UNIVERSITY OF TORONTO
FACULTY OF MEDICINE

Report of the
Task Force on Relations with Industry and the Private Sector

January 2011

The Task Force on Relations with Industry and the Private Sector began its work in 2007 at the invitation of the Dean, charged to make recommendations for the Faculty of Medicine at the University of Toronto for the management of potential or real conflicts of interest that might arise from relationships between private for-profit entities and the Faculty and its faculty, staff, students, and residents. Such relationships can facilitate activities and interactions that benefit our programs and ultimately benefit our patients and the Canadian public. However, such relationships can also lead to the development of perceived or actual conflicts of interest and the opportunity for undue influence that can inhibit fulfilment of the social responsibility that is a core value of this Faculty.

This report identifies principles and practices that further that social responsibility. The Task Force divided its work into sections:

- Education and Practice
- Research
- Commercialization

This report is circulated widely for comment. We recognize that there is a wide range of opinion on these issues, and that public opinions have changed in the time we have been working. Our goal was to produce recommendations that can achieve consensus, that move in the right direction, and that can build a common platform on which the Faculty can work over the years ahead. The next step in the process will be the formation of two groups to write actual guidelines to be submitted to the Faculty Council for approval. One group will consider Education and Practice, and the other Research and Commercialization.

Nothing proposed in this report is intended to conflict with existing policy or regulation of the University of Toronto. In the event of inadvertent conflict, existing policy will govern.

In addition to references cited in the document, we acknowledge our debt to the work of the Association of American Medical Colleges, in particular:

- *The Scientific Basis of Influence and Reciprocity: A Symposium*, January 2008 https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=215&cfid=1&cftoken=CE53CC1E-DFC3-AA6B-D302A5043FBE9762

- *Industry Funding of Medical Education: Report of an AAMC Task Force*, June 2008, https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=232&prv_id=281&cfid=1&cftoken=3AA7A011-02C1-80C6-3F91BAB322CD7A39

DEFINITIONS

Conflict of Interest

A *conflict of interest* may arise when a faculty or staff member's personal or other interests are in actual, potential, or perceived conflict with duties or responsibilities to patient care, the University, their hospital, or hospital research institute. Mere existence of a conflict of interest does not imply wrongdoing: conflicts of interest can arise naturally from an individual's engagement with the world outside the University. When conflicts of interest do arise, however, they must be recognized, disclosed and properly managed.[1] For purposes of this document, relevant potential conflicts will be those from the last five years.

Conflict of Commitment

A *conflict of commitment* occurs when commitment to external activities of a faculty or staff member adversely affects the capacity to meet academic responsibilities. For University paid faculty, no more than twenty percent of a full-time member's professional effort may be directed to outside work, not to exceed the equivalent of one working day per week.[2]

Consulting

Consulting relationships include contractual relationships, advisory boards and any relationship whereby the faculty member receives, or has the expectation to receive, income for services other than for clinical or university work. This includes, but is not limited to, honoraria, commissioned papers, and lectures for which money is received.

Executive Position:

A position with responsibility for a material part of the operations of a business such as Chief Executive Officer, Chief Operations Officer, Scientific or Medical Director.

Family

For purposes of this document, Family includes a faculty member's spouse or partner, parents, children or step-children, and the siblings of the faculty member.

Financial Interest:

An interest in a business consisting of:

(1) any stock, stock option or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the faculty member does not exercise control; or

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[1] See the University of Toronto Governing Council Policy on Conflict of Interest – Academic Staff, 1994
http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppjun221994.pdf

[2] See the University of Toronto Governing Council Statement on Conflict of Interest and Conflict of Commitment, 2007,
http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppfeb012007iii.pdf

(2) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof.

Gifts

In this report, the word 'gifts' refers to direct gifts to individuals or departments. This does not include donations or relationships managed through the Office of Advancement of the University of Toronto Faculty of Medicine or through Foundations of affiliated institutions.

