Institutional Financial Conflicts of Interest at Canadian Academic Health Science Centres: A National Survey

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Abstract

Background When an individual or an academic institution stands to benefit financially from research that they conduct or sponsor, there is a potential for bias. Academic institutions require accessible and comprehensive policies to identify and manage perceived and actual institutional financial conflicts of interest (fCOI).

Purpose To describe Canadian academic health science centres (AHSCs) institutional fCOI policies and to provide guidance on the development of comprehensive and accessible future policies.

Method We reviewed up to three key fCOI policies identified by Vice-Presidents (Research) at all 16 Canadian AHSCs (16 universities; 16 medical schools and 47 teaching hospitals) between August 2005 and February 2006. The main outcomes were the number of policies identified by site, their comprehensiveness (by comparison to a "gold standard" of policy elements) and accessibility (i.e. currency, ease of identification, and complexity).

Results Nine (56%) universities, 9 (56%) medical schools and 15 (36%) teaching hospitals reported having no institutional fCOI policies. From the remaining institutions, we received 72 policies of which 34 were identical and shared within university/AHSCs units leaving 38 unique policies.

Policy comprehensiveness was poor. The median number of 16 “gold standard” core items in each policy was 2 (Range 0 to 10), and 2 policies contained no core items. Only 9 (24%) policies specifically addressed institutional fCOI. Financial interests, specifically royalties from products, were addressed in only 8 (21%) and ownership of equity in companies in only 6 (16%) policies.

Policy access was difficult. Only 6 (16%) policies included “institutional conflicts of interest” in the title; 5 (13%) were cross-referenced to other relevant policies. Sixteen (42%) unique policies were longer than 2000 words. The policies were complex (mean Gunning FOG score 16.9 (SD=2.2) and the mean Flesch reading index score 36.2 (SD=11.0)).

Conclusions Over half of the Canadian academic institutions surveyed lacked institutional fCOI policies. When policies existed, they were not comprehensive and frequently difficult to access. To be more useful, future policies should contain comprehensive information, be accessible and clearly written.

Institutional financial conflicts of interest (fCOI) are of particular concern in the conduct of human subjects research (1). An institutional fCOI can occur in the research context when an institution, such as a teaching hospital or a university 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). When an academic institution has a fCOI in the outcome of the research that they conduct or sponsor, this impact can be detrimental to research subjects (4) and lead to an inappropriate degree of control over what should be an independent research agenda (5). Similar concerns are raised when senior institutional officials have a financial interest in the outcome of a study. Such cases, even in the absence of research misconduct, have had serious implications. 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 may inappropriately influence their work resulted in a national Blue Ribbon committee to examine NIH conflicts of interest policies (7). This committee recommended that senior management should not consult with companies whose interests could influence the outcomes of their research (6) and ultimately led to a moratorium on industry-paid consultancies held by any NIH employee.

Federal legislation in the United States (US) (8) (9) and government incentive programs in Canada have facilitated industry/academic partnerships (10) (11) (12) (13). In both countries, industry sponsored clinical trials are attractive to academic institutions due to the compensation they provide for administering or

participating in trials (e.g. overhead charges above those paid by federal funding agencies)(14) (15). As articulated in the 2009 Institute of Medicine report on conflict of interest in medical research (16) the question is "whether a relationship with industry can be maintained in a way that achieves the desired benefits but avoids the risks of undue influence on decision making". One approach to achieving this balance is for academic institutions to create strong policies to identify and manage perceived and actual institutional fCOI.

Academic institutions have been slow to develop policies related to institutional fCOI (1) even with increased scrutiny by government (6), the media (17), and the public (18) around this issue, and the repeated calls by national organizations to develop policies (2) (1, 19). A US survey found that national recommendations on the development of institutional conflict of interest policies were poorly adopted even four years after they were recommended (20). Less than 40% of the US medical deans surveyed indicated that they had adopted institutional fCOI policies.(20).

Little is known about the Canadian context and the adoption of conflict of interest policies. We conducted a detailed content analyses of the institutional fCOI policies in use at Canadian academic institutions and measured the degree to which each policy was comprehensive and accessible in order to guide improvements in the quality of institutional fCOI policies. Interestingly, the Canadian federal research institutes require institutions obtaining federal funds to

have conflicts of interest policies in place by January 2009 (21), although some time flexibility has been shown. This study provides empirical information to guide the development and updating of institutional fCOI policies and given the new federal requirements, we believe the results are timely.

