



CONFLICT OF INTEREST (COI) with COMMERCIAL ENTITIES

Effective date: November 29, 2013

Supersedes: none

Revised: n/a

INDEX

1.0 Introduction.....	1
2.0 Definitions	
Conflict of Interest (COI).....	2
Financial Interest.....	3
Ghost Authorship.....	3
Gift.....	3
Industry.....	4
Interest.....	4
Learner.....	4
NOSM Event.....	4
Professionalism.....	4
Sponsorship.....	5
3.0 Conflict of Interest Principles.....	5
4.0 Scope and Purpose of the Policy.....	6
5.0 Managing Conflict of Interest through Awareness, Dissemination, and Direct Communication.....	6
6.0 Managing Transparency and Disclosure.....	7
7.0 Gift Acceptance.....	8
8.0 Managing Gift Acceptance.....	9
9.0 Conflict of Interest in Research Activities.....	9
10.0 Managing Conflict of Interest in Research Activities.....	9
11.0 Conflict of Interest in Education.....	9
12.0 Managing Conflict of Interest in Education Activities.....	10
13.0 Managing Conflict of Interest in Clinical Learning Environments.....	10
14.0 Managing Learner Interactions with Commercial Entity Representatives.....	11
15.0 Sponsorship.....	11
15.1 Managing Conflict of Interest in Sponsorship Activities.....	12
15.2 Sponsorship Accountability.....	12
15.3 Managing Conflict of Interest in Commercial Named Awards.....	13
16.0 Failure to Comply with Disclosure.....	13
16.1 Presentations.....	13
16.2 Financial Reimbursements.....	13

16.3 Conflict of Interest in Clinical Learning Environments.....	13
16.4 Free Medication and Device Samples.....	13
17.0 Policy Review Process.....	14
18.0 Resource Documents.....	14
19.0 Evidence-Informed References and Readings.....	14
Version History.....	15

Appendixes

Implementation Plan (November 2013)

Situational Examples



CONFLICT OF INTEREST (COI) with COMMERCIAL ENTITIES POLICY

Approved By: NOSM Board of Directors

Responsible Office(s): Executive Group

Responsible Officer(s): Associate Deans

Supersedes: none

Effective date: November 29, 2013

Revised: n/a

1.0 Introduction

Society expects that health professionals and medical school personnel should act in ways that are unbiased, and in the best interests of individual patients and the wider community. Over the last decade, evidence has emerged that commercial interests, including pharmaceutical and medical device manufacturers, have at times exerted undue influence on physicians and other health professionals. This has led to the commitment by all Canadian medical schools to develop and implement a Conflict of Interest (COI) policy.

The Northern Ontario School of Medicine (NOSM) has a social accountability mandate to be responsive to the needs of the people and the communities of Northern Ontario with a focus on improving health care and health outcomes. The first new medical school in Canada for the 21st century, NOSM also has a commitment to innovation. The success of distributed, community-engaged learning, NOSM's distinctive model of education and research, depends on close collaboration with hospitals and health services, physicians and other health professionals, and the communities of Northern Ontario. In this context, this COI policy has been developed through an extensive collaborative process, and is anticipated to be consistent with the COI policies of partner clinical sites.

It is important to recognize that almost all NOSM clinical faculty members are stipendiary faculty who are primarily clinical service providers. Very few clinical faculty members have protected time away from clinical responsibilities to undertake education, research, or other academic activities. In this context, there will be a staged implementation of this policy to allow time for changes to occur in existing practices.

The intent of the COI policy is to enhance the professionalism of all NOSM faculty members, learners (including medical students and residents), and staff members in undertaking educational, research, clinical and other activities, while at the same time acknowledging and avoiding perceived, potential, and actual conflicts of interest. This policy provides a framework, which is designed to assist individuals and groups within and associated with NOSM to achieve success while ensuring the highest ethical and academic standards.

Every individual, group, and organization has interests that affect decision-making, behaviours, and interactions with others. An "interest" is defined as the advantage or benefit of a person or group, or having a stake or involvement in an undertaking, especially a financial one (*Oxford English Dictionary*). There are many types of interests, including personal, professional, social, and financial interests, for example, and these interests can combine and intersect.

A conflict of interest exists in any situation where there is a potential divergence between an individual's personal (or combined) interests and his or her obligations to the School such that an independent observer would reasonably question whether the individual's behaviour or decisions are in any way

motivated by considerations of personal interest, financial, or otherwise. A conflict of interest may be actual, perceived, or potential.

Conflicts that are thought to exist (e.g., perceived or potential) may be equally as damaging to NOSM as real or actual COIs. When a conflict of interest does occur, others should take care not to infer intent or guilt. Conflicts of interest may arise based on past practices and/or relationships. Dealing with COI should err on the side of transparency and disclosure.

2.0 Definitions

For the purposes of this document, the following definitions will apply:

Conflict of Interest (COI): A conflict of interest exists in any situation where there is a potential divergence between a member's personal interests and his or her obligations to the School such that an independent observer would reasonably question whether the member's behavior or decisions are in any way motivated by considerations of personal interest, financial, or otherwise. A conflict of interest may be actual, perceived, or potential. * (*Adapted from Memorial University*).

Conflict of interest occurs when an individual has a significant financial, professional or other personal consideration with commercial entities that may compromise, or have the potential to compromise, or the appearance of compromising, his or her professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other obligations.