Ownership interest:

Holding of stock, ownership or part-ownership or other financial interest in a business, including arrangements to receive royalties under institutional royalty-sharing policies.

Private Sector

In this report, Private Sector includes entities that do business with the intent or possibility of commercial gain, generating a profit, or increasing equity. It does not include charitable organizations, government, the military, non-governmental (NGO) or quasi-governmental organizations. Entities described as "non-profit" will require individual consideration.

Sponsored Research

Research, training and instructional projects involving funds, materials, or other compensation from outside sources under agreements which contain any of the following:

- The agreement binds the University or hospital research institute to a line of scholarly or scientific inquiry specified to a substantial level of detail. Such specificity may be indicated by a plan, by the stipulation of requirements for orderly testing or validation of particular approaches, or by the designation of performance targets.
- A line-item budget is involved, i.e., one that details expenses by activity, function or project period.
- Financial reports are required.
- The award is subject to external audit.
- Unexpended funds must be returned to the sponsor at the conclusion of the project.
- The agreement provides for the disposition of either tangible or intangible properties which may result from the activity. Tangible properties include equipment, records, technical reports, theses or dissertations. Intangible properties include rights in data, copyrights or invention

There are two overall recommendations:

1 DISCLOSURE

Each faculty member has a responsibility to manage existing or new conflicts of interest or commitment. While disclosure is not always an adequate management of conflicts, it is an essential first step.

We recommend that:

1.1. All Faculty divisions and departments institute regular annual reporting to the chair by every faculty member disclosing

- all sums in excess of $1000 received from single sources other than from the University, affiliated hospitals, or clinical practice
- financial interests or ownership interests greater than $5,000 of faculty members or their family or associated entities[3] in businesses operating in areas related to the faculty member's practice, research, or other professional activity..
  (Note: Holdings in mutual funds are not reportable in this category.)

1.2. Each division or department chair report a list of declarations annually to the Dean, or designate.

1.3. Where chairs believe that conflicts are not properly managed, advice should be sought from the Committee on Conflict of Interest of the Faculty or of the relevant hospital or research institution. (see below)

2. STANDING COMMITTEE ON CONFLICTS OF INTEREST

We recommend that:

2.1. The Dean of the Faculty of Medicine appoint a Committee on Conflicts of Interest (CCOI), with representatives from all sectors of the Faculty, persons with expertise in the ethics of conflict of interest, and public members.

- The CCOI will review cases brought to it by the Office of the Dean or division or department chairs.
- The Committee will develop procedures for implementing the disclosure and approval process, for oversight protocols, and for managing conflicts.
- The Committee will be available to consult with hospital and other affiliated Research Institutes on the application of such guidelines as may be in force to specific cases disclosed by their faculty.

2.2. Each hospital or research institution establish a similar Committee on Conflicts of Interest.

[3] "Associated entities" includes, but is not limited too, partnerships, personal corporations and family trusts.

SECTION 1

Education and Practice

One way in which health care professionals demonstrate professionalism is when they put the interests of their patients ahead of self-interest. In recent years, the potential conflict of interest in the relationships between physicians and industry has been recognized increasingly often in both the medical literature and the lay press. [4,5,6,7,8] At the core of the conflict is a different responsibility and accountability: the health care professional primarily to the patient and industry also to owners or shareholders. Properly managed, such interests can result in benefit to patients through improved products and better delivery of care.

Industry sponsorship of educational events can be beneficial. However, there is strong evidence that receiving gifts — of any value, including food — establishes a sense of obligation and results in undue and often unrecognized influence on practice. [9,10] Accepting gifts may also lead to a sense of entitlement that can perpetuate inappropriate relationships and influence. These effects apply to students, trainees and physicians and other professionals in practice.

The proposed guidelines set out in this section are intended to help both faculty and learners conduct appropriate relationships with industry and its representatives.