Methods

Sample

Between August 2005 and February 2006, we collected institution-level fCOI policies from all 16 Canadian Academic Health Sciences Centres (AHSCs) (16 medical schools and 47 teaching hospitals as well as their 16 partner universities). A seventeenth AHSC was excluded because its medical school was newly established and it was in the policy development stage. Canadian AHSCs are universities with medical schools that have affiliated teaching hospitals. These centres are the major sites for the conduct of 'academic' research involving humans.

We defined a document as a policy if the word "policy" was in the title or was used as a term to describe the document. Three sites (one university, one faculty of medicine, and one teaching hospital) submitted Canada's national Tri-Council Policy Statement, which describes principles, governing research involving human subjects (22). We excluded this policy, because it does not address institutional fCOI, and the principles outlined in the TCPS apply equally to all

sites administering money from one of the three Canadian federal granting agencies (CIHR, NSERC, SSHRC).

To identify relevant fCOI policies, we followed a three-step process. First, two 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. Second, we contacted the Vice President (VP) of Research at each site by email followed by letters distributed by post. French language institutions received the material in English and French. We asked the VPs to identify their three key institutional fCOI policies. Policies could be identified from our list obtained from their website or they could identify other more relevant policies. If an institution stated a policy was 'under development', we requested the draft policy and extended the option to send the final version (no finalized policies were received). Non-responders were sent a maximum of eight e-mail reminders. Finally, in 2006 we again contacted the VP Research. At this time we sent each VP (Research) a letter that listed their three key policies. In addition, each institution was provided their aggregate data related to their policy content so that they could evaluate their performance relative to other institutions in the country and identify gaps. We invited them to contact us in follow up if they had any questions or concerns related to their policy information.

Number and Currency of Policies

Canadian AHSCs involve affiliations (by agreement, regulation or other instruments) between a University and hospital(s) and/or health region which

allow the institutions to partner in providing clinical services, education and research opportunities. There is no standardized Canadian approach to creating such affiliations producing variation in the policy environment within AHSCs. Typically, the university policies prevail regarding academic issues while hospital policies prevail with respect to clinical issues. Research polices are required by all the institutions within an AHSC, leading to either harmonized or diverse policies among partner institutions.

We described the institutional fCOI policy environment within each AHSC. First, we counted the total number of policies (up to 3 per site) provided by each university, medical school, and teaching hospital. Second, we determined if the policies were internal within the site, or shared with the partner-institution. For example, a teaching hospital may have provided 3 policies, two of which originated in the teaching hospital (classified as internal) and one which originated from the partner-university (classified as shared).

To determine if the policies were recent, we calculated the time (in years) between January 2006 and the effective date of each policy (<1 year, 1-5 years, > 5 years).

Policy Comprehensiveness

To evaluate the scope of content covered by the policies, we compared each of

the unique policies to our “gold standard” of 16 core items derived from three key COI documents: the 2001 American Association of Universities (AAU) report on institutional fCOI (19), a 2002 AAMC Task Force on Conflicts of Interest in Clinical Research (2), and an AAMC survey designed to explore individual fCOI published in 2004 (23). These organizations have taken a leadership role in the area of institutional conflicts of interest and the core items derived from these documents have international relevance. We used documents that were available up to 2006 to correspond to the information available when the policies were initially developed.

The 16 core items relevant to institutional fCOI were divided into four domains (i.e., definitions, categories of institutional fCOI covered, scope of financial interests covered, and management of potential institutional fCOI). The source for these items is outlined in Appendix 1. A glossary of terms is provided in Appendix 2. Two reviewers independently reviewed each of the 38 unique policies (31 English {MS and JG} and 7 French {MS and MEC}) and determined the core items included in the policy. There was good agreement between the assessors (Kappa statistics: 0.77 and 0.81 respectively). All discrepancies were attributed to oversight by one reviewer.

We identified a subset of policies that were explicitly designed to address institutional fCOI (“specific policies”), versus policies addressing more general areas of conflicts of interest. Specific policies contained one of the three

elements: the term “institutional conflicts of interest” in the title; a definition of institutional fCOI within the policy; or a statement within the policy that it was designed to address institutional fCOI.

