

Institutional financial conflicts of interest policies at Canadian academic health science centres: a national survey

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FINANCIAL CONFLICTS OF INTEREST (fCOI) ARE OF particular concern in the conduct of human subject research, whether they occur at the level of individual investigators or at the level of the institution.¹ Institutional fCOI can occur when an institution that hosts the research, or a senior institutional official acting on behalf of the institution, has a financial interest in the study outcome.^{2,3} Such conflicts can be detrimental to research subjects,⁴ lead to an inappropriate degree of control over what should be an independent research agenda,⁵ and have serious implications, even in the absence of research misconducts.^{6,7} Moreover, undisclosed fCOI undermine the public's confidence in science.

For example, senior National Institutes of Health (NIH) officials were allowed to receive income as consultants to drug companies.⁶ The concern that this income might inappropriately influence their work resulted in the formation of a national Blue Ribbon committee to examine NIH conflict-of-interest policies.⁷ The committee's 2004 report recommended that senior management should not consult with companies whose interests could influence the outcomes of their research⁶ ultimately led to a moratorium on industry-paid consultancies held by any NIH employee. Despite increased scrutiny of this issue on the part of government,⁶ the media,⁸ and the public,⁹ academic institutions have been slow to develop policies

related to institutional fCOI.¹ We conducted a content analysis of the institutional fCOI policies in use at Canadian academic health science centres (AHSCs) to identify gaps in policy coverage and to guide policy improvement.

Our research methods are more fully described in Box 1. In brief, we collected institution-level fCOI policies from all 16 AHSCs (16 medical schools and 47 teaching hospitals as well as their 16 partner universities) from August 2005 to February 2006. These centres are the major sites of academic research involving humans in Canada. We contacted the vice president (VP) of research (or equivalent) at each site and asked him or her to identify 3 key institutional fCOI policies at their institution. To evaluate policy comprehensiveness, we compared each unique policy to our “standard” of 16 core items relevant to institutional fCOI derived from the key COI documents.^{2,10,11}

All 16 universities (100%), their 16 medical schools (100%), and 42 (89%) of the teaching hospitals responded to our request for policies. Nine (56%) universities, 9 (56%) medical schools, and 15 (36%) teaching hospitals responded that they had no policies on institutional fCOI.

Of the 72 policies identified, 34 were shared within AHSCs. Approximately a quarter (26%) of universities, medical schools, and teaching hospitals identified more than one institutional fCOI policy. Only 6 (16%) included “institutional conflicts of interest” in the policy title. Five (13%) policies were cross-referenced to other relevant policies from their institution. Of the 2 teaching hospitals that used internal and partner-university policies, neither cross-referenced the other’s policies. The ability of some leaders within an AHSC to identify a fCOI policy, while others based in the same AHSC could not, suggested that communication within AHSCs about fCOI policies was limited. For example, one teaching hospital said that its submitted fCOI policy was also used by its parent university; however, the parent university reported having no relevant policy.

Table 1 describes a content analysis of the 38 unique policies. Definitions that informed our content analysis are listed in Box 2. Of the policies analyzed, 2 contained no items of relevance to institutional fCOI. On average, individual policies contained 20% of the 16 core “standard” items: no individual policy contained more than 65% of the core fCOI items. Even when the content of up to 3 policies per site was combined, less than half of the core items were addressed. Less than a quarter of policies addressed royalties, equity interest, or ownership interests.

Our results demonstrate that more than half of Canadian universities, half of medical schools, and more than a third of teaching hospitals had no institutional

Box 1: Description of methods

We defined a document as a policy if the word “policy” appeared in the title or was used to describe the document. To identify relevant fCOI policies, 2 reviewers (JG and MS) identified all potential fCOI policies that were publicly available from the websites of each university, its medical school, and all its fully affiliated teaching hospitals. Next, we contacted the vice-president (VP) of research (or equivalent) at each site and asked him or her to identify 3 key institutional fCOI policies. The VPs could identify these from our list, or they could identify other policies they considered more relevant. Draft policies were accepted (no finalized policies were received). Non-responders were sent a maximum of 8 email reminders. Finally, in 2006 we sent each VP of research a letter listing their 3 key policies. In addition, each institution was given aggregate policy content data so they could evaluate their performance relative to other institutions in the country. We invited them to contact us with questions or concerns related to their information.