- a. **Real or Actual COI:** At least three prerequisites have to be established before a member or associate of the School can be said to be in a real conflict of interest. They are:
 - the existence of a private interest;
 - that it is known to the member; and,
 - that it has a connection with his/her teaching, administrative, or research duties or responsibilities that is sufficient to influence the exercise of those duties or responsibilities.
- b. **Perceived COI:** A perceived conflict of interest exists when there is a reasonable apprehension, which reasonably well-informed persons could have, that a conflict of interest exists.
- c. **Potential COI:** A potential conflict of interest is one that may develop into an actual conflict. The potential for conflict exists as soon as the faculty member, staff member, or learner can foresee that he or she has a private interest to the extent that there is influence on a duty, or responsibility. It may be real or perceived. * (*Adapted from Memorial University*).

Conflict of Interest (COI) may arise when a faculty member or staff member's personal or other interests are in actual, potential, or perceived conflict with duties or responsibilities to patient care, the School of Medicine, or their teaching site. 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 and

medical school. When conflicts of interest do arise, however, they must be recognized, disclosed, and properly managed. For purposes of this document, relevant potential conflicts will be those arising from relationships or financial interests within the **last five years**. (*Adapted from U of T.*)

Conflicts that are thought to exist can be equally as damaging to NOSM as actual COIs. When a conflict of interest does occur, others should take care not to infer intent or guilt. Conflicts of interest can arise based on past practices and/or relationships. Dealing with real, perceived, or potential COI should err on the side of transparency and disclosure.

Financial Interest

Financial Interest is anything of monetary value, and includes, but is not limited to a salary or other payments for services.

Examples may include:

- Payment for serving as a speaker or on a speaker's bureau;
- Payment for serving on an advisory board;
- Payment for enrolling patients in clinical trials;
- Payment for travel expenses for attending conferences;
- Payment for expert testimony for the funder;
- Equity interests (e.g., stocks, stock options) [Other examples include commercial business interests such as ownerships, partnerships, joint ventures]; and,
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

Ghost Authorship

Ghost Authorship “exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself. Ghost authors generally work on behalf of companies, or agents acting for those companies, with a commercial interest in the topic, and this compounds the problem. For example, a writer employed by a commercial company may prepare an article, then invite an expert in the field to submit the work, perhaps with minor revisions, under his or her own name. The submitting author may be paid, directly or indirectly, for this service. In other circumstances, investigators may pay a professional writer to help them prepare their article but not mention this assistance, gaining credit for writing they have not done. Although editors seek to avoid publication of ghost written articles, these articles are often very difficult to detect.”

(*World Association of Medical Editors.*)

Gift

Gift is defined as anything of value that is provided by a commercial entity or individual to a recipient or group of recipients for which the recipient(s) has not paid or provided services.

This policy, however, does include relationships with individuals or organizations that contribute donations received and managed through the NOSM Advancement Office.

Personal gifts to individuals must be avoided, regardless of value, and include, but are not limited to:

1. Cash
2. Gift certificates
3. Meals
4. Tickets
5. Merchandise
6. Travel and accommodations
7. Personal payments, in-kind support, and/or perceived remuneration (e.g., payments to spouse)

Gifts that are permissible include:

1. An honorarium for a specific service rendered, such as a speaker fee.

Industry

Industry typically refers to for-profit commercialized entities, and in particular, the pharmaceutical, biotech and medical devices, hospital and research supply industries and businesses. Industry typically includes organizations beyond those involved, and specifically charged, with the responsibility of medical education. For this document, industry is inclusive of not-for-profit organizations that are affiliated with a for-profit enterprise, in addition to financial organizations. It is understood that a significant number of Medical School faculty members are not part of the medical profession and need to interact with industry as researchers and educators for good and proper reasons related to their roles and responsibilities.

Interest

Interest is defined as the advantage or benefit of a person or group or having a stake or involvement in an undertaking, especially a financial one. (*Oxford English Dictionary*.)

Learner

Learner is defined as “a person formally registered in the Northern Ontario School of Medicine in a course or program of study. A learner may be registered in an undergraduate, a graduate, or a postgraduate program.” (NOSM Collaborative Agreements with Hospitals definition)

NOSM Event

NOSM event is defined as an activity organized by any School representative, staff member, learner, Board of Director, or group associated with NOSM, on or off campus.

Professionalism

The **ethics of professionalism** in medicine is more concerned with the characteristics and behaviours of physicians in the context of medicine as a profession. Specifically, it examines desirable and undesirable attributes of physicians (4). *Desirable* behaviours include altruism, accountability, excellence, duty, honour, integrity, respect for others, and a commitment to lifelong learning (1,4). *Undesirable* conduct, on the other hand, includes abuse of power, bias, sexual harassment, breach of confidentiality, arrogance, greed, misrepresentation, impairment, lack of conscientiousness, and conflicts of interest (1,4). The ethics pertaining to professionalism not only motivate patient-physician

interaction, but also outline expected behaviour with other physicians, health-care workers, medical students, and preceptors.

http://www.med.uottawa.ca/students/md/professionalism/eng/emergence_professionalism.html

Sponsorship

Sponsorship is a mutually beneficial agreement or contract between the School and an external organization, company, or enterprise where the external organization contributes funds, goods or services-in-kind to a program, event or activity in return for acknowledgement, recognition, or other promotional consideration related to the program, event, or activity.

