

# Conflict of Interest/Conflict of Commitment – An Issues Paper

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## **1. Introduction**

The three Federal Granting Agencies (Tri-Agency, Agencies), Canadian Institutes of Health Research (CIHR), Social Sciences and Humanities Research Council of Canada (SSHRC) and Natural Sciences and Engineering Research Council of Canada (NSERC), have developed a Memorandum of Understanding (MOU) on Expectations/Roles and Responsibilities. This MOU aims at codifying, clarifying and harmonizing the roles and responsibilities of the Agencies and of recipient Institutions in the management of federal grants and awards. Institutions must sign the MOU to remain eligible for Agency funding. Eight Schedules have been developed already, which define issues, such as the ethical review of research involving humans, the ethical review of research involving animals, and integrity in research. The Agencies want to add a Schedule dealing with Conflict of Interest and Conflict of Commitment (COI/COC) to the series.

Prior to drafting the issues paper, the COI/COC policies of a number of institutions (associations, government agencies and universities) in Canada, the USA and the UK were reviewed (see [Appendix 1](#)). An issues paper was drafted and a Working Group composed of Agency staff and academics (see [Appendix 2](#)) was convened to discuss the various issues raised, raise additional ones and propose the Framework for a Schedule on COI. The first draft of a COI Schedule was discussed by the Working Group to arrive at a final version to be distributed to the broad community for comments.

The present paper reflects this process and it is distributed to the research community as a means to inform and to provide models to institutions in setting or revising their own COI/COC policies.

## **2. Summary of the topic**

Several factors might compromise independence, objectivity, and perceptions of financial probity or ethical responsibility in research. The principal question here revolves around the respective roles and responsibilities of recipient institutions and the Agencies in the identification and management of situations giving rise to COI/COC. The commercial sponsorship of research is adding to the complexity of the question and, as a result, it is increasingly important to take steps to retain public trust.

Granting agencies in the USA and Canada, University Association and the institutions themselves have developed or are developing documents that focus on COI/COC. Many faculty associations have included sections dealing with COI/COC in their collective or other agreements.

On June 28, 1994 the USA Department of Health and Human Services (HHS) published proposed regulations (59 FR 33242) to ensure that the Public Health Service-funded research would not be compromised by financial interests of investigators that could be reasonably expected to bias the design, conduct or reporting of the research<sup>1</sup>. Several organizations, principally in the USA have studied the question and produced major reports<sup>2</sup>. Not surprisingly, because of their visibility and commercial potential, issues that bear on research on human subjects and on biotechnology have gained particular prominence.

Approaches to COI/COC in Canadian institutions vary, as do application and management of existing policies. Many Canadian institutions are currently developing or revising their policies. Therefore, it seemed an opportune time for the Agencies to study the question and develop guidelines.

The Agencies and the institutions both share a concern in ensuring that research is protected from even the appearance of COI/COC to ensure that the public's confidence in research and in the institutions that fund and carry it out is maintained.

The Association of American Universities (AAU), which represents 63 leading North American research universities (including McGill University and the University of Toronto), identified a number of key values that universities need to protect from such conflicts. They include the education of students, academic freedom, the creation, communication and dissemination of knowledge, the safety of patients under their care and of participants in research, the protection of the appearance and the actual integrity of research and public service<sup>3</sup>.

Most experts agree that situations of conflict are unavoidable, given the need to transfer knowledge to the private sector for the benefit of society<sup>4</sup>. Furthermore, all agree that it is impossible to provide guidelines that will cover all eventualities. Therefore, while situations of conflict should be avoided inasmuch as possible, there is agreement that the issue of a conflict is in itself less important than the management of that conflict.

The US Department of Health and Human Services (HHS) Guidelines state: *"Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts."*

The HHS Guidelines are meant to guide the identification, assessment, and management of COI relating to federally funded research<sup>5</sup>. These guidelines require institutions to:

- *"Maintain a written, enforced policy on financial conflict of interest;*
- *Inform research investigators of that policy, the associated reporting responsibilities, and related federal regulations;*

- *Report to awarding offices the existence of any conflicting interest(s) and assure that the interest(s) have been managed, reduced, or eliminated in accordance with the regulations."*

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<sup>1</sup> <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>

<sup>2</sup> Details are provided in Appendix 1.

<sup>3</sup> AAU, Task Force on Research Accountability. *Report on Individual and Institutional Financial Conflict of Interest.*

<http://www.aau.edu/research/COI.01.pdf>

<sup>4</sup> cf. *Issues with Respect to Commercializing Canadian University Research* (Dennis Rank & Mireille Brochu). A Report Prepared for the Advisory Council on Science and Technology's Advisory Panel on the Commercialization of University Research.

[http://acst-ccst.gc.ca/comm/rpaper/home\\_e.html](http://acst-ccst.gc.ca/comm/rpaper/home_e.html)

<sup>5</sup> *Responsibility of Applicants for Promoting Objectivity in Research.*

<http://grants.nih.gov/grants/guide/notice-files/not95-179.html>

### 3. Objectives of COI/COC policies

According to the National Institutes of Health (USA), the objectives that must be met for institutional conflict of interest policies to be effective are as follows:

- *“Assure that merit, intellectual importance, and a policy of unrestricted communication govern decisions concerning the nature and direction of research, and the publication of research results.*
- *Assure that the particular research proposed is appropriate for the research environment and that there is an acceptable congruence of interest between institution and the sponsor.*
- *Assure that the management of the disclosure process protects the faculty and the institution while facilitating the commercialization of research results for the public good.*
- *Assure the appropriate use and disclosure of intellectual property.*
- *Assure the appropriate use of the resources of the research institution in the conduct of research.*
- *Assure that the scholarly interests of the students govern the nature of decisions involving students, or the direction given to them.*
- *Assure the maintenance of the public trust through disclosure and the management of potential conflicts of interest.”<sup>1</sup>*

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<sup>1</sup> NIH – Regulatory Burden Work Group Report

<http://grants.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm>

## 4. Principal issues related to COI/COC policies

### 4.1. Definition of key terms

All major position papers consulted emphasize the importance of definition of key terms. For example, the members of a recent National Institutes of Health (NIH) work group<sup>1</sup> were concerned that many key terms used in the HHS Guidelines are vague and the potential exists for mis- or over-interpretation. Specifically identified were the terms "acceptable management of a conflict," "unacceptable financial relationship" and the term "reasonably appears to be affected by" in identifying conflicts needing disclosure. It is, therefore, important at the outset to ensure that appropriate terminology is used and that such terminology be defined in institutional policies.

a) **Conflict of Interest.** Several definitions of COI are given in [Appendix 3](#). [Appendix 4](#) gives examples of existing Agency statements on Conflict of Interest. It is clear that, given the multiple circumstances that could give rise to COI situations; it is not possible for the Agencies to propose as precise a definition as that needed in an institutional policy.

The following definition is proposed for the purpose of the Tri-Agency COI Schedule:

**Conflicts of interest are real, perceived or potential situations in which the judgments and subsequent actions of individuals, institutions or other entities could be affected because of multiple, competing interests.**

The way COI is defined by an institution should expand on this general definition<sup>2</sup> and highlight the notions of private vs institutional interests and of perceived as well as actual or potential conflicts. It should also deal with bias that might be introduced by conflicts of duties; this is necessary to ensure the objectivity of the research and to maintain public trust. It is also essential to enhance the protection afforded to the performers of research, the institutions and other entities, such as the funding entities and the users of research.

b) **Conflict of Commitment (COC).** In many of the documents consulted, COI and COC are not distinguished from one another. COC generally deals with the professional obligations of faculty and/or staff to the institution, such as time devoted to external duties and the use of institutional facilities.

Defining the duties of faculty, administrators, trainees and staff is the responsibility of the Institution, in keeping with local practices and regulations<sup>3</sup>. There are overlaps between COI and COC; the boundaries need to be defined in

an institutional policy. However, for the purpose of a Tri-Agency MOU, it is judged that a definition of COC separating it from COI is not necessary.

c) **Institution.** Given the multiple affiliations of some institutions (e.g., multiple campuses, multiple research institutes, federated institutions or colleges), a clear definition is needed of what constitutes "the Institution" for the purpose of a specific policy (see also [Applicability](#) section below).

