



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

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A. Application and Scope

- 1. These standards apply to all clinical (MD) faculty members and trainees.
- 2. 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. Conflict of commitment might result in actual or perceived conflict-of-interest. When conflict of commitment scenarios do arise they must be recognized, disclosed, and properly managed.
- 4. These standards do not address research relationships or activities or 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.
- 5. When learners in the Temerty Faculty of Medicine undertake research, all conflict-of-interest rules applying to trainees in the university will also apply¹.

B. Preamble

At the core of the professional relationship between physicians and patients is the primacy of the interest of the patient. As educators in the Temerty 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 entities (including those now licensed under the Integrated Community Health Services Centres Act and known as Integrated Community Health Services Centres ("ICHSCs")) do not introduce inappropriate influence on the educational environment of medical students or postgraduate medical trainees.

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.

Standards for the management of potential conflicts of interest are required for the accreditation of Undergraduate MD, Postgraduate Education, as well as Continuing Professional Development Programs. For additional information regarding continuing education accreditation standards, please see the separate document, *Policy on Sponsorship Support of University of Toronto Accredited Programs and Conferences*.²

In addition, the College of Physicians and Surgeons of Ontario sets out expectations in their *Conflicts of Interest and Industry Relationships* policy, which helps physicians navigate their interactions with industry and manage conflict of interest.³ The Canadian Medical Association also offers guidelines for physicians in their interactions with industry and provides recommendation for physician innovators.⁴

The trust of the public, including patients and family members, faculty, alumni, students, government, and donors is essential for the Temerty Faculty of Medicine to flourish. In order to safeguard that trust, these standards set out expectations for acceptable relationships with industry and private entities and ensure that relationships between the Faculty, its academic units and members, and business entities will be appropriate and transparent. The standards and measures for disclosure are intended to guide the conduct of faculty

³ <u>CPSO Policy on Conflicts of Interest and Industry Relationships</u>

¹ Division of the Vice-President Research and Innovation: Research Integrity

² Policy on Sponsorship Support of University of Toronto Accredited Programs and Conferences

⁴ CMA Guidelines for physicians in interactions with industry/Recommendations for physician innovators





members and trainees by managing potential conflicts to ensure an environment that protects the integrity and reputation of individuals and institutions. Each clinical education program must offer formal teaching to its learners on ethical standards related to interactions with industry and private entities and the resultant potential conflicts of interest.

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).

Nothing proposed in these standards is intended to conflict with existing policy or regulation of the University of Toronto. In the event of conflict, existing policy will govern.

C. Definitions

Clinical (MD) Faculty

Refers to an individual or individuals, licensed (in good standing) to practice medicine in Ontario and holding an appropriate Medical Staff appointment in a TAHSN affiliated teaching hospital or community practice or, working in a community hospital, community clinic, industry or in a private practice setting without affiliation, and appointed as clinical faculty in a Temerty Faculty of Medicine clinical department. All clinical (MD) faculty members belong to a clinical department and have an academic rank and appointment category and an academic position description.

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.⁵ 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.

Consulting

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).

Donor

A donor is an individual, group, corporation, or organization which contributes funds, goods or services to the Faculty through the Office of Advancement of the Temerty Faculty of Medicine or through foundations of affiliated institutions. For clarity, a donor does not receive anything of value in return for their donation.

⁵ See the University of Toronto Governing Council Policy on Conflict of Interest – Academic Staff, 20 June 2023





Fellows

Medical learners who have completed residency training and are doing advanced post-residency training in a clinical area and/or an area of academic scholarship such as research, quality and innovation, or education scholarship.

Financial Interest

Means an opportunity to receive anything of monetary value, e.g., salary, royalties, fees, work-in-kind, gifts, or other payments, dividends, or distributions, including through equity, partnership, or beneficial interests (e.g., stock, stock options, or other ownership interests) or any intellectual property rights.

Gifts

In this document, 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 Temerty Faculty of Medicine or through foundations of affiliated institutions which have their own guidelines and regulations.

Industry

The full range of commercial enterprises that may be associated with health care. These include, but are not limited to, the pharmaceutical industry, the biotechnology industry, the medical device industry, digital health technologies, and commercial providers of services related to clinical practice, research, and/or education.

Integrated Community Health Services Centres (ICHSCs)

Healthcare facilities licensed under the *Integrated Community Health Services Centres Act*. These clinics are typically non-hospital clinical organizations in which members of the public receive services and for which facility costs are charged to healthcare providers and/or government or corporate organizations.

Medical Students

Learners registered in the undergraduate MD program in the Temerty Faculty of Medicine at the University.

Ownership Interest

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

Personal Associate

Means a (i) spouse or spouse equivalent or (ii) family member or other person in a close personal relationship who could be perceived to influence your roles, responsibilities, and commitments to the University, your hospital(s) and its patients and/or research participants. For purposes of this document, a family member includes a faculty member's spouse or partner, parents or step-parents, children or step-children, grandparents, uncles, aunts, siblings, nieces, nephews, and grandchildren of the faculty member.