3.0 Conflict of Interest Principles

A conflict of interest exists when there is:

- **any actual, perceived, or potential personal gain** by a faculty member, staff member, or learner as the result of an interaction with a commercial entity, OR,
- **any actual, perceived, or potential influence** by commercial entities on a faculty member, staff member, or learner as a result of industry interactions, events, or activities such as sponsorship, fundraising, revenue generation, monetary compensation, or gift giving.

COI principles uphold standards of professionalism and eliminate any activities that may undermine this policy objective. It is the overall intent that policy adherence shall result in optimal care, education, and research, and equally retain high standards of professionalism and sustain public trust. Assisted and guided by the “CMA Guidelines for Physicians in Interactions with Industry,” this policy sets out clear COI and professionalism expectations for faculty, staff, and learners in managing such situations.

To safeguard the integrity and reputation of NOSM and its related academic networks and health service and other partners, the following principles shall foster evidence-informed conduct that is free from undue external influence in situations where an interaction takes place with commercial entities inclusive of for-profit and non-profit organizations that are affiliated with a for-profit enterprise.

The three principles supporting this policy to alleviate actual, perceived, or potential commercial interests in the shaping of teaching and professional activities, the direction of research, and/or the promotion of individual interests, are:

- 1) That NOSM and its partners' independence and autonomy, as well as the academic freedom of individuals, are not influenced unduly by any external commercial interests;
- 2) That there be no actual or perceived personal benefit to any faculty member, staff member, or learner from the inappropriate use of their NOSM affiliation or their association with any commercial entity; and,
- 3) That faculty, staff members, and learners do not act in any way contrary to the public interest or NOSM's social accountability mandate according to the definition of COI.

Commercial entity COI situations may arise due to the distributed nature of the Northern Ontario School of Medicine; however, situations that are most apparent and will most likely directly impact the organization and its members may occur when faculty, staff, and learners:

- 1) use their influence in the purchase of equipment, products, or materials or services;
- 2) use their NOSM affiliation to gain access to and/or use privileged/confidential information for themselves, their family members, or an organization with which they are associated for personal gain;
- 3) accept gifts, benefits, or financial favours that would be construed as personal gain;
- 4) use their NOSM affiliation for personal gain while seeking commercial entity sponsorship;
- 5) fail to disclose their financial relationship in education and research activities; and,
- 6) use their relationship with NOSM to shape future professionals' practices and preferences in either the classroom or clinical settings.

4.0 Scope and Purpose of Policy

The scope of this policy includes any person(s) acting on behalf, or at the request, of NOSM including, but not limited to: Board members; employed, joint, and stipendiary faculty members (except for members of Unit 1 OPSEU 677, who are covered by the *Faculty Collective Agreement*); medical learners (inclusive of undergraduate medical students, postgraduate residents, and other health professional learners affiliated with NOSM); and, contract, part-time, and full -time staff members.

The purpose of this policy is to:

1. provide clarity when a conflict of interest situation is actual, perceived, or potential, and to identify what needs to be disclosed when, and by whom, when a conflict of interest exists or is perceived to exist;
2. define the levels of COI, COI principles, and the responsibilities and risk management practices required to avoid and manage conflict of interest situations;
3. identify mechanisms that refer to specific protocols and processes related to COI situations; and,
4. contribute to the discourse of medical professionalism and industry relations at all levels of education and practice of being a learner, faculty member, and/or practising health professional.

5.0 Managing Conflict of Interest through Awareness, Dissemination, and Direct Communication

Part-time faculty (e.g. stipendiary, joint) in the Divisions of Clinical, Human, and Medical Sciences, and faculty in senior administrative positions shall be aware of the policy through the faculty appointment and re-appointment application process, as well as made aware, or provided with a copy, of the *Conflict of Interest with Commercial Entities* policy by NOSM's Faculty Affairs Office upon receiving a faculty appointment ranking. Faculty members will be asked to sign a form identifying that they have read and

reviewed the policy as part of their acceptance of their faculty position and ranking with the Northern Ontario School of Medicine.

Similarly, new staff members and learners should be provided with a copy of the policy and be asked to acknowledge in writing that they have read and received the policy as part of their orientation.

Members of the Unit 1 bargaining unit (full-time faculty, professional librarians, and professional staff) are bound by the Unit 1 Collective Agreement and need to be familiar with the articles that are relevant to conflict of interest in their agreement, such as Article 1.3 (Academic Freedom), Article 2.1 (Rights, Responsibilities and Duties of Teaching Faculty and Librarians), Article 2.7 (Promotion Procedures), and Article 2.17 (Fraud and Misconduct in Academic Research and Scholarly Activity).

Staff supervisors shall ensure that all staff members are familiar with and regularly refer to and review the COI policy.

NOSM learners shall be informed of institutional conflict of interest policies through their orientation to NOSM and NOSM-affiliated clinical learning institutions. Additionally, curriculum and learning objectives and outcomes across all programs should include specific content related to COI, including transparency and an understanding of the limitations of disclosure. Educational materials shall be developed by faculty to ensure that an awareness of ethics, professionalism, and the relevance of interactions with commercial entities with respect to COI, is integrated into existing learner curricula and continuing professional development activities.

