

Standards for Clinical (MD) Faculty on Managing Relationships with Industry and Private Entities

FREQUENTLY ASKED QUESTIONS



A. APPLICATION AND SCOPE

1. What is this all about?

The Temerty Faculty of Medicine of the University of Toronto and its faculty members have many valuable relationships with industry and private entities. These relationships encourage and support innovation and accelerate delivery of new health care products and methods to our patients. Financial support from industry and private entities has been and continues to be beneficial to the development and delivery of many educational programs. At the same time, these relationships may give rise to benefits (actual or perceived) for faculty members and/or for the Faculty itself, which may lead potential conflicts of interest to arise.

The standards and requirements for disclosure are intended to guide the conduct of faculty members and trainees by managing potential conflicts to ensure an environment that protects the integrity and reputation of individuals and institutions.

2. Is this a new requirement?

These standards have existed since 2013, the previously named document was the "Relationships with Industry and the Educational Environment in Undergraduate and Postgraduate Medical Education".

The Standards, now called "Standards for Clinical (MD) Faculty on Managing Relationships with Industry and Private Entities" is an updated document.

3. Are the changes consistent with TAHSN policies?

All changes and revisions are consistent with TAHSN policies, including the revisions to definitions.

4. The Standards only address MD faculty. What are the policies for non-MD faculty?

The scope of the Standards is specific to Clinical (MD) Faculty. Non-MD faculty fall under the jurisdiction of the central University; however, we are sharing these standards with all TFOM departments for their review so that expectations for all faculty are aligned to the extent possible.

Please see the following link for the guidelines for Faculty Members and Librarians, which has embedded links for additional policies and

guidelines: <u>https://www.provost.utoronto.ca/planning-policy/conflicts-of-interest-and-intimate-or-familial-relationships/</u>

B. STANDARDS

1. Why do the Standards refer to Relationships? Is this different from conflicts of interest?

For the purposes of the Standards, relationships are defined as "*Any past or present relationship, activity, or situation in which a faculty member or their personal associate(s) has/have/had personal, business, professional or other interests that may impact, or be perceived to impact, the faculty member's duties and/or responsibilities to patient care.*" Not all relationships lead to the potential for real or perceived conflicts of interests. Our objective was to define identify what relationships might exist and provide guidance to our faculty members on how best to prevent conflicts of interest and what must be disclosed. Certain relationships may provide a context in which conflicts of interest – either real or perceived - may arise.

2. For the educational event section, does this refer exclusively to U of T educational events?

No, they are not limited to U of T educational events. Section A(2) states "Because the principles in these Standards arise out of the professional and trust relationship with patients, learners, and colleagues, they apply at all times and in all places including in "off hours" and off-site" regardless of the presence of trainees."

3. I am holding an educational event which is sponsored by funds provided through my hospital foundation- do I still need to disclose this?

Funds that are provided to a hospital foundation or university advancement office are donations that are bound by the agreement/contract terms and conditions managed by the foundations. Donations do not need to be disclosed to UofT; however, if you are in doubt we welcome you to disclose and indicate that the funds are managed by a university or hospital foundation.

4. What is included under consulting?

It is important to reference the definitions outlined at the start of the Standards. For the purposes of the Standards, "Consulting means providing a professional service related to your field or discipline to a third party where the main objective is to further the interests of the third party. Consulting shall include but is not limited to providing advice and services to industry (e.g., a pharmaceutical or medical device company), acting as an advisory board member in a for-profit organization, acting as an expert witness, speaking engagements supported in whole or in part by a for-profit organization, and independent medical evaluations when conducted outside of the University or your hospital(s)."

5. Is it "consulting" if I am not financially compensated for the advice and/or services?

At times, industry might provide goods or services in place of financial compensation. These goods or services might include and are not limited to gifts, meals, travel, access to supplies and or technologies that might not otherwise be available to those not providing advice and/or services. If unsure whether in kind or other perquisites ("perks") might give rise to real/perceived conflicts of interests, it is best to disclose so that you receive the correct guidance.

- 6. Are faculty permitted to participate in user groups even if they are not consulting? Industry might bring experts together to get input on a new product or device without a formal consultation agreement. There is nothing in the Standards that prohibit participation in the above type of meetings. In section D(9) of the Standards the only overt restrictions stated are:
 - D(9.2) "Faculty members should not participate in speakers' bureaus. Programs run by for-profit educational companies are included in this category".
 - D(9.3) "Faculty members should not participate in industry marketing or sales programs, including sales and advertising for industry and private entities. The College of Physicians and Surgeons of Ontario sets out expectations for physician advertising in their Advertising policy."

