**1.0 Reason for Policy**

The University of Manitoba’s Faculty of Medicine 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 Manitoba and the wider community.

This mission requires that faculty, staff, students and trainees interact with representatives of the pharmaceutical, biotechnology, medical device, and hospital and research equipment and supplies industry (“Industry”) in a manner that advances the use of the best available evidence so that medical advancements and new technologies become broadly and appropriately used. Interactions with 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 in research activities. Faculty, 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 any actual, potential or perceived conflicts of interest that may 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 or the institution. Because provision of financial support or gifts, even in modest amounts, can exert a subtle but measurable impact on recipients’ behaviour, the University of Manitoba’s Faculty of Medicine has adopted the following policy to govern the interactions with Industry.

This policy is intended to provide a set of guiding principles that faculty, staff, students, and trainees, as well as representatives of Industry will use to assure that their interactions result in optimal benefit to clinical care, education and research, and maintenance of the public trust.
2.0 Statement of Policy

It is the policy of the University of Manitoba’s Faculty of Medicine that clinical decision-making, education, and research activities be free from influence or perceived influence created by improper relationships with, or gifts provided by, Industry. The principles outlined in this policy shall guide all potential relationships or interactions between members of the Faculty of Medicine and Industry representatives.

2.1. Definitions

Conflict of Interest (COI): A conflict of interest may be actual, potential or perceived. A conflict of interest occurs when an individual has a significant financial or other personal consideration 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.

Industry: For the purpose of this policy, “Industry” includes pharmaceutical, biotechnology, medical device, and hospital and research equipment and supplies industries.

Gifts: For the purpose of this policy, “Gifts” are defined as items of any value that are given by a business or individual that does or seeks to do business with the Faculty of Medicine or its affiliates to either the recipient or his/her close family members, and for which the recipient neither paid nor provided services. This includes, but is not limited to items such as pens, notepads, textbooks, electronic media, meals, gift certificates, tickets, devices, products or services, travel, hotel accommodations, entertainment or payments for attending a meeting.

2.2 Scope of Policy

This policy applies to all faculty and staff (whether independent contractor or employee), students and trainees of the University of Manitoba’s Faculty of Medicine.

Industry representatives are also expected to be aware of this policy and to adhere to its principles.

This policy incorporates the following types of interactions with Industry:

a) Gifts, Meals and Compensation
b) Drug and Device Samples
c) Access by Industry Representatives to Faculty, Staff, Students and Trainees
d) Industry Support for Educational Programs
e) Industry-Sponsored Scholarships or Other Educational Funds for Students and Trainees
f) Off-Campus Industry Sponsored Meetings or Activities
g) Industry Support for Research
a) Gifts, Meals and Compensation

Gifts

University of Manitoba Faculty of Medicine faculty, staff, students, and trainees shall not accept Gifts (including food) from representatives of Industry, regardless of the nature or value of the gift.

Gifts of educational materials directed at 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.

Meals

Meals or other hospitality funded directly by Industry may not be offered in any facility owned, operated or affiliated with the University of Manitoba’s Faculty of Medicine. Faculty and staff should use discretion in participating in any industry-sponsored meals off-campus. Specifically faculty and staff shall not facilitate the attendance of students or trainees at meals off campus sponsored by industry or at educational events off campus that are not accredited.

Compensation

Individuals may not accept compensation in exchange for listening to a sales talk, for attending a CME or other activity in which the attendee has no other role.

Consulting arrangements that simply pay Faculty of Medicine faculty, staff, students or trainees a guaranteed amount without any associated duties (such as participation on scientific advisory boards that do not regularly meet and provide scientific advice) or excessive compensation shall be considered Gifts and are consequently prohibited.

In order to avoid Gifts disguised as contracts, where Faculty of Medicine faculty or staff have been engaged by Industry to provide consulting services or speaking services, the contract must provide specific tasks and deliverables, with payment commensurate with the tasks assigned. All such arrangements between individuals or units and outside commercial interests must be reviewed and approved prior to initiation by the Department Head or, in the case of a Department Head, by the Dean.

The Faculty reserves the right to require faculty and employees to request changes in the terms of their consulting agreements to bring those consulting agreements into compliance with University or Faculty of Medicine policies.

Appendix A provides guidance as to what is considered reasonable compensation for services provided to Industry.
b) Drug and Device Samples

The provision by manufacturers of “free” samples of prescription drug or device products is a marketing practice designed to promote the use of these products and to gain access to prescribing professionals to attempt to influence their behaviour. At the same time, this practice provides 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, sampling 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.

University of Manitoba faculty, staff, students and trainees should utilize pharmaceutical or device samples only within the policies and procedures established by the affiliated healthcare facility and/relevant regional health authority.

c) Access by Industry Representatives to Faculty, Staff, Students and Trainees

Faculty, staff, students and trainees at affiliated sites must abide by the policies and procedures established by the affiliated facility and/or relevant regional health authority with regard to meeting with Industry representatives. In general, Industry representatives are permitted in non-patient care areas only by appointment. Industry representatives are not permitted in patient care areas except to provide in-service training on devices or other equipment as requested by the facility and then only by appointment and, if applicable, with appropriate consent by the patient or surrogate.

Industry representatives are prohibited from having any non-faculty mentored interactions with students or trainees.

Students and/or trainees are not to solicit financial or non-financial support from Industry for any educational or non-educational activity.

Commercial exhibits intended to showcase Industry products are permitted if directly related to an educational activity and must comply with the Office of Continuing Medical Education’s Policy on Commercial Exhibits.

d) Industry Support for Educational Programs

When accepted, Industry support for educational programs must be free of actual or perceived conflict of interest and must be provided in the form of an unrestricted grant. Funds that are provided by educational groups or other entities that act as “intermediaries” for Industry must also be provided as unrestricted grants.