Policy Accessibility and Understandability

We assessed policy accessibility by evaluating the ability to identify relevant fCOI policies and by measuring their complexity. We measured ease of policy identification by determining if institutional COI was in the policy title. When more than one policy was identified, we determined if the policies were cross-referenced. To measure the complexity of the policies, we recorded word count, the number of pages, and their readability. Readability was evaluated by sentence and word length using two established measures: Flesch reading ease index (24) and the Gunning FOG index(25). The Flesch index generates scores from 0 to 100 (lower scores indicate more difficult reading) with a score of 30 or less associated with a college level reading ability. The Gunning FOG index also measures reading difficulty (higher scores indicate more difficult reading) with a score of 17 or more indicating a reading level too difficult even for medical writing. The readability score was based on the entire policy using Readability Calculations software version 7.0 (Micro Power & Light Co., Dallas, Texas) (26).

Statistical Analyses

The median number of 16 core “gold standard” items covered in individual policies and in groups of policies reported by an institution (maximum of three)

was calculated and compared by policy level (university vs. teaching hospital) and policy intent (general policy vs. specific policy addressing institutional fCOI). We used the Mann-Whitney U test to assess these differences.

Group policy coverage of these items was calculated by counting the total number of mutually exclusive core fCOI items identified in all of the policies that were internal or shared with a partner-university (maximum of three policies) reported by an institution.

We used SAS statistical software version 9.1 (SAS Institute Inc. Cary, NC) to conduct our analysis. $P<.05$ was considered statistically significant.

Results

All 16 universities (100%) their 16 medical schools (100%) and 42 (89%) of the teaching hospitals responded to our request for policies. AHSCs had one or more teaching hospital(s) (range 1 to 8). Nine (56%) universities, 9 (56%) medical schools and 15 (36%) teaching hospitals responded that they had no policies on institutional fCOI. A total of 72 policies were submitted by the remaining 41 sites.

One teaching hospital said its submitted fCOI policy was also used by its partner-university; however, the partner-university reported having no relevant policy. We kept this policy in our sample as a university policy used by the teaching hospital as it contained some items of general relevance to fCOI.

Seven (44%) medical schools identified an institutional fCOI policy originating from their partner-university. As no medical school reported having an internal policy, we did not analyze them separately. Of the 27 (64%) teaching hospitals identifying an institutional fCOI policy, 15 (36%) reported only internal policies, 10 (24%) reported only policies adopted from their partner-university and 2 (5%) reported both types of policies without any cross-referencing to the other site's policy.

Of the 72 policies identified, 34 were shared within AHSCs. Table 1 describes the 38 unique policies. Twenty-four (63%) policies were dated within five years of our survey and 10 (26%) within the past year. One university policy and two teaching hospital policies were sent as "draft".

Policy Comprehensiveness

Table 2 presents a content analysis of the 38 unique policies identified. Four domains were evaluated to determine the degree of comprehensiveness: definitions, categories of institutional fCOI covered, scope of fCOI coverage, and management of potential institutional fCOIs. The median number of the 16 core institutional fCOI items contained in an individual policy was 2 (Range 0 to 10 (62.5%)). Two (5%) policies contained none of these core items.

We identified 9 unique “specific policies” designed to address institutional fCOI (i.e. the title included “institutional conflicts of interest” (n=5), institutional fCOI was defined (n=3), or both (n=1)). These 9 policies covered a median of 4 (Range 2 to 10) core institutional fCOI items.

Individual policy item coverage was better in the university relative to the teaching hospital policies (Median: 3 vs. 2, P=0.03), and in the specific policies rather than the general policies (Median: 4 vs. 2, P=0.006).

The Definitions domain included three core items. The policy title included “institutional conflicts of interest” in 6 (16%) policies. Definitions of institutional and financial conflicts of interest were included in 4 (11%), and 8 (21%) policies respectively.

The Categories of Institutional fCOI Covered domain included two core items. Only 7 (18%) of the policies covered institutions themselves, while the majority 35 policies (92%) applied to senior institutional officials. These senior officials were described in a variety of ways: senior institution officials in 3 (8%), ‘senior officials’ in 18 (47%), (i.e., Member of Board of Trustees (n=3), Member of the Board of Governors (n=14), President, VP, Deans, Directors) and all staff in 14 (37%) policies.

The Scope of Financial Interests Coverage included four items. Royalties from sale of investigational products were covered in 8 (21%). Only 6 (16%) addressed ownership of equity in public or private companies and institutional officials with a financial interest in research was covered in 21 (55%) policies.