7. Are faculty permitted to speak at educational events for physicians?

There is nothing in the Standards prohibiting faculty from speaking at educational events for physicians. Conflict of interest would arise in circumstances where a private entity chose and/or provided the educational content; paid the faculty member a fee directly (or provided other perquisites to the speaker); and/or, paid for the attendees to have a lavish meal at the event.

8. Are advisory boards considered permitted consulting activities if faculty create their own slides, etc., versus 'speakers bureau' activities (not permitted) where slides are provided by the vendor.

Assuming that you are being compensated for advisory board consultancy work, these activities meet the definition of consulting. As such, it would be important to disclose this and as long as it falls within the scope of permitted consulting activities in D9 and the disclosures follow the policy, these activities would be considered to be compliant.

Speakers' Bureau: Membership in a Speakers' Bureau is a relationship in which a faculty member is paid by or under contract to a company to provide talks and presentations and where the company selects or has influence over any or all of: the topic, any part of the content of a talk, or any members of the audience.

9. What constitutes a gift? For example, are honoraria or fees for lectures, educational events, and consulting excluded?

Gifts include articles of value, services, favours, travel, accommodation, extravagant meals, event admissions, use of property or facilities, or anything else of more than a nominal value from a third party, given for the purposes of (or that may be perceived to be for the purposes of) influencing an act or decision of the faculty member. "Gifts" do not include items of nominal value, token courtesies, or circumstances where a reasonable person would not believe that a faculty member would be influenced in any material way.

10. Is consuming coffee at an industry booth at a society meeting permitted (versus a gift)?

Section D(4.1.3) states that for educational events that otherwise meet the requirements of the Standards, "Hospitality, including food/beverages, may appropriately be part of events such as full day or longer programs or conferences but should have no direct link to a sponsor, be modest, and must be arranged by the event organizers, and accounted for in the event budget." While the term "modest" is subjective, consider using a reasonableness in your assessment – would an objective third party agree that the hospitality provided is in keeping with the needs of the event attendees?

11. If faculty members are consulting and/or attending sessions outlined in question A5 above as audience members, can they eat?

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12. It is implied that faculty may not eat or drink coffee during an industry-associated meetings, which is inconsistent with their ability to consult for industry at the same meeting.

The language in the Standards is intended to provide examples but is not intended to be an exhaustive list. A degree of professional judgement will need to be made as to the context and type of food/beverages being provided. Please see the answer to question 9 regarding the test for reasonableness.

C. DISCLOSURE

1. How am I supposed to provide detailed information about relationships held by my Personal Associates?

Any request for information that would include the relationships held by a Personal Associate is on the basis of your immediate knowledge. You are not expected to proactively ask each of your Personal Associates the questions on this form.

2. What if I don't receive any money, do I still need to disclose a relationship?

Yes. There is no specific monetary threshold which triggers disclosure. The focus of the disclosure process is on relationships and the potential for perceived or real conflict which may exist even in the absence of any direct financial benefit [please refer to question A5].

3. What are the timelines for disclosure?

Section E(2) of the Standards states that "Each full-time clinical (MD) faculty member will complete the TAHSN relationship attestation and disclosure module annually. The responses from the completed form will be made available to the Temerty Faculty of Medicine Department Chair and to Clinical and Faculty Affairs in the Temerty Faculty of Medicine."

Currently most of the disclosures are tied to the hospital reappointment process through CMaRS at participating hospital sites.

All other faculty are expected to disclose in accordance with E(4), which is commonly when relationships giving rise to real or potential COI concerns arise.

4. Do I have to complete a disclosure every year?

Full-time clinical (MD) faculty members are asked to complete the University Questions annually as part of the CMaRS process through the Hospital. Unlike the Hospital tabs in the Form, the UofT tabs must be newly completed annually. Information from a prior year will not be pre-populated. You are asked to disclose new activity from the 12 months prior to when you submit the Form.

5. I have questions about the Standards and/or the disclosure process. Who do I ask?

The interpretation and implementation of these Standards for Clinical (MD) Faculty on Managing Relationships with Industry and Private Entities are managed by Temerty Medicine's Professional Relationships Management Committee (PRMC).

For any questions, please contact Professional.Values@utoronto.ca

6. What happens if I do not disclose? What are the repercussions if I do not agree with the management plan?

As a clinical (MD) faculty member, you are subject to the policies, guidelines, standards, laws and regulations associated with the practice of academic medicine at the University, Hospitals, and other organizations, as set out in your signed Letter of Offer. The importance of disclosure is highlighted in our Standards of Professional Behaviour and failure to disclose would be considered a breach of the Standards.

If you are issued a management plan which you do not agree with, you may appeal the decision with the Dean or otherwise in accordance with processes set out in the <u>Procedures</u> <u>Manual for the Policy for Clinical Faculty</u>. The Dean will consider the PRMC's recommendations prior to instituting any management plan or sanctions in accordance with this Policy.