

Responsible unit: Dean's Office (Operations & Policy Unit)

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Guidelines for the Relationship between the Faculty of Medicine and Health-Related Industries

A. Background & Purpose

The Faculty of Medicine's mission is fulfilled through diverse activities, including relationships with industry. Universities interact with a range of health-related industries (pharmaceutical, medical devices, health supplies, advocacy groups, government, not-for-profits organizations, disease-related funding agencies, health services) that may each carry biases in relation to their own objectives. It is critical to address these relationships in a way that protects the Faculty of Medicine's brand value and uses consistent and well-managed approaches that have been identified by medical organizations and industry associations alike.

In November 2008, the Association of Faculties of Medicine of Canada (AFMC) endorsed the principles set out in the Association of American Medical Colleges' (AAMC) report: 'Task Force on Industry Funding of Medical Education'. Each Canadian medical school developed or reviewed their guidelines within the context of the report. Dalhousie's Faculty of Medicine formed a working group tasked with developing the initial Guidelines, which were approved in 2010 and subsequently revised and approved in 2017.

The purpose of these guidelines is to serve as a resource to promote consistent and well-managed relationships between members of the Faculty Medicine and health-related industries. This document is not intended to discourage appropriate interactions, as the benefits of these relationships are recognized. However, the health industries also have a financial interest in promoting their products to medical professionals. These guidelines aim to promote consistent approaches for the various constituencies of the Faculty of Medicine including faculty, staff, and learners. The objective is to develop practices to avoid conflict of interest and to promote a commitment to scientific methodology, evidenced-based information, and professionalism.

These guidelines aim to complement (and do not supersede) any existing and relevant Dalhousie University policies, including the Policy on Conflict of Interest and the Purchasing Policy. (See Appendix A for a complete list of relevant policies and other documents.)

B. Application

These Guidelines apply to all Faculty of Medicine members (faculty, staff, learners), regardless of site or location, who enter into relationships with health-related industries. This includes meetings and conferences in clinical and other milieus that are supported in whole or in part by industry.

C. Guidelines & Procedures (General)

1. Guiding Principles

- a) The primary objective of professional interactions with health industries is the advancement of health care for patients.
- b) While substantive, appropriate, and well-managed interactions with industry are vital to public health, these activities should be conducted in a way that is principled and upholds the public trust. Clear and thoughtful guidelines will optimize the benefits inherent in the relationship between academic medicine and industry and minimize the risks.
- c) When interacting with health industries, it is important to recognize that certain companies (e.g., member companies of Canada's Research-Based Pharmaceutical Companies – Innovative Medicines Canada) abide by a Code of Ethical Practices. It is important to note the Innovative Medicines Canada Code does not address all practices of its member institutions, and non-Innovative Medicines Canada member companies may not have a written or transparent policy.
- d) The absence of a guideline on any specific industry funding practice does not imply endorsement of such practice. Professionalism, as an individual responsibility, is the guiding principle for all types of activities that relate to medical education at all levels, whether or not there is a stated guideline that specifically applies to the situation.

2. Disclosure

- a) Faculty and staff, must disclose relationships with industry to their department head or supervisor on an annual basis, or when changes in industry relationships occur. This must be part of the annual performance review completed by department heads, associate/assistant deans, and unit leadership.
- b) Learners must disclose relationships with industry that could impact their training, research, or student led events they are involved in. Disclosure for PGME, UGME or MPAS learners should be to the appropriate Associate or Assistant Dean; Postgraduate learners should also notify their Program Director. For Graduate Students, their primary supervisor is the appropriate individual to receive such disclosures.
- c) The presence of relationships with industry must be disclosed by presenters, both verbally and by way of slides or other presented materials, to the audience, prior to any educational activity such as lectures, seminars, or workshops. In cases where there are no slides/other presentation software,

the disclosure should be printed on some other program material (e.g. brochure/program, website, etc.). Information provided in this manner includes the name of the individual, the name of the commercial interest, and the nature of the relationship the person has with each commercial interest, and any mitigation of the conflict of interest. Information that an individual has no relevant financial relationship should also be disclosed in advance to the learning audience.

