



## Relationships with Industry and the Educational Environment in Undergraduate and Postgraduate Medical Education

At the core of the professional relationship between physicians and patients is the primacy of the interest of the patient. As educators in the Faculty of Medicine, we have a duty to model appropriate professional behaviours to our learners. Both as a Faculty and as individuals we must ensure that relationships with industry and private sector entities do not model inappropriate behaviours or introduce inappropriate influence on the educational environment of medical students or postgraduate medical trainees.

The Faculty of Medicine of the University of Toronto and its faculty members have many valuable relationships with private-sector entities. These relationships encourage and support innovation and accelerate delivery of new health care products and methods to our patients. Financial support from private sector entities has been and continues to be beneficial to the development and delivery of many educational programs.

Standards for the management of potential Conflicts of Interest are required for the accreditation of Undergraduate MD and Continuing Education Programs and such a requirement is pending for Postgraduate Accreditation. For Continuing Education policy see the separate document, *Policy on Sponsorship from Commercial Sources of University of Toronto Accredited Continuing Education Activities*<sup>1</sup>

This document sets out standards that will provide best practices to ensure that relationships between the Faculty, and its academic units and members, and business entities (hereafter “industry”) will be appropriate and transparent. The standards and measures for disclosure are intended to guide the conduct of faculty members and learners by managing potential conflicts to ensure an environment that protects the integrity and reputation of individuals and institutions.

### NOTE:

1. When these standards refer to “gifts” or “sponsorship” they do not refer to donations or relationships arranged or managed through the Office of Advancement of the Faculty of Medicine, University of Toronto or through Foundations of affiliated institutions. Such gifts and donations will be managed under rules as set out for those offices.
2. Nothing proposed in these standards is intended to conflict with existing policy or regulation of the University of Toronto. In the event of perceived conflict, existing policy will govern.

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<sup>1</sup> <http://www.cepd.utoronto.ca/brochures/Sponsorship-Policy-2012.pdf>

3. These standards do not address relationships with charitable organizations, governments, the military, non-governmental (NGO) or quasi-governmental organizations although there may be potential for improper influence and conflict of interest with such entities. Entities described as “non-profit” will also require individual consideration.

## Definitions

### Conflict of Interest

A *conflict of interest* may arise when a faculty or staff member’s personal or other interests are in actual, potential, or perceived conflict with duties or responsibilities to patient care, the University, their hospital, or hospital research institute. Mere existence of a conflict of interest does not imply wrongdoing: conflicts of interest can arise naturally from an individual’s engagement with the world outside the University. When conflicts of interest do arise, however, they must be recognized, disclosed, and properly managed.<sup>2</sup> For purposes of this document, relevant potential conflicts will be those arising from relationships or Financial Interests existing within the last five years.

### Conflict of Commitment

A *conflict of commitment* occurs when commitment to external activities of a faculty or staff member adversely affects the capacity to meet academic responsibilities.<sup>3</sup>

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<sup>2</sup> See the University of Toronto Governing Council Policy on Conflict of Interest – Academic Staff, 1994

<http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppjun221994.pdf>

<sup>3</sup> See the University of Toronto Governing Council Statement on Conflict of Interest and Conflict of Commitment, 2007,

<http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppfeb012007iii.pdf>

### Consulting

Consulting relationships include contractual relationships, advisory boards and any relationship whereby the faculty member receives, or has the expectation to receive, income or other benefit for services other than for clinical or university work. This includes, but is not limited to, honoraria, commissioned papers, and lectures for which money is received.

### Executive Position:

A position with responsibility for a material part of the operations of a business such as Chief Executive Officer, Vice-President, Chief Operations Officer, Scientific or Medical Director.

### Family

For purposes of this document, Family includes a faculty member’s spouse or partner, parents, children or step-children, and the siblings of the faculty member.

### Financial Interest:

An interest in a business consisting of:

- (1) any stock, stock option or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the faculty member does not exercise control; or

- (2) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof.

### **Gifts**

In this report, the word 'gifts' refers to direct gifts to individuals, personal professional corporations, or departments. This does not include donations or relationships managed through the Office of Advancement of the University of Toronto Faculty of Medicine or through Foundations of affiliated institutions which have their own guidelines and regulations.

### **Ownership interest:**

Ownership, part-ownership, including owning shares, or other Financial Interest in a business, including arrangements to receive royalties.

### **Position of Influence**

For these standards, a position of influence in a company includes being a major shareholder (>10% of outstanding shares), a senior officer (CEO, COO, Chief Scientific Officer), or a member of the Board of Directors.

