UNIVERSITY OF OTTAWA FACULTY OF MEDICINE POLICY

Interactions between the Faculty of Medicine and the Pharmaceutical, Biotechnology, Medical Device, and Hospital and Research Equipment and Supplies Industries

Effective date: Sept 2011

Purpose

1. This document establishes the Faculty of Medicine’s principles that govern the interaction between the Faculty, its faculty members, staff, students, trainees and Industry representatives in order to assure that their interactions result in optimal benefit to clinical care, education and research, and maintenance of the public trust in health care.

Application

2. This Policy applies to the Faculty of Medicine, faculty members, support staff, students and trainees. Industry representatives are also expected to adhere to this Policy in its interactions with the Faculty.

3. This Policy replaces the 2008 Faculty of Medicine Policy statement on “Interacting with Industry and outside Agencies in a Teaching Environment”\(^1\).

Definitions

For the purposes of this Policy,

4. **Conflict of Interest (COI)** may be actual, potential or perceived. A conflict of interest occurs when an individual has a significant financial, professional or other personal consideration with Industry that may compromise, or have the potential to compromise or the appearance of compromising, their professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other obligations.

5. Faculty member includes members of APUO, clinicians with academic appointments whether paid or volunteer and clinicians with administrative appointments including Dean, Vice-Deans, Associate and Assistant Deans, Program Directors, Department Heads.

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\(^1\) Available at http://www.med.uottawa.ca/assets/documents/policies_procedures/Policy_Interacting_Industry_Septembre2008.pdf
6. **Industry** shall refer to for-profit enterprises: including pharmaceutical, biotechnology, medical services, medical device, and hospital and research equipment and supplies industries and businesses; and including those related not-for-profit enterprises affiliated with a for-profit enterprise (such as industry or trade associations).

7. **Gift** refers to items of any value given by Industry to the Faculty, its faculty members, support staff, students and trainees and for which the recipient neither pays nor provides services. This includes, but is not limited to items such as pens, notepads, textbooks, electronic media, food and meals, gift certificates, tickets, devices, products or services, travel, hotel accommodations, entertainment or payments for attending a meeting.

**Faculty of Medicine and Interaction with Industry**

8. The mission statement of the Faculty is as follows: “We explore, we learn, we care”. To accomplish this mission, the Faculty strives to develop, deliver and evaluate high quality educational programs; to conduct research and other scholarly enquiry into the basic and applied medical sciences; to plan for the development and delivery of health care services; and to help improve health status and service delivery to the Province of Ontario and the wider community. These activities may sometimes benefit from interaction with Industry representatives in a manner that advances the use of the best available evidence, so that medical advances and new technologies become broadly and appropriately used. The Faculty undertook in its Standards of Ethical and Professional Behaviour\(^2\), adopted 1994, “to uphold the highest standards of ethical and professional behaviour in regard to Industry”.

9. Interactions between the Faculty, its faculty members, support staff, students, trainees and Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices and/or equipment; on-site training for newly purchased devices; educational support of medical students and trainees, and continuing medical education; and research activities. Faculty members, support staff, students and trainees also participate in interactions with Industry off-campus and in scholarly publications. While the interaction with Industry can be beneficial, these interactions must be ethical and avoid Conflict of Interest situations that could lead to increased costs of healthcare, compromise of patient safety, bias, or affect the integrity of the Faculty’s education, training and research programs, or the reputation of either the faculty member, the Faculty or the University and its affiliated hospitals. Provision of financial support or Gifts, even in modest amounts, can exert a subtle but measurable impact on a recipient’s behaviour.

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\(^2\) Available at http://www.medicine.uottawa.ca/assets/documents/policies_procedures/Standards_Ethical_Professional_Behavior1994.pdf
Policy Statement

10. It is the policy of the Faculty that clinical decision-making, education, and research activities be free from influence or perceived influence created by improper relationships with Industry or by the receipt of Gifts. The principles outlined in this policy shall guide all potential relationships or interactions between Industry and the Faculty, its faculty members, support staff, students and trainees.

