HEALTH POLICY

National Evaluation of Policies on Individual Financial Conflicts of Interest in Canadian Academic Health Science Centers

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BACKGROUND: Conflicts of interest (COI) in research are an important emerging topic of investigation and are frequently cited as a serious threat to the integrity of human participant research.

OBJECTIVE: To study financial conflicts of interest (FCOI) policies for individual investigators working in Canadian academic health centers.

DESIGN: Survey instrument containing 61 items related to FCOI.

SETTING: All Canadian academic health science centers (universities with faculties of medicine, faculties of medicine and teaching hospitals) were requested to provide their three primary FCOI policies.

MEASUREMENTS: Number of all centers and teaching hospitals with policies addressing each of the 61 items related to FCOI.

MAIN RESULTS: Only one item was addressed by all 74 centers. Thirteen items were present in fewer than 25% of centers. Fewer than one-quarter of hospitals required researchers to disclose FCOI to research participants. The role of research ethics boards (REBs) in hospitals was marginal.

LIMITATIONS: Asking centers to identify only three policies may not have inclusively identified all FCOI policies in use. Additionally, policies at other levels might apply. For instance, all institutions receiving federal grant money must comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

CONCLUSIONS: Canadian centers within the same level (for instance, teaching hospitals) differ significantly in the areas that their policies address and these

policies differ widely in their coverage. Presently, no single policy in any Canadian center informs researchers about the broad range of individual FCOI issues. Canadian investigators need to understand the environment surrounding FCOI, be able to access and follow the relevant policies and be confident that they can avoid entering into a FCOI.

KEY WORDS: investigator; financial conflicts of interest; academic health science centers.

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INTRODUCTION

Conflicts of interest (COI) in research are an important emerging topic of investigation. A COI in the research context has been defined as “a set of conditions in which professional judgment concerning a primary interest (e.g., a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (e.g., financial gain).”¹ COI in research may affect multiple areas, including study design and conduct, reporting, investigators' access to data and control over publication. Friedman and Richter have reported that based on the COI criteria published by the International Council of Medical Journal Editors, almost 40% of drug-investigation studies published in JAMA and the New England Journal of Medicine had authors with reported COI.²

COI are frequently cited as a serious threat to the integrity of human participant research, especially as the proportion of research funded through the private sector continues to grow.³ While other forms of COI exist (e.g., the desire for a promotion interfering with an investigator's judgment), we focus here on financial COI (FCOI). In addition to their impact on the research enterprise,^{2,4,5} FCOI are more tangible, making them easier to identify.

It has been estimated that between 60 and 70% of protocols reviewed by Canadian Research Ethics Boards (REBs) are industry-sponsored,⁶ making industry the leading funder of

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health research. Ferris and Naylor⁷ estimated that thousands of physicians may be involved in such studies, and have signed contracts with industry sponsors. The interaction between researchers and industry is, in many cases, productive and is responsible for significant public benefits through the development of many major medical advances. It is important to recognize, however, that such collaborations can potentially result in a FCOI that influence professional judgment and the conduct and reporting of research results. The case of Jesse Gelsinger at the University of Pennsylvania has been well documented.⁸ Another example is the questionable research on the benefit of a specific multivitamin and mineral supplement in improving cognitive function published by Professor Ranjit Chandra, who happened to hold a patent on that same supplement in North America.⁹

Although there have been anecdotal reports of arrangements regarding individual-level FCOI at some teaching hospitals,¹⁰ there been no systematic collection of information on this issue in Canada. Our objective was to assess the current policy environment in all Canadian academic health science centers at which research oversight may be performed (universities with faculties of medicine, faculties of medicine and affiliated teaching hospitals) as it relates to individual-level FCOI. Specifically, we designed this study to document, describe, and analyze existing FCOI policies related to human participant research in centers throughout Canada. This paper reports on individual-level FCOI policies generally, and in particular focuses on those utilized in teaching hospitals, given the growth of clinical health research in this setting.

METHODS

Study Design and Sample

Between August 2005 and February 2006, two members of the research team (JG and MS) independently conducted a preliminary search of publicly available Web sites of centers for policies related to FCOI. All policies relevant to this form of COI were included in the original sample. Our sample of 79 centers consisted of 16 universities, 16 faculties of medicine and 47 teaching hospitals.