The Management of Potential Institutional fCOI domain included two sub-domains. In the reporting and review process sub-domain, an institutional conflicts of interest committee was identified in 4 (11%) of the policies. Disclosure or reporting of institutional conflicts of interest was required in 7 (18%) policies. Disclosure specifically to the Research Ethics Board, the Canadian equivalent of an Institutional Review Board, was required in 2 (5%) policies, and a rebuttable presumption against the conduct of human subjects research (i.e., individual investigators may not conduct research that is related to their own financial interest) was identified in 1 policy. A procedure for conducting institutional level audits for conflicts of interest was outlined in 3 (8%) policies. In the separation strategies sub-domain, only 2 (5%) policies specified that technology transfer should be administered independently of human subject research. No policies discussed appropriate behaviors with regard to endowments/investments managed externally through legally separate organizations.

The median number of core fCOI items contained in the group of policies was a median of 0 (Range 0 to 11 (69%)) at universities and a median of 2 (Range 0 to

11 (69%)) at teaching hospitals. The fCOI core item count was highest in the group of policies identified in one university site (11 of 16 fCOI items covered using three university-level policies) and two teaching hospital sites (11 core fCOI items covered using three university level policies at one site and using two internal policies at the second site). The fCOI policy environment at medical schools was exactly the same as the environment at universities. In those 18 sites that had a policy that was designed to address institutional fCOI, a median of 7 core institutional fCOI items were included for the universities, a median of 7 core items for medical schools and a median of 7.5 core items for the teaching hospitals.

Policy Accessibility

Only 6 (16%) policies included “institutional conflicts of interest” in the policy title. Five (13%) policies were cross-referenced to other relevant policies from their institution. From a complexity perspective, policies were lengthy and complex to read based on our readability index measurements. Policy length ranged from 1 to 84 pages (median=5). Sixteen (42%) unique policies were longer than 2000 words. The mean Gunning FOG score for these policies was 16.9 (SD=2.2) and the overall mean Flesch reading index score was a mean of 36.2 (SD=11.0) indicating a high degree of complexity.

Discussion

Our results demonstrate that the institutional fCOI policy environment in Canadian AHSCs has been inadequate. More than half of Canadian universities,

half of medical schools, and more than a third of teaching hospitals had no institutional fCOI policy at the time of our survey. Our results are consistent with others indicating the lack of institutional fCOI policies and the need to fill this void. In 2001 the AAU Task Force noted that institutional fCOI policies were rare (19). In 2002 The AAMC Task Force on Financial Conflicts of Interest in Clinical Research (2) provided a conceptual framework for assessing institutional fCOI. A follow up to this initiative in 2006 indicated that institutions had not implemented these recommendations. Specifically, a survey of 86 Deans of U.S. medical schools (response rate 86/125), found that fewer than half (38%) reported adopting an institutional fCOI policy (20). In that study, 37% of the Deans said their institution was working on adopting a policy, while 25% said they were not.

Our analyses suggest that academic institutions may overestimate the comprehensiveness of their policies. Our study demonstrates the importance of examining the policy contents. Although we explicitly asked institution leaders to submit institutional fCOI policies, only a minority of the policies addressed institutional fCOI. Of the 38 unique policies submitted, 2 contained no items of relevance to institutional fCOI and others lacked important elements. On average, individual policies contained 20% of the 16 core “gold standard” items that should be included in such a policy and no individual policy contained more than 65% of the core fCOI items. Further, the scope of financial interests covered in the policies was poor. Less than a quarter of policies addressed royalties, equity interest, or ownership interests. Even when the content of up to

three policies per site were combined and examined for the inclusion of any items related to fCOI, the total number of core items addressed by the group of policies was, on average, less than half of the desired items.

Policy Development Guidance

Our results provide an important baseline on institutional fCOI policies in Canadian academic institutions and our findings provide guidance to academic institutions that will enable them to improve their current policies. As institutions move forward with developing their policies, we recommend having a single policy that can provide comprehensive information. Further, we recommend that this policy resource be widely disseminated and available on-line that it identifies all the applicable institutional policies (and where to find them). In the US, the AAMC created a template for an institutional fCOI that could be used by institutions to assist them in developing a comprehensive fCOI policy (1). Due to the complexity of institutional fCOI, we also recognize that multiple policies may be required to address the range of fCOI issues. Almost a quarter of universities, medical schools, and teaching hospitals within our sample (26%) identified more than one institutional fCOI policy. Our findings are consistent with other centres. For example, the Pennsylvania School of Medicine reports having more than 90 policies regarding conflicts of interest (27). When multiple policies are being used, these policies should be cross-referenced.

