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# Policy Regarding Interactions with Industry
# University of Toronto
# Department of Obstetrics and Gynecology

## GENERAL PRINCIPLES:

1. The primary objective of professional interactions between the physician/trainee and industry should be the advancement of the health of our patients. Through education and research, such professional interactions should promote this objective.

2. The physician/trainee's primary obligation is to the patient. Relationships with industry are appropriate only insofar as they promote research and education and do not affect the integrity of the physician-patient relationship.

3. The physician/trainee must disclose the nature of any relationship with industry to patients, organizers, and audiences involved in educational events or research.

4. The physician/trainee must resolve any conflict of interest resulting from interactions with industry in favor of the patient.

5. In any interaction with industry, the physician/trainee must maintain professional autonomy and commitment to the scientific method.

6. At the end of each academic year, each academic health sciences centre within the Department of Obstetrics and Gynecology will provide its department head, who will in turn forward to the Department Chair, an accounting of industry-sponsored educational activities.

7. All physicians holding University appointments in the Department of Obstetrics and Gynecology must disclose annually to their Chief potential sources of conflict of interest related to industry.

## EDUCATION

### Summary Statement:

Industry involvement in educational activities will be supported through Unrestricted Educational Grants. These grants will be administered by the Department of Obstetrics and Gynecology and the educational activities and speakers which it supports will be chosen by the department, the faculty or the residents. Industry support, the fact that it comes from multiple sources and the arm's length nature of the support will be acknowledged.

**Recommendations:**

1. Formal teaching on conflict of interest will be introduced into the core undergraduate and postgraduate educational curriculum. This will be led by faculty members with an interest in the area and is mandated by the Faculty of Medicine in its educational guidelines.
    a. Specific sessions will be aimed at teaching residents in this regard. This will assist in training residents to understand marketing and detect bias. This may also provide a potential opportunity for academic collaboration with the Department of Pharmacy, which also has an interest in this area.
    b. Teaching will be geared to promote faculty/resident discussion of these issues.

2. Faculty development will be undertaken through dissemination of this report, dissemination of CMA guidelines and devotion of one educational event/year/teaching hospital to an element of this interaction.

3. Industry shall contribute to a centralized Unrestricted Educational Grant within the Department of Obstetrics and Gynecology to support speaking events and educational activities where our faculty and residents exclusively select the speakers, topics and formats based on the results of needs assessments, clinical and academic criteria. Support of industry will be appropriately acknowledged as will the arm's length nature of the support. Support from multiple sources is preferred.

4. When a potential speaker is in Toronto in the context of industry sponsorship, the invitation to the speaker from the academic health sciences centre or the Department of Obstetrics and Gynecology must come directly from those parties and must include the following requirements:
    a. University of Toronto faculty speaking at The University of Toronto or affiliated hospital will not receive honoraria directly from industry. Instead, any necessary funds will be dispersed through the Department of Obstetrics and Gynecology.
    b. Industry representatives are welcome in large group, plenary sessions. Promotional material at any presentation is prohibited.
    c. The content of the presentation must not be promotional and generic names used wherever possible.
    d. Disclosure statements will be required and should be provided to the audience at the onset of the presentation.

5. There will be no product marketing or displays at rounds, seminars and special lectures. The presence of industry marketing/sales representatives is prohibited at internal academic events other than as per 4b.

6. Formal conferences with industry sponsorship may, as per the University of Toronto Faculty of Medicine continuing education program guidelines, include industry booths where these are physically separate from the area where education is being provided.

7. Direct sponsorship of retreats for faculty and residents by industry is prohibited.

8. It is appreciated that some industry-sponsored events fill areas of specific expertise in the curriculum for students, residents and faculty. The appropriate departmental curriculum committee should examine their content and determine whether these events indeed fill a void in our undergraduate, postgraduate and continuing education curricula in order to develop balanced and valued alternatives. The content of such events will be approved by departmental faculty.

9. Direct individual sponsorship (i.e. covering travel costs, registration, hotels) by industry of individual residents and faculty (other than faculty speaking at industry-sponsored symposia) to attend local, national and international conferences (such as the Society of Obstetricians and Gynecologists of Canada and American College of Obstetrics and Gynecology annual meetings) is prohibited. Industry-sponsored travel awards for residents and fellows, awarded competitively through a process determined and controlled entirely by the Department of Obstetrics and Gynecology, will be allowed. These travel awards, however, must be consistent with the ethos of this document.