We contacted the vice-president (VP) for research or equivalent at the 79 centers by e-mail and by post, requesting assistance in determining their primary FCOI policies. The request included the partial list of FCOI policies located on their centers' Web sites. Independent of the list of policies sent to the VPs, they were asked to identify what they considered to be the three primary policies used by their centers in governing FCOI at the individual level within the context of human participant research. If a policy considered to be 'primary' was not among the ones obtained from the search of publicly available on-line material, the VP was asked to identify the policy and to provide a copy. A total of eight follow-up emails were sent over a period of 8 months from 21 November 2005 to 29 May 2006 to obtain policy information. For centers stating that their policies were 'under development', we requested a draft of the policy, extending the option to send a formalized version at a later date for inclusion and analysis. Since any center administering funds from one or more of the three federal granting councils (the Tri-Council—Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, Social Sciences and Humanities Research

Council of Canada) is required by a memorandum of understanding (MOU) to follow the Tri-Council policy statement,¹¹ we assumed all 79 centers governed themselves accordingly.

Of 79 centers, 74 sent information about policies while five teaching hospitals did not participate. Our final sample included all 16 universities with faculties of medicine, all 16 faculties of medicine, and 42 of 47 fully affiliated teaching hospitals.

Content Analysis

We constructed an instrument to abstract data from the individual-level FCOI primary policies by adapting tools from the American Association of Medical Colleges^{12,13} and a survey of American academic health science centers by Cho and colleagues.¹⁴ Two members of the research team (JG and PR) independently pilot-tested the instrument using ten policies. The final instrument consisted of six domains: "Definitions", "Interests requiring disclosure", "Designated reviewers and decision-makers about FCOI", "Strategies for managing FCOI", "Disclosure details" and "Investigator publication rights" such as the right to publish the results, restrictions on publication beyond a reasonable time-frame or editorial control over publication of results). Domains 1–3 were broken down into nine subdomains. In total, the domains and subdomains contained 61 different items covering issues including the types of conflicts, the process for disclosure, decision-making, and managing FCOI. (See Table 1).

After identifying all of the relevant policies of each center, two members of the research team (JG and MS) independently abstracted data from each VP-identified individual-level English policy. A third reviewer (MEC) contributed to data abstraction of French policies (n=17). Eliminating duplicate policies, we analyzed a total of 92 individual-level policies (cited a total of 161 times) and assessed initial inter-rater reliability, with a mean agreement of 88%. Following this, up to three reviewers engaged in data conferencing regarding discrepancies in data abstraction and resolved all differences through consensus.

Analysis and Ethics

Summary statistics and descriptive analysis were used to evaluate the data from the primary FCOI policies from each center. The study was approved by the ethics review board of the Baycrest Centre, Toronto, Ontario, Canada.

RESULTS

Universities identified 33 unique policies, faculties of medicine identified five, and teaching hospitals identified 54. All universities had their own unique policies; 13 of 16 faculties and 10 of 42 hospitals, used the policy(ies) of their parent institution as opposed to having their own policies. The plurality of all three types of centers reported using three different policies (Table 2). Faculties variably used university and faculty-level policies, while teaching hospitals variably used policies originating at all three levels. More than half (50/92 or 54%) of the policies were revised within three years of the study and only 16 predated 2000 (data not shown).

Table 1 lists each of the 61 items within the six domains and nine subdomains related to conflicts-of-interest. There was considerable variation in the number of centers with policies addressing domains and items within those domains, with