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[4] Rothman DJ, McDonald WJ, Berkowitz CD, Chimonas SC, DeAngelis CD, Hale RW, Nissen SE, Osborn JE, Scully JH Jr, Thomson GE, Wofsy D. Professional medical associations and their relationships with industry: a proposal for controlling conflict of interest. JAMA. 2009 Apr 1; 301(13):1367-72

[5] Grande D, Frosch DL, Perkins AW, Kahn BE. Effect of exposure to small pharmaceutical promotional items on treatment preferences. Arch Intern Med. 2009 May 11;169(9):887–893.

[6] Grande D, Frosch DL, Perkins AW, Kahn BE. Effect of exposure to small pharmaceutical promotional items on treatment preferences. Arch Intern Med. 2009 May 11;169(9):829-31.

[7] Landefeld CS, Steinman MA. The Neurontin Legacy — Marketing through misinformation and manipulation. N Engl J Med 2009;360:103-4

[8] Duff Wilson. Harvard Medical School in Ethics Quandary. New York Times. March 3, 2009

[9] *The Scientific Basis of Influence and Reciprocity: A Symposium,* January 2008 https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=215&cfid=1&cftoken=CE53CC1E-DFC3-AA6B-D302A5043FBE9762

[10] Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving. Am J Bioethics 2003;3:39-46

Proposed Guidelines for relations with industry

These proposed guidelines were developed with reference to the CMA Policy, *Guidelines for Physicians in Interactions with Industry*[11] and the report of the AAMC Task Force *Industry Funding of Medical Education*[12] and the AAMC Report of the Task Force on Financial Conflicts of Interest in Clinical Care *In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making*[13].

1. Sales representatives for pharmaceutical and other industries have as an objective the sale of their products. Information they supply about health care related to their products should be considered part of their marketing strategy and they should not be relied upon as a major source of health-care information[14].
   1.1. Meetings between industry product or sales representatives and students or trainees should occur only in educational settings and when a faculty member is present. The faculty member has a responsibility to ensure that any discussion about specific products is medically and scientifically sound, balanced and includes alternatives.

2. Faculty members should consider the educational value of meeting with representatives of industry and recognize that in doing so they model such interactions for trainees.
   2.1. Meetings with representatives should be by appointment.
   2.2. Meetings with industry representatives should not normally take place in the presence of patients unless the representatives are specifically needed for patient care.
   2.3. If representatives are to be present during patient care, patients should be so informed. If representatives have permission from hospital authorities to be in patient care areas, it is recommended that they wear identification that clearly indicates they are not part of the health care team.
   2.4. Representatives should not ordinarily take part in patient care. Appropriate demonstration of technical use of equipment by industry representatives is acceptable. However, if an industry representative must take part in patient care it must only be with:
      - the knowledge of the patient;
      - authorization and credentialing by the institution; and,
      - if needed, approval by regulatory authorities (for delegated acts.)

   Such participation should only be at the request of the responsible physician or practitioner. Industry representatives must respect patient privacy and confidentiality.

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[11] CMA Policy: Guidelines for Physicians in Interactions with Industry, December 2007, http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf accessed 13 May 2009

[12] Industry Funding of Medical Education: Report of an AAMC Task Force (PDF) June 2008, https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=232&prv_id=281&cfid=1&cftoken=3AA7A011-02C1-80C6-3F91BAB322CD7A39 accessed 13 May 2009

[13] In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making (PDF) June 2010 https://services.aamc.org/publications/index.cfm?fuseaction=Product.displayForm&prd_id=303&prv_id=375 accessed 26 November 2010

[14] This does not refer to official prescribing or technical information.

3. Each clinical education program must offer formal teaching to its students and residents about ethical guidelines related to interactions with industry and the resultant potential conflicts of interest.