- d) Speakers must disclose any potential conflict of interest prior to the educational event. Disclosure should be made to the unit leader associated with the event (eg. Associate Dean of CPDME).
- e) Disclosure slides are mandatory for all accredited CPDME programs/speakers, all medical school curricular presentations, research presentations, or any presentation with the potential for financial, professional, or personal conflicts of interests.
- f) In scholarly publications, individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (<u>http://www.icmje.org</u>) and in accordance with the requirements of the funding or granting agency.
- g) Individuals leading research which involves humans must comply with the University's Policy on Ethical Conduct for Research Involving Humans and obtain the requisite approval of the appropriate Research Ethics Board. Subject to any further specific direction or requirements from the research ethics board, participants should be informed if the researcher will be compensated for their involvement in the research and by whom such compensation will be paid. In addition, individuals may not conduct research with humans if they or their immediate family have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions may be permitted if it is determined by Dalhousie's or an affiliated hospital's Research Ethics Board that an individual's participation is essential for the conduct of the research and an effective mechanism for managing the conflict and protecting the integrity of the research has been established.

D. Guidelines & Procedures (Specific)

1. Gifts to Individuals

- a) Faculty of Medicine members should not accept personal or group gifts from industry representatives regardless of the nature or value of the gift. This includes any gifts, payments, services, privileges or favours from equipment and service providers as well as pharmaceutical and device providers (Also see 'Food'). Notwithstanding the foregoing, donations made to a research program may be accepted. Such donations must be done via a foundation accountable for the appropriate use of the funds. Further, researchers must disclose this support to their department head as a potential conflict of interest, and also as a conflict of interest with any presentations they deliver.
- 2. Distribution of Samples

- a) Faculty of Medicine members must abide by established policies and procedures of the affiliated health care centres and their department regarding distribution of samples. The distribution of clinical evaluation packages, including samples, should be managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.
- b) If central management is not feasible, alternative ways to manage sample distribution should be developed to avoid risks to professionalism. It is acknowledged that the handling of samples should be efficient and not overly bureaucratic.
- c) Consideration should be given to the provision of medications at a reduced cost for hospitalized patients and the implications for potential ongoing costs to patients or their insurers should be clarified.
- d) The distribution of samples must not involve any form of material gain for the Faculty of Medicine member or physician or for the Faculty of Medicine member's physician's practice.

3. Site Access by Industry Representatives

- a) Faculty of Medicine members must abide by established policies and procedures of the affiliated health care centres regarding meetings with industry representatives. In general, access by industry representatives should occur in areas that are separated from direct patient contact. Industry representatives may provide in-service training or assistance on devices or equipment in patient care areas if there is appropriate consent by the patient or substitute decision maker.
- b) Industry representatives are to be appropriately registered with the affiliated health care centre as required by institutional policy and meetings should take place only by appointment or by invitation.
- c) Involvement of learners in meetings with industry representatives must occur under the supervision of a Faculty of Medicine member for educational purposes only (e.g., demonstration of a proprietary device made by private industry to ensure safe use in patient care).

4. Continuing Professional Development (CPD)

- a) All CPD programs involving Dalhousie faculty must be accredited by the CPD office, the appropriate national specialty society, Royal College of Physicians and Surgeons or the College of Family Physicians of Canada.
- b) As part of this accreditation process, industry support for any program must comply (at a minimum) with the guidelines developed by the Canadian Medical Association (see Appendix A).
- c) Financial independence from industry is mandatory for Dalhousie's CPD office. This removes any sense of financial incentive in planning events. Topics identified through CPD needs assessments would receive equal attention regardless of funding availability.