6.0 Managing Transparency and Disclosure

Faculty members, staff members, and learners, subject to this policy, must disclose in writing to their direct reporting relationship, supervisor (for staff members and learners) or the Associate Dean of Faculty Affairs or designate (for faculty members) prior to engaging in any activities that have a real, perceived, or potential COI. If in doubt, the individual should consult and seek clarification before engaging in the activity. NOSM's commitment to transparency and disclosure, while recognizing the School's commitment to commercial entity collaboration, requires transparency and disclosure by individual(s). The disclosure of relevant financial interests is imperative to sustaining a transparent organization that is free from undue external influence.

As part of their professional responsibilities, faculty members, staff members, and learners who have received financial reimbursements for education and research should report any financial relationships annually to their supervisors (for staff members and learners), or Associate Dean, Faculty Affairs or designate (for faculty members) in order to manage any conflict of interest through transparency and disclosure.

Certain COIs may not be considered to be relevant, but may influence teaching and attitudes towards industry, and industry-sponsored or provided information.

Faculty members, staff members, and learners should be aware of other applicable existing NOSM policies, such as Administration's Supply Chain Code of Ethics (2010) and Procurement of Goods and Services Protocol (2011); Office of CEPD's Continuing

Education and Professional Development Policy on Relationships with Industry (January 2013); Faculty Affairs' policy on Professionalism for Clinical Faculty (2012); and, Advancement's Donor Approach Management Policy (2009).

7.0 Gift Acceptance

COI that undermines the integrity of the institution and/or the health professional–patient relationship must be avoided. The acceptance of gifts of any value has been shown to have the potential to influence clinical decision-making. Interactions with industry must be ethical, and should neither create conflicts of interest that hold the potential to put patient safety or data integrity at risk, nor compromise the integrity of education, the reputation of individuals, and the institution. Individuals must be aware that no matter how energetically they consciously disassociate themselves from influence, gifts will still have an unconscious influence. It is considered unacceptable for patient care decisions to be influenced by the possibility of a personal gain. COI arises in situations that are representative of, but not exclusive to:

- an influence on action, duties, or purchases;
- unauthorized disclosure for professional gain; and,
- giving, offering, or promising things that have an attached value.

Gifts include not only articles of value, but also include, and are not limited to, travel, accommodation, meals, and the like, including those that might be provided by commercial external sponsors of continuing education programs, or conferences in which the faculty or staff member or learner is playing no role other than that of an attendee, or by external organizations which offer products or services related to the faculty or staff member's profession or learner's future profession in situations in which the faculty or staff member or learner may be in a position to influence others to use the external organization's products or services.* (*Adapted from the University of Toronto Conflict of Interest Policy.*)

NOSM supports the need for its research and educational initiatives to be free of undue external influence. Compensation to a faculty member, staff member, or learner includes direct and indirect remuneration, and gifts or favours regardless of a monetary amount or material value. Any acceptance of such compensation from a commercial entity or individual on-campus or off-campus to an individual faculty member, staff member, or learner that may result in a conflict of interest needs to be disclosed within direct reporting relationships, as per the requirement of this policy.

Faculty and staff members shall not arrange for, or facilitate, the attendance of students and residents at non-accredited educational events sponsored by a commercial entity.

Because COI principles arise out of the professional and trust relationship with patients, learners, and colleagues, they apply to faculty members, staff members, and learners at all times and in all places, including during "off hours" and when "off-site," whether or not on the campus of the university, or at an affiliated teaching site.

Any activity(s) that may compromise the School's mission, integrity, or public trust may, in turn, compromise future collaborations and innovations through commercial entity funding.

8.0 Managing Gift Acceptance

The acceptance of gifts from commercial entities (individuals or organizations) by an individual is not an appropriate practice. If an individual faculty or staff member or learner has any doubts about the propriety of accepting a particular gift, the faculty or staff member or learner should openly discuss the matter with the person to whom the faculty or staff member or learner reports.

9.0 Conflict of Interest in Research Activities

With regard to the integrity of research, conflict of interest, and academic freedom, as per the NOSM Board Policy Manual (2013),

The Corporation (NOSM) is committed to protecting the Integrity of Research, to abiding by ethical principles in all its research and to prohibiting conflicts of interest between members of the Corporation and third parties.

With respect to risks associated with research involving human subjects, all contracts, protocols or investigator agreements for industrial sponsorship of clinical trials or for participation in such clinical trials shall be deemed to provide that the clinical investigators shall not be prevented by the sponsor or anyone else from informing participants in the study, members of the research group, other physicians administering the treatment, research ethics boards, regulatory agencies and the scientific community, of risks to participants that the investigators identify during the research. These provisions also apply to any risks from a treatment so identified following the conclusion of a trial if there are patients being administered the treatment in a non-trial setting.

*The term "risk" includes but is not limited to the inefficacy of the treatment and direct safety concerns. All contracts, protocols or investigator agreements for industrial sponsorship of clinical trials or for participation in such clinical trials shall reproduce this declaration on Integrity of Research and the declaration on Academic Freedom. * Excerpt from the Academic Freedom and Integrity of Research, Board Policy Manual (2013)*

10.0 Managing Conflict of Interest in Research Activities

Faculty members, staff members, and learners should:

- not participate in either ghostwriting or activities that incorporate the practices of ghostwriting by industry;
- reveal their conflict of interest to sponsors or to those who commission work, or when asked to undertake reviews of research grant applications or manuscripts for publication, or to test products for sale or for distribution to the public;
- disclose all conflicts of interest when submitting work for publication or for consideration by granting organizations; and,

11.0 Conflict of Interest in Education

Academic-led education in the classroom and within the clinical teaching environments must adhere to COI policies and protocols. While NOSM maintains a multiplicity of relationships with many organizations and institutions, the participation in industry-sponsored programs is acceptable and appropriate only if the funds are pooled and in

the form of an education grant that does not identify any one industry or organization as the sole sponsor of any part of, or the whole, program.