### **Private Sector**

In these standards, Private Sector includes entities that do business with the intent or possibility of commercial gain, generating a profit, or increasing equity.

### **Speakers' Bureaus.**

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 the company selects or has influence over any of: the topic, any part of the content of a talk, or any members of the audience.

## Standards

1. These standards apply to faculty members, medical students, and trainees in all practice settings where there are learners: both university affiliated institutions and in the community.
2. Because the principles in these standards arise out of the professional and trust relationship with patients, learners, and colleagues, they apply to faculty members, medical students and trainees at all times and in all places, including in “off hours” and “off-site,” that is, whether or not on the campus or at an affiliated clinical institution.
3. **Sales Representatives**
  - 3.1. Sales representatives for pharmaceutical and other industries have as an objective the sale of their products. Information they supply about health care related to their products should be considered part of their marketing strategy. Information provided by sales representatives should not be relied upon as a sole or major source of health-care information.
  - 3.2. If meetings between industry product or sales representatives and students or trainees occur, they must be for the purposes of education and should have a faculty member present. The faculty member has a responsibility to ensure that discussions about products are medically and scientifically sound, balanced, and include discussion of any appropriate alternatives.
  - 3.3. Faculty members should consider the educational value of meeting with representatives of industry and recognize that in doing so they model such interactions for medical students and trainees.
    - 3.3.1. Meetings with industry representatives should be by appointment only.
    - 3.3.2. Meetings with industry representatives should not normally take place in the presence of patients unless the representatives are specifically needed for patient care.
  - 3.4. If representatives are to be present during patient care, patients must be so informed. If representatives have permission from hospital authorities to be in patient care areas, it is recommended that they wear identification that clearly indicates they are not part of the health care team.
  - 3.5. Representatives should not ordinarily take part in patient care. Appropriate demonstration by industry representatives of the technical use of equipment, including implantable devices, is acceptable.
    - 3.5.1. If an industry representative must take part in patient care it must only be at the request of the responsible physician or practitioner and with:
      - the knowledge of the patient;

- authorization and credentialing by the institution;
- documentation in the patient record, and,
- approval by regulatory authorities for delegated acts, if required

3.6. Industry representatives must respect patient privacy and confidentiality.

3.7. Medical student or trainee contact information must not be provided to industry representatives.

4. Each clinical education program must offer formal teaching to its medical students or trainees about ethical standards related to interactions with industry and the resultant potential conflicts of interest.

5. **Gifts** must not be accepted from industry.

5.1. This includes food and entertainment which are considered gifts.

## 6. EDUCATIONAL EVENTS AND PROGRAMS

This section includes educational activities within undergraduate and postgraduate programs including rounds, seminars, lectures, and journal clubs and continuing education programs and conferences.

6.1. Educational events must be planned to address the educational needs of the learners, whether practising physicians, medical students, or trainees. Content, organization, and financial arrangements must all be controlled by faculty organizers without influence from sponsors. (See the CMA Guidelines<sup>4</sup>.) Events within postgraduate training programs must be managed by the program administration.

6.2. Funding for educational events must be in the form of unrestricted grants in which the donor has no influence over program content, choice of speakers, or those in attendance. Donors must be acknowledged at each event where the funds are used through mention of company/organization name but not by product names.

- When possible, events should be sponsored by multiple sources to avoid any one company developing a perception of ownership of or influence over the event or a perception of bias by attendees.
- Funds should not be held by an individual event organizer but should be held centrally at the level of an institutional (hospital) or university department or division.

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<sup>4</sup> Guidelines for Physicians in Interactions with Industry <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf>

- Responsible use of sponsorship funding must include only reasonable and properly documented expenses that correspond to a prepared itemized budget.
  - Expected use of any unexpended funding should be discussed in advance with sponsors.

6.3. Financial statements for sponsored events must be prepared and available for audit, including by the sponsors.

**6.4. Guest Speakers**

Choice of speakers, subjects of presentations, travel arrangements, expenses, and honoraria must all be arranged and paid through the faculty organizers of the event and not by sponsors or their agents. Speakers should not be nominated by sponsors or chosen from a list prepared by them.

6.5. Organizers of events may engage conference management companies but they should be hired through the event budget and not directly by commercial sponsors or donors.

6.6. Registration for sponsored events must be through the university or faculty member organizers or conference management company and not through an industry or sponsor's representative.