Table 1. Summary of the Individual Abstraction Form for the 74 Centers

Item	Centres with policies that address item No. (%)
1. Definitions	
Policy applicable to:	
Staff	63 (85)
Trainees/ students	56 (76)
Post-docs	58 (78)
Academic staff/ faculty	74 (100)
Other	27 (36)
Definitions and examples	
Definition of conflict of interest provided	58 (78)
Examples of conflict of interest provided	46 (62)
Definition of financial interest provided	27 (36)
Types of conflicts regulated by the policy	
FCOI* related to personal financial interests	70 (95)
FCOI related to family's financial interests	61 (82)
Conflicts of commitment (conflicts re: time, outside activities)	58 (78)
FCOI related to hiring of person's family	36 (49)
FCOI related to trainees/ education	32 (43)
2. Interests requiring disclosure	
Financial compensation	
Salary	32 (43)
Honoraria/ donations	36 (49)
Consulting fees	40 (54)
Research sponsorship	
Grant	11 (15)
Research support/ overhead	18 (24)
Contracts	42 (57)
Per capita payments for recruiting research participants	17 (23)
Indirect Financial Benefits	
Intellectual property rights	42 (57)
Stock or stock options	41 (55)
Gifts	47 (64)
Other benefits	
Management position in company	31 (42)
Advisory board memberships in company	32 (43)
Establishing a corporation/ spin-off company and related activities	9 (12)
Speakers list of company	10 (14)
3. Who reviews and makes Decisions about FCOI	
Disclosed to	
Department chair/ supervisor ('administrative head')	52 (70)
VP†/Chief research or VP academic	35 (47)
Dean of faculty	27 (36)
Legal counsel	6 (8)
REB‡	31 (42)
Committee	16 (22)
Other	40 (54)
Decision-maker	
Department chair/ supervisor ('administrative head')	41 (55)

Table 1. (continued)

Item	Centres with policies that address item No. (%)
VP/chief research or VP academic	30 (41)
Dean of faculty	27 (36)
Legal counsel	6 (8)
REB	24 (32)
Committee	18 (24)
Other	38 (51)
4. Strategies for managing FCOI	
Disclosure of information to the center	71 (96)
Disclosure to public	21 (28)
Disclosure to funder	16 (22)
Monitoring/ oversight	28 (38)
Disqualification from/ discontinuation of research	29 (39)
Divestiture/ prohibition of financial interests	19 (26)
Disclosure to research participants	25 (34)
Other	32 (43)
5. Disclosure details	
Disclosure is independent in nature	51 (69)
Disclosure must occur prior to the commencement of the activity	47 (64)
Regular review of potential conflicts of interest is required	41 (55)
Committee on conflicts of interest exists at the institution	23 (31)
Sanctions described for those who fail to comply	39 (53)
Appeals process described	32 (43)
Rebuttable presumption that financially interested individuals may not conduct research without undergoing review and receiving permission	16 (22)
FCOI review must be done prior to REB approval	25 (34)
REB members must disclose any potential FCOI they may have with research under review	21 (28)
6. Publication rights	
Publication rights addressed	29 (39)
Specifies time limit related to publication	9 (12)
Specifies exceptions related to publication	11 (15)

*Financial conflicts of interest

†Vice president

‡Research ethics board

only one item—whether the policy was applicable to academic staff and/or faculty—universally addressed by all 74 centers. Only nine items were covered by more than 75% of the centers; eight of those were in the “Definitions” domain, while the ninth was in the “Strategies for managing FCOI” domain and

Table 2. Number of Policies in Place by Type of Center

Number of applicable policies	Type of center and number of each type			
	University (n=16)	Faculty of medicine (n=16)	Teaching hospital (n=42)	Total (n=74)
One	5	3	11	19
Two	5	6	13	24
Three	6	7	18	31

specified that disclosure of information related to FCOI was mandatory. Conversely, 13 items were present in fewer than 25% of centers. Particularly poorly covered were the subdomains of “Items required to be disclosed: research sponsorship” and “items required to be disclosed: other benefits” in which three of the four items and two out of four, respectively, fell below 25%, and the domain of “Publication rights”, in which only a third of the items was covered by more than 25% of the centers.