For the purpose of the MOU, the Agencies have defined Institutions as: "*the universities, hospitals, colleges, research institutes, centres and other organizations eligible to receive and manage grant funds on behalf of the Agencies and Grant Holders.*"

Given this broad definition, it is essential that there be a clear definition of what "Institution" means in terms of a specific policy. For example, The University of Western Ontario (UWO) has two affiliated research institutes and several affiliated/federated colleges. One of the research institutes is considered an "Institution" by one of the Agencies, for the purpose of receiving and managing grant funds. Nevertheless, all human research at UWO comes under the aegis of the same Research Ethics Review Board (REB). Therefore, for the purpose of human ethics review, the "Institution" includes all the component parts. If, however, the affiliated research institutes or colleges decided that they needed separate COI policies, the definition of "Institution" might need to change for that particular purpose.

d) **Individual.** Who is considered an individual covered by the policy must be defined (see [Applicability](#) section below).

e) **Research.** Institutions need to clearly define the types of research covered by the policy.

**In practice, the institutional COI/COC policy should cover all research activity at the Institution including entities partially owned or controlled by the Institution. It should include Agency-sponsored research, and research sponsored by provincial agencies, charities, business and industry, research sponsored under the auspices of the Institution itself, and research that is self-funded by a researcher.<sup>4</sup>**

The Agencies are concerned with:

- The protection of the research carried out by principal investigators and the management of conflicts where they exist;
- The protection of research carried out by trainees or other members of the research team and the management of conflicts that may arise, for example, through commercial activities carried out independently by trainees or other members of the team;

- The protection of trainees and others from power relationships, for example, situations where a trainee is expected to participate in the commercial activities of the supervisor;
- Ensuring that the expenditure of research funds is free of conflict of interest situations, for example, in situations where material management staff select providers of service or of materials;
- Ensuring that family or other close relationships do not cause COI situations;
- Ensuring that COI situations (real or perceived) are well managed by institutions;
- The need for disclosure to the Agency of COI (real or perceived) that may affect the decision on proposals for grants or awards.

## 4.2. Applicability

COI policies should clearly state to whom they apply.

Principal investigators, trainees and employees (or members of their immediate family) may be involved in business activities; these need to be acknowledged and managed. University administrators take decisions that affect the expenditure of grand funds (e.g., through the tendering process). These need to be free of conflicts of interests. Adjunct professors, visiting researchers and others involved in the research enterprise must also be covered by such policies.

**Faculty, undergraduate students taking part in research, graduate students and postdoctoral fellows, other research personnel, such as research associates, technical staff, adjunct professors, visiting professors, and university administrators should all be covered by the Institution's COI/COC policy.<sup>5</sup> There should be one COI/COC policy that applies to everyone. This is the most efficient way to ensure that coverage is universal and that all players are informed.**

Given the diversity and the complexity of relationships between medical schools and their affiliated research institutes and given the importance of COI/COC issues related to research carried out in these institutions, it is important to ensure that, where affiliated institutions are themselves considered Institutions by the Agencies, policies are harmonized and that the line of responsibility is clear.

For example:

- Many health researchers hold courtesy (or "status only") academic appointments in the university while they are employees of an affiliated hospital or research institute. The university defines their relationships to students, since it controls the academic programs and awards degrees, but the hospital/research institute defines the conditions of their employment.

- Many hospital/research institutes administer all grants, including those from the federal agencies, and elaborate and manage their own policies, for example those governing the ethical review of research on humans or integrity in research.<sup>6</sup>
- In many cases, the university administers federal agency grants on behalf of affiliates, but other grants and contracts, such as those from industry, are administered by the hospital or the research institute.

It is, therefore, evident that individual policies will need to respect this variety of relationships, while avoiding gaps.

**It is an Institution's responsibility to define clearly to whom its COI/COC policy applies and, where needed, to negotiate areas of potential overlap or gaps with its partner Institutions.**

**An Institution is responsible for ensuring that all persons who are covered by a given policy are appropriately informed of their obligations under that policy.**

This is a challenge, given the changing nature of the research workforce. Individuals should be reminded yearly of the COI/COC policy of the Institution and of the need for disclosure of potential conflicts, if applicable. Posting policies on the institution's Web site, although a good practice, is not sufficient.

The Tri-Agency COI Schedule will require institutions to ensure that all researchers with university appointments (even unpaid ones, such as researchers paid by an affiliated institute<sup>7</sup> or adjunct professors from industry or government agencies and visiting investigators) abide by the institution's policies on COI/COC while performing duties at that institution (e.g., the supervision of trainees). This means that some researchers may be subjected to the COI policies of more than one institution, hence the need for a common basic framework, some harmonization and internal agreements. In this respect several universities and affiliated research institutions have harmonized or are attempting to harmonize their policies;<sup>8, 9</sup> such experiences should serve as examples of best practices.

### **4.3. Scope**

The scope of institutional policies needs to be defined. As noted above, the HHS guidelines include topics such as conflicts associated with collaborators, publication, financial conflicts, and obligations to other constituencies, and other types of conflicts.

The Agencies have already elaborated two policy statements (TCPS) that broach conflict of interest issues.

[The Tri-Council \[sic\] Policy Statement on Integrity in Research and Scholarship.](#)<sup>10</sup>

This document is concerned with scientific integrity and covers issues, such as: recognizing significant contributions of others; rigour in the gathering, recording and interpretation of data; disclosure of conflicts of interests when submitting work for publication or evaluating work for publication or in reviewing grants.

[Tri-Council \[sic\] Policy Statement: Ethical Conduct for Research Involving Humans.](#)<sup>11</sup> This statement distinguishes three types of conflicts of interests, those involving researchers and the Research Ethics Board (REB)<sup>12</sup> and those involving the institution, which is enjoined to respect the autonomy of the REB.

**The COI Schedule developed by the Tri-Agency should not go over issues that are dealt with by other Schedules or policies but should cross-reference these TCPS. In addition, existing MOU Schedules should reference the new COI Schedule where appropriate.**<sup>13</sup>

In response to these TCPS, Institutions have elaborated their own policies to deal with these issues. In institutional COI/COC policies, reference should be made to the COI/COC sections of institutional policies on Human Ethics Review and Integrity in Research and Scholarship.

The Agencies also have their own COI policies with respect to peer review and allocation of funds. These are summarized and referenced in [Appendix 4.](#)

#### **4.4. Significant financial interests**

The most prominent issue in conflicts of interest guidelines in Canadian and US institutions is that of financial conflicts. The purpose is to enhance the likelihood that the design, conduct and reporting of research are free of any bias that may be induced by conflicting financial interests of the investigator and/or the institution. Most Canadian university policies on COI state that significant financial involvements that could be construed to produce a personal benefit must be reported. However, a definition of significant is often not provided.<sup>14</sup> By contrast, the original HHS regulations in the US set a monetary limit of \$10,000 on financial interests that required disclosure and management.<sup>15</sup> A subsequent review of the Guidelines by an NIH work group found these thresholds to be too low and recommended that they be increased or at least periodically adjusted for inflation. The members of the work group also suggested that each research institution be allowed to tailor the threshold to its own circumstances.<sup>16</sup> However, the US Government definition of Significant Financial Interests had not changed by the time the latest modification to the policy was made in 1999.<sup>17</sup>

**Given the variety in the size and mission of Institutions that are involved, it would be inappropriate for the Tri-Agency Schedule on COI to set limits that would apply to all Institutions. Institutions are urged to establish such**

limits to facilitate the disclosure and review of COI and avoid mis-, over- or under-reporting.