Postgraduate Medical Education (PGME) Learners

Medical graduates registered with the PGME Office in the Temerty Faculty of Medicine at the University as residents or as fellows.

Private Entities

There are many types of hybrid public-private and solely private entities that have historically existed in the Canadian healthcare system. These include entities that do business or provide healthcare with the intent or possibility of commercial gain, generating a profit, or increasing equity. These entities include Integrated Community Health Service Centres.





Relationships

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.

Residents

Post-graduate MD learners whose training will lead to specialty or subspecialty certification by the Royal College of Physicians and Surgeons of Canada (RCPSC) or to certification as a family physician by the College of Family Physicians of Canada (CFPC).

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 presentations and where 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.

Sponsor

A sponsor is an individual, group, corporation, or organization which contributes funds, goods or services to support accredited educational activities, learning resources, or tools, and receives something of value in return (i.e., the activity or event advertises or promotes the business' brand, products or services.)

Trainees

Include Fellows, Medical Students, PGME learners, residents and learners registered in a continuing education program.





D. Standards

1. Industry Sales Representatives in an Educational Setting

- 1.1. Industry sales representatives have as an objective the sale of their products. The information that sales representatives 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, credible, or major source of information.
- 1.2. Faculty members should consider the educational value of meeting with representatives of industry and recognize that in doing so they model such interactions for trainees. If meetings between industry product or sales representatives and 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.
- 1.3. Meetings with sales representatives should not normally take place in the presence of patients unless the representatives are specifically needed for patient care, or for the appropriate demonstration by industry representatives of the technical use of equipment or devices.
- 1.4. If sales representatives are to be present during patient care, it must be at the request of the responsible physician or practitioner and patients must be so informed. If sales representatives have permission from hospital authorities or facility leadership to be in patient care areas, it is required that they wear identification that clearly indicates they are not part of the health care team.
- 1.5. Sales representatives must respect patient privacy and confidentiality.
- 1.6. Trainee contact information must not be provided to industry representatives.

2. Referrals

2.1. Circumstances that are or could be perceived as being a self-referral or referral where the faculty member stands to benefit is considered a conflict of interest and disclosure to both trainees and patients is expected.

3. Gifts

- 3.1. Gifts must not be accepted from industry or private entities.
- 3.2. For clarity, gifts include but are not limited to food/beverages, travel, and entertainment.

4. Food/Beverage

- 4.1. Offering hospitality and/or food/beverages may be appropriate at medical educational events. However, arrangements for private entities to provide and/or pay for food/beverages have been found to engender obligation and give rise to potential conflict of interest and undue influence among participants. For these reasons:
 - 4.1.1. Industry representatives and private entities must not provide food/beverages directly for rounds and undergraduate or postgraduate teaching events. If food/beverages are provided, they 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 D7 and representatives of sponsors must not be in attendance.
 - 4.1.2. Accepting invitations to private entity or 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.





4.1.3. 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.

5. Educational Events and Programs

For the purposes of this section, educational programs include educational activities within undergraduate and postgraduate programs including rounds, seminars, lectures, and journal clubs, and continuing education programs and conferences. Faculty members who are speakers, organizers, committee members and/or who have any relationship with private-sector sponsors providing funding are responsible for confirming the unrestricted nature of the funds, where the funds are held, and the name(s) of the sponsors.

- 5.1. Planning and Registration
 - 5.1.1. Educational events must be planned to address the educational needs of the learners, whether practicing physicians, or trainees. Content, organization, and financial arrangements must all be controlled by faculty organizers without influence from sponsors (see the CMA Guidelines6). Events within postgraduate training programs must be managed by the program administration.
 - 5.1.2. Organizers of events may engage conference management companies, but they should be hired through the event budget and not directly by sponsors or donors.
 - 5.1.3. 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.
- 5.2. Funding
 - 5.2.1. Funding for educational events must be in the form of unrestricted grants in which the donor or sponsor has no influence over program content, choice of speakers, or those in attendance. Donors/sponsors must be acknowledged at each event where the funds are used through mention of company/organization name but not by product names.
 - 5.2.1.1. 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.
 - 5.2.1.2. Funds should not be held by individual faculty members organizing an event but should be held centrally at the level of an institutional (hospital) or university department or division.
 - 5.2.1.3. Responsible use of sponsorship funding must include only reasonable and properly documented expenses that correspond to a prepared itemized budget.
 - 5.2.1.3.1. Expected use of any unexpended funding should be discussed in advance with sponsors.
 - 5.2.1.4. Financial statements for sponsored events must be prepared and available for audit, including by the sponsors.
- 5.3. 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 CMA Guidelines for interacting with industry





5.4. Disclosure at Educational Events and Programs.

All speakers at educational events, whether faculty or guests, must fully disclose any relationship with industry or private entities which may give rise to a conflict of interest, including financial and non-financial conflicts of interest. This includes teaching rounds and lectures within university undergraduate and postgraduate programs.