12.0 Managing Conflict of Interest in Education Activities

For all educational events associated with NOSM:

1. The Office of Continuing Education and Professional Development (CEPD) must accredit all commercial entity-funded CEPD programming, abiding by the policies and procedures of accreditation and regulatory bodies.
2. Commercial entity funds received for accredited education events must be received in the form of an unrestricted grant and funds pooled where applicable. The funds must be directed to the Office of CEPD and must not be directed to an individual faculty member, staff member, or learner. To mitigate the risk of COI, it is encouraged that more than one specific sponsor be involved in an event to allow for the pooling of funds for educational events with no sole sponsor identified as singly aligning with the event.
3. Presenters and members of education planning committees must complete a Declaration of Conflict of Interest form.
4. Presenters must visually display a COI slide(s) and verbally acknowledge affiliations that may cause a perception of bias, financial or otherwise (i.e., sitting on a Board of a pharmaceutical company), or verbally declare that no conflict of interests exists related to their presentation content.
5. Acknowledgement of relationships between academics and industry requires faculty members, staff members, and learners to be transparent and abide by protocols of disclosure, thereby alleviating elements of risk that may harm the reputation and integrity of the institution and the person at potential risk. Those education and research situations of perceived and potential conflict of interest, if disclosed and managed appropriately, may be permissible, while other situations that cannot be dealt with and/or managed appropriately should not be pursued.
6. Faculty members, staff members, and learners should use evidence-informed decisions and their professional judgment in:
 - Attending non-accredited industry-sponsored events even when they are advertised as continuing medical education.

13.0 Managing Conflict of Interest in Clinical Learning Environments

Ensuring patient safety and avoiding any undue external influence on clinical decision making as a result of interactions and relationships with commercial entities is at the forefront of clinical care and teaching responsibilities. NOSM faculty members, staff members, and learners in clinical learning environments as part of their professional responsibilities are expected to comply with their respective clinical teaching institutional COI policies on interactions with commercial entities. Failure to comply with policies may result in a meeting with their clinical supervisor within the respective institution, and/or the Associate Dean of the respective health professional program at the Northern Ontario School of Medicine.

14.0 Managing Learner Interactions with Commercial Entity Representatives

As a general rule, commercial entity representatives should not interact independently with learners, either on campus, or in clinical teaching environments. However, from time to time, there may be the opportunity for the expertise of a representative required for instructional teaching of a device. In these situations, the student or resident learning experience must be in the presence of a faculty member to supervise the interaction.

Faculty members have a teaching responsibility to ensure that commercial entity discussions with learners and residents are about the products, and that information presented is evidence informed, and demonstrates a balanced approach inclusive of any discussion of appropriate alternatives. Faculty members need to recognize that in doing so, they role model the professionalism of engaging in interactions for the health professional and medical learners. Regardless of the locale, meetings should be by invitation or appointment only.

An example of acceptable interaction and involvement of an industry representative in an educational environment with learners may be the demonstration of only the technical use of the equipment/implants. Pharmaceutical sales representatives will not have direct contact with students and residents.

Faculty members, staff members, and learners in the clinical learning environments as part of their professional responsibilities are expected to abide by the policies and procedures of the teaching facility with regard to meeting with commercial entities such as industry representatives.

The following situations may lead to a conflict of interest, if not managed appropriately. The following guidelines outline the policy adherence for faculty members, staff members, and learners when, and if, interactions occur with commercial entities and industry representatives:

- Health professional, medical learner, and medical resident contact information must not be shared with commercial entities and industry representatives.
- Industry representatives in clinical teaching facilities are only permitted in non-patient care areas, and by appointment only.
- Permission is required by the clinical teaching facility for representatives to attend an event. If they do attend, representatives can only be there as listeners, or observers, not as participants. In addition, industry or commercial representatives are not permitted to participate or attend scientific and content planning meetings, nor play a role in content development.
- Industry or commercial representatives cannot assume a role of a speaker or educator.
- Faculty members, staff members, and learners are not to solicit financial or non-financial support for any NOSM-specific educational events or other activities with an individual commercial representative before advising the NOSM Advancement Office of the application.

15.0 Sponsorship

The Northern Ontario School of Medicine is committed to pursuing a sponsor-centric approach to its fundraising and sponsorship endeavors. This conflict of interest policy

aligns with NOSM's "Sponsor Approach Management Policy" for faculty members, staff members, and learners, and has been developed to ensure that there is congruency between a sponsor's request or a request to a sponsor, and the needs of the Northern Ontario School of Medicine. Both policies will guide internal processes for staff members and learners, while ensuring the same due process is undertaken in the solicitation, cultivation, and stewardship of prospective sponsors. Individuals who hold an affiliation with NOSM and who choose to participate in fundraising that is non-NOSM related through their affiliation with other associations or institutions should abide by conflict of interest policies in their respective institutions.