- d) Academic medical centres offering CPD programs must develop audit mechanisms to assure compliance with the standards of the AFMC's Committee on Accreditation of Continuing Medical Education (CACME), including those with respect to content validation and support of meals. All centers must at a minimum comply with the National Standard to ensure the content of their medical programs is in compliance and this is a requirement for the scientific planning committee.
- e) It is ethically preferable for the CPD office to review content for bias prior to all educational events that they provide or review for CPD credits.
- f) Requests for industry support and receipt/administration of funds for CPD activity should be coordinated and monitored centrally through CPD offices of the academic medical centre or university office/department. As the term "unrestricted educational grant" can be problematic, the program objectives for all funded events must be congruent with those of the CPD office. The planning committee must determine content independently of industry sponsors.
- g) The term "satellite symposium" must be restricted to industry sponsored nonaccredited events as it is open to interpretation. These events must not be advertised with, or considered part of, the accredited event. Tagging segments of an educational event as provided by an industry is not acceptable.
- A learner registration fee for all educational events is recommended.
 Providing quality CPD is a time and resource-intensive endeavour, and this must be recognized and valued.

5. Participation in Industry-Sponsored Programs, Advisory Boards, and Consulting

This guideline is directly aligned with CMA Guidelines for Physicians in Interactions with Industry. Individuals affiliated with Dalhousie Faculty of Medicine may be approached by industry representatives and asked to become members of advisory or consultation boards, or to serve as individual advisors or consultants for various aspects of business operations, including but not limited to product development, research programs, medical/scientific and marketing issues. These individuals must be mindful of the potential for this relationship to influence decision making (e.g. in research or prescribing activities).

When participating in advisory and consulting boards¹:

a) The exact deliverables of the arrangement must be clearly set out and put in writing in the form of a contractual agreement, which must be reviewed and executed in accordance with Dalhousie's Contract Approval and Execution Policy if the individual is participating in the arrangement in their capacity as a Dalhousie faculty member. The purpose of the arrangement should focus on imparting specialized medical knowledge that could not otherwise be

¹ Advice sought for medical opinion and not remunerated in any form differs significantly and provides an honest scientific opinion that may serve to inform Innovative Medicine Canada members and others in an honest way without bias.

acquired and must not include any promotional or educational activities on the part of the company itself.

- b) Full transparency and disclosure are required when participating in such programs, and payments are to be only at fair market value and should consider the complexity of the involvement.
- c) Whenever possible, meetings should be held locally, virtually, or as part of a meeting which would normally be attended. When these arrangements are not possible, basic travel and accommodation expenses may be reimbursed. Meetings should not be held outside of Canada, except for international boards.
- d) University members must comply with the Dalhousie University 'Policy on Conflict of Interest' (See Appendix A). This policy must be reviewed and would require full disclosure, to the university, of income or other benefits received from industry including expense reimbursements.
- e) Faculty should be discouraged from speaking at industry-sponsored nonaccredited events.
- f) The Faculty of Medicine discourages its members from:
 - i. Attending non-accredited industry events billed as CPD.
 - ii. Accepting payment for attendance at industry-sponsored meetings.
 - iii. Accepting personal gifts from industry at such events.
 - iv. Accepting a speaker fee at such events.

6. Industry-Sponsored Scholarships and Other Educational Funds for Trainees

- a) All scholarships or other educational funds from industry must be given centrally to the administration of the affiliated health care centre or Faculty of Medicine.
- b) There is no implicit or explicit expectation that the participant must provide something in return for participation in the educational program.
- c) The evaluation and selection of recipients of such funds must be the sole responsibility of the academic medical centre or university office/department, with no involvement by the donor industry.

7. Food and Consumables

a) Except for modest meals and refreshments provided in connection with accepted programming as outlined above (see Participation in Industry-Sponsored Programs, Advisory Boards, and Consulting), industry-supplied food, meals, other consumables (alcohol, cannabis, tobacco, etc.), or meal vouchers are considered personal gifts and should not be permitted or accepted within academic medical centres. The same standard of behaviour should be met off-site. As a guideline, the value of any meals and refreshments accepted should align closely with the University's reimbursement policy limits. (See per diem rates in Appendix A.)