The Undergraduate medical education program will not solicit or accept direct funding from Industry for its’ educational activities.
Funds for Postgraduate educational activities may be provided to the Faculty of Medicine, or to an individual Department, but must not be given to an individual faculty member, staff, student or trainee. The Division of Postgraduate Medical Education (Faculty PGME) must be informed in advance of requests to Industry for grants to support educational events. Agreements governing grants supporting educational activities must receive prior approval by Faculty PGME.

Funds for continuing medical education activities may be provided to the Faculty of Medicine, to an individual Department or to the Office of Continuing Medical Education, but must not be given to an individual faculty member, staff, student or trainee. The Office of Continuing Medical Education must be informed in advance of requests to Industry for grants to support educational events. Agreements governing grants supporting educational events must receive prior approval by the Office of Continuing Medical Education.

The content of all educational programs must be determined by the program planning group. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs and, in the case of CME activities, the organization of events must comply with policies of the Office of Continuing Medical Education and meet accreditation standards of the Royal College of Physicians and Surgeons and/or the College of Family Physicians of Canada.

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

Industry support for students’ and trainees’ participation in education programs must be free of any real or perceived conflict of interest. All educational grants or support of educational programs must be specifically for the purposes of education and must comply with the following requirements:

a) The Faculty of Medicine’s Department, Program or Division must select the student(s) or trainee(s) for participation.
b) The funds must be provided to the Department, Program or Division and not directly to the student or trainee.
c) The Department, Program or Division determines that the education conference or program has educational merit.
d) There is no implicit or explicit expectation that the participant must provide something in return for participation in the educational program.

This provision does not apply to regional, national or international merit-based awards which will be considered on a case-by-case basis.

f) Off-Campus Industry Sponsored Meetings or Activities

Individuals who actively 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) All of the content of the meeting or session must be determined by the speaker(s), not the industry sponsor.
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 comments and content reflects the individual views of the speaker(s) and not the University of Manitoba’s Faculty of Medicine.
e) Compensation is reasonable and limited to reimbursement of reasonable travel expenses and an honorarium proportional to the defined service.

g) 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, conduct of analysis or reporting of Industry funded research shall ensure that there is a signed multi-partner agreement which is satisfactory to the researcher, the head of the department in which the researcher holds his/her primary appointment, the Industry partner, and the institution(s) where the research will be conducted. All research projects must be approved by the Research Ethics Board of the University of Manitoba and comply with policies of the Office of Research.

Research grants 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, staff, student and trainee shall 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.

Because of the potential to influence judgment, remuneration for participating in research studies should not constitute enticement. It 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.

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

3.0 Disclosure of Relationships with Industry

Faculty and staff will formally 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 must be disclosed by faculty or staff, verbally or by way or 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 must also be disclosed in advance to the learning audience.

Faculty or staff with supervisory responsibilities for students or trainees or staff should ensure that the faculty or staff’s conflict, potential conflict or perceived conflict of interest does not affect or appear to affect his or her supervision of the student, trainee, or staff member.

University of Manitoba Faculty of Medicine faculty, staff, students and trainees are prohibited from publishing articles, presentations or producing other forms of media, under their names 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 International Committee of Medical Journal Editors (http://www.icmje.org).

Individuals having a direct role making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any relationship with Industry 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.

Individuals leading research which involves 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. Exceptions may be permitted only 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.

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

All students, trainees, faculty, and staff within the University of Manitoba’s Faculty of Medicine shall receive appropriate initial and subsequent awareness training regarding interactions with Industry. The Faculty of Medicine will develop appropriate education materials and methods, and each program will oversee such training and its quality.
5.0 Reporting and Non-compliance

Suspected breaches of this policy shall be referred to the individual’s immediate supervisor and Department Head, who shall determine what actions, if any, shall be taken.

Breaches of this policy may result in the following actions (singly or in any combination), 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:

a) Counselling of the individual involved;

b) Written reprimand, entered into the individual’s employment, faculty or student record;

c) Banning the individual from any further outside engagements for a period of time;

d) Requiring that the individual return any monies received from the improper relationship with a third party in contravention of this policy;

e) Requiring the individual to complete additional training on conflict of interest;

f) Removing the individual from supervision of trainees or students;

g) Termination for cause.

Any disciplinary action taken hereunder shall follow the established procedures of the University of Manitoba.

Violations of these policies by Industry representatives will be managed through progressive warnings and restrictions on access.

Faculty, staff, students or trainees witnessing contraventions of these policies shall report such breaches to the Department Head or to the Associate Dean of Academic Affairs.

6.0 Review of policy

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

Source documents:


Department of Internal Medicine, University of Manitoba. “Policy Governing Relationships Between the Pharmaceutical Industry and Physicians”(2005)


Winnipeg Regional Health Authority. “Conflict of Interest Policy” (2004)
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 $3000 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

For speaking engagements that do not require overnight travel, the provided honoraria shall not exceed $1500 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 $1500 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 $1000 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 $3000 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 research study (including budgeting, ethics submission, etc…) shall not exceed $1500 in total.

Compensation for attendance at an investigators’ meeting shall not exceed $1500 per day plus reimbursement of reasonable out-of-pocket expenses documented with receipts.

Payments to an investigator for study-related procedures, examinations, follow-up visits required by protocol may not exceed the Manitoba Health tariff for these services.

Payments to an investigator for research-related services required for the conduct of a study not covered by Manitoba Health tariffs (administrative work, letters, reports, etc…) may not exceed $750 per patient enrolled in the study.

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