15.1 Managing Conflict of Interest in Sponsorship Activities

Responsibility for the administration of the Sponsorship Approach Management Procedures, including approval and coordination of specific sponsorship requests, resides with the Office and Manager of Advancement at the Northern Ontario School of Medicine. No group or individual involved in sponsorship solicitation may engage in any activity that may create, or appear to create, a conflict of interest. Such activities may include (but are not limited to): accepting gifts or favours, providing preferential treatment, or publicly endorsing suppliers or products.

15.2 Sponsorship Accountability

The Advancement Office, in a collaborative working relationship with the event organizer(s), draws upon an approval process based upon the following requirements:

- a. Prior approval of soliciting sponsorship is sought in writing from the Manager of Advancement before any prospective sponsor is approached by the event organizer(s).
 - a. The organizer(s) responsible for soliciting sponsorship will provide the Manager of Advancement and the Director of Communications the sponsorship appeal documents for approval at minimum of 60 calendar days prior to the event. Documentation will include the financial levels and the recognition of each level.
 - b. The organizer(s) responsible for soliciting sponsorship for the event will also provide the Manager of Advancement of NOSM a list of prospective sponsors a minimum of 60 calendar days prior to the event.
- b. The Manager of Advancement will provide the event organizers with approval of the approach within 7 calendar days of the submission. The response may include additional information to assist in the successful approach of the prospective sponsor.
- c. Open communication and consultation inherently involves all parties directly affected, including the Dean of the NOSM.
- d. Sponsorship must occur only through pooled funding that is publically acknowledged and available, including financial value being transferred to NOSM in this capacity.
- e. Although sponsorships are permitted for educational events, the funds, however, cannot be solely used for social activities during or after the educational event.

- f. Sponsorship funds cannot be used for the purchase of alcohol.
- g. Any use of NOSM logos requires the approval of both the Advancement Office and the Communications Unit.
- h. Sponsorship should not be drawn from commercial entities that involve selling medical products to patients.

15.3 Managing Conflict of Interest in Commercial Named Awards

Commercial entity named scholarships and academic awards must be free of any real or perceived conflict of interest, and comply with the policies of the Office of Advancement

16.0 Failure to Comply with Disclosure

16.1 Presentations

While every effort is made to ensure that presenters provide a COI(s) slide with their content presentation, it is recognized that auditing these events may be difficult. In the event that evaluation data (feedback data collated from attendees at a presentation) convey that a presenter did not provide appropriate declaration, this will be noted on the presenter's letter of acknowledgement and summary evaluation form, along with a copy of the CEPD policy on declaring COI in accredited education events. The Director of CEPD shall meet with the presenter who fails to comply with the policy to determine what activity should ensue (ranging from improving awareness of the policy to changing their education content and processes). Refer to: Office of CEPD Policy - NOSM Continuing Education and Professional Development Policy on Relationships with Industry (January 2013).

16.2 Financial Reimbursements

It is the requirement that faculty members, staff members, and learners who have received financial reimbursements for education and research should report annually to their direct report, or supervisors, or equivalent, to manage any conflict of interest through transparency and disclosure of any financial relationships.

16.3 Conflict of Interest in Clinical Learning Environments

Clinical learning environments in which learners gain competencies in professional skills development along with administrative and leadership skills must be prepared to ensure that learners are not individually subjected to the interactions with undue influence by external commercial entities. Should such situations arise, these experiences should be in the presence of a clinical faculty member who can then take a teaching and mentoring role as to best practices in dealing with, and managing, COI as a future health-care professional. Reinforcing and upholding efforts that foster and role model professionalism in teaching and learning environments are respected and valued, and have long-lasting impacts on learners.

16.4 Free Medication and Device Samples

Where possible, all efforts for distributing pharmaceutical samples to patients should be administered and managed centrally (e.g., pharmacy services). This practice is only acceptable where a financial hardship of patients exists, or where there is a specific educational component required. Faculty members and learners should be cautious in

distributing sample medications that may not be the most cost-effective or evidence-based drug of choice.

Faculty members and learners should use pharmaceutical and device samples only within the guidelines and policies established by the clinical learning environments. Samples should not be solicited by faculty members or learners for personal use or used by family members. Equally, supplying samples to patients should not involve a material gain for the physician or other prescribing health-care professionals (e.g., pharmacists, nurse practitioners), or for the practice setting.

17.0 Policy Review Process

This policy shall be reviewed annually, and revised accordingly, during the next three years of a phased-in implementation process by an Implementation Working Group, and every three years thereafter.

18.0 Resource Documents

This document is to be read in conjunction with the following policies and statements. In all cases concerning a conflict of interest where these documents provide differential direction, administration, faculty members, staff members, and learners are expected to uphold the standard that holds the greatest rigour.