#### **4.5. Relationships between principal investigators and trainees (students and postdoctoral fellows)**

Some institutions' policies define what is permissible in terms of employment of trainees in the commercial ventures of faculty members. For example, the McGill University policy states: *"The enterprise in which a member has an economic interest may not employ University students. However, such an enterprise may enter into contractual agreements to this effect with the University or be a partner with the University within a program of one of the granting agencies."*<sup>18</sup> The MIT policy has an extensive discussion of the relationships between a faculty member's outside activities and students. *"Generally, if the faculty member has a role in supervising the student's thesis or in supervising the work of the student as a graduate teaching assistant or instructor, such outside involvement should not be undertaken--thus avoiding potential conflicts of interest in the evaluation of the student's performance... If faculty members are already associated with students in outside professional activities, they should disqualify themselves from becoming research supervisors, academic program advisors, or examiners for an advanced degree of those students."*<sup>19</sup>

**Institutions must assume a primary role in protecting trainees. The Tri-Agency's role is to ensure that appropriate and effective policies are in place to protect all trainees, whether or not they are paid from Agency funds. Institutional COI policies must, therefore, address specifically the relationships between supervisors and trainees.**

The underlying principles are that:

- The supervision, evaluation and advising of trainees must be independent of the private interests of the person responsible for these activities.
- Trainees must not be used in research activities in a manner that could lead to exploitation or be construed to do so.
- Research funding must not be used to support the private interests of a grantee.

#### **4.6. Relationships between principal investigators and support staff**

McGill University's policy reads: *"When a member uses his or her research for a commercial enterprise on or off campus, University administrators, academic staff and support staff may not be employed in the service of such enterprise during University working hours as established by the relevant faculty or department nor allow interference with their University duties."*<sup>20</sup> By contrast, the MIT policy is more permissive and allows, within reason, university support staff to assist members in their outside activities.<sup>21</sup>

**Institutions must assume a primary role in protecting staff, but also must not reasonably deny them the possibility of earning additional income. The Tri-Agency's role is to ensure that appropriate and effective policies are in place to protect employees, especially those paid from Agency funds. Institutional COI policies must, therefore, address specifically the relationships between supervisors and staff.**

The underlying principles are that:

- Grant funds must not be used to further the private interests of an investigator.
- Situations that might lead to exploitation of staff must be avoided.

#### **4.7. Administrators**

University administrators at various levels can find themselves in conflict of interest situations with respect to research carried out at their institution. For example, they may be researchers themselves, in which case, the situations in which they are involved would come under the institutional conflict of interest policies in research. There may, however, be other situations (termed **Institutional conflicts** by the AAU) arising for those with decision-making powers or other position of influence within the institution.<sup>22</sup> Such an institutional conflict might arise if the institution has an equity position in a spin-off, for example. Institutional Policies must include provisions to disclose and manage "Institutional Conflicts."

**Institutional policies must deal with the management of complex relationships and address the issue of "institutional conflicts."**

#### **4.8. Human subject research and clinical trials**

The American Association of Medical Colleges (AAMC), of which the Canadian Association of Medical Colleges (ACMC) is a member, states in its December 2001 Task Force report:<sup>23</sup> *"The Task Force acknowledges significant ongoing public concern about the existence of financial interests in human subjects research, and strongly encourages academic institutions to respond in ways that instill confidence in their capacity to identify these interests and to manage them safely and effectively."*

In 1989, the American Medical Association published a Joint Report<sup>24</sup> of its Council on Ethical and Judicial Affairs and its Council on Scientific Affairs in which it urges medical centres to develop guidelines on conflict of interest in clinical research to protect all parties but also to ensure that productive collaborations between academic institutions and researchers could continue to flourish.

As is the case in the USA, current Canadian federal and provincial policies encourage private sector investment and the commercialization of university research, including biomedical and health research with human subjects.<sup>25</sup> In the past ten years, in Canada, there have been widely publicized cases where at least the appearance of conflicts of interest in research have eroded public trust in research institutions and regulatory agencies.

*"The relationship among physicians, patients, industry and government is conflicted. Unless we admit this, we will be providing meaningless solutions to conflicts that are obvious or of media interest only, while failing to address the real issues."*

*"We should define all potential conflicts, support disclosure and be very careful about regulating the path of individual professional conscience. In the end, the physician still has the personal responsibility to just do the right thing."<sup>26</sup>*

*"Good conflict-of-interest guidelines help us to prevent situations that we know create serious risk of irremediable conflicts, and they give us a structure to deal with conflicts when they do arise. They also help physicians and the public to identify situations in which patient care and scientific integrity can be threatened, and they allow these groups to seek external support for tackling such issues. The increasing dependence on industry funding augments the potential for conflicts of interest and suggests the need for appropriate control."<sup>27</sup>*

*"Ethical guidelines for circumstances in which clinical researchers face economic conflicts of interest ultimately turn on two principles. First, the researcher may ethically share in the economic rewards of his or her efforts. If a drug, device, or other product becomes financially remunerative, the researcher should not be required to surrender the portion of the profit that reasonably resulted from his or her contribution."*

*"However, the researcher may not reap profits that are not justified by the value of his or her actual efforts. Thus, for example, the researcher could not ethically sell or purchase stock in a company whose drug is being tested on the basis of preliminary results from the research. The investigator would not be profiting from his or her substantive contributions, but rather would be exploiting access to information not readily available to the public, a form of "inside" trading."<sup>28</sup>*

The Medical Research Council (MRC) in the UK has evolved guidelines specifically for Clinical Trials<sup>29</sup> that define the respective roles of the MRC, the Host Institution, the Principal and other Investigators and recommends making provision for the independent supervision of a trial through a Trial Steering Committee (TSC) and a Data Monitoring and Ethics Committee (DMEC), which essentially provide independent expert advice to the investigator(s), the institution(s) and the MRC.

As noted above, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*<sup>30</sup> contains a statement on COI as it pertains to investigators, members of REBs and institutions. The Policy Statement requires the disclosure of potential COI situations but does not include specific limits beyond which financial COI must be disclosed.

Once they have defined limits of financial involvement requiring disclosure in their COI/COC policies, Institutions should apply these limits to all COI/COC situations, including those involving human research by cross-references to their Policies on the Ethics of Research on Humans.

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<sup>1</sup> NIH Regulatory Burden III. Financial Conflict of Interest – Workgroup Report

<http://grants.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm>

<sup>2</sup> See examples in Appendix 2 and resources in Appendix 1.

<sup>3</sup> For example, there are regulations defining the terms of external employment of full-time students in some provinces.

<sup>4</sup> See Association of American Universities. Task Force on Research Accountability.

<http://www.aau.edu/research/conflict.cfm>

<sup>5</sup> See the McGill policy.

<http://www.mcgill.ca/researchoffice/policies/sponsored/policies/proprietary/>

<sup>6</sup> Given the hospitals responsibility to ensure that the patients under their care receive proper treatment, Human Research Ethics Boards are generally operating in hospitals and affiliated research institutes. However, it is less clear that all affiliated institutions that administer their own research funding have well defined policies on research integrity, for example.

<sup>7</sup> Unless the affiliated institute has provided evidence that it has policies that are acceptable to the institution.

<sup>8</sup> The Quebec universities and their research institutes have harmonized their policies. cf. ***Resolution of Challenges with Affiliated Hospitals by Consensus Development: The Quebec Experience***. Michel Bureau, President, Fonds de la recherche en santé du Québec.

<sup>9</sup> The University of Toronto: In March 1991, the Governing Council of the University of Toronto approved the University Policy on Ethical Conduct in Research. Because of the great diversity in research disciplines among the various university divisions, the University Policy on Ethical Conduct in Research expects the various divisions to formulate their own guidelines. Accordingly, the Faculty of Medicine produced two related documents: the Faculty of Medicine Framework to Deal with Misconduct in Research and the Faculty of Medicine Guidelines for Ethical Conduct of Research. **The two documents were reviewed and approved by the Faculty Research Committee, the Hospital University Research Coordinating Committee, Departmental Chairs and the Faculty Council** (see [http://eir.library.utoronto.ca/medicine/calendar/reg\\_framework.cfm](http://eir.library.utoronto.ca/medicine/calendar/reg_framework.cfm) ). There is an effort currently underway spearheaded by the Dean of Medicine to ensure that the various ethics policies of the eight affiliated research centres and those of the Faculty of Medicine are harmonized (private communication from C.C. Yip, Vice-dean, research, University of Toronto).

