM student group to discuss career options, the lunch would not be allowed. If you receive direct payment for this student program from any of industry sponsor, this must be declared on the COI form. If there is no **direct** payment, there is nothing to report.

5) Must a mentor who does not hold a TUSM appointment and does not have responsibility for curricular oversight, but does mentor TUSM ALE students and participate as "guest lecturers" disclose industry relationships?

At present, non-TUSM faculty or administrators are not required to report industry relationships. They or the faculty member are required to disclose industry relationships to audiences when they guest lecture and mentor students.

6) Does the COI reporting requirement pertain only to industry relationships that are paid and ongoing, i.e., would it be necessary to

report an event hosted by industry at which you engaged in a speaking event but received no compensation?

For the annual disclosure we only require payments to be disclosed. It does not matter whether it is a single event or ongoing. By the same token, a speaking event that is not permitted (e.g. a speaking bureau) is still not permitted even if it is unpaid.

7) I am participating in a clinical science advisory board meeting for a device manufacturer. I receive no compensation and no CME credit. However, meals are provided during which important material is discussed. May I accept lunch or even sit where lunch is served without eating it? What if coffee and/or cookies are served in the afternoon during an advisory committee meeting?

Participating in the lunch provided by industry is fine if it is pursuant to an advisory committee meeting and the “important material” is educational in nature and not marketing. If any part of the event is purely marketing, you can still attend but may not accept meals.

8) Is it permissible under TUSM’s policy to accept meals that are provided in conjunction with conferences that are of educational/research benefit but do not offer CME credits?

Yes. Modest meals that are served in conjunction with educational programs, whether or not CME credit is awarded, and whether or not ACCME accredited, is acceptable.

9) What is the definition of a Speakers’ Bureau?

Speaking engagements that convey information about a Company’s products or their drug classes that are sponsored and controlled by a Company are promotional activities, also known as Speakers’ Bureaus. A promotional activity, whether or not compensated, is characterized by the following:

- 1) The speaker appears to act as a Company’s agent or spokesperson for the purpose of disseminating Company or product information; and

- 2) The Company controls the content of the presentation, which may include creating or having final approval over the slides or presentation materials or setting limits on the scope of discussion.

10) I believe the TUSM COI policy regarding donations of devices and drugs is too restrictive and would greatly inhibit innovative clinical use and studies. Investigator initiated clinical trials with new-FDA approved drugs and devices would stop if we had to buy them in order to study their use. The publication of seminal case reports describing novel, out of label use of new, FDA-approved drugs would cease entirely if we had to purchase these drugs. Insurance companies, especially in Massachusetts, do not cover the costs of off-label use of drugs in most cases.

The TUSM policy does not apply to activities at the hospitals. TUSM does not receive drug samples or complimentary devices. It is not our intent to influence what goes on at the hospitals.

11) Will conflict of interest inquiries be administered as part of the hiring process, and should a copy of the policy be distributed to each potential candidate?

Candidates should be advised of TUSM's COI policy but there is no reason to anticipate that it will have a major impact on hiring decisions since most candidates are not yet to the provisions of the policy.

12) For more information and resources on specific activities and events that are subject to COI management, see also:

Council of Governmental Relations (COGR): Recognizing and Managing Personal Financial Conflicts of Interest. Winter, 2002)

http://www.cogr.edu/Pubs_Conflicts.cfm

UCLA School of Medicine:

http://dgsom.healthsciences.ucla.edu/guidelines/one-faq?faq_id=307930#307931