Accessibility is an important part of a good policy. Individuals must know about existence of the policies that govern their conduct and be able to understand these policies. Our data suggest that steps could be taken to make the existing policies more accessible. First, fewer than 20% of policies included the words "institutional conflicts of interest" in the title, making them difficult to locate. Second, of the two teaching hospitals using internal and partner-university policies, neither cross-referenced the other's policies, making it difficult for investigators to know whether there were other relevant policies. The ability of some leaders within an AHSC to identify a fCOI policy, while others based in the same institution could not, illustrated the problem. Further, policies were difficult to understand based on their length and their readability index. These policies discuss technical and legal issues, such as technology transfer and equity interest and entitlement that are likely unfamiliar to many investigators. Our findings are similar to those of William-Jones and McDonald (28) who also document that COI policies are difficult to understand. While having a written policy that is comprehensive, accessible and understandable is important, future work needs to ensure that these policies are implemented within the institution.

Limitations

We requested a maximum of three policies from each site and some may speculate that this truncated our results if sites had more than three policies relating to the core fCOI items. However, as 33 of 74 (45%) sites reported no relevant policies and only 10 (13%) sites identified three, we think this is unlikely.

Second, 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. Third, we conducted our analyses of policies used in academic institutions. Institutional fCOI will also need to be considered by other organizations that may have financial relationships with industry including professional societies, and those that are involved in clinical practice guideline development (16). Our general findings may be useful to these organizations as they develop policies. Finally, the list of the 16 “gold standard” items we used to evaluate the comprehensiveness of a policy was based on information from the AAMC (2) (23) and AAU (19) that was available at the time of our survey. The 2008 AAMC template policy (1) contains all of the 16 core items we identified as being central to an institutional fCOI policy and adds further clarification by adding some additional items. Accordingly, our results likely overestimate the performance of our policies. We expect that the “gold standard” of items that should be included in an institutional fCOI policy will continue to evolve.

Conclusion

Over half of the Canadian academic institutions surveyed lacked institutional fCOI policies. When policies existed, they were not comprehensive and frequently difficult to access. To be more useful, future policies should contain comprehensive information, be accessible and clearly written.

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Table 1: Institutional fCOI Policies at Canadian Academic Health Sciences Centers.

Description		University (n = 13)	Teaching Hospital (n = 25)	Overall (n = 38)
Currency				
Number of years*	Mean (SD)	2.8 (3.2)	4.6 (3.9)	4.0 (3.7)
Number of policies revised within given time period	<1 year	5	5	10
	1-5 years	6	8	14
	>5 years	2	10	12
	Unknown	0	2	2
Accessibility				
Ease of Identification				
Institutional fCOI in the title		3	3	6
Policy Cross-referencing		3	2	5
Complexity				
Page Length	Median (Range)	5 (1-84)	5 (2-34)	5 (1-84)
Word Count	Median (Range)	1695 (293-26,843)	1516 (332-4,527)	1593.5 (293-26,843)
Flesch Reading Ease score†	Mean (SD)	31.6 (10.5)	38.6 (10.7)	36.2 (11.0)
Gunning FOG score‡	Mean (SD)	16.8 (2.0)	16.9 (2.4)	16. 9 (2.2)

Notes:

Abbreviations: fCOI, Financial conflict of interest

* Years since policy implemented or most recent revision up to January 2006

† The Flesch Reading Ease generates scores from 0 to 100 with higher scores indicating easier reading. A score of 30 or lower was associated with a college level reading ability (24).

‡ The Gunning FOG scores reflect reading difficulty with lower scores indicating easier reading. A score of 17 or more is considered too difficult for medical writing (25).

Table 2: Comprehensiveness of Institutional fCOI Policies at Universities, Medical Schools*, and Teaching Hospitals

Institutional fCOI Domains and Items	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)
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	5(38)	3(12)	4(44)	4(14)	8(21)

Institutional fCOI Domains and Items	Level	Policy Description				
	University	Teaching Hospital	Specific to Institutional fCOI	General		
	No. (%) (N=13)	No. (%) (N=25)	No. (%) (N=9)	No. (%) (N=29)	Any Level	No. (%) (N=38)
of the investigational product that is the subject of research						
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 fCOI Domains and Items	Level	Policy Description			
	University	Teaching Hospital	Specific to Institutional fCOI	General	
	No. (%) (N=13)	No. (%) (N=25)	No. (%) (N=9)	No. (%) (N=29)	No. (%) (N=38)
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)