- <sup>10</sup> [http://www.nserc.gc.ca/professors\\_e.asp?nav=profnav&lbi=p9](http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=p9)
- <sup>11</sup> <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
- <sup>12</sup> "Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest."
- <sup>13</sup> For example, Schedule 1 – Financial Management should probably have an additional statement in 2.1 i) "*ensure that financial decisions are free of conflicts of interest.*"
- <sup>14</sup> The policy of the University of Winnipeg, which states ownership of more than 10% of traded shares and consulting fees in excess of \$1,000. <http://www.uwinnipeg.ca/admin/ovpa/integrit.html>; the current University of Alberta policy defines "major interest" as anything that is not a "minor interest," which, in turn is defined as an aggregate interest of less than \$250,000 in one business. <http://www.ualberta.ca/~unisecr/policy/sec35.html> . (This policy is currently under review.)
- <sup>15</sup> Investigators do not need to disclose "An equity interest that when aggregated for the investigator, spouse and dependent children does not exceed \$10,000 and does not represent more than 5% ownership interest in a single entity; or salary, royalties, or other payments when aggregated for the investigator, spouse and dependent children that do not exceed \$10,000 over the next 12 months."  
<http://grants1.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm>
- <sup>16</sup> cf <http://grants1.nih.gov/grants/policy/regulatoryburden/conflictinterest.htm>
- <sup>17</sup> cf [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/45cfr94\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr94_01.html)
- <sup>18</sup> McGill University Research Policies <http://www.mcgill.ca/researchoffice/policies/sponsored/policies/proprietary/>
- <sup>19</sup> MIT Policy (Section 4.5.2) <http://web.mit.edu/policies/>
- <sup>20</sup> McGill University Research Policies <http://www.mcgill.ca/researchoffice/policies/sponsored/policies/proprietary/>
- <sup>21</sup> MIT Policy (Section 4.5.2) <http://web.mit.edu/policies/>
- <sup>22</sup> The AAU definition: *institutional* financial conflict of interest, ... may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the university. The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the university. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or the values of the university.
- <sup>23</sup> AAMC: Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. <http://www.aamc.org/members/coitf/start.htm>
- <sup>24</sup> American Medical Association: Conflicts of Interest in Biomedical Research. [http://www.ama-assn.org/ama/upload/mm/369/ceja\\_report\\_025.pdf](http://www.ama-assn.org/ama/upload/mm/369/ceja_report_025.pdf)
- <sup>25</sup> cf Advisory Council on Science and Technology (ACST). Expert Panel on

the Commercialization of University Research.

[http://acst-ccst.gc.ca/comm/home\\_e.html](http://acst-ccst.gc.ca/comm/home_e.html)

- <sup>26</sup> Sacks, S. L. The myth of freedom from conflict of interest. *CMAJ* 1999;160:784 <http://www.cmaj.ca/cgi/reprint/160/6/784-a>
- <sup>27</sup> Lemmens, T. The myth of freedom from conflict of interest. *CMAJ* 1999;160:784 <http://www.cmaj.ca/cgi/reprint/160/6/784-a>
- <sup>28</sup> American Medical Association: Conflicts of Interest in Biomedical Research. [http://www.ama-assn.org/ama/upload/mm/369/ceja\\_report\\_025.pdf](http://www.ama-assn.org/ama/upload/mm/369/ceja_report_025.pdf)
- <sup>29</sup> MRC. MRC Guidelines for Good Clinical Practice in Clinical Trials <http://www.mrc.ac.uk/pdf-ctg.pdf>
- <sup>30</sup> <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

## 5. Institutional processes

*“Although conflicts of interest between commercialization and the teaching and research mandates of universities are unavoidable, few respondents believe that this is a critical problem as long as there are explicit mechanisms for managing conflicts and everything is in the open. In fact, conflicts were seen by many as a necessary (if unwanted) corollary of commercialization. For this reason, university administrators must be alert and deal quickly and effectively with problems as soon as they arise. In fact, to prevent problems from happening, universities should ensure that staff and students are all well informed of their obligations and their rights.”*<sup>1</sup>

The major problem is seldom the existence of a particular conflict. Problems mostly occur when conflicts are not disclosed, or when they are not assessed or managed. This means that institutions must devise effective ways to deal with conflict of interest situations, both by educating their various communities and by devising appropriate procedures to uncover and manage eventual conflict situations.

The challenge facing institutions and the Agencies is, therefore, to devise appropriate mechanisms for dealing with conflicts of interest situations without unduly burdening an already overburdened system. Given the diversity in size and mission of Canadian institutions, some flexibility is required in the mechanisms acceptable to the Agencies.

Although many Canadian universities statements on COI/COC require disclosure, it seems that relatively few have evolved robust mechanisms for the assessment and management of conflicts when they occur.<sup>2</sup>

In some institutions, the only COI clauses are those included in Collective Agreements. These do not cover students, postdoctoral fellows, or visiting investigators and may not cover administrative staff.

*The Tri-Council Policy Statements: Ethical Conduct for Research Involving Humans and Integrity in Research and Scholarship* require compliance. The Agencies have usually taken a softer stance on other issues in the sense that they define minimum standards, identify best practices and encourage institutions to set their own standards. The Agencies reserve the right to monitor these policies.

### **Minimum standards:**

To be eligible for Agency funding, institutions must maintain a written policy on COI containing the following required elements:<sup>3</sup>

- The objectives of the policy (see [section 3](#)).
- A definition of “Institution” for the purpose of the application of the COI policy.
- A definition of COI highlighting the notions of private vs institutional interests and of actual, perceived, and potential conflicts and establishing the boundaries with COC.
- A definition of key terms, avoiding terminology that could lead to mis- or over-interpretation and setting appropriate limits beyond which “financial interests” must be declared.
- A definition of the target population(s) with specific issues relating to each group.
- The mechanism(s) used to identify and manage potential conflicts.
- A structure for the reporting and reviewing of COI disclosures.
- A coherent and accountable central mechanism to manage COI applicable to all members of the Institution.
- Cross-references to other policies, as appropriate, for example to the Institution's policy on Ethical Conduct for Research Involving Humans.
- A mechanism to inform all members of the Institution of the policy.
- A mechanism to inform the community of any amendments.
- A requirement for yearly disclosure of financial COI, as defined by the institutional policy and within the financial limits set locally.
- A requirement for yearly disclosure of all conflicts involving start-ups in which members of the institution have equity.
- A statement on the employment of trainees in commercial activities.
- A statement on the employment of support staff in commercial activities.
- Where necessary, mechanisms for harmonization with affiliates and identification of respective duties.
- Provisions to protect the privacy of individuals.
- Provisions to enable access to information by the Tri-Agencies for monitoring purposes.

Some "**best practices**" relating to COI include:

### **Institutional commitment**

- Accepting a continuing duty of due diligence.
- Creating a climate of trust and cooperation by appropriate consultation with the community, prior to finalizing the policy.
- Writing policies in a positive and non-threatening manner.
- Providing positive reinforcement through education of the community.
- Ensuring the visibility and application of the policy.

### **Flow of information**

- Instituting robust mechanisms to inform the community targeted by the policy of its existence and requirements, for example, on hiring (for staff), at registration (for students) or at orientation sessions (for new department chairs or deans, university administrators, visitors, adjunct professors, other trainees, etc.).
- Requesting an acknowledgement by individuals that they have been informed of the policy, for example by requesting a signature.
- Posting the policy on a Web site reserved for institutional policies; however Web postings on their own are not a sufficient dissemination mechanism.
- Holding yearly workshops on COI similar to those held for Animal Care or the handling of hazardous materials.

### **Disclosure and reporting**

- Selecting mechanisms that are appropriate for the size and mission of the Institution.
- Putting in place a clear and coherent delegation of powers and inform all each members of the institution of the reporting structure.
- Where the first steps for disclosure take place at the level of a department or a faculty, providing for an overview mechanism at the institutional level, for example, by providing information on the number of disclosures, the number of disclosures that required decisions and management, the number of disclosures that could not be managed and, therefore, led to prohibition of an activity.
- Providing a mechanism to identify conflicts that may arise following the awarding of grants.
- Providing a central reporting mechanism to assess unresolved matters and arrive at final decisions.

### **Definitions**

- Clearly defining **all terms** used in the policy.

