



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*¹

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.

¹ <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.² 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.³

² 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/ppiun221994.pdf>

³ 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 Guidelines⁴.) 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.

⁴ Guidelines for Physicians in Interactions with Industry <http://policybase.cma.ca/dbtw-wpd/Policy/pdf/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*⁵, 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.

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

Section 4.1 m

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 file a confidential disclosure form (see Appendix) with the Department Chair that declares:
 - 2.1. **INCOME:** all sums in excess of \$5,000 annually received from a single source EXCEPT :
 - 2.1.1. Income from the University, affiliated hospitals, or research institutes, from clinical practice, and personal investments.
 - 2.1.2. Honoraria from other universities, agencies such as national or provincial Colleges, or granting agencies.
 - 2.1.3. Income from consultation for national and international agencies such as the Canadian Medical Protective Association (CMPA,) the World Health Organization (WHO,) the Public Health Agency of Canada, and Health Canada
 - 2.2. **HOLDINGS:** financial interests or ownership interests greater than \$5,000 of faculty members or their family or associated entities⁶ in businesses operating in areas related

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

to the faculty member's practice, research, or other professional medical activity.

Note : Holdings in mutual funds are not reportable in this category

- 2.3. For purposes of this declaration, both sections 2.1 and 2.2 apply to income received by or relevant holdings of a personal professional corporation and should be included in the annual disclosure form.
 - 2.4. Each Department Chair will report a list of declarations annually to the Dean or designate.
3. All clinical (MD) faculty members (full-time, part-time, adjunct, and visiting clinical professors) will disclose 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. This 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.
- 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 a completed disclosure form is received from each full-time clinical (MD) faculty member annually.
- 1.2. At the discretion of Chairs, review of disclosures may be by the chair or by a panel.
- 1.3. Each Department Chair will report the declarations annually to the Dean or designate. This annual report should also include financial statements of educational events as in section 6.3
- 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.
- 1.5. Department Chairs should work with faculty members to manage any real, potential, or perceived conflict of interest. Advice may be sought from the Committee on Conflict of Interest of the Faculty or of the relevant hospital or research institution
- 1.6. Where Chairs believe that conflicts of interest are not properly managed, the matter may be referred to Committee on Conflict of Interest of the Faculty or of the relevant hospital or research institution.

2. The Faculty of Medicine

- 2.1. The Dean or designate will
 - 2.1.1. annually review the reports from departments.
 - 2.1.2. identify areas of risk from actual, potential, or perceived conflict of interest at the level of individual faculty members, departments, or divisions, or the Faculty itself.
 - 2.1.3. identify areas of risk if a large proportion of funding is coming from a single private source
 - 2.1.4. provide assistance to Chairs and faculty members to manage and resolve any real, potential, or perceived conflicts of interest.
- 2.2. The Faculty Conflict of Interest Committee will provide advice on request to the Dean or Department Chairs.

Appendix

Annual Disclosure Form — Relationships with Private Sector Entities CLINICAL (MD) FULL-TIME FACULTY ONLY

This form is confidential when completed.
Information collected will be used by Department Chairs and the Faculty
to assess potential Conflict of Interest of the individual.
Deidentified data may be used for aggregated reports.

Note: Faculty members already submitting a disclosure form to a clinical or research institution affiliated with the Faculty may submit a signed current copy of the same form.

Name			
Reporting period	20__	to	20__
Department			
Clinical institution(s)			
Research institution(s)			

1. INCOME

Report all amounts greater than \$5000 received from a single source

- This includes, but may not be limited to, salary support, consultancy fees, honoraria, research support, Ownership Interest, or Financial Interest as defined in these Standards.
- Do not declare income from:
 - The University of Toronto, an affiliated clinical or research institution, or from clinical practice.
 - Honoraria from other universities, agencies such as national or provincial Colleges, or granting agencies.

I have nothing to declare

Source	Amount	Reason for payment					Notes
		Salary	Honorarium	Consultancy fee	Research support	Other (specify in notes)	
	\$	<input type="checkbox"/>					
	\$	<input type="checkbox"/>					
	\$	<input type="checkbox"/>					
	\$	<input type="checkbox"/>					

(Insert further rows as needed)

(continued)

2. HOLDINGS

Report the existence of Financial Interest or Ownership Interest greater than \$5000 in businesses operating in areas related to your practice, research, or other professional activity.

Report for yourself, immediate family members, or associated entities⁷

NOTE:

- Report that holdings exceed \$5000, do not declare amounts
- Mutual fund holdings are not reportable in this category

I have nothing to declare

Financial or Ownership Interests > \$5000

Company	Self	Spouse/ Partner	Family	Relationship to practice, research, or professional activity	Measures to manage potential conflict of interest
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Signature

⁷ Associated entities includes, but is not limited to, partnerships, personal corporations, and family trusts