Coverage of Financial Conflicts of Interest Domains by Teaching Hospitals Policies

i. *Definitions related to FCOI*

Of the 42 teaching hospitals, 32 (76%) had unique policies that covered academic staff and faculty. Coverage for the other groups was lower, ranging from 23 hospitals that had policies applicable to trainees and/or students to 26 hospitals that covered post-doctoral fellows (Table 3). Only half the hospitals supplied a definition of FCOI. Even fewer 17 (40%) provided examples of FCOI, and only six (14%) supplied a definition of financial interest. Whereas a majority of the hospitals mentioned FCOI related to the investigator's personal or family's financial interests, fewer than 50% covered conflicts of commitment or FCOI related to either the hiring of the investigator's family or to trainees.

ii. *Interests requiring disclosure*

As stated previously, the policies were generally silent regarding which financial interests required disclosure to the institution. Thirty-eight percent of teaching hospitals required the disclosure of gifts. Coverage for the remaining 13 items ranged from a low of 2% for grants and “establishing a corporation/spin-off company and related activities”, to a high of 36% for disclosure related to intellectual property rights.

iii. *Who reviews and makes decisions about FCOI in hospital policies*

Most often, teaching hospital-based investigators had to disclose their conflicts either to department chairs/supervisors (38% of hospitals) or to the REB (38% of hospitals). No hospital required disclosure to legal counsel and only one hospital required that notification be provided to the faculty dean. The most frequent decision-maker regarding conflicts was either the REB (26% of hospitals) or the department chair/supervisor (19% of hospitals).

iv. *Strategies for managing FCOI*

The only strategy for managing FCOI specified in a majority of teaching hospitals (69%) was the general disclosure of information to the hospital. Other strategies were infrequently specified; for example, only four (10%) hospitals mandated disclosure to the research funder, and ten (24%) required disclosure to research participants.

Disclosure Details

None of the nine items in the “Disclosure details” domain were mentioned by a majority of teaching hospitals. Only 45% of hospitals specifically stated that disclosure had to be indepen-

dent in nature; that is, disclosure had to be to someone independent of the research endeavor. Further, researchers only had to disclose conflicts prior to the commencement of research at 19 (45%) hospitals, with just 18 (43%) requiring a regular review of potential conflicts. Only four (10%) hospitals had a committee on FCOI. The role of REBs in helping to manage conflicts was marginal, with only 12 (29%) of hospitals reporting that they required FCOI disclosure to the REB prior to a study's initial ethics review.

Publication Rights

Most teaching hospital level policies do not appear to protect investigator publication rights, as these were only addressed in general by 14 (33%) hospitals. The two specific items related to publication that we abstracted from the policies were whether there were exceptions with respect to researchers' rights to publish and whether there was a maximum time limit as to when publication should take place. The former was mentioned by seven (17%) of hospitals and the latter by five (12%).

Supplementary Hospital Policies

Fourteen teaching hospitals specifically stated that they followed policies from universities, and two hospitals specifically incorporated policies from their parent faculty of medicine. When policies at the faculty and the university were added to hospital policies, coverage for 58 of the 61 items increased, but coverage for two-thirds of the publication items (exceptions and time limits) and grants requiring disclosure remained at the same low levels (Table 3). Even adding these two additional layers of policy coverage, 38 of the 61 items remained unaddressed by more than 50% of the hospitals.

At individual teaching hospitals, combining the policies of the hospital, faculty and university still left large gaps in coverage (Table 4). Only four (10%) hospitals covered more than three-quarters of the items, and in these cases it was due to the addition of university level policies (data not shown). At the majority of the hospitals, fewer than half the items were covered by the combination of the policies.

DISCUSSION

Our results indicate that, while there are many individual-level FCOI policies within the various levels of Canadian centers, there is a high degree of variability in these policies in at least two respects: 1) centers within the same level (universities, faculties and teaching hospitals) differ significantly in the areas that their policies address and 2), individual policies differ widely in their coverage. Despite this diversity, there are some domains that are uniformly overlooked, for example, strategies for managing FCOI and publication rights.