- Where words such as “appropriate,” “significant” are used, defining the boundaries.
- Setting limits for “financial interests” to avoid over- and under-reporting of conflicts.
- Including Conflict of Commitments (COC) in the policy and establishing the boundaries with COI.

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<sup>1</sup> Rank D. & Brochu M. Issues With Respect to Commercializing Canadian University Research. A paper prepared for the Advisory Council on Science and Technology Panel on the Commercialization of University Research. [http://acst-ccst.gc.ca/comm/rpaper/home\\_e.html](http://acst-ccst.gc.ca/comm/rpaper/home_e.html)

<sup>2</sup> The policy of the University of Alberta is one of the most complete in this and other respects. <http://www.ualberta.ca/~unisechr/policy/sec35.htm>

<sup>3</sup> To be modified as a result of the Working Group's discussions.

## 6. Compliance

The experience of the Agencies with the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* indicates that Institutional processes can be lengthy. The Agencies should, therefore, provide a two-year window to enable institutions to establish or modify their policies and then impose the requirement. Institutions must have appropriate COI Policies in place by fall of 2004.\* Compliance will be indicated by filling a box on grant application forms. Signatures on grant applications will attest to the fact that the applicant(s) and the Institution have complied met the Agency's requirements for disclosure and management of COI.

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\* Comment by the Agencies: Agree to provide additional time

## 7. Conclusion

This issues paper constituted a framework for discussion by the Tri-Agency (CIHR, SSHRC and NSERC) Working Group on COI/COC. Members of the Working Group believed that it might also be used as a resource by Institutions setting or revising their COI/COC policies.

## 8. Appendix 1. Selected Conflict of Interest and Conflict of Commitment Policies of Associations, Government Bodies and Universities

*Excerpts are presented in the language originally submitted by the organization.*

- 8.1. [Canada](#)
- 8.2. [United States](#)
- 8.3. [United Kingdom](#)
- 8.4. [Other](#)

## **8.1. Canada**

### **Associations**

#### **Royal College of Physicians and Surgeons of Canada Policy on Conflict of Financial Interest**

<http://rcpsc.medical.org/publications/index.php>

#### **What is a Conflict of Interest?**

A conflict of interest may be considered to exist if a speaker in an annual meeting program is affiliated with, or has a financial interest in, commercial organizations that may have a direct or indirect interest in the subject matter of his/her presentation. A "financial interest" may include, but is not limited to, being a direct shareholder in the organization; being on retainer with the organization; or having research or honoraria paid by the organization. An "affiliation" may be holding a position on an advisory committee or some other role of benefit to a sponsoring organization.

*The intent of this disclosure requirement is not to prevent a speaker with a conflict of interest from making a presentation but to make known the relationship, in advance, to the audience. It is intended that any conflict be openly identified so that with full disclosure of the facts, attendees may form their own judgements about the presentation.*

#### **Reporting Conflicts of Interest**

If a speaker has an actual or potential conflict of interest relating to the annual meeting session, he or she must indicate this on the appropriate form and return it to the Royal College as instructed on the form. When an actual or potential conflict is reported the College or NSS may, time permitting, publish this information in the annual meeting program. Nevertheless, individuals must verbally disclose this information before beginning their presentation.

*Approved by RCPSC Scientific Program Committee, April 1996*

#### **National Council on Ethics in Human Research**

<http://www.ncehr-cnerh.org/>

The Council's mission is: to advance the protection and promotion of the well-being of human participants in research; and to foster high ethical standards for the conduct of research involving humans. It acts as an advisory body to Institutional Review Boards (IRB) and conducts periodic assessments of IRBs. The site contains links to PHS and FDA Regulations and other Web sites.

**Conflict of Interest in Human Research Ethics by D. Jones, NCBHR *Communiqué* CNBRH, 1995; 6 (2)** provides an overview of the various elements of conflicts of interest with definitions.

## **Government Sites**

**Advisory Council on Science and Technology  
Issues with Respect to Commercializing Canadian University Research  
(Dennis Rank & Mireille Brochu)**

[http://acst-ccst.gc.ca/comm/rpaper/home\\_e.html](http://acst-ccst.gc.ca/comm/rpaper/home_e.html)

## **Conflicts of interest**

Although conflicts of interest between commercialization and the teaching and research mandates of universities are unavoidable, few respondents believe that this is a critical problem as long as there are explicit mechanisms for managing conflicts and everything is in the open. In fact, conflicts were seen by many as a necessary (if unwanted) corollary of commercialization. For this reason, university administrators must be alert and deal quickly and effectively with problems as soon as they arise. In fact, to prevent problems from happening, universities should ensure that staff and students are all well informed of their obligations and their rights.

There must be clear policies for faculty members involved in transfer activities, for students who are involved, for faculty members having equity in start-up companies, for partnerships, or when clinical trials are involved. There must also be a clear mechanism for reviewing and resolving potential conflict situations, and for protecting the institution against liability. Although university policies discuss the interests of faculty members, the rights of students are not always clearly stated (Canadian Graduate Council, 1994).

One of the unintended effects of more aggressive technology transfer is a recent tendency for some researchers to shut out collaborators. They choose to work alone (even without graduate students) to ensure that they keep sole control of the intellectual property. We are told that this phenomenon is not widespread. Nevertheless, it is important for university officials and granting agencies to monitor this type of behaviour. Indeed, if this problem were to expand, it could undermine research programs that require collaboration and partnerships.

## Universities

### University of Alberta

#### **Conflict of Commitment and Conflict of Interest Policy**

<http://www.ualberta.ca/~unisechr/policy/sec35.htm>

The policy currently on the Web site contains definitions, applications and a method for investigating potential conflicts. This policy is currently being revised.

### Concordia University

#### **Concordia University Code of Ethics Guidelines for Ethical Actions**

[http://relish.concordia.ca/Legal\\_Counsel/policies/english/BD/BD-4.html](http://relish.concordia.ca/Legal_Counsel/policies/english/BD/BD-4.html)

Chapter 4 of the document deals with Conflicts of Interest. It defines various types of conflicts and related issues such as disclosure and consultation, seeking resolution, gifts. The policy does not deal specifically with COI/COC in research. There is not a mechanism for individuals to report potential conflicts.

### Université Laval

#### **Déclaration et traitement du conflit d'intérêts**

[http://www.ulaval.ca/vrr/rech/integrite\\_scientifique.html](http://www.ulaval.ca/vrr/rech/integrite_scientifique.html)

L'existence d'une situation de conflit d'intérêts n'entraîne pas en soi une impossibilité d'agir. Dans certains cas, la transparence permet des aménagements qui sauvegardent le climat de confiance nécessaire au maintien de la réputation d'intégrité et d'objectivité de l'Université et de ses membres.

Tout chercheur ou toute chercheuse qui se retrouve dans une situation réelle, potentielle ou apparente de conflit d'intérêts doit en informer sans délai le ou la responsable de son unité ou encore son supérieur ou sa supérieure hiérarchique.

La politique donne des exemples de situations qui pourraient donner lieu à des conflits, mais ne donne pas de renseignement sur les mécanismes utilisés pour évaluer et résoudre les situations de conflit.

### McGill University

#### **Regulations governing conflicts of interest in proprietary research**

<http://www.mcgill.ca/researchoffice/policies/sponsored/policies/proprietary/>

The regulations apply **to all members of the University including academic, administrative and support staff and, where appropriate, students** (members) and constitute part of the formal relationship between the member and the University.

A member shall fully disclose his or her interest, the extent of his or her time commitment, and the nature and scope of his or her activity in relation to any direct or indirect economic interest the member or his or her family may have or acquire in any enterprise to develop the research findings.

The policy is quite detailed and clear about roles and responsibilities, conditions regulating the use of university property to develop commercial enterprises, relationships with students and other considerations.

### **Policy on conflict of interest and duty of loyalty**

<http://www.mcgill.ca/researchoffice/policies/sponsored/policies/conflict/>

#### 1. Application

This policy applies to all members of the University community, including members of the Board of Governors, academic, administrative and support staff and, where appropriate, students who are also employed by the University (hereinafter collectively referred to as "members"), and constitutes part of the formal relationship between the member and the University.

