

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

Updated: September 2011

NOTE: 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.”*** Currently, each Canadian medical school is developing/reviewing their guidelines within the context of the report.

The Dalhousie Faculty of Medicine formed a task group (including Dr. A. Purdy, Dr. A. Cruess, Dr. G. Johnston, Dr. C. LeBlanc, Dr. J. Holland, Dr. D. Bell and D. Gorsky) to develop the guidelines. The goal is to promote consistent and well-managed approaches for the various constituencies of the Faculty of Medicine. The contribution of the health industries is recognized, and this document is not intended to discourage appropriate interactions. This will be issued as a guideline (not a policy -- no “policing” process).

The consultation process has included Faculty of Medicine Clinical and Basic Science Department Heads, as well as CDHA, IWK and Dalhousie University (for legal and research perspective.) As a guideline (vs. policy), we acknowledge that individual departments will have circumstances that require additional consideration. This guideline will be reviewed in one year.

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1. Executive Summary

Dalhousie University's mission is "learning, discovery and innovation, and social engagement." This mission is fulfilled through diverse activities – and increasingly so. Uniform use of the Dalhousie University "brand" in work affiliated with industry should be recommended to maintain their value. More and more, 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, advocacy groups and health services may all be biased due to their own agendas). The need to address this relationship has been identified by medical organizations and industry associations alike.

The Faculty of Medicine has developed guidelines to serve as a resource to guide well-managed relationships with industry (as defined above). This document is not intended to discourage appropriate interactions, as the benefits of these relationships are recognized. However, the health industries also have a fiduciary duty to their shareholders that requires them to promote their products to medical professionals. These guidelines promote consistent approaches for the various constituencies of the Faculty of Medicine including undergraduates, postgraduates, graduate students, postdoctoral fellows, basic medical scientists, and faculty. The objective is to develop practices to avoid conflict of interest and to promote a commitment to scientific methodology, evidenced-based information and professionalism.

2. Preamble

Dalhousie University's mission is "learning, discovery and innovation, and social engagement." This mission is fulfilled through diverse activities – and increasingly so. Uniform use of the Dalhousie University "brand" in work affiliated with industry should be recommended to maintain their value. More and more, 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, advocacy groups and health services may all be biased due to their own agendas). The need to address this relationship has been identified by medical organizations and industry associations alike.

The following guidelines have been developed by the Faculty of Medicine, Dalhousie University, to serve as a resource to guide well-managed relationships with industry (as defined above). This document is not intended to discourage appropriate interactions, as the benefits of these relationships are recognized. The health industries make significant contributions to medical education at Dalhousie University and there are many examples of positive partnerships. However, the health industries also have a fiduciary duty to their shareholders that requires them to promote their products to medical professionals. Industry marketing approaches can be direct or indirect, there are a variety of different regulations within the groups mentioned above, and it is important to understand the related issues.

These guidelines promote consistent approaches for the various constituencies of the Faculty of Medicine including undergraduates, postgraduates, graduate students, postdoctoral fellows, basic medical scientists, and faculty. The objective is to develop practices to avoid conflict of interest and to promote a commitment to scientific methodology, evidenced-based information and professionalism.

It is important to note that these guidelines are not a substitute for Dalhousie University policies, including "Policy on Conflict of Interest" and "University Purchasing Policy." All university members must comply with these policies. It is important that CME and other stakeholders strive for consensus regionally and nationally to provide a level playing field for all industry sponsors and consistent rules will avoid any sense of strategic marketing for events where rules are less stringent.

Dalhousie University Policy on Conflict of Interest

http://senate.dal.ca/Files/policies/Conflict_of_Interest.pdf

Dalhousie University Purchasing Policy

http://purchasing.dal.ca/Policies/Purchasing_Policy/Code_of_Conduct.php

3. Guiding Principles

- The primary objective of professional interactions with health industries is the advancement of health care for patients.
- 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 well thought-out guidelines will optimize the benefits inherent in the relationship between academic medicine and industry and minimize the risks.
- When interacting with health industries, it is important to recognize that certain companies (e.g., member companies of *Canada's Research-Based Pharmaceutical Companies – Rx&D*) abide by a Code of Ethical Practices. However, it is important to note the Rx&D Code does not address all practices and non-Rx&D member companies may not have a written or transparent policy.
- These guidelines apply to all individuals affiliated with Dalhousie University Faculty of Medicine whether in Dalhousie facilities or off-campus, including meetings and conferences that are supported in whole or in part by industry.
- The absence of a guideline on any specific industry funding practice does not imply endorsement. 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.

