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Comparison of Conflict of Interest Policies and Reported Practices in Academic Medical Centers in the United States

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Abstract

Purpose—To assess the level of consistency between academic medical centers' conflict of interest policies and reported practices.

Method—The authors reviewed the written conflict of interest policies of 9 academic medical centers in the United States and interviewed members of the institutional review boards (IRBs) and conflict of interest committees (COICs) at those institutions. Topics of interest included communication between IRBs and COICs, processes for reporting and managing conflicts of interest, and disclosure of conflicts of interest to potential research participants.

Results—Reported relationships between IRBs and COICs varied, but only 2 institutions had written policies governing these relationships. Many institutions used processes for reporting and managing conflicts of interest that were more decentralized than the processes described in their formal policies. Policies and practices regarding disclosure of conflicts of interest also varied. At most institutions, no clear and comprehensive policy existed to guide investigators regarding disclosure of financial conflicts of interest to potential research participants.

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Conclusions—This study confirms the need to ensure that institutions' practices match their policies. Considerable differences in understanding of conflict of interest policies were observed between IRB and COIC officials, suggesting that clear, comprehensive, and well-disseminated policies may lead to more consistent practice within institutions.

Introduction

Although biomedical research has historically been funded in large part by the federal government and private philanthropies, in recent years private industry has provided the majority of support.[1] In the past decade, 57% of funding for all biomedical research in the United States came from industry sources.[2] The dominance of industry in funding biomedical research has led to concerns about the quality, outcomes, and dissemination of research and has increased public scrutiny of relationships between academic medical centers and commercial enterprises. Government agencies[3-6] and professional organizations[7-9] have made recommendations regarding conflicts of interest in research. Many of these statements suggest that institutions should extend their formal conflict of interest policies for federally funded research to commercially funded human subjects research.

Researchers have examined how academic medical centers manage conflicts of interest,[10-12] as well as the attitudes of investigators and patients toward conflicts of interest in clinical research.[13] One study assessed what investigators at two California universities knew about their institutions' conflict of interest policies and found substantial discrepancies between what was stated in the policies and what investigators knew about them.[13] In a recent study, we found that the policies of 57 of 120 (48%) academic medical centers made reference to disclosing financial conflicts of interest to potential research participants.[14] Of these institutions, 33 included template language in their policies that could be used in informed consent documents. These policies showed considerable variability concerning the specific information that should be disclosed, and most policies seemed designed to address regulatory requirements or to protect against potential legal action. One limitation of the study was that the policies may not have been current with respect to actual practices.

Although the amount of research regarding conflicts of interest in clinical research continues to increase, no study has compared the understanding and practices of institutional review board (IRB) and conflict of interest committee (COIC) officials with the written policies of the institutions in which they work. We sought to assess the consistency between formal conflict of interest policies and reported practices in selected academic medical centers in the United States.

Methods

We combined data from two studies conducted by members of our study team. The first study reviewed all publicly available policies of academic medical centers in the United States regarding disclosure of financial conflicts of interest to potential research participants.[14] The second study consisted of interviews conducted with investigators, IRB members, and COIC officials at selected academic medical centers.[15] The institutional review boards of the Duke University Health System and the Johns Hopkins Medical Institutions approved this study.

Policy Review

We identified the 123 academic medical centers with internal IRBs in the United States and obtained their institutions' written policies regarding conflicts of interest in research. The conflict of interest policies were content-coded for the following information: whether disclosure of conflicts of interest to potential research participants was required; whether specific language regarding conflicts of interest was proposed; internal reporting requirements

for conflicts of interest; the level of discretion of the IRB in managing conflicts of interest; and the type of communication mandated between the IRB and the COIC. [14]

Interview Study

We selected 10 academic medical centers from among the top 40 medical institutions as ranked by grant awards from the National Institutes of Health. We attempted to interview the chairpersons of the IRB and the COIC at each institution. Interview transcripts were coded with content codes derived from the main domains of the interview script. The final list of content codes included codes for the process of reporting conflicts of interest, the type of communication between the IRB and the COIC, the level of discretion of the IRB in managing conflicts of interest, and whether disclosure to potential research participants is required in the informed consent document. These methods are detailed elsewhere.[15]