Scope of Policy

11. This Policy covers the following:

- Gifts, Meals and Compensation
- Drug and Device Samples
- Access by Industry Representatives to Faculty, Staff, Students and Trainees
- Industry Support for Educational Programs
- Industry-Sponsored Scholarships or Other Educational Funds for Students and Trainees
- Off-Campus Industry-Sponsored Meetings or Activities
- Industry Support for Research
- Disclosure of Relationships with Industry
- Training
- Reporting of Non-compliance
- Review of the Policy

Gifts, Meals and Compensation

Gifts

12. The Faculty, its faculty members, support staff, students, and trainees shall not accept Gifts from Industry representatives, regardless of the nature or value of the gift. Gifts of educational materials directed at physicians or patients are permitted only if appropriate materials are not available from a public source (e.g., government agency, foundation, or disease-related association) or commercially available. This restriction also applies to product information that Industry representatives leave in or outside the room for participants to pick up after rounds. It also applies to collections of peer-reviewed scientific articles, since such collections may be highly selective and not representative of the literature.

Meals

13. Meals or other hospitality funded by Industry may not be offered in any facility occupied and operated by the Faculty or owned by the University. This includes coffee, snacks or lunches. Faculty members and support staff should use
discretion to ensure that the principles in this Policy are respected when participating in any Industry-sponsored meals off-campus. Specifically, faculty members and staff shall not facilitate or condone the attendance of students or trainees at meals off-campus sponsored by Industry or at educational events off-campus that are not accredited.

Compensation

14. Compensation in exchange for listening to a sales talk, or attending a continuing medical education session or other activity in which the attendee has no other role is not permitted.

15. Arrangements with Industry whereby faculty, support staff, students or trainees are guaranteed the payment of an amount or other benefit without any duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) are considered Gifts and are not permitted. In order to avoid Gifts disguised as consulting contracts, speaking engagements or other arrangement for services, a contract should be signed by the faculty member prior to the event which provides specific tasks and deliverables with payment commensurate with such tasks and deliverables. This contract should be retained on file by the faculty member and disclosed as part of the member’s annual “Conflict of Interest” disclosure to the Office of Professional Affairs or reappointment review as indicated in section 33.

16. The Faculty may, subject to applicable collective agreements, require faculty members and support staff to change the terms of consulting agreements or request use of a standard contract template to ensure compliance with this Policy. If the terms cannot be followed, the Faculty may withhold its approval of such consulting activities.

Drug and Device Samples

17. The Faculty views the provision by Industry manufacturers of “free” samples, for example, of prescription drug or device products as a marketing practice designed to promote the use of these products and to gain access to prescribing professionals in an attempt to influence their behaviour. At the same time, the Faculty recognizes that this practice can assist some patients to quickly begin a course of treatment or to determine which therapeutic option is most beneficial for that patient. While societal benefits may result from the availability of medications at the point of care, provision of samples is also accompanied by regulatory and security concerns, poses potential safety risks for patients, and encourages prescribing of new, high cost medications whose safety and efficacy may not be different from existing treatments. In this context, faculty members, support staff, students and trainees should utilize pharmaceutical or device samples only within the policies and procedures established by the affiliated healthcare facility and relevant provincial health authorities. In general, samples should be provided to a central bureau, e.g., ideally a hospital dispensary or
organized clinic and not to individual faculty members or trainees. The clinic note should document the use of free samples and the reason for their use. The Faculty also recognizes that the contribution of these samples may be a valid in-kind contribution to a research program seeking peer-reviewed third party funding.

Access by Industry Representatives to Faculty and Support Staff, Students, Trainees

18. Faculty members, support staff, students and trainees in the clinical setting or at health care facilities associated with the Faculty must abide by the policies and procedures established by such facilities and/or relevant provincial health authorities with regard to meeting with Industry representatives. In general, Industry representatives are permitted in non-patient care areas only by appointment. They may attend meetings or rounds only if permission has been granted by the health care facility, Department Head or delegated Division Head, and they have signed an agreement which prohibits their participation in discussions. Industry representatives are not permitted in patient care areas except to provide in-service training on devices or other equipment as requested by the health care facility, Department Head or delegated Division Head, and then only by appointment and, if applicable, with appropriate consent by the patient or surrogate. Documentation of permission must be retained by the health care facility, Department Head or delegated Division Head.