**6.7. Disclosure at Educational Events and Programs**

6.7.1. All speakers at educational events, whether faculty or guests, must fully disclose in writing prior to the event to the organizers and again at the beginning of each lecture any potential Conflicts of Interest with industry, including relationships with competing corporations. This includes teaching rounds and lectures within university undergraduate and postgraduate programs.

- Potential conflicts include, but are not limited to, partnerships, ownership of shares, receipt of consultation fees, membership on advisory boards or speakers' bureaus, and funding for research.
- Relevant conflicts include those of immediate family members: spouses/partners, children, and parents.

6.7.2. In presentations, written, and AV materials, the use of generic names for drugs, devices, or other products is preferable to the use of trade names. If a trade name is used, the generic name should also be given and other commonly available alternatives should also be mentioned.

6.7.3. If faculty members or trainees use presentation slides prepared by industry, medical communication companies, or any other organization there must be specific verbal and written (on each slide) acknowledgement. Such use should be informed by a consideration of potential bias in the production of such materials. The usual rules of attribution require that use of slides prepared by any other person should be acknowledged.

6.8. Faculty members must disclose potential Conflicts of Interest when participating in curriculum committees or in guideline or standard-setting committees or panels. Occasionally potential Conflicts of Interest will preclude participation in some parts of an agenda.

This applies to faculty members involved in curriculum committees in all programs within the Faculty, not only those sponsored by industry.

#### 6.9. Ghostwriting

As outlined in the University of Toronto *Framework to Address Allegations of Research Misconduct*<sup>5</sup>, faculty members must not agree to publish as author any article written in whole or part by the employees or agents of a company unless contributions are clearly disclosed by authorship or acknowledgement.

(Rules for authorship such as those the International Committee of Medical Journal Editors (ICMJE) and World Association of Medical Editors (WAME) should be observed. These rules would not prevent collaboration with industry researchers who are named authors.)

#### 6.10. Food

Offering hospitality and sharing food may be appropriate at medical educational events. However, arrangements for commercial entities to provide and/or pay for food have been found to engender obligation and give rise to potential Conflict of Interest and undue influence and have fostered an inappropriate sense of entitlement among participants.

6.10.1. Industry representatives must not provide food directly for rounds and undergraduate or postgraduate teaching events. If food is provided, it must be arranged by the program or department. Use of “unrestricted” educational grant funding for refreshments must be in keeping with departmental policies and section 6.2 and representatives of sponsors must not be in attendance.

6.10.2. Accepting invitations to industry-sponsored dinners, even those labelled as educational events, falls into the category of accepting gifts. It is not consistent with these standards and faculty members may attend only at their own expense.

6.10.3. Hospitality, including food, 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.

#### 6.11. Commercial Displays

Any commercial displays at a Continuing Education (CE) event should be in a separate room from educational activities. Commercial displays have no place in undergraduate or postgraduate educational events.

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<sup>5</sup> <http://www.facmed.utoronto.ca/Assets/FacMed+Digital+Assets/research/Research+Misconduct.pdf?method=1>

#### 6.12. **Audit**

Audit mechanisms should be established to assure compliance of CE and other educational events with University and national Conflict of Interest standards.

### 7. **Funding for Postgraduate Programs**

Industry may contribute to educational funding of postgraduate training programs, unrelated to specific events, provided that:

- 7.1. support is received as an unrestricted educational grant. Ideally there will be multiple donors.
- 7.2. it is publicly acknowledged
- 7.3. the funds are managed centrally by the program or division director. Financial statements should be prepared and available for audit.
- 7.4. the industrial donor plays no role in selecting recipients of any scholarships or travelling funds
- 7.5. no *quid pro quo* is established in any such arrangement.

### 8. **Consultation to Industry**

8.1. Faculty members may receive compensation for provision of special expertise in consultation to industry. Such remuneration must be commensurate with the work done and must be disclosed in the annual disclosure report. (See Disclosure, section 3, below.)

Acceptable activities include:

- 8.1.1. Scientific education sessions to improve the knowledge of company personnel
- 8.1.2. Consultation for public advocacy, health promotion, or to develop better products for health care
- 8.1.3. Participation in industry-funded public education not related to a specific brand product

8.2. Faculty members should not participate in **Speakers' Bureaus**.

This is defined as any relationship in which the faculty member is paid by or under contract to a company to give talks and the company selects or has influence over any of: the topic, any part of the content of a talk, or any members of the audience.

Participation in a speaker's bureau makes a faculty member a *de facto* employee of the company. Programs run by for-profit educational companies are included in this category.