The omission of many important areas is surprising given that the majority of policies were revised within 3 years of our survey. It is possible that the gaps in coverage may also be a reflection of the rapidly evolving debate regarding what constitutes a FCOI and how conflicts should be managed. The low level of coverage of some items may be due to a general lack of perceived importance about these issues. For instance, although only one-third of hospitals required disclosure of researchers' FCOI to research participants a survey of cancer

Table 3. Summary of the Individual Abstraction Form for 42 Hospitals

Domain	Sub-domain	Item	Hospital level policies		All policies*	
			Number of hospitals	(%)	Number of hospitals	(%)
1. Definitions	Policy applicable to	Staff	24	(57)	35	(83)
		Trainees/ students	23	(55)	34	(81)
		Post-docs	26	(62)	35	(83)
		Academic staff/ faculty	32	(76)	42	(100)
		Other	10	(24)	14	(33)
	Definitions and examples	Definition of conflict of interest provided	21	(50)	34	(81)
		Examples of conflict of interest provided	17	(40)	25	(60)
		Definition of financial interest provided	6	(14)	15	(36)
		FCOI† related to personal financial interests	29	(69)	40	(95)
		FCOI related to family's financial interests	27	(64)	39	(93)
	Types of conflicts regulated by the policy	Conflicts of commitment (conflicts re: time, outside activities)	20	(48)	32	(76)
		FCOI related to hiring of person's family	6	(14)	16	(38)
		FCOI related to trainees/ education	5	(12)	15	(36)
	Financial compensation	Salary	10	(24)	17	(40)
		Honoraria/donations	10	(24)	19	(45)
		Consulting fees	12	(29)	23	(55)
2. Items Required to be Disclosed	Research sponsorship	Grant	1	(2)	1	(2)
		Research support/ overhead	11	(26)	12	(29)
		Contracts	14	(33)	24	(57)
		Per capita payments for recruiting research participants	8	(19)	12	(29)
		Indirect financial benefits	15	(36)	25	(60)
	Other benefits	Intellectual property rights	14	(33)	23	(55)
		Stock or stock options	16	(38)	27	(64)
		Gifts	6	(14)	15	(36)
		Management position in company	9	(21)	18	(43)
		Advisory board memberships in company	1	(2)	5	(12)
	Disclosed To	Establishing a corporation/ spin-off company and related activities	4	(10)	8	(19)
		Speakers list of company	16	(38)	26	(62)
		Department chair/ supervisor ('administrative head')	8	(19)	15	(36)
		VP‡/Chief research or VP academic	1	(2)	10	(24)
		Dean of faculty	0	(0)	4	(10)
3. Review, decision - making of disclosed FCOI	Decision-maker	Legal counsel	16	(38)	23	(55)
		REBS§	5	(12)	10	(24)
		Committee	20	(48)	27	(64)
		Other	8	(19)	18	(43)
		Department chair/ supervisor ('administrative head')	5	(12)	12	(29)
	Decision-maker	VP/Chief research or VP academic	3	(7)	12	(29)
		Dean of faculty	0	(0)	4	(10)
		Legal counsel	11	(26)	18	(43)
		REB	4	(10)	9	(21)
		Committee	20	(48)	27	(64)
	Decision-maker	Other	5	(12)	12	(29)
		VP/Chief research or VP academic	3	(7)	12	(29)
		Dean of faculty	0	(0)	4	(10)
		Legal counsel	11	(26)	18	(43)
		REB	4	(10)	9	(21)

(continued on next page)

Table 3. (continued)

Domain	Sub-domain	Item	Hospital level policies		All policies*	
			Number of hospitals	(%)	Number of hospitals	(%)
4. Strategies for managing FCOI		Disclosure of information to center	29	(69)	40	(95)
		Disclosure to public	5	(12)	12	(29)
		Disclosure to funder	4	(10)	10	(24)
		Monitoring/ oversight	9	(21)	18	(43)
		Disqualification from/ discontinuation of research	14	(33)	19	(45)
		Divestiture/ prohibition of financial interests	8	(19)	13	(31)
		Disclosure to research participants	10	(24)	15	(36)
5. Disclosure details		Other	7	(17)	17	(40)
		Disclosure is independent in nature	19	(45)	29	(69)
		Disclosure must occur prior to the commencement of the activity	19	(45)	30	(71)
		Regular review of potential conflicts of interest is required	18	(43)	26	(62)
		Committee on conflicts of interest exists at the institution	4	(10)	13	(31)
		Sanctions described for those who fail to comply	14	(33)	24	(57)
		Appeals process described	9	(21)	17	(40)
		Rebuttable presumption that financially interested individuals may not conduct research without undergoing review and receiving permission	5	(12)	10	(24)
		FCOI review must be done prior to REB approval	12	(29)	19	(45)
		REB members must disclose any potential FCOI they may have with research under review	9	(21)	13	(31)
		Publication rights addressed	14	(33)	18	(43)
		Specifies time limit related to publication	5	(12)	5	(12)
		Specifies exceptions related to publication	7	(17)	7	(17)
6. Publication rights						