19. Industry representatives are prohibited from having any interactions with students or trainees that are not supervised by a faculty member. Commercial exhibits at the Faculty intended to showcase Industry products are permitted only if directly related to an educational activity, and must comply with the Office of Continuing Medical Education’s Policy on Sponsorship of OCME events by Industry.

Industry Support for Faculty Educational Programs

20. When accepted by the Faculty, Industry support for educational programs must be free of Conflict of Interest and must be provided in the form of an education grant. Funds that are provided by educational groups or other entities that act as “intermediaries” for Industry must also be provided as education grants.

21. Because of the vulnerability of students to external influences, the Faculty will not solicit or accept funding from Industry directly for educational activities in its undergraduate medical education program.

22. Funds from Industry for postgraduate educational activities may be provided to the Faculty, to a Department or Division within the Faculty, but must not be given directly to a faculty member, staff, student or trainee.

23. Funds for continuing medical education activities may be provided by Industry in the form of an education grant to the Faculty of Medicine, to an individual
Department or to the Office of Continuing Medical Education ("OCME"), but must not be given directly to an individual faculty member, staff, student or trainee. OCME must accredit all Industry-funded CME programs using the University or Faculty name or logos (except for rounds and journal clubs), and budgets for these programs must be registered with OCME. Agreements governing grants supporting educational events must receive prior approval by the Office of Continuing Medical Education.

24. The content of all continuing educational programs must be independently determined by the Faculty program planning group consisting of physicians and healthcare professionals representing the target audience. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs nor participate in such decisions, and in the case of CME activities, the organization of events must comply with policies of the OCME and meet accreditation standards of the Royal College of Physicians and Surgeons and/or the College of Family Physicians of Canada.

**Industry-Sponsored Scholarships or Other Educational Funds for Students and Trainees**

25. Direct use of industry funds, in which the industry can be identified, to support students and trainees to attend conferences or off-campus courses is not acceptable.

26. Industry support for scholarships and academic prizes must be free of any real or perceived Conflict of Interest, and must comply with the following requirements:

a) The Faculty of Medicine’s Department, or Division must select the student(s) or trainee(s) for participation or for receipt of prizes or awards at ceremonies and convocation.

b) Such prizes must be named for the achievements they recognize and not for the Industry that provided the funds, although the accompanying citations may identify the Industry organization.

c) The funds must be provided to the Department, or Division and not directly to the student or trainee.

d) The presentation of the award must be made by a representative of the Department, not of Industry.

e) There is no implicit or explicit expectation that the recipient must provide something in return for receipt of the award.

**Off-Campus Industry-Sponsored Meetings or Activities**
27. Faculty members, support staff, students and trainees who participate in off-campus meetings or conferences that are supported in whole or in part by Industry, including lecturing, organizing the meeting or moderating sessions, must abide by the following requirements:

a) Financial support should be fully disclosed to participants by the meeting sponsor.
b) The content of the meeting or session should be determined according to the conditions described in Section 24.
c) The speaker(s) must provide a fair and balanced discussion of the current science and treatment options.
d) The speaker(s) must make clear that the content and comments reflect the individual views of the speaker(s) and not the Faculty.
e) Compensation is reasonable and limited to reimbursement of reasonable travel expenses and an honorarium proportional to the defined service.

Industry Support for Research

28. A prerequisite for the participation of faculty members, staff, students and trainees in any research activity is that these activities are ethically conducted, socially responsible and scientifically valid.

29. All faculty members, staff, students and trainees who participate in the design, conduct of analysis or reporting of Industry-funded or industry co-sponsored research which is based at the University shall ensure that the budget includes all applicable overhead costs and that there is a signed multi-partner agreement that is satisfactory to the researcher, the Head of the Department in which the researcher holds his/her primary appointment, and the Industry partner. In the case of research conducted at affiliated institutions (i.e. the contract will be administered outside the university) research projects involving Industry must comply with the policies and procedures of the affiliated institution. These policies and procedures must be agreed to by the University. Those research projects involving the participation of human subjects or the use of their data must be also be approved by the University’s or the Hospital’s Research Ethics Board.