4. Student or trainee contact information must not be provided to industry representatives.

5. Gifts should not be accepted from industry. This includes food and entertainment which must be considered gifts.

6. EDUCATIONAL EVENTS

This section includes continuing education programs and educational activities within undergraduate, postgraduate, and graduate programs including rounds, seminars, lectures and journal clubs.

6.1. Educational events must be planned to address the educational needs of the audience, whether practising faculty, students or trainees. Content, organization and financial arrangements must all be controlled by faculty organizers without influence from sponsors. (See the CMA Guidelines.) Events within postgraduate training programs must be managed by the program administration.

6.2. Funding for educational events must be in the form of unrestricted grants in which the donor has no influence over program content or choice of speakers. Donors must be acknowledged each time the funds are used.

- Ideally, if events have sponsorship it will be from multiple sources to avoid any one company developing a perception that it is its event.
- Funds should not be held by an individual event organizer but should be held centrally at the level of an institutional (hospital) or university department or division.
- Responsible use of sponsorship funding should include only legitimate expenses that correspond to a prepared itemized budget. (See #6.6). Financial statements for sponsored events should be available for audit, including by the sponsors.

6.3. Guest Speakers: choice of speakers, subjects of presentations, travel arrangements, expenses, and honoraria should all be arranged and paid through the faculty organizers of the event and not by sponsors or their agents.

Organizers of events may engage conference management companies but they should be hired through the event budget and not by sponsors or donors.

6.4. All speakers at educational events, whether faculty or guests, must fully disclose any potential conflicts of interest with industry. This includes teaching rounds and lectures within university undergraduate and postgraduate programs. Potential conflicts include, but are not limited to, partnerships, share holdings, receipt of consultation fees, membership on advisory boards or speakers' bureaus[15], and funding for research. Relationships with competing corporations are also relevant and should be declared. (Some jurisdictions also require declaration of conflicts involving immediate family members: spouses/partners, children, and parents.)

6.4.1. The use of generic names for drugs or other products is preferable to the use of trade names. If trade names are used, all other available products should be mentioned, and the generic name should also be used.

6.4.2. Faculty members must also disclose potential conflicts of interest when participating in curriculum committees or in guideline or standard-setting committees or panels. Occasionally potential conflicts will preclude participation in some parts of an agenda.

[15] See recommendation 8.2

6.5. Registration for sponsored events must be through the university or faculty member organizers and not through an industry representative.

6.6. FOOD

There is a long tradition of offering hospitality and sharing food when people gather for events of any kind; it has certainly been a custom in medical educational events. Our Task Force does not propose to stop this practice; however, past and existing arrangements for commercial entities to provide and/or pay for food have engendered obligation and at least the potential for conflict of interest and undue influence and have fostered an inappropriate sense of entitlement.

6.6.1. The practice of having industry representatives provide food directly or indirectly for rounds and teaching sessions should not occur.

6.6.2. Industry-sponsored dinners, even those labelled as educational events, fall into the category of gifts. They are not consistent with these guidelines and should not occur.

6.6.3. Hospitality, including food, may appropriately be part of events such as full day or longer programs or conferences but should have no direct link to a sponsor, should be arranged by the event organizers, be modest, and be accounted for in the event budget.

6.7. Any commercial displays at an event should be in a separate room from educational activities. Commercial displays should have no place in undergraduate or postgraduate educational events.

6.8. Audit mechanisms should be established to assure compliance of CE and other educational events with university and national standards.

7. Industry may contribute to educational funding of postgraduate residency programs, unrelated to specific events, provided that:

7.1. support is received as an unrestricted grant. Ideally there will be multiple donors.

7.2. it is publicly acknowledged

7.3. the funds are managed centrally by the program or division director. Financial statements should be prepared and available for audit.

7.4. the industrial donor plays no role in selecting recipients of any scholarships or travelling funds

7.5. No *quid pro quo* is established in any such arrangement.

8. Consultation to Industry

8.1. Faculty members may legitimately receive compensation for provision of special expertise in consultation to industry. Such remuneration should be commensurate with the work done and must be fully disclosed.