To evaluate the policy comprehensiveness, we compared each unique policy to our “standard” of 16 core items relevant to institutional fCOI derived from 3 key COI documents^{2,10,11} (see Table 1). Two reviewers independently reviewed each unique policy (31 English [MS and JG] and 7 French [MS and MEC]) to identify the core items. There was good agreement between the assessors (Kappa statistics: 0.77 and 0.81, respectively).

We identified a subset of “institutional fCOI-specific policies” as those containing the phrase “institutional conflicts of interest” in the title, a definition of institutional fCOI within the policy, or a statement indicating that the policy addressed institutional fCOI.

We assessed policy accessibility by evaluating the ability of an individual to access the policy. First, we determined whether institutional COI was in the policy title. Second, we determined whether the policies were cross-referenced to the policies of other affiliated institutions.

fCOI policy at the time of our survey. This is consistent with a 2006 survey of 86 deans of US medical schools (response rate 86/125), which found that fewer than half (38%) reported adopting an institutional fCOI policy.¹⁸ Further, policies were inadequately comprehensive and often difficult to locate.

Like all studies, our work has limitations. First, we requested a maximum of 3 policies from each site; some may speculate that this truncated our results if sites had more than 3 policies relating to the core fCOI items. (For example, the Pennsylvania School of Medicine reports having more than 90 policies regarding conflicts of interest.¹⁹ However, given that 33 of 74 (45%) sites reported no relevant policies and only 10 (13%) sites identified 3, we think this is unlikely.

Second, we used a stringent definition of “policy” and recognize that this would have excluded other terms used to label policies (e.g., “protocols,” “statements” or “standards”). Moreover, a strategic position taken by the institution or mechanisms to deal with institutional fCOI could have been in place without being articulated

in a policy and thus would have been missed by our research method.

Third, our research focused on the adoption of policies and gave particular attention to their comprehensiveness.

This does not capture the measures established at each institution to manage fCOI. Some AHSCs may have very detailed policies that are ineffective because they are not implemented or enforced, while others may have a

Table 1: Comprehensiveness of institutional fCOI policies* at Canadian academic health sciences centres† (universities, medical schools‡ and teaching hospitals)

	Level		Policy description			
	University	Teaching hospital	Specific to institutional fCOI	General	Any level	
	No. (%) (N=13)	No. (%) (N=25)	No. (%) (N=9)	No. (%) (N=29)	No. (%) (N=38)	
Institutional fCOI domains and items§						
Definitions	7 (54)	7 (28)	9 (100)	5 (17)	14 (37)	
Policy title includes "institutional COI"	3 (23)	3 (12)	6 (67)	0	6 (16)	
Definition of institutional COI	2 (15)	2 (8)	4 (44)	0	4 (11)	
Definition of financial COI	5 (38)	3 (12)	3 (33)	5 (17)	8 (21)	
Categories of institutional conflicts covered	12 (92)	24 (96)	9 (100)	27 (93)	36 (95)	
Institution	4 (31)	3 (12)	4 (44)	3 (10)	7 (18)	
Senior institutional officials¶	12 (92)	23 (92)	9 (100)	26 (90)	35 (92)	
Scope of financial interests covered	8 (62)	14 (56)	5 (56)	17 (59)	22 (58)	
Royalties from sale of the investigational product that is the subject of research	5 (38)	3 (12)	4 (44)	4 (14)	8 (21)	
Equity interest or an entitlement to equity of any value in a non-publicly traded sponsor of human subjects research at the institution	5 (38)	1 (4)	3 (33)	3 (10)	6 (16)	
Ownership interest or an entitlement to equity in a publicly traded sponsor of human subjects research at the institution	5 (38)	1 (4)	3 (33)	3 (10)	6 (16)	
Institutional officials with direct responsibility for human subjects research hold a significant financial interest in a commercial research sponsor or investigational product	8 (62)	13 (52)	5 (56)	16 (55)	21 (55)	
Management of potential institutional fCOI	6 (46)	6 (24)	4 (44)	8 (28)	12 (32)	
Reporting and review process						
Institutional COI committee exists	2 (15)	2 (8)	1 (11)	3 (10)	4 (11)	
Disclosure/reporting of institutional COI required	3 (23)	4 (16)	3 (33)	4 (14)	7 (18)	
Disclosure to the REB required	1 (8)	1 (4)	1 (11)	1 (3)	2 (5)	
Rebuttable presumption against conduct of human subjects research when institutional level fCOI exists	1 (8)	0	0	1 (3)	1 (3)	
Procedure for conducting institutional-level audits for COI	1 (8)	2 (8)	1 (11)	2 (7)	3 (8)	
Separation strategies						
Technology transfer at the institution separate from the human subjects research administration	2 (15)	0	0	2 (7)	2 (5)	
Endowment/investments managed externally through legally separate organizations	0	0	0	0	0	
Overall						
Number of core items covered	Mean (SD)	4.5 (3.3)	2.4 (1.8)	5.2 (3.2)	2.5 (2.0)	3.2 (2.6)
(Total 16 core items)	Mean percentage	28	15	32	16	20
	Median (range)	3 (0–10)	2 (0–9)	4 (2–10)	2 (0–8)	2 (0–10)

Abbreviations: COI = conflicts of interest; fCOI = financial conflicts of interest; REB = research ethics board.