- 1) Northern Ontario School of Medicine Board of Directors Conflict of Interest Policy (2007)
- 2) NOSM Code of Student Conduct (2009)
- 3) Collective Agreement between OPSEU and NOSM (2008)
- 4) NOSM Financial Policies: 1) Supply Chain Code of Ethics (2010) and 2) Procurement of Goods and Services Protocol (2011)
- 5) Academic Freedom and Integrity of Research Policy, Board Policy Manual (2013)
- 6) Office of CEPD Policy: NOSM Continuing Education and Professional Development Policy on Relationships with Industry (January 2013)

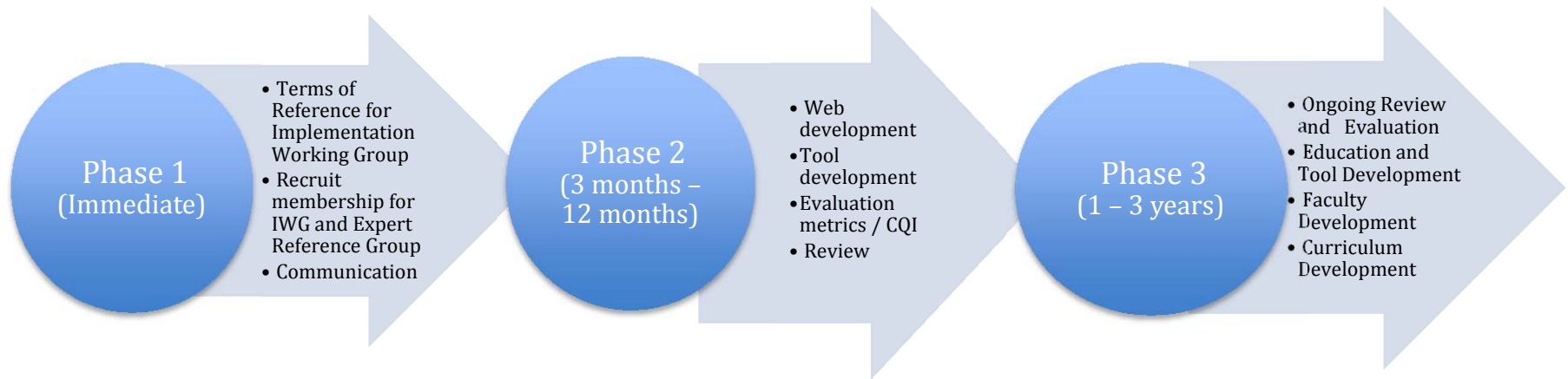
19.0 Evidence-Informed References and Readings:

- 1) Conflict of Interest Literature Search dating from 2008 – 2013. Listed Abstracts on NOSM website.
- 2) Association of Faculties of Medicine of Canada (2010). SCCPD Position Paper on the Role of Industry in University-Based CME/CPD. Available online: http://www.afmc.ca/pdf/committees/SCCPD_Position_Paper_on_Role_of_Industry_in_University_Based_CME-CPD_Dec%201_2010.pdf Ottawa: AFMC.
- 3) AAMC – The Scientific Basis of Influence and Reciprocity: A Symposium (2007); In the Interest of Patients: Recommendations for Physician Relationships and Clinical Decision Making. (June 2010)
- 4) Canadian Medical Association (2005). Medical Professionalism. Available online: <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD06-02.pdf> Ottawa: CMA

- 5) Canadian Medical Association (2007). Guidelines for Physicians in Interactions With Industry. Available online at: <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf> . Ottawa: CMA.
- 6) Northern Ontario School of Medicine (2007). Northern Ontario School of Medicine Board of Directors Conflict of Interest Policy. Sudbury: NOSM.
- 7) Northern Ontario School of Medicine (2011). Discussion Paper Northern Ontario School of Medicine Naming Opportunity. Sudbury: NOSM.
- 8) CMFS Paper: (2011) Defining the relationship: An evidence based review and recommendations on the role of industry funding in medical schools.
- 9) Collective Agreement between Ontario Public Service Employees Union and its Northern Ontario School of Medicine Local 677 (Unit1). July 1, 2011 to June 30, 2015.
- 10) Memorial University’s Conflict of Interest Policy (March 31, 2009)
- 11) University of Toronto Conflict of Interest Policy – Academic Staff (June 22, 1994)
- 12) R & D Canada’s Research-based Pharmaceutical Companies (2012). Code of Ethical Practices.

DO NOT REMOVE THIS VERSION RECORD FROM THIS DOCUMENT		
Version	Date	Authors/Comments
V1.0	October 25, 2013	Confirmation by Academic Council with 2 noted amendment recommendations
V2.0	November 29, 2013	Approved by the Board of Directors (noted amendment approved)

Proposed Policy Implementation Plan & Timelines Presented to the Board - November 29, 2013



Developing a Communication Strategy

- Awareness - Website Page
- Awareness - Incorporating Policy into Current Handbooks / Guidebooks

Creating Teaching and Learning Tools

- Questions and Answer Sheets
- Case Studies
- Situational Examples
- Template Slide Decks

Reviewing Disclosures and Transparency

- CEPD / Faculty Appointment Renewals
- Conversations with Supervisors

Developing a Policy Evaluation Process

- Metrics to Measure Success
- Evaluation Timelines for Review

Triple “E” Implementation Approach

- **Expertise Resource**

COI Reference Group

- **Educational Resources**

Case Studies / Vignettes

FAQs

Tool Developments - Algorithms & Checklists (CEPD /
Learners / Researchers)

COI Website

- **Evaluation Development**

ongoing continuous quality improvement approaches

CONFLICT OF INTEREST (COI) with COMMERCIAL ENTITIES Situational Examples – FAQs

Effective date: November 29, 2013

Supersedes: none

Revised: n/a

Examples of Conflict of Interest with Commercial Entities policy put into action (what works, what doesn't work, what the policy means):

1. When do I need to disclose?

- When preparing a talk or presentation, a verbal and in-writing disclosure statement is required regardless of whether or not research or speaker funding was received.
- When there is a financial relationship to a medical device or pharmaceutical company, or any other commercial organization may directly benefit from the talk or presentation.