4. Gifts to Individuals

- Dalhousie University Faculty of Medicine faculty, staff, students and trainees should not accept 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. (See also “9. Food”)
- All travel, gifts, dinners, favours, honoraria and other benefits received from industry should be reported to the university. (See “15. Disclosure of Relationships with Industry”)

5. Distribution of Samples

- Dalhousie University faculty, staff, residents, students and trainees must abide by established policies and procedures of the affiliated health care centres in regard to distribution of samples. In general, the distribution of clinical evaluation packages, including samples, should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.
- 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.

- Attention 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.
- The distribution of samples should not involve any form of material gain for the physician or for the physician's practice.

6. Site Access by Industry Representatives

- Faculty, staff, students and trainees must abide by established policies and procedures of the affiliated health care centres with regard to meetings with industry representatives. In general, access by industry representatives should occur in areas that are separated from direct patient contact. 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 surrogate.
- 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.
- Involvement of students and trainees in meetings with industry representatives should occur under the supervision of a faculty member for educational purposes only.

7. Continuing Medical Education (CME)

All CME/CPD programs involving Dalhousie faculty should be accredited by the CME office, the appropriate national speciality society, Royal College of Physicians and Surgeons or the local chapter of the College of Family Physicians of Canada.

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 [reference *CMA Guidelines for Physicians in Interactions with Industry.*]

- Financial independence from industry is desirable for the CME office. This would remove any sense of financial incentive in planning events. Topics identified through CME needs assessments would receive equal attention regardless of funding availability.
- Academic medical centres offering CME programs should 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.
- It is ethically preferable for the CME office to review content for bias prior to all educational events that they provide or review for CME credits.
- Requests for industry support and receipt/administration of funds for CME activity should be coordinated and monitored centrally through CME 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 CME office. The planning committee must determine content independently of industry sponsors.

- The term “satellite symposium” should be restricted to industry sponsored non-accredited events as it is open to interpretation. These events must not be advertised with, or considered part of, the accredited event.
- A learner registration fee for all educational events is recommended. Providing quality CME is a time and resource-intensive endeavour and must be recognized as such.

8. 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 should 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 boards,:
 1. the exact deliverables of the arrangement should be clearly set out and put in writing in the form of a contractual agreement. The purpose of the arrangement should focus on imparting specialized medical knowledge that could not otherwise be acquired and should not include any promotional or educational activities on the part of the company itself.
 2. full transparency and disclosure is required when participating in such programs, and payments are to be only at fair market value and should take into account the complexity of the involvement.
 3. whenever possible, meetings should be held locally 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, with the exception of international boards.
 4. university members must be in compliance with the Dalhousie University “Policy on Conflict of Interest.” This policy should be reviewed and ideally would require full disclosure, to the university, of income or other benefits received from industry including expense reimbursements.
 5. faculty should be discouraged from speaking at industry-sponsored non- accredited events.
- The Faculty of Medicine discourages faculty, residents, students and trainees from:
 1. attending non-accredited industry events billed as CME.
 2. accepting payment for attendance at industry-sponsored meetings.

3. accepting personal gifts from industry at such events.
4. accepting a speaker fee at such events.

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

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

10. Food

- With the exception of modest meals and refreshments provided in connection with accepted programming as outlined above, industry-supplied food and meals 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.

11. Professional Travel

- Faculty, residents, student and trainees should not directly accept travel funds from industry, other than for legitimate reimbursement or contractual services. Exorbitant travel arrangements or accommodations are considered gifts from industry and are discouraged. (See also “**7. Participation in Industry-Sponsored Programs, Advisory Boards, and Consulting**”)

12. Ghostwriting

- Presentations, publications, slides or media products of any kind, oral or written, should 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 should be noted for materials prepared for someone other than the presenter.
- Transparent writing collaboration (with attribution) between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting.