Comparison of Policy Review and Interview Studies

For the comparison between the policy review and interview studies, we examined the interviews of all COIC officials (n = 7) and IRB officials (n = 8) and compared the respondents' answers with the codes from the policy reviews for the matching institutions. The goal of this analysis was to determine the degree of concordance between academic medical centers' written conflict of interest policies and the oral responses of the IRB and COIC officials about those policies. We compared the written policies and interview data with respect to the following issues: the type of communication between the IRB and the COIC, whether there is joint membership between the committees, the committee to which conflicts of interest are reported, the level of discretion of the IRB in managing conflicts of interest, whether disclosure to potential research participants is required, and information regarding template disclosure language.

Communication

Both the written policies and the interview transcripts were coded for the direction of communication between the IRB and the COIC. Coding options included unidirectional (ie, the IRB contacts the COIC only, or vice versa), bidirectional (ie, the IRB and the COIC communicate with each other), and no communication. The written policies also were coded for whether there was mention of joint membership between the IRB and the COIC. These data were compared to the interviews in which IRB and COIC officials were asked if there was joint membership between the two committees. The responses for this question were coded as no joint membership, full joint membership, or nonvoting/liaison membership.

Reporting and Management

Another area of comparison was the requirement to report conflicts of interest. The written policies were coded according to whether they stated that conflicts of interest should be reported to the COIC, the IRB, both groups, or some other reporting requirement. We compared this information to the interview responses coded as "process for reporting conflicts of interest," and we analyzed the data according to whether the IRB and COIC officials referred to the same reporting requirement mentioned in their institutions' written policies.

Both the written policies and the interview transcripts were also coded for the "level of discretion of the IRB," or the level of authority that the IRB has in determining how conflicts of interest will be managed. Options included the IRB having no discretion, partial discretion, or full discretion.

Disclosure

We examined the written policies to determine whether disclosure to potential research participants was mentioned explicitly. This information was compared to the interviews in which IRB and COIC officials were asked whether disclosure to potential research participants is required at their institutions. Finally, we reviewed the written policies to determine whether the institutions provided template language to be used when disclosing conflicts of interest to potential research participants. Although IRB and COIC officials were not asked explicitly whether their institutions provided template language for disclosure of conflicts of interest, we later reviewed the interview transcripts to determine whether any voluntary mention of template language was made during the interview.

Results

Of the 10 academic medical centers selected for the interview study, officials at 9 institutions agreed to participate. A total of 8 IRB officials and 7 COIC officials from these institutions were interviewed, with 6 institutions represented in the study by both IRB and COIC officials. In the discussion that follows, quotations from the interviews are indexed by a unique identifier (A = IRB official, B = COIC official). We do not quote directly from the written policies, because the policies are readily available on the Internet, and quoting from them could undermine the confidentiality of participants' responses.

Communication

Two institutions had at least 1 written policy that explicitly described bidirectional communication between the IRB and the COIC. Both the IRB and COIC officials from these institutions described IRB-COIC communication consistent with their formal policies (Table 1). Most institutions did not have a formal policy describing the type of communication between the IRB and the COIC. Nevertheless, most COIC and IRB officials agreed about the type of communication they employed (Table 1). COIC officials from 2 institutions did not respond to our invitation to be interviewed. According to the IRB officials at those institutions, the IRB and the COIC did not interact at all.