8. Professional Travel

 a) Faculty of Medicine members should not directly accept travel funds from industry, other than for legitimate reimbursement or contractual services. Travel arrangements or accommodations are considered gifts from industry and are discouraged. (Also see 'Participation in Industry-Sponsored Programs, Advisory Boards, and Consulting') As a guideline, these must align closely with the Faculty of Medicine reimbursement policy limits. (See Appendix A.)

9. Ghostwriting

- a) Presentations, publications, slides, or media products of any kind, oral or written, must not be ghostwritten by any party, industry or otherwise. To be listed as an author indicates responsibility for the content and meaningful participation in preparation of the document. Appropriate authorship and contribution must be noted for materials prepared by someone other than the presenter.
- b) Transparent writing collaboration (with attribution) between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting.

10. Purchasing

a) Any personal or family financial interests (as defined by the university's Conflict of Interest policy) in any manufacturer of pharmaceuticals, devices or equipment, or any provider of services, must be disclosed according to the University's Policy on Conflict of Interest' and 'Procurement Policy' when such products or services are being contemplated or pursued. They must also disclose any research or educational interests they or their department have that might substantially benefit from the purchasing decision.

11. Industry Support for Research

- a) A prerequisite for Faculty of Medicine member participation in research activities is that these activities are ethically defensible, socially responsible, and scientifically valid. All Faculty of Medicine members who participate in the design and conduct of industry funded research shall ensure that there is a signed agreement which is satisfactory to the researcher, the industry partner, and the institution(s) where the research will be conducted. Agreements must include any "special pricing" that will be granted for inclusion in promotional materials or media events. All research Ethics Board of the University and/or affiliated hospital to comply with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.
- b) Research grants must not be accepted or utilized to support research unless it is carried out objectively for the purposes of the advancement of scientific knowledge or clinical efficacy. Faculty of Medicine members must not enter into agreements that limit their right to publish or disclose results of the study or report adverse events which occur during the course of the study.

Exceptions may occur where there is a narrow time window and, in these cases, there must be consultation with Dalhousie (or appropriate health authority) Legal Counsel prior to engaging in the work. Without these agreements, trainees (undergraduate and graduate) must be excluded from this work.

- c) Remuneration for participating in research studies may cover reasonable time and expenses and must be approved by the relevant research ethics board. Finder's fees, whereby the sole activity performed by the faculty or staff is to submit the names of potential research subjects, are not acceptable.
- d) For further policy requirements regarding research ethics, below is the link to the research ethics pages for Dalhousie University. More information may be available through any of the following: Nova Scotia Health, IWK Health Centre, the Vitalité Health Network, the Horizon Health Network, Health PEI, and the Office of Research Services at Dalhousie University. http://researchservices.dal.ca/research 1482.html

E. Other

1. Education Regarding Interactions with Industry

a) The Faculty of Medicine will develop appropriate educational materials and methods to build critical evaluation skills to reinforce high individual and institutional standards, norms, and behaviours.

2. Review of Guidelines

a) These guidelines will be reviewed one year after adoption, and every five years subsequently.

APPENDIX A – Relevant Policies and Other Documents

Dalhousie University

- Policy on Conflict of Interest (2002)
- <u>US Public Health Service Financial Conflict of Interest Policy</u> (2013)
- <u>Procurement Policy</u> (2021)
- Travel Expense Policy (2024)
- <u>Per Diem rates</u> (current)
- Policy on Ethical Conduct for Research Involving Humans (2024)

Canadian Medical Association (CMA)

• <u>Guidelines for Physicians in Interactions with Industry</u> (2021)

Royal College of Physicians & Surgeons of Canada/The College of Family Physicians of Canada

• <u>National Standard for Support of Accredited CPD Activities</u> (2017)

Association of American Medical Colleges (AAMC)

• <u>Industry Funding of Medical Education</u> (Report of an AAMC Task Force; Principles approved by AFMC) (2008)

Other Universities

 Interactions between the Max Rady College of Medicine and health-related industries (University of Manitoba) (2018)