8.2. Faculty members should not participate in speakers' bureaus. This is defined as a relationship in which the faculty member is under contract to or paid by a company and the company selects any of: the topic, any part of the content of a talk, or any members of the audience. Programs run by for-profit educational companies are included in this category.

8.3. Faculty members should not participate in industry planning or training programs designed for marketing or sales purposes. (e.g., opinion panels for marketing or training programs for sales staff.)

9. DRUG SAMPLES

There are several concerns about the use of drug samples provided by the manufacturers to physicians:

- One goal of the donor is to develop the market for the drug.

- Samples are usually of the latest product, may or may not be the best one for the patient, and are often expensive if there is a decision to continue after the sample.
- Providing samples to physicians may inappropriately affect their choice of drug because this choice may be based on the availability of the sample.
- Drug safety is a concern, including off-label use, theft, improper storage, use of expired products, lack of proper instruction, and failure to note interactions with other medications.

9.1. Hospitals should consider the establishment of central repositories for drug samples to be administered by pharmacists.

9.2. Physicians and their families should not use free drug samples that have been given to the physician by industry.

9.3. Physicians who continue to dispense sample drugs must keep appropriate records and ensure the drugs are stored and dispensed in a safe manner.

10. Faculty members and trainees should use presentation slides prepared by industry or CME companies only with specific verbal and written (on each slide) acknowledgement. Such use should be informed by a consideration of potential bias in the production of such materials.

10.1. The usual rules of attribution require that use of slides prepared by any other person should be acknowledged.

11. When undergraduate or postgraduate trainees in the Faculty of Medicine undertake research, all rules applying to graduate students in the university will also apply.[16]

12. Faculty members involved in the selection of drugs or devices used in the hospital should declare any potential conflicts of interest. Some conflicts will require that the faculty member withdraw from the particular decision-making process.

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13. These guidelines apply to faculty members and trainees in all practice settings: both university affiliated institutions and in the community.

14. Because the principles in these guidelines arise out of the professional and relationship with patients, faculty and trainees should observe them at all times, including in "off hours" and off-site.

[16] http://www.facmed.utoronto.ca/Research/ethicspolicy.htm

SECTION 2

Research and Graduate Training

Biomedical research institutions have cultivated a growing variety of relationships with industry which both fund research and expedite its translation into the clinical setting. The Faculty of Medicine remains strongly committed to continued growth in these mutually beneficial relationships.

However, partnerships between for-profit enterprises, the University, and affiliated Research Institutes have also created possibilities for conflicts of interest. Clear guidelines and principles, and appropriate mechanisms for disclosure, supervision and monitoring can facilitate productive cooperation between industry and academic medicine and biomedical sciences while sustaining public confidence in its moral and scientific integrity.

The policy recommended in this section is intended to serve as a guide for faculty members in structuring their relationships with industry while considering their academic responsibilities. An integral part is disclosure, whereby faculty activities are regularly reviewed. These guidelines are intended to maintain the professional autonomy of scientists and researchers and should be viewed as complementing and elaborating the policies of the Hospital Research Institutes.

1 RESEARCH INVOLVING STUDENTS AND TRAINEES

NOTE: Restrictions applied to a "supervisor" or "faculty member" in this section also apply to family members' associated entities.

1.1. Special care must be taken to assure that a trainee's research is not designed or appear to be designed to enhance the financial interests of their supervisor(s).

1.2. Contractual aspects of a Sponsored Research agreement must not prevent scientific communication.

1.3. Graduate education relies on an atmosphere of open discourse. If graduate students are held to non-disclosure of an aspect of their work in meetings within the University, this work should not form part of their research thesis. Special consideration may be required for projects involving patent filings and intellectual property (IP), and these issues must be discussed (see 1.4.3) with students in advance of their initiating work on a project with potential IP implications.