*32 hospitals had their own hospital level policies, 14 hospitals had additional policies from universities and two hospitals had additional policies from faculties as part of their policies

†Financial conflicts of interest

‡Vice president

§Research ethics board

patients in the US found that only 31% wanted such a disclosure.¹⁵ We did not inquire about plans to revisit policies, and so we do not know if centers are actively engaged in seeking to expand their policies. However, the three federal granting councils are currently re-signing their MOU with research institutions, implementing strengthened requirements including the necessity for institutions to develop and maintain a written policy on COI (Schedule 14).¹⁶

The variability seen in policies, along with significant gaps in coverage, means that researchers across the country are facing very different environments when dealing with potential FCOI. In some teaching hospitals, policies will not apply to post-doctoral students, while in others they will. In a few hospitals conflicts-of-interest applies to hiring members of one's family, but in most cases it does not. Occasionally the dean of the faculty is the person to whom reports are made, but in many hospitals it is the departmental chair. This inconsistency across Canadian teaching hospitals raises the prospect that industry sponsors could potentially "shop around" for hospitals with relatively lenient policies, a concern that has also been voiced in American

studies.¹⁷ Whether or not this actually occurs should be explored in future research perhaps by examining correlations between the strength of FCOI policies and the amount of money the hospital receives in industry research funding or the degree to which publications from its researchers support take positions favourable to industry.

Though the results of our study pertain to Canadian centers, we feel that they represent an important part of the North American research relationship with industry as both the US and Canada share similar industry funders. These similarities are reinforced by the fact that our finding of substantial variation in policies on FCOI is broadly in line with

Table 4. Number of Items Covered at Individual Hospitals Combining Policies from Teaching Hospital, Faculty and University

	No. of items covered (total=61)			
	<15	15-30	31-45	>45
Number of hospitals	2	26	10	4

the results of similar surveys that have been undertaken in the US. Van McCrary and colleagues¹⁸ surveyed 250 medical schools and other research centers and found marked differences in the definition and management of FCOI. Only 8% had policies requiring disclosure to funding agencies, similar to our results where 10% of hospital policies had clauses addressing disclosure of FCOI to funders. A second survey of the 100 US centers with the most funding from the National Institutes of Health likewise found widespread differences in policies across centers.¹⁴ Although the most recent survey of US medical schools shows that 98% of respondents now have policies that include a monetary definition of significant FCOI, other forms of FCOI are variably included.¹³

Based on the policies we received from responding centers, REBs do not seem to be a major factor in dealing with FCOI issues in Canadian teaching hospitals; only 38% require reporting of conflicts to REBs. REBs are decision-makers in COI only 26% of the time. This figure improves somewhat when we include faculty and university policies used by some hospitals, but even in these cases disclosure to the REB is specified only 55% of the time and the REB is specified as the decision-maker in 43% of policies. The limited mention of REBs in these policies despite Tri-Council policy statement requirements, points to the difficulty that individual investigators have in determining all the policies that they are required to follow and raises the question as to whether or not REBs can adequately protect the interests of research participants if they are unaware of the potential FCOI of the investigators. Additionally, this finding about the role of REBs raises the question as to whether centers should establish FCOI committees to specifically deal with this aspect of research as is being done in the US.¹⁹

Any system regulating FCOI operates on at least two levels: the oversight body at the research center and the investigators who report their potential conflicts. For the latter to occur, investigators need to be aware of the policies within their centers. When policies change across teaching hospitals or faculties, or policies do not cross-reference each other, such awareness may not be possible. Our survey did not probe for researchers' knowledge of the policies within their centers. In the US, Boyd and colleagues interviewed active clinical investigators at Stanford University and the University of California San Francisco.²⁰ Despite the fact that the policies of these centers were posted on university Web sites and staff at each center were specifically employed to enforce them, fewer than half of the faculty could accurately identify their centers' policies.