## RESEARCH

In the area of research we are committed to scientific advancement. This means that investigator autonomy must be maintained as outlined in by Faculty of Medicine requirements for participation in research. Scientific objectivity must be ensured according to the principles of ethics review.

**Industry-sponsored research:**

1. A prerequisite for physician participation in industry-sponsored research is evidence that these activities are ethically defensible, socially responsible and scientifically valid.

2. All industry-sponsored research projects should be formally approved by an ethics review body according to the standards and procedures set out in the Tri-Council Policy Statement.

3. Patient enrolment and participation in research studies shall occur only with full, informed, competent and voluntary consent of the patient or his or her proxy. It is preferable that the informed consent be obtained by a qualified person who is independent of the patient-physician relationship. However, the responsibility of assuring that proper consent has been obtained remains with the enrolling physician.

4. Practicing physicians should not participate or enroll patients in research studies unless they are assured by the sponsors that the results will be made available within a reasonable period of time.

5. It is acceptable for physicians to be compensated for the time involved in enrolling patients or participating in approved research studies only if such activity exceeds their

normal practice pattern. This remuneration should not constitute enticement, but is meant to replace lost income as a result of the enrollment process. Research subjects must be informed if their physician will receive a fee for enrolling them in a study.

6. Each Chief of a teaching hospital department shall report annually to the Department Chair on total research funding and the proportions that reflect industry and other non-peer-reviewed support vs. peer-reviewed funding.

## CLINICAL CARE

**Recommendations:**

1. Physicians must avoid any self-interest in their prescribing practices and must always disclose to their patients any significant conflict of interest when recommending a treatment.

2. Practicing physicians who are affiliated with pharmaceutical companies should not allow these affiliations to influence their medical practices inappropriately.

3. Physicians/trainees may accept teaching aids from pharmaceutical companies provided that these are consistent with Rx and D guidelines.

4. Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided within a reasonable time frame, and then only on a cost-recovery basis, which must be demonstrable to the patient.

5. Physicians should only give "samples" of pharmaceuticals to patients under the following conditions:

    a. To get the treatment started promptly while the patient obtains ongoing medication from the pharmacy.
    b. To illustrate the proper way to take the product or drug and initiate treatment.
    c. For compassionate use, when the patient cannot afford the cost of the medication or the product and other alternatives are not available or recommended.

## REFERENCES


1. Interactions with the Pharmaceutical Industry, David S. Goldbloom, December 2003.

2. CODE of Marketing Practices, Canada's Research-Based Pharmaceutical Companies, January, 2003.

3. Physicians and Industry-Conflicts of Interest, RCPSC Publications, January 21, 2005.

4. Physician-Industry Relations, Part 1: Individual Physicians, 2002 American College of Physicians-American Society of Internal Medicine, Position Paper, page 396-402.

5. Ethical Opinions and Guidelines, American Medical Association, November 3, 2004.

6. Guidelines: Relationship Between Physician Trainees, Postgraduate Training Programs and Industry, University of Toronto-Faculty of Medicine, 2004. Relationships with Industry, January, 2004, page 107.

7. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. SSHRCWebsiteLink: http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf

**Principles Governing Relationships between Health Professionals, Health Professional Trainees and Industry in the Faculty of Medicine**

## General Principles

The following principles apply to activities sponsored by the University of Toronto. Central to these are the integrity and the fiduciary nature of the health professional - patient relationship, the confidentiality of information regarding the patient, and the avoidance of any conflict of interest for the physician-trainee and for the training program.

1. The primary objective of professional interactions between the health professional/trainee and industry is the advancement of health care. Through education and research, such professional interactions should promote this objective.

2. The relationship between the health professional/trainee and industry is guided by the Canadian Medical Association Code of Ethics.

3. The health professional/trainee has as her/his primary obligation the care and welfare of the patient. Relationships with industry are appropriate if they promote education and research and do not affect the integrity of the physician-patient relationship.

4. The health professional/trainee must resolve any conflict of interest resulting from interactions with industry in favour of the patient. In particular, she/he must avoid any self-interest in prescribing and referring practices.

5. In any interaction with industry, the health professional/trainee must maintain professional autonomy and commitment to the scientific method.

6. The health professional/trainee must disclose the nature of any relationship with industry to patients, to organizers and to audiences involved in educational events or research.