30. Research grants from, or contracts with Industry should not be accepted or utilized to support research unless it is carried out independently and objectively for the purposes of the advancement of scientific knowledge or clinical efficacy. Faculty members, staff, student and trainee shall not enter into research agreements with Industry that limit their right to publish or disclose results of the study or report adverse events that occur during the course of the study. The Faculty recognizes that as part of a formal research contract between the institution and Industry that there may be publication review or limited delays to enable the filing of intellectual property protection.

31. Because of the potential to influence judgment, remuneration for participating in Industry-funded research studies, including clinical research studies, should not
constitute enticement. It may cover reasonable time and expenses and should be approved by the University’s or the Hospital’s Research Ethics Board for studies involving the participation of human subjects or the use of their data. Remuneration should be disclosed in the annual “Conflict of Interest”, or re-appointment review. Finder’s fees, whereby the sole activity performed by the faculty or staff member is to submit the names of potential research subjects, are not acceptable.

32. All research funding received from Industry will be administered through special purpose project-specific research accounts at the University or at an affiliated institute, centre or teaching hospital. Statements disclosing all expenditures, transfers and transactions from these accounts will be provided to Department Heads on a quarterly basis.

Disclosure of Relationships with Industry

33. On an annual basis, faculty members and staff will disclose, in writing, relationships with Industry to the Faculty of Medicine’s Office of Professional Affairs. Disclosures will be reviewed and if a significant unmanaged conflict of interest is identified, then the disclosure will be forwarded to Department heads or supervisors. The written disclosure must specify nature of the relationship with Industry, the work performed, and total amount and type of compensation or other benefit received. Similarly, faculty members and staff will verify annually that their reporting was accurate and complete. Management of unresolved conflicts of interest will be done in collaboration between the faculty member, the Office of Professional Affairs’ Conflict of Interest Resolution Committee, the Department head and/or supervisor.

34. Prior to any educational activity such as lectures, seminars or workshops, faculty members, staff or speaker must disclose to the learning audience whether or not the faculty member or staff believes he or she has any relevant Conflict of Interest or other interest with Industry. If the faculty member, staff or speaker has a Conflict of Interest or any other interest with Industry, the disclosure must be contained in their written presentation materials. The disclosure must include the name of the individual, the nature of the interest and the relationship between the faculty member or staff and Industry or the interest in Industry. Information that an individual has no relevant financial relationship must also be disclosed in advance to the learning audience.

35. Faculty members or staff with supervisory responsibilities for students or trainees or staff must disclose any Conflict of Interest as outlined in section 33 and ensure that the faculty or staff's Conflict of Interest does not affect or appear to affect his or her supervision of the student, trainee, or staff member.

36. Faculty members, staff, students and trainees are prohibited from publishing articles or presentations or producing other forms of media under their names (ghost writing) that are written in whole or in part by Industry representatives. In
scholarly publications, individuals must disclose their related financial interests in accordance with the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org).

37. Faculty members, staff, students and trainees having a direct role in making decisions on equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any Conflict of Interest that they or their immediate family have in companies that might substantially benefit from the decision. Such relationships could include equity ownership (excluding indirect ownership such as stock held through mutual funds), compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. They must also disclose any research or educational interest they or their department have that might substantially benefit from the decision. The purchasing unit will decide whether the individual must excuse him/herself from the purchasing decision.

38. Faculty members leading research involving human subjects must inform participants that the researcher will, or will not, 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.

Training of Faculty, Staff, Students and Trainees Regarding Interactions with Industry

39. Faculty members, staff, students and trainees shall receive awareness training regarding interactions with Industry. The Faculty will develop appropriate educational materials and methods, and each Department within the Faculty will oversee such training and its quality.