- 5.4.1. Potential conflicts include, but are not limited to, partnerships, ownership interests, consulting, membership on advisory boards or speakers' bureaus, and funding for research.
- 5.4.2. Relevant conflicts include those of personal associates.
- 5.4.3. 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.
- 5.4.4. 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.
- 5.5. Commercial Displays
 - 5.5.1. Any commercial displays or advertising for industry and private entities at a Continuing Education (CE) event should be in a separate room from educational activities. Commercial displays and advertising for industry and private entities have no place in undergraduate or postgraduate educational events.

6. Academic Leadership

6.1. Faculty members must disclose potential conflicts of interest, including ownership in private entities, when participating in leadership positions, 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.

7. Ghostwriting

7.1. As outlined in the University of Toronto *Framework to Address Allegations of Research Misconduct*⁷, 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.)

8. Funding for Postgraduate Programs

- 8.1. Industry and private entities may contribute to educational funding of postgraduate training programs, unrelated to specific events, provided that:
 - 8.1.1. support is received as an unrestricted educational grant. Ideally there will be multiple funders.
 - 8.1.2. it is publicly acknowledged.

⁷ University of Toronto Framework to Address Allegations of Research Misconduct, Section 4.1 m





- 8.1.3. the funds are managed centrally by the program or division director. Financial statements should be prepared and available for audit.
- 8.1.4. The industry or private entity funder plays no role in selecting recipients of any scholarships or travel funds.
- 8.1.5. No *quid pro quo* is established in any such arrangement.

9. Consulting

- 9.1. Faculty members may receive compensation for consulting services. Such remuneration must be commensurate with the work done and must be disclosed in the annual disclosure report. Acceptable activities may include (unless prohibited by other sections outlined in the standards):
 - 9.1.1. Scientific education sessions to improve the knowledge of company personnel. This may be in relationship to research in which the company is engaged.
 - 9.1.2. Consultation for public advocacy, health promotion, or to develop better products for health care.
 - 9.1.3. Participation in industry-funded public education not related to a specific brand product.
- 9.2. Faculty members should not participate in speakers' bureaus. Programs run by for-profit educational companies are included in this category.
- 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.⁸

10. Drug Samples

- 10.1. Faculty members should make use of central repositories for drug samples where they exist. Ideally, they will be administered by pharmacists.
- 10.2. 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 personal associates and comes under those regulations.
- 10.3. 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.
- 10.4. 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.

E. Disclosure

- 1. 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.
- 2. 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.

⁸ CPSO Advertising Policy





- 3. All clinical (MD) faculty members (full-time, part-time, adjunct, and visiting clinical professors) will disclose any relationships which may give rise (or be perceived to give rise) to a conflict of interest using the standardized University of Toronto, Temerty 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). Disclosure includes, but may not be limited to, salary support, consultancy fees, honoraria, research support, participation in a private entity, ownership interest, or financial interest. Declarations should identify that the relationship exists, not the amounts involved.
 - 3.1. This disclosure is required: in all lectures or seminars, whether in the University or elsewhere; in all manuscripts submitted for publication; and when consulting to government, public, or private agencies, including foundations, charities, or non-governmental organizations.
- 4. All clinical (MD) faculty members are expected to disclose to both trainees and patients if they have any financial or personal interest in medical products or procedures they recommend.
- 5. All clinical (MD) faculty members must declare potential conflicts of interest when providing advice or interviews to the media.

F. Monitoring

- 1. Review
 - 1.1. Review mechanisms have been established through the Clinician Management and Reappointment System (CMaRS), PRMC, and Annual Activity Reporting to assure compliance of Continuing Professional Development and other educational events with University and national conflict of interest standards.

2. Clinical Departments

- 2.1. Clinical Departments should ensure that each full-time clinical (MD) faculty member completes the TAHSN disclosure module annually.
- 2.2. Review of disclosures will be done by the Chair or designate, in collaboration with Temerty Faculty of Medicine Clinical and Faculty Affairs.
- 2.3. Each Department Chair will report annually to the Dean or designate a list of individuals who have not completed the Relationship Management disclosure module in CMaRS.
- 2.4. 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.
- 2.5. Chairs should have a mechanism to review financial statements for departmental educational events as part of their budgetary process.
- 2.6. Department Chairs should work with faculty members to manage any real, potential, or perceived conflict of interest.
- 2.7. Where appropriate and at the discretion of the Chair, advice should be sought from PRMC about how the conflict should be managed.





3. **Professional Relationships Management Committee (PRMC)**

- 3.1. The PRMC will undertake the following in relation to these standards:
 - 3.1.1. 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.
 - 3.1.2. Make recommendations for additional bodies, experts and activities needed to support the PRMC, faculty members, students, and staff in managing relations with industry and private clinics.
 - 3.1.3. Develop and approve tools and educational resources for Chairs and other stakeholders.
 - 3.1.4. Review any disclosures of real, potential, or perceived conflict of interest at the request of the Dean or relevant Chair.
 - 3.1.5. Advise the Dean and, as applicable, the relevant affiliated institution with jurisdiction over the case as to how a conflict should be resolved or managed. Any management plan or potential disciplinary measure recommended by the PRMC will be considered by the Dean and/or Chair, as applicable, prior to implementation.