Members of the University community may become involved in situations where their loyalties are divided or where their personal interest may conflict with their duty to the University. Situations can also arise in which members may be tempted to act in violation of their duty of loyalty to the University. This policy sets standards to govern conduct in such situations.

This policy is in addition to other University regulations, policies, and guidelines relating directly or indirectly to conflicts of interest and the duty of loyalty owed by members to the University. Management of conflict situations is vested in the immediate superior of the person who is in conflict (e.g., Department Chair, Dean); should a resolution not be possible at that level, the issue is referred to a higher authority. Appendix A gives examples of Conflict of Interest situations.

### **Université de Montréal Règlement sur les conflits d'intérêts Politique numéro 10.23**

Ce document s'applique au personnel enseignant et au personnel non-enseignant. Le document définit certaines situations qui pourraient donner lieu à un conflit d'intérêt, contient une procédure de divulgation et des mécanismes pour le traitement des divulgations selon qu'il s'agit du personnel enseignant ou non-enseignant.

**University of Northern British Columbia  
General Research Ethics**

<http://www.unbc.ca/policy/pdf/rese-g1.pdf>

This document sets out the University policy on integrity in research, and policies on authorship, and on the responsibilities of supervisors to research assistants. Finally, a Research Ethics Complaints policy is set out to deal with any alleged breaches of the policies in this document.

**Excerpts from the Faculty Collective Agreement**

<http://www.unbc.ca/hr/> (faculty association)

Faculty Members have the right to participate in the work of learned societies and professional organizations, including the Association, the Confederation of University Faculty Associations of BC, and the Canadian Association of University Teachers. When a Faculty Member's service to such societies or associations conflicts with scheduled teaching or administrative duties, the Faculty Member shall make arrangements, subject to the approval of her/his Chair or Dean, as appropriate, to make sure that those duties and responsibilities are fulfilled.

**Excerpt from the Staff Collective Agreement**

[http://www.unbc.ca/hr/CUPE\\_Collective\\_Agreement\\_1999.pdf](http://www.unbc.ca/hr/CUPE_Collective_Agreement_1999.pdf)

**28.05 ADMINISTRATION OF THE JOB EVALUATION PLAN**

(a) It is the responsibility of all participants in the administration of the job evaluation plan to ensure that evaluations are conducted honestly, objectively and without bias. Each member of the JEC has an obligation to avoid any conflict of interest, real or apparent, and must declare any conflict involving the interests of other employees of the University with whom they have a familial, marital (marriage or common law), business or other relationship that might reasonably be construed as giving rise to concerns about conflict and bias.

**University of Ottawa**

**Policy 48 Grants and Contracts Administered by the University**

<http://www.uottawa.ca/sec-univ/eng/reg48-a.html>

7. No professor may be the principal investigator for any grant or contract between an agency or company and the University that interferes with the fulfilment of the professor's scheduled duties or with the professor's obligations to the University as set out in the relevant collective agreement unless authorized in writing by the dean.

8. Professors are prohibited from participating in or having a substantial business interest in the ownership of any enterprise which has entered, or proposes to enter, into a contractual or commercial relationship with the University or from

which or through which one or more other University employees receive or may receive remuneration for consultative or other services.

9. Professors are prohibited from participating in or having a substantial business interest in the ownership of any enterprise from which professors receive or will be receiving a research grant or contract to be administered by the University.

10. Prior to accepting a grant or contract, the principal investigator shall disclose to the University all relationships through kinship, marriage, or business association, with persons whom the investigator knows or may reasonably be expected to know have a direct financial interest in the products of the investigator's research. In the case of the member of the teaching staff, disclosure is to the dean of the faculty. In all other cases, disclosure is to the appropriate Vice-Rector or Secretary of the University. The Dean, Vice-Rector or Secretary of the University, through the Assistant Vice-Rector (Research), shall inform Research Services that a disclosure has taken place and the situation has been approved.

**Policy 70 Conflict of Interest – Members of Staff**

<http://www.uottawa.ca/sec-univ/eng/reg70-a.html>

The objectives of this Policy are to avoid conflicts of interest between the University and members of its staff, and to maintain sound and equitable relationships with its staff and with members of the business community. The policy applies to Staff Members in general and there are special considerations for members of the faculty (regular professors).

The University considers as a non-trivial activity: i) all teaching for another institution or in the context of a professional development program, with the exception of occasional lectures; ii) any project or consultation service necessitating more than a few days work per year.

**Collective Agreement: Article 10 - Professional Ethics Article 10.2 Conflict of Interest**

<http://www.apuo.uottawa.ca/Info/Convention/10.htm#10.2>

Members of the bargaining unit and representatives of the employer shall avoid actions on any matter in which they have a conflict of interest; such actions include, but are not limited to, participation in a decision-making process by discussion or vote. Some situations are described in further detail.

**Université du Québec à Montréal**

**Politique no 18 Politique sur les conflits d'intérêts**

[http://www.unites.uqam.ca/instances/politiques/Politique\\_18.html](http://www.unites.uqam.ca/instances/politiques/Politique_18.html)

Champ d'application : Cette politique s'applique à tout le personnel de l'Université, c'est-à-dire à toute personne à l'emploi de l'Université et qui en reçoit un traitement ou un salaire. Cette politique vise l'utilisation des ressources de l'Université, l'usage du nom de l'Université, la mise sur pied d'une compagnie, société ou entreprise, les contrats avec l'Université ainsi que la non discrimination dans l'embauche et l'évaluation.

Préambule; 1 | Énoncé de principe; 2 | Cadre juridique; 3 | Objectif 4 | Champ d'application 5 | Définition 6 | Description des activités

- o 6 | 1 Utilisation des ressources de l'Université
- o 6 | 2 Usage du nom de l'Université
- o 6 | 3 Mise sur pied d'une compagnie, société ou entreprise
- o 6 | 4 Affaires avec l'Université
- o 6 | 5 Non discrimination dans l'embauche et l'évaluation

7 | Structure fonctionnelle

### **University of Toronto**

#### **Conflict of Interest Policy – Academic Staff**

[http://www.library.utoronto.ca/rir/ethics\\_conduct.html](http://www.library.utoronto.ca/rir/ethics_conduct.html)

In 1994, the Governing Council approved a Policy on Conflict of Interest – Academic Staff.

In summary, the Policy requires that academic staff must obtain the approval of the person to whom they report before they can do the following:

- engage in "major paid professional activities," defined as teaching for remuneration outside the University, commitment to any single paid professional activity totaling more than 20 days a year, or any combination of paid professional activities likely to exceed more than 45 days a year;
- use University facilities, supplies, staff or students in privately undertaken work or paid professional activity;
- influence the use of University funds to convey or deny a financial or commercial benefit on a member of the faculty member's immediate family or a person with whom there exists, or has recently existed, an intimate personal relationship;
- evaluate, or confer or deny academic benefit on, a member of the faculty member's immediate family or a person with whom there exists, or has recently existed, an intimate personal relationship;
- undertake research sponsored by a company or organization in which a significant financial interest is held by the faculty member or any member of his/her immediate family or any person with whom there exists or has existed an intimate person relationship.

The Policy also requires that, when publishing the findings of research, a faculty member must name the source of funding in the publication.

**Wilfrid Laurier University**

**Collective Agreement Between Wilfrid Laurier University and Wilfrid Laurier University Faculty Association**

<http://www.wlu.ca/~wwwwlufa/ptcontract/ptca9.htm>

Governs the behaviour of members regarding relations with the university, students and other staff. Defines the appropriate use of resources and the lines of reporting of potential conflicts. Section 9 deals specifically with Conflicts of Interest.

**University of Winnipeg**

**Policy and Procedures on Integrity in Research and Scholarship**

<http://www.uwinnipeg.ca/admin/ovpa/integrit.html>

Sections 7 and 8 of the document deal with Conflict of Interest as follows:

Failure to reveal to those who sponsor or commission work any material conflict of interest when asked to undertake reviews of funding applications, manuscripts for publication, theses, etc., or to test products for sale or distribution to the public.

“A conflict of interest occurs when the personal interests of a researcher or scholar clash, or have the potential to clash, with the interests of other researchers or scholars, the University, or the interests of research sponsors. Personal interests include, but are not necessarily limited to, a business, commercial or financial interest, whether of the person involved or arising from family or marital relationships, from friends, or from former, existing or prospective business associations.”