1.4. Before embarking on a research project, the supervisor must provide their student with a clear statement regarding:
(1) the source of funding of the research project if it includes corporate support,
(2) whether the supervisor has a financial interest (that it exists, not the amount) in a business that sponsors the research, and
(3) any conditions that might be imposed on the communication of scientific data.
The student's Graduate Department Chair, who is responsible for the integrity of the training environment, must also be informed.

1.5. Following Faculty of Medicine guidelines[17] that apply to students engaged in business-sponsored research, written approval of the Graduate Departmental Chair must be obtained before a trainee can be assigned to conduct research which is sponsored by a business in which the supervisor has any financial interest or which involves a technology to which such a business has licensing rights.

1.6. When a student feels that he or she is being adversely affected by involvement in any business-sponsored research because of a conflict of interest (real or apparent) resulting from the supervisor's relations with the sponsoring business, the student has the right to bring the matter to the attention of the Graduate Chair, Dean, and/or the Research Institute's Vice-President for Research.

1.7. A faculty member must disclose to members of the research laboratory/team, including employees working on the research, financial interests in a business that sponsors research. This includes disclosure to prospective students, and new faculty members before those individuals make a decision to join the team. For team members, the required disclosure is that interests exist, not their nature or amount.

1.8. Students, trainees, new faculty members and employees should receive training regarding potential conflicts of interest in interactions with industry.

2. ASSESSING CONFLICT

Conflict of interest must be assessed and closely monitored in research when it could be inferred that the activity of the investigators might be influenced by the expectation or realisation of personal material gain.

Conflicts of interest are assessed by classification into the following four categories. These are intended to define a framework for dealing with conflict of interest, rather than a set of rigid rules. The guidelines and their interpretations should be reviewed on a continuing basis.

2.1. **ROUTINELY ALLOWABLE** (activity not a conflict of interest)**:**

2.1.1. receiving royalties for published scholarly work and other writing.

2.1.2. receiving license fees, milestone payments and post-market royalties under institutional royalty-sharing policies.

2.2. **ORDINARILY ALLOWABLE** WITH **DISCLOSURE** and, where necessary, **OVERSIGHT**:

2.2.1. Research:

participating in or assigning students, post-doctoral fellows or other trainees to**:**

- research on a technology developed by that faculty member, unless the activity falls under category 2.4.
- projects sponsored by a business in which the faculty member has a financial interest, unless the activity falls under category 2.4.

[17] to be established

2.2.2. Board Membership**:** serving on the Scientific Advisory Board of a business from which that faculty member receives sponsored research support or with which the University has a contractual relationship known to the faculty member, unless the activity falls under category 2.4.

2.2.3. External Activities**:** A faculty member assuming an Executive Position in a not-for-profit business engaged in commercial or research activities of a biomedical nature.

2.3. Activities that are **ALLOWABLE ONLY AFTER DISCLOSURE, REVIEW, APPROVAL AND ONGOING OVERSIGHT** by the University or Research Institute with advice from the Committee on Conflict of Interest when requested:

2.3.1. Research Activities: Research conducted by faculty member externally that would ordinarily be conducted within the University or Research Institute.

2.3.2. Committee Participation: Participation in consideration by a committee of a governmental agency (such as Health Canada) on a technology which is owned by or obligated to a business in which the faculty member has a financial interest.

2.3.3. Administrative Responsibilities: Taking administrative action within the University or Research Institute or participating in decisions which ultimately may be beneficial to a business in which the faculty member has a financial interest.

2.3.4. Ownership Interest:

- When a faculty member conducts research on a technology owned by or contractually obligated to a business in which the faculty member has an ownership interest.
- When a faculty member receives sponsored research support (direct or in kind) from a business in which he/she has an ownership interest.