To further assess the degree of communication between COICs and IRBs, we asked whether joint membership on the two committees was allowed or required. The prevalence of joint membership covered the full range of possibilities, including no joint membership, nonvoting joint membership, and full joint membership. Half of the interview participants agreed about the status of joint membership at their institutions (Table 2). IRB and COIC officials from 2 institutions appeared to disagree about the status of joint membership at their institutions. When asked if there was joint membership, one IRB official responded:

> I think both committees take a lot of time, and it would be hard to imagine that anybody would have enough time or energy to be on both. There are certainly people on the Conflict of Interest Committee who have served at one time or other on the IRB. I am not sure I know of anybody who has a history of being on the Conflict of Interest Committee who is now on the IRB, but it is possible. But I think that is about the only way that there is really shared membership. [8-A]

The COIC official from the same institution stated, "We have two IRB staff members that sit as staff on the committee. They are nonvoting members." [1-B] It is important to note that there is some ambiguity in this statement as "IRB staff" may or may not refer to board members. At 2 other institutions, the IRB officials did not know who served on the COIC.

None of the institutions had policies that mentioned joint membership. Similarly, no interview respondents cited guidelines, policies, or specific restrictions regarding joint membership.

Instead, the interviewed officials described the membership that existed at the time of the interview.

Reporting and Management

We also examined how conflicts of interest are reported and managed at the respondents' institutions. We asked the COIC and IRB officials how they become aware that an investigator has a potential financial interest in research. According to the interviews, practices varied among the institutions, with most institutions having potential financial interests reported to the COIC via forms accompanying grant or research applications, annual disclosures made by faculty, or a combination of the two. We found general agreement between the IRB and COIC officials on this topic, but there were some exceptions (Table 3).

Many institutions used processes for reporting and evaluating conflicts of interest that were more decentralized than the processes described in their formal policies. For example, many institutions allowed for low-level conflicts of interest to be addressed by department chairs, without review by the COIC, despite written policies to the contrary. At 1 institution, the written conflict of interest policy required financial relationships to be disclosed to the COIC. However, the IRB official from that institution [12-A] reported that "those declarations...are reviewed by the chair of the department, and it stops there if there is no conflict or no perceived conflicts of interest. If there is a conflict, then it goes to the [COIC] chair, and if it is a trivial one or one that is not really relevant to the issues of [COIC], then the chair of the [COIC] signs off on it."

Similarly, another institution's policy stated that disclosure forms would be reviewed by the COIC, but the IRB official described a system with many intermediate steps not outlined in the policy:

The disclosure goes to their department chair, who does the first-pass review of it. And, depending on the school or institution, it may go to the dean or director, as well. Then, after that, it comes to the [COIC] for review and management. [6-A]

We also asked respondents about the level of discretion that the IRB has in managing conflicts of interests. Many officials agreed that the COIC makes recommendations regarding what actions or management strategies should be adopted, and the IRB has the authority to accept or strengthen—but not weaken—the recommended conflict management (Table 4):

> Our IRB cannot lessen the recommendation made by the committee, but they can strengthen it. So, if they feel that the committee has not adequately addressed human subjects safety needs, from conflicts of interest perspective, they could say, "No, we think the conflict is too significant. The investigator cannot participate." Or they could say, "We think we need to have additional oversight of this study." They can strengthen it, but they cannot weaken it. [1-B]

At other institutions, COIC recommendations were generally accepted by the IRB, with 1 official stating, "They say that they accept our recommendations. They agree that they have enough to do. They do not need to second-guess ours." [7-B]

At other institutions, it was less clear what was done with recommendations made by the COIC:

> Interviewer: Do they have to accept that recommendation?
>
> Respondent [2-B]: I don't know. I don't actually quite know what they do with that.

Only 2 of the written policies stated whether the IRB had final authority for determining conflict of interest management strategies. Most conflict of interest policies made more general

statements saying that officials would do what was necessary to effectively manage conflicts of interest and ensure the integrity of the institution.