8. Failure by those involved in contract vetting and awarding or otherwise aware of the contract, to reveal to the University any material financial interest in a company that contracts with the University to undertake research, to participate in research involving the company's products, or to provide research related materials or services. (Material financial interest means ownership, substantial stock holdings [i.e., **greater than or equal to 10% of shares being traded**], a **directorship, or honoraria or consulting fees over \$1,000, but does not include minor stock holdings in publicly traded corporations, or minor royalties or license fees.**)

**9. Appendix 2. Composition of the Tri-Agency Working Group**

Isabelle Blain, Chair	Vice-President, Grants and Scholarships, NSERC
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Lawrence Aronovitch	Senior Policy Analyst, Research and Policy Analysis Division, National Affairs Branch, AUCC
Margaret Caughey	Director, Information, Communications and Manufacturing, Research Partnerships Program Directorate, NSERC
Carole Crête-Robidoux	Manager, Review, Investigations and Awards Administration, Common Administrative Services Directorate, NSERC, SSHRC
Joseph Hubert	Doyen, Faculté des arts et des sciences, Université de Montréal
Digvir Jayas	Associate Vice-president (Research) University of Manitoba
Derek Jones	Executive Director, Secretariat on Research Ethics
Mary Ann Linseman	Deputy Director, Research Portfolio (Neurobiology)
Ruth Marfurt	Manager, Corporate Secretariat and Access to Information and Privacy Coordinator, SSHRC
William McBlain	Associate Vice-president (Research) University of Alberta
Nicole Bégin-Heick	Principal Consultant, Nicole Bégin-Heick & Associates Inc.

## 10 Appendix 3. Definitions

*Excerpts are presented in the language originally submitted by the organization.*

### 10.1. Conflict of Interest

*Dictionary definition:*

"A conflict between the private interests and the public obligations of a person in an official position."<sup>1</sup>

*Definitions found in University documents:*

"A member is involved in a conflict of interest when: the member owes a duty of loyalty in some matter to act in the interests of a person, group of persons, or institution; and at the same time, the member has a personal interest in the matter or owes a duty of loyalty to act in the matter in the interests of a different person, group of persons, or institution.

A conflict of interest exists under this definition even if the action or decision called for under the first duty is identical with the personal interest or with the action or decision required under the second duty."<sup>2</sup>

"A conflict of interest occurs when a situation arises in which there is a divergence between the private interests of a staff member and that staff member's obligations to the University, such that an impartial observer might reasonably question whether actions or decisions to be taken or made by the staff member relating to that situation would be influenced by consideration of that private interest."<sup>3</sup>

"Conflicts of interest are situations in which the judgments and subsequent actions of individuals are likely to be affected because of multiple, competing interests. In such situations, we need to find responsible ways of balancing personal autonomy, privacy, professional integrity, and accountability.

. major kinds of conflict of interest: those involving personal relationships, those emanating from the multiple roles played by University members, those arising in relation to the use of University resources, those arising out of material financial interests, and those arising out of external collaborative activities."<sup>4</sup>

« Un membre du personnel est en conflit d'intérêts lorsque, notamment, il se trouve dans l'une ou l'autre des situations suivantes :

- a. lorsqu'à cause de ses fonctions, il exerce une influence sur les décisions de l'Université d'une façon qui puisse lui procurer des gains ou avantages personnels directs ou indirects;
- b. lorsqu'il a un intérêt direct ou indirect dans une entreprise et que, en conséquence de cet intérêt, il prend avantage de ses fonctions à l'Université pour favoriser l'intérêt de cette entreprise plutôt que celui de l'Université. »<sup>5</sup>

"A conflict of interest occurs when the personal interests of a researcher or scholar clash, or have the potential to clash, with the interests of other researchers or scholars, the University, or the interests of research sponsors. Personal interests include, but are not necessarily limited to, a business, commercial or financial interest, whether of the person involved or arising from family or marital relationships, from friends, or from former, existing or prospective business associations."<sup>6</sup>

"Typically, a conflict of interest may arise when a member has the opportunity to influence the University's business, administrative, academic or other decisions in ways that could lead to personal gain or advantage of any kind."<sup>7</sup>

"A Faculty Member is considered to have a conflict of interest when he/she, any of his/her Family, or any Associated Entity possesses a Financial Interest in an activity which involves his/her responsibilities as a member of the Faculty of Medicine. Included in these responsibilities are all activities in which the Faculty Member is engaged in the areas of teaching, research, patient care and administration."<sup>8</sup>

"Some questions on conflict of interest arise from outside professional activities of the faculty and staff ... Others, in the more traditional meaning of conflict of interest, derive from the opportunities an individual may have because of his or her position at the Institute to influence MIT's relationship with an outside organization in ways that would lead directly to the individual's personal financial gain."<sup>9</sup>

"Private interests of a University employee influence University decisions, research directions or interactions among Faculty staff and students. Apparent conflicts may undermine trust and be as damaging as an actual conflict. This can include both direct influence of decisions, and conflicts arising from misuse of privileged access to confidential information or the acceptance of gifts or ex gratia payments."<sup>10</sup>

"It is not possible to provide a comprehensive definition of circumstances which necessarily give rise to a conflict of interest ."<sup>11</sup>

*Definitions found in documents of Associations and Government bodies:*

"Conflict of interest in clinical research defies simple definition: one researcher's conflict of interest may be another's mutually beneficial working relationship. Conflict of interest must be clearly distinguished from scientific misconduct.

. Conflict of interest is defined by Webster's Third New International Dictionary as "a conflict between the private interests and official responsibilities of a person in a position of trust."<sup>12</sup>

"A **conflict of interest** refers to situations in which financial, professional, ideological, or other personal considerations may compromise, or have the appearance of compromising, a scientist's professional judgment in conducting, interpreting, evaluating or reporting research, or when asked to provide independent expert advice. Such conflict could unduly affect the choice of research protocol, the collection, analysis, interpretation, and reporting of data, the use of certain instruments or statistical methods, the recruitment of research

subjects, the evaluation of products, the communication of results, and the proffering of advice."<sup>13</sup>

"A conflict arises when a person's judgement concerning a primary interest, such as scientific knowledge, could be unduly influenced by a secondary interest, such as financial gain or personal advancement. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognize the fact and deal with it accordingly. Researchers must pay as much attention to perceived and potential conflicts of interest as to actual conflicts."<sup>14</sup>

## **10.2. Conflicts of Commitment**

With the acceptance of a full-time appointment in the Faculty of Medicine, an individual makes a commitment to the University (and Hospital, if part of a hospital-based department or other health-care institution) that is understood to be full-time in the most inclusive sense. Full-time members of the Faculty of Medicine are expected to devote their primary professional loyalty, time, and energy to their teaching, research, administrative responsibilities and, where applicable, patient care at the School and its affiliated Hospitals. Accordingly, they should arrange outside activities and financial interests so as not to interfere with the primacy of these commitments. The Faculty of Medicine recognizes that its members may engage in outside professional work, and to the extent these activities serve the Faculty's interests, as well as those of the participant, the Faculty of Medicine approves of such involvement. However, no more than twenty percent (20%) of a full-time faculty member's total professional effort may be directed to outside work, not to exceed the equivalent of one working day per week. Potential conflicts of commitment must be disclosed and resolved as described in the section on implementation in Appendix B.