8.3. Faculty members should not participate in industry marketing or sales programs.

### 9. **DRUG SAMPLES**

- 9.1. Faculty members should make use of central repositories for drug samples where they exist. Ideally, they will be administered by pharmacists.
- 9.2. Physicians and their families should not use free drug samples themselves that have been given to the physician by industry. Using a sample is equivalent to prescribing for self or family and comes under those regulations.



- 9.3. Physicians who continue to dispense sample drugs must keep appropriate records and ensure the drugs are stored and dispensed in a safe manner. (This is required by CPSO policy.) Concerns are off-label use, theft, improper storage, use of expired products, lack of proper instruction, and failure to note interaction with other medications.
10. When medical students or postgraduate trainees in the Faculty of Medicine undertake research, all Conflict of Interest rules applying to graduate students in the university will also apply.
11. Faculty members involved in institutional selection of drugs or devices for clinical use must declare any potential Conflicts of Interest during the selection process. In some instances, faculty members will need to recuse themselves and withdraw from the particular decision-making process.

## DISCLOSURE

Openness and transparency are key elements in dealing with potential conflict of interest. While disclosure is not always an adequate management of actual or perceived conflicts, it is an essential first step.

1. The following applies to clinical (MD) faculty members appointed to the University in Clinical Departments under the Policy for Clinical Faculty
2. Each **CLINICAL (MD) FULL-TIME** faculty member will annually complete the TAHSN disclosure module, which will be made available to the Department Chair.
3. All clinical (MD) faculty members (full-time, part-time, adjunct, and visiting clinical professors) will disclose using the standardized University of Toronto, Faculty of Medicine disclosure form and/or disclosure slide, unless a different format is required by the sponsoring or organizing entity in question, (e.g. government, educational or professional organization). This disclosure is required in all lectures or seminars, whether in the university or elsewhere, all relationships that might be perceived as creating a potential conflict of interest relevant to the subject being discussed. Disclosure includes, but may not be limited to, salary support, consultancy fees, honoraria, research support, Ownership Interest, or Financial Interest. Declarations will be that the relationship exists, not the amounts involved.

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<sup>6</sup> See definitions, page 2., "Associated entities" includes, but is not limited to, partnerships, personal corporations, and family trusts.

- 3.1. Clinical (MD) faculty members will disclose relationships that might be perceived as creating potential conflicts of interest in the same categories as above
  - 3.1.1. in all manuscripts submitted for publication.
  - 3.1.2. when consulting to government, public, or private agencies, including foundations, charities, or non-governmental organizations.
- 3.2. Clinical faculty members are advised to declare potential conflicts of interest when providing advice or interviews to the media.

## **MONITORING**

### **1. Clinical Departments**

- 1.1. Clinical Departments should ensure that each full-time clinical (MD) faculty member completes the TAHSN disclosure module annually.
- 1.2. Review of disclosures will be done by the Chair or designate.
- 1.3. Each Department Chair will report annually to the Dean or designate a list of individuals who have not completed the TAHSN disclosure module.
- 1.4. Clinical Departments will be asked to report annually to the Dean or designate on departmental adherence to these standards and identify any potential risks to academic independence, integrity, or reputation that may arise from the activities of faculty, for example if it is determined that a large proportion of funding is coming from consistent private sources.
- 1.5. This annual report from the clinical department Chairs should also include financial statements of educational events as in section 6.3.
- 1.6. Department Chairs should work with faculty members to manage any real, potential, or perceived conflict of interest.
- 1.7. Where appropriate and at the discretion of the Chair, advice should be sought from the Professional Relationships Management Committee (PRMC) of the Faculty about how the conflict should be managed.

### **2. The Professional Relationships Management Committee (PRMC)**

- 2.1. The PRMC, advisory to the Dean, will undertake the following in relation to these standards:
  - 2.1.1. Advise the Dean and, as applicable, affiliated institution with jurisdiction over the case as to how the matter should be resolved or managed. Any management plan or sanction recommended by the PRMC will be considered by the Dean and/or Chair, as applicable, prior to implementation.
  - 2.1.2. Facilitate the alignment of the Standards with affiliated hospitals and research institutes, including harmonized disclosure mechanism developed by TAHSN (2017) and other relevant regulatory directives.
  - 2.1.3. Make recommendations for additional bodies, experts and activities needed to support the PRMC, faculty members, students and staff in managing relations with industry.
  - 2.1.4. Develop and approve tools and educational resources for FoM Chairs and other stakeholders.
- 2.2. Review any declarations of real, potential or perceived conflict of interest at the request of the Dean or relevant Chair.