Institutional fCOI Domains and Items	Level		Policy Description			
	University	Teaching Hospital	Specific to Institutional fCOI	General		
	No. (%) (N=13)	No. (%) (N=25)	No. (%) (N=9)	No. (%) (N=29)	Any Level	No. (%) (N=38)
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)

Institutional fCOI Domains and Items	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)
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					

Institutional fCOI Domains and Items	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)	
Number of core items covered (Total 16 core items)	Mean(SD)	4.5(3.3)	2.4(1.8)	5.2(3.2)	2.5(2.0)	3.2(2.6)
	Mean percentage	28	15	32	16	20
	Median (Range)	3 (0-10)	2 (0-9)	4 (2-10)	2 (0-8)	2 (0-10)

Notes:

Abbreviations: COI, Conflicts of Interest; fCOI, Financial conflict of interest; REB, Research Ethics Board.

* No Medical School level policies.

Appendix 1. Source of Institutional fCOI Core Items

Institutional fCOI Domains and Items	Item Source			
	AAU Report 2001*	AAMC Report 2002†	AAMC Survey 2004‡	AAMC Report 2008§
Definitions				
Policy title includes Institutional COI	Yes	Yes	No	Yes
Definition of Institutional COI	Yes	Yes	No	Yes
Definition of Financial COI	Yes	Yes	Yes	Yes
Categories of Institutional Conflicts Covered				
Institution	Yes	Yes	Yes	Yes
Senior Institutional Officials	Yes	Yes	Yes	Yes
Scope of Financial Interests Covered				
Royalties from sale of the investigational product that is the subject of research	Yes	Yes	Yes	Yes
Equity interest or an entitlement to equity of any value in a non-publicly traded sponsor of human subjects research at the institution	Yes	Yes	Yes	Yes
Ownership interest or an entitlement to equity in a publicly-traded sponsor of human subjects research at the institution	Yes	Yes	No	Yes
Institutional officials with direct responsibility for human subjects research hold a significant financial interest in a commercial research sponsor or investigational product	Yes	Yes	No	Yes
Management of Potential Institutional fCOI				
Reporting and Review Process				
Institutional COI committee exists	Yes	Yes	Yes	Yes
Disclosure/ reporting of Institutional COI required	Yes	Yes	Yes	Yes
Disclosure to the REB required	Yes	Yes	Yes	Yes
Rebuttable presumption against conduct of human subjects research when institutional level Financial COI exists	No	Yes	Yes	Yes
Outlines procedure for conducting institutional-level audits for COI	Yes	No	Yes	Yes
Separation Strategies				
Technology transfer at the institution separate from the human subjects research administration	Yes	Yes	No	Yes
Endowment / investments managed externally through legally separate organizations	Yes	Yes	No	Yes

Notes:

Abbreviations: COI, Conflicts of Interest; fCOI, Financial conflict of interest; REB, Research Ethics Board.

* 2001 Association of American Universities (19)

† 2002 American Association of Medical Colleges (AAMC) (2)

‡ 2004 American Association of Medical Colleges (AAMC) survey (23)

§ 2008 American Association of Medical Colleges (AAMC) (1)

Appendix 2. Glossary of Terms

Academic Health Science Centers (AHSC)	An academic health center refers to the university, its medical school and the teaching hospitals who agree to have collective action for a mission of excellence in education, research and clinical care. (15)
Investigator Conflict 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. (29)
Financial Conflicts of Interest	When the primary goal of conducting valid and objective research is, or appears to be, compromised by the existence of a secondary objective of financial gain (12)
Institutional Financial Conflict of interest	Institutional fCOI occurs when either an institution that hosts the research or any of its senior institutional official, acting on behalf of the institution has a direct or indirect financial interest or an external relationship that can lead to actual or possible bias, in the review or conduct of research at the institution.(2) (3)
Royalties	Payment for the right to use intellectual property or natural resources. (30)
Equity Interest	Ownership interest in a company or investment in stocks. (30)
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 the federal securities laws. (30)
Rebuttable Presumption	The presumption that individual investigators may not conduct research that is related to their own financial interests.(31)
Technology Transfer	Technology transfer is the process by which basic science research and fundamental discoveries are developed into practical and commercially relevant applications and products.(www.gdrc.org/uem/techtran.html)(32)
Endowment	Gift of money or property to a specified institution for a specified purpose. (30)