Reporting of non-compliance

40. Faculty members, staff, students or trainees who are aware of contraventions of this Policy shall report such breaches to the Department Head or to the Associate Dean of Professional Affairs. Violations of these policies by Industry representatives will be managed through progressive warnings and restrictions on access to Faculty personnel, facilities and events.

41. Subject to the provisions of applicable collective agreements, suspected breaches of this Policy shall be referred to the individual's immediate supervisor and Department Head or equivalent, who shall determine what actions, if any, shall be taken. Depending upon the seriousness of the breach, whether the breach is a first or repeat occurrence and whether the individual knowingly breached the policy or attempted to conceal the breach, breaches of this policy may result in the imposition of sanctions and measures. The handling of
breaches of this Policy and the imposition of sanctions and measures may be subject to applicable collective provisions, may depend on other University policies and may require the approval of other authorities at the University. The following list provides examples of sanctions or other measures and is not meant to be exhaustive nor necessarily represents a progression of sanctions or measures:

a) Counselling, educational sessions on Conflict of Interest for the individual involved;
b) Employment-related disciplinary measures, such as a reprimand, removal of supervisory duties, suspension or dismissal;
c) Academic-related measures, such as suspension or expulsion.
d) Banning the individual from any further outside engagements for a period of time;
e) Requiring that the individual return any monies received from the relationship with Industry in contravention of this Policy;

Review

42. This Policy will be reviewed 1 year after adoption and every 3 years subsequently.

To be submitted to Faculty Advisory Board on September 28th 2010

Approved by:

Faculty Advisory Board on September 28th, 2010
Faculty Council on October 26th, 2010
Executive Committee of University Senate March 16, 2011
Source documents:


Faculty of Medicine, University of Ottawa Policy on INTERACTING WITH INDUSTRY AND OUTSIDE AGENCIES in a teaching environment. http://www.med.uottawa.ca/assets/documents/policies_procedures/Policy_Interacting_Industry_Septembre2008.pdf


Guidelines for approval of CPD activities developed by a physician organization
Guidelines for an accredited provider to co-sponsor a CPD event with a non-physician organization
Guidelines for Support of Continuing Medical Education by Industry

The Ottawa Hospital

Appendix A: Guidelines for compensation for services provided to Industry

1. Honoraria and expense reimbursement for Industry-sponsored Continuing Education

For speaking engagements that require overnight travel, the provided honoraria shall not exceed $3,000 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts. Exceptions would require prior written approval by the head of OCME, VP Medical Affairs of the Health Care Facility, CEO or appropriate Director of the affiliated research institute, Department Head, or Division Head.

For speaking engagements that do not require overnight travel, the provided honoraria shall not exceed $1,500 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

For the development of enduring materials, the provided honoraria shall not exceed $1,500 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

For the review of enduring materials, the provided honoraria shall not exceed $1,000 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

Fees exceeding the above guideline must be approved in advance by the Department Head.

2. Compensation for acting as a consultant to Industry

Compensation for consulting work shall not exceed $3,000 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

Fees exceeding the above guideline must be approved in advance by the Department Head.

3. Compensation for work-related to Industry-sponsored research

Compensation to an investigator for administrative activities required to initiate a clinical research study (including budgeting, ethics submission, etc.) shall not exceed $1,500 per day.

Compensation for attendance at a clinical investigators’ meeting shall not exceed $1,500 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

Payments for study-related procedures, examinations or follow-up visits required by protocol may not exceed the Ontario tariff for these services.
Payments for research-related services required for the conduct of a study not covered by Ontario Health tariffs (letters, reports, etc.) may not exceed $750 per patient per year enrolled in the study.

Fees exceeding or in addition to the above guideline must be approved in advance by the Department Head.

4. Cumulative Total (or Total Annual) Compensation from Industry

Where a Faculty member receives a total of more than $10,000 for services to Industry during a calendar year, the member shall inform the Department Head of the total. This should be reported prior to completing the annual conflict of interest statement or annual reappointment review.

Where the total exceeds $20,000 during a calendar year, the member shall also inform the Dean.