Our findings demonstrate that individual FCOI concerns are typically covered by a series of discrete policies that are governed by different levels of administration. We believe that there is a need to bring a degree of uniformity to Canadian policies so that there is a common definition of FCOI, and a common policy for its management. The current revision of the MOU with Canadian federal granting agencies will help bring about this change. Such a policy needs to be respectful of fundamental differences in centers where these differences are meaningful. For example, policies for investigators based in children's hospitals may need to incorporate additional disclosure provisions regarding parents and guardians. At the same time, all policies must be based on a common set of values that apply both to the investigator and their center. Action at both levels is required for there to be improvement with respect to the prevention and management of FCOI in research involving humans. One step along this path would be the creation of a

comprehensive FCOI checklist that investigators can use to help them identify and disclose all of the relevant FCOI information in a single document. Such a checklist could also be publicly accessible to a broad range of stakeholders like ethics boards, grant reviewers, trial registries, journal editors and others involved in clinical research and could become a tool for information sharing among the involved stakeholders. We have recently convened a workshop of Canadian and international experts to discuss the elements of such a checklist and its development is ongoing.

LIMITATIONS

In an attempt to ensure that we obtained a comprehensive list of the most important policies in place at our sampled centers, we relied on the VP of research, on the assumption that he or she would have the necessary insight and expertise to do so correctly. We only identified center-level FCOI policies, and did not examine whether or not certain practices may be governed by other policies and procedures within teaching hospitals. For instance, human resource policies may prohibit investigators from hiring family members, and REBs may have their own policies that require researchers to notify the REBs and trial participants about FCOIs. Future research should survey REBs in these centers to see if there are similarities, differences, and gaps in how they do or do not handle FCOI.

Similarly, policies at other levels might apply to certain groups of people in teaching hospitals. For instance, trainees and students within teaching hospitals are governed by university policies. In another example, all institutions receiving federal grant money must comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹¹ (TCPS), which requires REBs to examine clinical trial budgets for researchers' COI considerations (Article 7.3). The TCPS was, however, developed to guide research ethics broadly and not specifically for the purpose of regulating FCOI. Sensitivity regarding the wide range of FCOI issues has expanded in the decade since the release of the TCPS. In addition it has been questioned whether or not REBs have the resources to adequately undertake all of the tasks assigned to them.²¹ Finally, in some US centers the practices of Institutional Review Boards differ from their policies.¹⁹

We did not examine FCOI policies to see whether or not they referred to other policies and procedures for dealing with practices that they themselves did not cover. Furthermore, in limiting teaching hospitals and other centers to their "three most important policies" we may have missed policies that covered FCOI more comprehensively. A larger number of policies, though, means an increase in the difficulty an investigator may encounter in trying to assimilate the rules or guidelines that he or she is required to follow. The likelihood of an investigator missing a policy increases with the number of policies governing the matter.

We have treated each of the 61 items as having equal significance in the absence of any consensus among the research community as to which ones might be considered to be of greater or lesser value. It is possible that items of higher importance have greater coverage but we do not believe that this is the case since items guaranteeing publication rights are amongst the most neglected. In reporting on the results in domain 3 (Who reviews and makes decisions about FCOI), we have treated each item as if it were independent of the others;

however, this is probably not the case. As an example, if FCOI is disclosed to the department chair then it may not be necessary to additionally disclose it to the dean of the faculty. As a result, we may have underestimated coverage in this domain. Finally, although other forms of COI exist, we focused only on FCOI as we consider this the most important area.

CONCLUSION

Centers within the same level (for instance, hospitals) differ significantly in the areas that their policies address and similarly, individual policies differ widely in their coverage. Presently, no single policy in any Canadian center informs researchers about the broad range of investigator FCOI issues and some areas such as strategies for managing FCOI and publication rights are not addressed at all. Canadian investigators need to understand the environment surrounding FCOI in the teaching hospitals where they work. They must be able to easily access and follow the relevant policies and to be confident that they can avoid entering into a conflict situation that can be perceived to, or actually does, compromise their research.

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