NOTE:

- Faculty members may manage the potential conflict of equity ownership by divesting ownership interest, for example to a blind trust or institutional foundation, for the duration of related research.
- A *de minimis* exception on ownership and consulting may apply, as defined by the faculty member's employer, i.e., University or Hospital research institute.) It is suggested that all the following apply:

  a) The stock or similar ownership interest is in a publicly held, widely traded business;

  b) The current value of the stock or ownership interest does not exceed a threshold value of $5,000;

  c) There is no relationship between acquired stock or ownership interest and the faculty member's clinical practice or proposed research.

2.4. Relationships and activities that are generally **NOT ALLOWABLE**.

2.4.1. Failure of Public Disclosure: Publishing or formally presenting research results without simultaneously disclosing any financial interest in a business which owns or has a contractual relationship to the technology being discussed or which sponsors the research being discussed.

2.4.2. External Activities

- A faculty member is not permitted to take an Executive Position in a for-profit business engaged in activities of a biomedical nature.
  The potential conflict may be managed if the faculty member declares and takes a leave of absence from the university.
- A faculty member who serves on the Board of Directors of a business is not permitted to participate in human subject research on a technology owned by or obligated to the business and is not permitted to receive sponsored research from that business.
  The potential conflict may be managed by leaving the Board of Directors.

3 RELATIONS WITH RESEARCH SPONSORS[18]

3.1. Agreements with research sponsors must not limit the access of investigators to data or allow sponsors to suppress or edit data.

3.2. Sponsors must not have the right to prevent or delay publication or dissemination of results as investigators see fit, beyond a reasonable period to secure intellectual property; this period should not exceed four months.

3.3. Faculty members must not agree to publish as author any article written in whole or part by the employees or agents of the sponsors of a study (ghostwriting.) Rules for authorship such as those the International Committee of Medical Journal Editors (ICMJE) and World Association of Medical Editors (WAME) should be observed. These rules would not prevent collaboration with industry researchers who are named authors.

3.3.1 Faculty members and students should be responsible for the content of their abstracts, presentations, and lectures, including the content of slides.

ACKNOWLEDGEMENTS:

For this section, we acknowledge a debt to the policies of other institutions, including the Hospital for Sick Children, Harvard Medical School, Stanford University, and Yale University.

[18] See the TAHSN statement on Protection of Intellectual Freedom and Publication Rights http://www.facmed.utoronto.ca/Research/researchpolicies.htm

SECTION 3

Commercialization of New Knowledge and Techniques

Commercialization within the context of the university and affiliated hospitals and research institutes is an avenue to enhance the mission of basic and applied research and can expedite translation of research results into practical uses that enhance patient care. Profound improvements in the quality of health care delivery have resulted from the commercialization of basic science research and technology. These benefits are best realized if commercialization is properly managed. Our changing research funding environment places value on commercialization as it can lead to partnerships that foster knowledge exchange. However, the mission of knowledge generation, discovery, and dissemination may be successfully pursued independent of commercialization and lead to similar or greater improvements and enhancements in patient care without being driven by the need for financial returns. Basic and applied research may proceed independently or in partnership with efforts toward commercialization; patient benefit may ensue in both scenarios.

Financial returns from commercialization can be used to support research infrastructure and the core institutional budget, and provide support for basic or applied research or clinical care. This is important, especially in our current financial environment; however, partnership with or funding from the commercial sector may lead to a number of conflicts, which are addressed below. Research must be protected against the pressure to pursue only projects with potential to generate financial returns. Institutions should advocate and have policies and procedures that reflect values supporting the scientific independence that permits quality research regardless of potential for commercialization.

1. Commercialization — translating research results into products, services or processes — is a natural and positive outcome of research. Nevertheless, a distinction between research and commercialization should exist where possible in institutional policy and practice.

    1.1. Research and commercialization activities at public institutions should be governed separately from each other.

    1.2. Funds from commercialization activities should be managed in a transparent manner.

    1.3. Institutional resources needed to support research and commercialization activities should derive from separate budgets, with each reflecting the unique value these activities contribute in an academic environment.