13. Purchasing

- Any personal or family financial interests (as defined by the university's conflict of interest policy) in any particular manufacturer of pharmaceuticals, devices or equipment, or any provider of services, should be disclosed according to the Dalhousie University "Policy on Conflict of Interest" and Dalhousie University "Purchasing Policy". They should also disclose any research or educational interests they or their department have that might substantially benefit from the decision.

14. Industry Support for Research

- A prerequisite for faculty, staff, student, and trainee participation in research activities is that these activities are ethically defensible, socially responsible and scientifically valid. All faculty, staff, students and trainees, 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. All research projects involving human subjects are to be approved by the appropriate Research Ethics Board of the University and/or affiliated hospital to comply with Tri-council policies.
- Research grants should 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, staff, student and trainee should 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.
- Remuneration for participating in research studies may cover reasonable time and expenses and should 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.
- For further policy requirements regarding research ethics, below are the links to the research ethics pages for Capital Health, IWK Health Centre and Dalhousie University:

<http://www.cdha.nshealth.ca/default.aspx?page=SubPage&category.Categories.1=310¢erContent.Id.0=5296>

<http://www.iwk.nshealth.ca/index.cfm?objectid=C107FB97-C614-BA77-180A7868F581037F>

http://researchservices.dal.ca/research_1482.html

15. Disclosure of Relationships with Industry

- Faculty and staff should disclose relationships with Industry to his or her Department head or supervisor on an annual basis, or when changes in Industry relationships occur.
- The presence of relationships with Industry should be disclosed by faculty or staff, both verbally and by way of a slide, to learners prior to any educational activity such as lectures, seminars or workshops. 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. Information that an individual has no relevant financial relationship should also be disclosed in advance to the learning audience.
- Whenever possible, speakers should disclose to the Associate Dean of CME any potential conflict of interest prior to the educational event.
- Disclosure slides should be mandatory for all accredited CME speakers.
- In scholarly publications, individuals should disclose their related financial interests in accordance with the International Committee of Medical Journal Editors.
(<http://www.icmje.org>)
- Individuals leading research which involves human subjects should inform participants if the researcher will receive a fee for their participation and by whom the fee will be paid. In addition, individuals may not conduct research with human subjects 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 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.

16. Education Regarding Interactions with Industry

- The Faculty of Medicine will develop appropriate educational materials and methods to build critical evaluation skills, including an understanding of the social psychology, to reinforce high individual and institutional standards, norms and behaviours.

17. Review of Guidelines

- These guidelines will be reviewed one year after adoption, and every three years subsequently.

18. Related Documents

1. CMA Guidelines for Physicians in Interactions with Industry
<http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf>
2. Royal College Guidelines for Support of CME by Industry
http://rcpsc.medical.org/publications/policy/cme_e.html
3. AAMC Task Force Report Industry Funding of Medical Education (principles approved by AFMC)
www.aamc.org/industryfunding
4. Dalhousie University, Policy on Conflict of Interest
http://senate.dal.ca/Files/policies/Conflict_of_Interest.pdf
5. Dalhousie University Purchasing Policy
http://purchasing.dal.ca/Policies/Purchasing_Policy/Code_of_Conduct.php
6. Rx&D Code of Conduct
http://www.canadapharma.org/Pharm_comm/Code/new_e.html
7. Guidelines from other universities
<http://www.fmd.uwo.ca/Equity/Documents/NUPGuidelines.pdf>
http://www.umanitoba.ca/faculties/medicine/media/Industry_relations_policy_june_2009.pdf
<http://www.princeton.edu/chw/lectures-conferences/lectures/past-lectures/spring2005/conflicts.pdf>
http://cme.medicine.dal.ca/files/Position_Paper_on_Role_of_Industry_in_University_Based_CME-CPD_Dec_1_2010.pdf