7. The health professional/trainee must not receive personal rewards from industry, except for educational material of minimal monetary value.

8. No teacher who is a University of Toronto faculty member may be directly supported by, or receive gifts from, commercial organizations while taking part in University of Toronto-sponsored activities. Indirect payments through unrestricted grants for University of Toronto-sponsored Continuing Education events are similarly proscribed unless an unusual commitment has been made by the faculty member and there is previous agreement on the stipend by the department Chair or delegate.

9. Speakers at teaching hospital Grand Rounds and seminars should provide disclosure statements at the outset regarding potential conflict of interest with the subject matter (e.g., honoraria, consultancies, advisory boards).

10. Direct individual sponsorship (i.e., covering travel costs, registration, hotels and meals) by industry of individual residents and faculty (other than faculty speaking at industry-sponsored symposia) to attend local, national and international conferences is prohibited. Industry-sponsored travel awards for residents and fellows, awarded competitively through a process determined and controlled entirely by the Departments and programs will be allowed. However, these travel awards must be consistent with the ethos of this document.

11. All physicians holding University appointments shall disclose annually to their Chief and/or University Program Director potential sources of conflict of interest related to industry (honoraria, consultancies, advisory Boards).

**12. <u>Education</u>**

13. A training program (undergraduate, graduate, postgraduate) should determine that an educational event offered on behalf of the members of that training program is appropriate for the curriculum offered by that training program. The educational event must address educational needs of the health professional trainee.

14. The training program must control the content, organization and funding arrangements for an educational event offered on behalf of the health professional trainees.

15. The training program must ensure that a balanced presentation of information regarding therapeutic interventions offered within any educational event for its health professional trainees. Any agent or device discussed must be discussed within the context of the disease or condition and of the available therapeutic interventions. Generic names of agents and devices, where possible, should be used within educational events.

16. Special funds, scholarships and other support to allow health professionals/trainees to receive salary support or attend educational events are permitted, as long as the training program administers such funds. Health professionals/trainees may apply equally for such funding support.

17. A description of educational support must be provided to the University, to industry supporting the educational event, and to the attendees of an educational event.

18. The training program must include formal training within the curriculum regarding the ethical guidelines for the relationship and interaction of health professionals/trainees with industry.

19. Formal teaching on conflict of interest will be introduced into the core curriculum for health professional trainees.

20. Faculty development will be undertaken through dissemination of this report and dissemination of the CMA guidelines.

21. With regard to educational events targeted specifically to health professionals/trainees, and consistent with University requirements, faculty members/trainees may not receive honoraria specifically for such teaching within our academic community.

**22. Research**

23. Health professionals/trainees may participate in research sponsored by industry if the research is ethically defensible, socially responsible and scientifically valid.

24. Participation by a health professional/trainee in research sponsored by industry must occur within the context of formal approval and monitoring of the research by an appropriate ethics review board, agency or body.

25. A health professional/trainee must not accept any remuneration or reward for proposing patients as subjects of research.

26. Each Chief of a teaching hospital shall report annually to the Department Chair on total research funding and the proportions that reflect industry and other non-peer-reviewed support versus peer-reviewed funding.

27. All health professionals/trainees conducting research will read, consider and adhere to the Tricouncil Policy Statement (TCPS) governing the ethical conduct of research, and will also adhere to policies promulgated by the University, the Faculty of Medicine and/or individual teaching hospitals. The goal of this is the protection of human subjects, investigator autonomy and academic freedom.

28. Issues not specifically addressed in this document which departments/programs or hospitals may wish to address include among others the presence of industry representatives and/or promotional material at presentations, the sponsorship by industry of retreats for health professionals/trainees and the monitoring by departments of issues related to the interaction with industry on an ongoing basis.

29. Further, the document does not address Continuing Education activities outside of the University of Toronto. While it is understood that honoraria may be paid to speakers, such payment should be made by an organizing committee, or by the sponsoring University or hospital, rather than directly by a for-profit or business entity. All such fees collected must be reported annually to the Department Chair. The usual requirements of disclosure at the time of any presentations apply as set out above; control of the content of the lecture or presentation must remain in the hands of the Faculty member(s), so that any interpretations are based on the best available scientific evidence. All professional guidelines about fees/payments/gifts from commercial interests should be observed. See www.cme.utoronto.ca under 'Policies' for additional information.