2. Actual or potential commercialization should not be the primary driver of the research agenda at an institutional level.

    2.1. While commercialization is important, it must not be valued more than other types of research, or be seen to be valued more highly.

        2.1.1. Basic and applied research, independent of commercialization goals or potential, should be valued as a core and essential component of a healthy research environment.

        2.1.2. Indices of research productivity or impact (for the purposes of ascribing financial or other resources or rewards) should be based largely on metrics independent of commercialization potential.

2.1.3. Recruitment of faculty and/or students should be guided by academic goals, free from consideration of commercialization potential or ties to commercial efforts.

2.2. While recognizing the potential benefits of commercialization, institutions should also recognize and be vigilant in regard to the potential harmful impact of conflict between different organizational priorities that might be a by-product of commercialization efforts.

2.2.1. Institutions should establish policies to ensure commercialization efforts are in synchrony with the mission and vision of the institution, and do not result in conflict for the institution, or for individuals developing commercializeable products.

2.2.2. A mechanism should be established to monitor the intersection of commercialization and research to ensure institutional policies (see 2.2.1 above) are followed. This monitoring may, for example, occur through the use of an institutional Conflict of Interest committee struck for this purpose.

2.3. Scientists, and their students, should have autonomy in the selection of research agendas.

2.3.1. Scientists ought not to be coerced by any member of their institution to alter their research agendas on the basis of commercialization potential, nor should the Scientists interfere with research plans of their students, colleagues or research personnel on that basis.

2.3.2. Individual Conflict of Interest policies should speak to issues of personal and interpersonal conflicts in the commercialization context.

3. Issues regarding the selection and recruitment of students, the scope of their work and academic program requirements in a commercialization context are the subject of Guidelines produced by the Faculty of Medicine, University of Toronto:
   - *Guidelines for Faculty of Medicine Graduate Students and Supervisors in the Context of Commercialization of Inventions Based on Thesis-Related Research*[19];
   - *Guidelines: Relationship between Physician Trainees, Postgraduate Training Programs and Industry*[20].

3.1. Institutions should put in place policies mandating the dissemination of these and related Guidelines to all existing and new personnel, and monitor compliance with them, possibly through institutional bodies such as Research Training Centres.

4. Institutions should take a leadership role in educating funding agencies about the need for appropriate funding for all research, regardless of its commercialization potential. Although the potential for commercialization is one reasonable goal for research projects and institutions, it should not be the primary driver for decisions about the funding of peer-reviewed grants from public agencies.

5. Where research outcomes involving clinical care have commercialization potential, special care should be taken to protect participants and patients from the potential consequences of conflicts of interest.

5.1. Research Ethics Boards should receive continuing education on the topic of commercialization as it might pertain to the safety and welfare of research participants.

[19] http://www.facmed.utoronto.ca/Assets/graduate/ind.pdf
[20] http://www.pgme.utoronto.ca/quickinfo/relationship.htm

5.2. Research Ethics Boards should be fully informed of the commercialization potential of each human subject research project they review. If commercialization opportunities arise during the course of the research, the REB should be informed.

6. Research contracts with for-profit organizations should be reviewed in a coordinated and systematic way by the institution using established criteria to ensure the terms and conditions protect the public interest, as well as the clinical, educational and research interests of the institution.

Appendix A Members of the Task Force

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Jeannette Goguen	Endocrinology
Ray Guo	Student, MD program
David Kaplan	Family Medicine
Michael Jewett	Surgery (Urology)
Alex Levin	Ophthalmology [to December 2008]
Anthony Levitt	Psychiatry
Muhammad Mamdani	Li Ka Shing Knowledge Institute, St Michael's Hospital
Martin McKneally	Surgery
David McKnight	Associate Dean, Equity & Professionalism (Chair)
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