At 1 institution where the policy provided no clear guidance, the oversight officials had devised an unofficial policy to help guide actions in the case of disagreements between the IRB and COIC. One COIC official stated:

> We did, however, come up with a policy a while ago that I think says something about what we do if there is a disagreement.... And, as I said, it has not happened yet. It is not an official university policy, but it is just sort of a procedural document that we wrote up and distributed to the IRB members and to the Conflict of Interest Committee members to clarify roles.... It says any disagreement between the two committees will be resolved by the committee chairs or by the vice president for research, if necessary. So it does not say definitely that the more strict management plan would be adopted, but just that it would be worked out. [6-B]

At the same institution, the IRB official stated, however, that the stricter management plan would always be adopted. Furthermore, there was no guidance set forth in the institution's written policy and no mention of the “unofficial” policy referred to by the COIC official. At another institution, exact language regarding IRB discretion was present in the policy. The policy, the IRB official, and the COIC official at this institution all agreed on the level of discretion. The policy explicitly stated that the IRB had final discretion when determining how to effectively manage conflicts of interest. In fact, when the COIC official was asked about the institution's policy on IRB discretion, the chair directly referenced the formal policy:

> Our policy provides, in fact, a specific clause. It says the IRB is authorized to do whatever in addition they think is necessary to preserve the protection of human subjects in a given study. So they can go above and beyond what we post. [9-B]

Disclosure to Study Participants

The majority of the interview respondents stated that some form of disclosure was required by their institutions, and the IRB and COIC officials largely agreed with one another (Table 5). The threshold for disclosure varied greatly among the institutions, with 2 institutions requiring complete disclosure:

> Our stance on that is we disclose to, regardless of the value of financial interest, we disclose to any research participant in which there is any financial conflict of interest, regardless of the level. There is no threshold there, and that is always a part of our management. [1-B]

The remaining institutions had various thresholds for requiring disclosure, although all respondents agreed that any significant financial interest should be communicated to study participants. One IRB official expressed the commonly held view that participants should be notified “whenever there is a significant financial interest on the part of the investigator, coinvestigators, or study staff who are involved in the project.” [6-A]

One official mentioned a specific financial threshold that triggered the required disclosure, although they stated that many researchers voluntarily disclosed interests below the threshold. Not every official agreed, however, that all conflicts of interest should be disclosed regardless of the magnitude of the financial interest. One COIC official expressed the opinion that information about low-level financial interests was not material to potential research participants:

> Well, again, I think it has to be on a per-protocol basis. For example, if somebody is developing or evaluating a new technology that they have developed and happen to

> own a company that has licensed that technology and stands to make a small fortune if it were to work, I think people ought to know about that kind of relationship. If it is someone who has given a couple of lectures for the company across the United States, and they are sponsoring the study that the patient is involved in, I am not sure that it is critical that they know that professor X made $20 000 last year giving seminars about this treatment across the country. [9-B]

The nature of the information to be disclosed also varied greatly among the institutions. One official described a disclosure statement that contained detailed quantitative information:

> [I]n that disclosure statement, there will be one or two disclosures made. One disclosure would be the conflict of interest, or the nonfinancial conflict of interest if the health care provider is also the investigator. And two would be any financial or economical conflicts of interest.... The level of detail is typically something to the effect of the investigator, regarding financial conflicts of interest, and we have described investigator so-and-so, Dr X, received up to $500 in the last year for giving talks for a sponsor company X. OK, something like that investigator is the president, secretary, and chief bottle washer for a company X, which is sponsoring the study that you are being asked to participate in. Or Dr X owns $10 000 stock in company Y. So it is pretty explicit disclosure. [19-A]

Most institutions did not require specific, quantitative information in their disclosures:

> There is at a minimum a statement if it is true that the sponsor named is paying the investigator named to conduct this study. Or the sponsor is providing funds to [the institution] for the investigator named to conduct the study. Numbers are not put in ever. [22-A]

None of the conflict of interest policies described what level of information should be provided to study participants; however, 2 institutions included specific template language for notifying potential research participants about who was paying for the study. For example, 1 institution included a statement in all consent forms, when applicable, that provided the name of the sponsor and specified that the principal investigator was being paid by the sponsor to conduct the study.

At the majority of institutions, no clear and comprehensive policy existed to guide investigators regarding disclosure of financial conflicts of interest to potential research subjects.