* One university policy and 2 teaching hospital policies were sent as drafts.

† Canadian academic health sciences centres (AHSCs) are universities with medical schools that have affiliated teaching hospitals. There were 16 AHSCs in Canada. A 17th Canadian academic health sciences centre was excluded because its medical school was newly established and it was in the policy development stage.

‡ No medical school level policies.

§ The 16 core items relevant to institutional fCOI used in our survey were derived from 3 key COI documents (AAU Report 2001,¹⁰ AAMC Report 2002,² and AAMC Survey 2004¹¹). The most current report (AAMC Report 2008¹) also contained these core items and provided further clarification around these issues.

¶ Senior institutional officials were described as senior institution officials, member of board of trustees, member of the board of governors, president, vice presidents, deans, directors, or all staff in the policies.

Box 2: Glossary of terms**Academic health science centres (AHSCs)**

"Academic health science centre (AHSC) refers to [the] university, its medical school, and the teaching hospitals who agree to [work collectively toward] a mission of excellence in education, research, and clinical care."¹²

Conflicts of interest

"A set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)."¹³

Endowment

"Gift of money or property to a specified institution for a specified purpose."¹⁴

Equity interest

"Ownership interest in a company."¹⁴

Institutional financial conflicts of interest

"An institution may have a conflict of interest in human subjects research whenever the financial interests of the institution, or of an institutional official acting within his or her authority on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the conduct, review, or oversight of human subjects research."²

Investigator conflicts of interest

"A situation in which a person [such as a public official, an employee, or a professional] has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties."¹⁵

Publicly traded

"A company that has held an initial public offering and whose shares are traded on a stock exchange or in the over-the-counter market. Public companies are subject to periodic filing and other obligations under federal securities laws."¹⁴

Rebuttable presumption

"The presumption that individual [investigators] may not conduct research [that is related to their own financial interests]."¹⁶

Royalties

"Payment for the right to use intellectual property or natural resources."¹⁴

Technology transfer

"The process by which basic science research and fundamental discoveries are developed into practical and commercially relevant applications and products."¹⁷

poorly developed formal policy while still having effective mechanisms to address and manage institutional fCOI. Even detailed policies may not be sufficient to anticipate all issues related to institutional fCOI that could arise within an academic institution.²⁰ While simply having a comprehensive policy is not sufficient, it is a usual means of communicating expected standards in academic institutions.¹⁸

Fourth, the list of the 16 items we used to evaluate the comprehensiveness of a policy was based on information from the AAMC^{2,11} and the AAU¹⁰ that was available at the time of our survey. The 2008 AAMC template policy¹

contains the 16 core items we identified as being central to an institutional fCOI policy and adds further clarification. We expect that relevant policy items will continue to evolve. Further, we evaluated only whether the policy mentioned the core fCOI items. An evaluation of the quality of information provided about each core item may reveal further deficiencies.

Finally, this study was conducted on policies in place in 2006. Given the requirement for Canadian institutions holding federal funds to put conflict-of-interest policies in place by January 2009,²¹ we expect that many Canadian AHSCs are actively developing and implementing their institutional fCOI policies. Attention will need to be paid to having university-wide fCOI policies that are sensitive enough to capture issues specific to medical schools, or allowances will need to be made for medical schools to have a supplemental fCOI policy.

In summary, over half of the Canadian AHSCs lacked institutional fCOI policies at the time of our survey. Where policies existed, they were not comprehensive and were frequently difficult to access. The 2008 Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research¹ offers a thoughtful discussion on the complex institutional fCOI issues and provides a useful template for institutional policy. Other hospitals and universities that are not affiliated with AHSCs will also need to develop fCOI policies if they receive Canadian Tri-Council federal funds. Professional societies and those involved in clinical practice guideline development may also wish to develop these policies.²² We trust that our results related to core policy items will support appropriate policy development in this area.

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