Members of the Faculty whose appointments are less than full-time are expected to devote professional loyalty, time, and energy to their teaching, research, patient care, and administrative activities, in accordance with their agreed-upon time commitments.<sup>15</sup>

**Outside Professional Activities** – The Institute believes that its educational program and effective teaching in all its aspects can flourish only when sustained by continuous, active participation of its faculty in research, enriched in many cases by interaction with industry, business, government, and other activities and institutions of our society. This interaction, including outside consulting service to and research for government and industry, is of greatest value when it contributes significantly to the public welfare, offers an opportunity for professional challenge and growth, or otherwise enhances the effectiveness of a faculty member's service to the Institute. The potential magnitude of such outside professional activity is such that orderly procedures must be followed to ensure the evolution of policy to avoid ethical and legal conflicts of interest and to ensure

that such activities do not conflict with the proper discharge of Institute responsibilities. Essential to the effectiveness of such procedures are:

- a. complete disclosure of outside professional activities; and
- b. the availability of the best advice and consultation that can be obtained.<sup>16</sup>

*Conflict of Commitment.* Private interests or non-University activities harm or interfere with the productivity and involvement of University employees. This refers to an individual's distribution of effort between employment obligations to the University and to outside professional activities.<sup>17</sup>

A conflict of commitment occurs where the external or personal activities and undertakings of a staff member are so substantial or demanding or organized in such a manner as to interfere with the staff member's obligation to the University.<sup>18</sup>

The policy includes in its statement on ethical principles that the professor "determines the amount and character of the work he does outside his institution with due regard to his paramount responsibilities within it..." The policy also lists as one type of unacceptable conduct the "unauthorized use of University resources or facilities on a significant scale for personal, commercial, political, or religious purposes" and contains sanctions when abuse is demonstrated.<sup>19</sup>

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<sup>1</sup> Excerpted from *The American Heritage® Dictionary of the English Language*, Third Edition © 1996 by Houghton Mifflin Company. Electronic version licensed from INSO Corporation; further reproduction and distribution in accordance with the Copyright Law of the United States. All rights reserved.

<sup>2</sup> McGill University  
<http://www.mcgill.ca/research-policies/sponsored/policies/conflict/>

<sup>3</sup> University of Alberta  
<http://www.ualberta.ca/~unisechr/policy/sec35.html>

<sup>4</sup> Concordia University  
[http://relish.concordia.ca/Legal\\_Counsel/policies/english/BD/BD-4.html#Chapter%20Four:](http://relish.concordia.ca/Legal_Counsel/policies/english/BD/BD-4.html#Chapter%20Four;)

<sup>5</sup> Université du Québec à Montréal  
<http://www.unites.uqam.ca/instances/politiques/5>

<sup>6</sup> University of Winnipeg  
<http://www.uwinnipeg.ca/admin/ovpa/integrit.html>

<sup>7</sup> Cornell University  
<http://www.univco.cornell.edu/policy/conflicts.html#IIA>

<sup>8</sup> Harvard University Faculty of Medicine  
<http://www.hms.harvard.edu/integrity/guide.html>

<sup>9</sup> MIT <http://web.mit.edu/policies/4.4.html>

<sup>10</sup> University of Glasgow  
[http://www.gla.ac.uk/R-E/pub/policies/conflicts\\_12-12-01.rtf](http://www.gla.ac.uk/R-E/pub/policies/conflicts_12-12-01.rtf)

<sup>11</sup> University of Oxford

- <http://www.admin.ox.ac.uk/rso/pol/conflict.shtml>
- <sup>12</sup> American Medical Association  
[http://www.ama-assn.org/ama/upload/mm/369/ceja\\_report\\_025.pdf](http://www.ama-assn.org/ama/upload/mm/369/ceja_report_025.pdf)
- <sup>13</sup> Mark Frankel, American Association for the Advancement of Science  
<http://www.aaas.org/spp/dspp/RCP/Vtconf/papers/frankel.htm>
- <sup>14</sup> Medical Research Council (UK)  
[http://www.mrc.ac.uk/pdf-good\\_research\\_practice.pdf](http://www.mrc.ac.uk/pdf-good_research_practice.pdf)
- <sup>15</sup> Harvard Medical School  
<http://www.hms.harvard.edu/integrity/conf.html>
- <sup>16</sup> MIT <http://web.mit.edu/policies/4.5.html>
- <sup>17</sup> University of Glasgow  
[http://www.gla.ac.uk/R-E/pub/policies/conflicts\\_12-12-01.rtf](http://www.gla.ac.uk/R-E/pub/policies/conflicts_12-12-01.rtf)
- <sup>18</sup> University of Alberta  
<http://www.ualberta.ca/~unisecr/policy/sec35.html>
- <sup>19</sup> University of California  
<http://www.ucop.edu/research/policies/welcome.html>

## **11. Appendix 4. Agencies' Existing Statements on Conflicts of Interest**

### **11.1. Policy on Conflict of Interest (NSERC)<sup>1</sup>**

As applicant or co-applicant, you must have no financial or personal interest in any transaction chargeable against an NSERC grant. Contact your research grants office and follow the institution's policies.

Conflict of interest may arise when you or the university have an ownership position in a company that is sponsoring your research. It may be difficult to distinguish between university activities and company activities, and between your contributions as a university researcher and as a principal in the company. NSERC may therefore request evidence that the company has objectively assessed the commercial potential of the research being undertaken, and that the academic interests of the students and postdoctoral fellows are protected. This request may come at the beginning or during the course of the project. NSERC deals with each case individually.

### **11.2. Guidelines for Organizations Participating in Research Partnerships Programs (NSERC)<sup>2</sup>**

#### **Researcher-Owned Companies**

A researcher's own consulting company or sole proprietorship is not eligible to collaborate on a project in which the researcher is the applicant or a co-investigator. Situations where the researcher is a part owner are reviewed on a case-by-case basis; the company is usually considered eligible if the following conditions are met:

- there is significant investment by sophisticated investors, indicating there has been an objective assessment of the commercial potential of the research and the company's viability;
- the company has its own facilities, physically separated from the university researcher's laboratory (e.g., located off campus or in a university incubator facility);
- the company employs its own professional staff, apart from the university personnel, that is able to receive and incorporate the results of the university research into company operations;
- the company is under the effective day-to-day management control of someone other than the university researcher;
- the company has a board of directors with external members (i.e., some of whose members, including the Chair of the Board, are at arm's length);
- the commercial activity conforms to the university's established policies relating to the disclosure of commercial interest and conflict of interest; and
- the university is prepared to ensure that the academic interests of students and postdoctoral fellows are protected.

### **11.3. General Guidelines for the University-Industry Program (CIHR)<sup>3</sup>**

By signing applications to the CIHR, applicants and administrators undertake that any research carried out with funds from the Council will respect all of CIHR's requirements for the ethical conduct of research as expressed in policy documents, including the following:

- Ethical Conduct for Research Involving Humans
- Guidelines on Laboratory Biosafety
- Integrity in Research and Scholarship
- Guide to the Care and Use of Experimental Animals

Any research involving human subjects, animals, or those agents identified in the Guidelines on Laboratory Biosafety must be approved by the appropriate local review committee, established and operating in accordance with the relevant CIHR statements of policy, before the research is started. The institution is responsible for withholding CIHR funds from the researcher(s) until the required approvals have been given.

#### **11.4. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans<sup>4</sup>**

Researchers hold trust relationships with research subjects, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty. Although the potential for such conflicts has always existed, pressures to commercialize research have led to increased concerns. Researchers, their institutions and REBs should identify and address conflicts of interest – real or apparent – to maintain the public confidence and trust, discharge professional obligations and ensure accountability.

“Researchers and REB members shall disclose actual, perceived or potential conflicts of interest to the REB. REBs should develop mechanisms to address and resolve conflicts of interest.”

#### **11.5. Research involving humans – NSERC Guide<sup>5</sup>**

The signature of the institutional authorities on the grant application signifies that the institution fully complies with the Tri-Council Policy Statement and agrees to release funds only to researchers who have the necessary certification.

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<sup>1</sup> [http://www.nserc.gc.ca/professors\\_e.asp?nav=profnav&lbi=info](http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=info)

<sup>2</sup> [http://www.nserc.gc.ca/professors\\_e.asp?nav=profnav&lbi=p4](http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=p4)

<sup>3</sup> [http://www.cihr-irsc.gc.ca/services/funding/grants\\_awards\\_guide/2001-2002/c/sectc\\_e.shtml](http://www.cihr-irsc.gc.ca/services/funding/grants_awards_guide/2001-2002/c/sectc_e.shtml)

<sup>4</sup> <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

<sup>5</sup> [http://www.nserc.gc.ca/professors\\_e.asp?nav=profnav&lbi=p7](http://www.nserc.gc.ca/professors_e.asp?nav=profnav&lbi=p7)