2. What are examples of financial relationships that I may need to disclose?

- Acting as a paid consultant with a pharmaceutical company or medical device company.
- Paid membership on an Advisory Board that has an affiliation with your presentation topic or research.
- Investment in a commercial interest.
- Holding a patent on a drug, product, or device.
- Membership on a speaker's bureau.
- Receiving research grants from a commercial organization.
- Receiving travel grants from a commercial organization.

3. Can I accept an honorarium for a slide deck that is an evidence-based presentation developed by pharma?

- You could accept the honorarium as a speaker delivering a presentation as reimbursement of your time; however, participating in this context of education when you have not developed the content of the presentation is considered ghostwriting, and not considered an acceptable practice.

4. How do I eliminate COI?

- Refuse individual gifts (meals) when you have provided no service in receipt of the gift.
- Plan education that involves pooled funding (unrestricted educational grants) for educational events.
- Do not allow the use of your name when you have not created the presentation content. This is considered ghostwriting.

- Disclose any financial relationships that you have with commercial entities at the beginning of a presentation. Being transparent allows the audience to consider any undue external influence while listening to the presentation. Additionally, one may want to consider including in their presentation evidence of multiple drug interventions options to alleviate any bias towards one pharmaceutical company.

5. What does the COI with commercial entities policy not allow?

- Clinical teachers inviting learners to attend a non-accredited pharma dinner sponsored event or any pharma-sponsored social events.
- Faculty or staff arranging non-curricular educational events with commercial entities for students and residents.
- Pharma representatives and medical equipment representatives approaching and interacting with students and residents directly without a clinical faculty member present. Having a clinical faculty member present allows for teachable moments with the students and residents about the ethical and professional issues of physician–commercial entity relationships and interactions.
- Pharma representatives actively participating in educational presentation discussions. Pharma reps can attend but cannot participate in or contribute to the discussion, and must be free of any visible identity of drug promotion.

6. What difference does it make if events use unrestricted grants or educational pooling of funds?

Unrestricted grants and pooling of funds, such as securing several sources of funds, to run an educational event(s) eliminates the undue external influence of one industry or company over another. Unrestricted grants also allow full responsibility of organizers (participants) to take ownership in the selection of topics based on their clinical practice and personal learning needs, develop their own curriculum, and select their choice of speakers. **The pooling of funds does allow for meals and other amenities to be part of the educational event, as there is no undue external influence present.**

7. Can educational programs use industry educational material?

Industry can be a valuable source of educational material for students and residents. Industry educational material should be reviewed and approved for use by the faculty and program for its appropriateness in content in aligning with curricular objectives, ensuring that the material is peer-reviewed and that it does not endorse specific products. Any material developed by industry must be clearly labeled as such.

- 8. As a practising physician/health professional and a NOSM clinical faculty member, if I wish to assist with recruiting sponsorships or assisting in fundraising for my community hospital, do I need to seek approval from the NOSM Advancement Office?**

No, is the simple answer. For fundraising or events seeking sponsorship that are not related to NOSM, you do not need to seek approval from the NOSM Advancement Office. You should, however, note the importance of abiding by the conflict of interest policy of the organization or institution that you are working with in soliciting those funds.

- 9. As a practising physician/health professional and a NOSM clinical faculty member, if I wish to assist with recruiting sponsorships or assisting in fundraising for an event or purpose that is a collaborative effort between my organization and NOSM, do I need to seek approval from the NOSM Advancement Office?**

It would be helpful for you to seek the wording in the agreement that your organization currently holds with NOSM. In many of the current collaborative agreements between NOSM and its affiliated teaching hospitals/institutions, there is guidance on the joint relations of fundraising by informing the other of its fundraising plans and priorities where it is anticipated they might impact upon the other through the Joint Relations Committee.

- 10. In submitting a research ethics application, why do I need to disclose all financial relationships, and for how long back do I need to report?**

Disclosure is the basic requirement. Researchers must disclose their financial interests to REBs, to the research subjects, in publications, and in all presentations of their findings. It may be helpful for you to review the evidence-based and validated tool of a “financial checklist” as a measure that you have covered all disclosures. Rochon, P. et al (2010). Financial conflicts of interest checklist 2010 for clinical research studies. *Open Medicine*, 4(1):e70

- 11. How many years back do I need to disclose my financial relationships?**

Five years is the acceptable practice.

12. Can I accept samples from pharmaceutical companies?

Samples can only be accepted for use by patients. Personal use of samples, or use by friends or family, is not permitted. Samples must be stored under proper conditions. If samples are given to patients then proper recordkeeping must be ensured, which includes recording the name of the drug, quantity given, and ensuring that the expiry date has not passed.

13. Does conflict of interest with the pharmaceutical industry only apply to physicians?

No. All health professionals (e.g., nurses, nurse practitioners, pharmacists, dietitians, etc.) need to be aware of any undue external influences and abide by their professional association guidelines, policies within their practice environment, and their teaching roles with academic institutions.

14. As a health professional and clinical teacher holding a NOSM faculty appointment, to whom do I annually disclose my financial relationship?

At annual reviews, faculty should convey financial relationships to the Associate Dean, Faculty Affairs or designate.