Discussion

In this study, we compared academic medical centers' written policies on conflicts of interest with the practices described by officials charged with oversight of conflicts of interest. One of the most striking findings was the extent to which institutional policies did not seem to guide actual practice as reported by IRB and COIC officials. We often found that, in the absence of explicit language in formal policies, oversight officials did not always agree about the actual practices of the institution. This finding conflicts with the 2001 recommendation of the Association of American Medical Colleges (AAMC) that "institutional policies governing financial interests in human subjects research should be comprehensive, unambiguous, well-publicized, consistently applied, and enforced through effective sanctions."[7]

In some cases, what was agreed upon by IRB and COIC officials did not reflect or was not included in formal policies. In practice, the majority of IRB and COIC officials mentioned communication between the committees, but only 2 of the 9 policies described or mandated such interaction. For institutions where both IRB and COIC officials were interviewed, the officials generally agreed about whether the IRB had final authority over the management of conflicts of interest in human subjects research, although this issue was not addressed in the

written policies. According to the 2001 AAMC guidelines, “institutional policies should specify which responsible institutional officials are empowered to make final and binding decisions about who may conduct IRB-approved research.” Our findings suggest that either increased adherence or modifications to this guideline is needed. Finally, almost all officials agreed on the degree of disclosure required, although only 2 of the 9 written policies provided direction in this regard. In these instances, formal policies did not appear necessary to ensure agreement among interviewed officials; however, such discrepancies between policy and practice contrast with the AAMC recommendation that all institutions should have “comprehensive, unambiguous policies” so as to achieve significant or complete compliance.

Discrepancies also appeared in several institutions between the statements of IRB officials, the statements of COIC officials, and written policies. The clearest example was the lack of agreement concerning joint membership between the IRB and the COIC and their respective policies. Nearly a third of the institutions’ IRB and COIC officials were not in agreement about joint membership, and the issue was not addressed in written policies. In these cases, the IRB officials were unaware that IRB members have the option of joint membership with the COIC at their institutions.

At institutions with clear written policies, there was rarely inconsistency between the responses of the IRB and COIC officials. One institution's policy contained precise language regarding IRB discretion. This was the only institution at which the policy, the IRB official, and the COIC official agreed on the level of discretion. In fact, the COIC official cited the policy, indicating that the existence of clear guidelines is linked to consistent application of policy. Additional examples of the relationship of clear policy with reports of consistent practice were 2 institutions where the conflict of interest policies provided template disclosure language. All officials from these institutions were aware of the template, its content, and its practical application.

We found a reasonable level of knowledge of policy among oversight officials, but substantial areas in which officials in the same institutions did not interpret their policies the same way. This finding raises concerns about which aspects of written policies are likely to be implemented as intended. When explicit written policies existed, as was the case regarding IRB discretion at 1 institution, the policy was referenced directly by both the IRB and COIC officials. Similarly, written template language for consent forms also provided guidance. In general, explicit language appeared to guide practice. Policies that were vaguely worded, as in the majority of the institutions we studied, appeared to be less effective in ensuring thorough, consistent application.

The main limitation of this study is that data were available for only 9 institutions, of which only 6 yielded a comprehensive data set, including written policies and interviews from both IRB and COIC officials. Due to the small number of institutions, the results of the study may not be applicable to all academic medical centers. However, the institutions we examined are ranked among the top 40 institutions with regard to grant awards from the National Institutes of Health. One study found that “the top 40 institutions reflect greater consistency with core AAMC recommendations” than those ranked 41 and below with regard to conflict of interest practices in clinical research.[16] Thus, the lack of policy specificity that we observed in a subset of top-ranked institutions may be even more widespread among less research-intensive institutions.

Many reviews of academic medical centers in the United States have documented substantial variations in conflict of interest policies, with most policies considered inadequate.[11,12] In recent years, academic observers and others have called for uniform conflict of interest policy standards to reduce inconsistencies across institutions and thereby enhance public trust in the

biomedical research enterprise.[17,18] Our study confirms the need to ensure that institutions' practices match their policies.

Regardless of the differences identified among academic medical centers, published and widely cited recommendations by the AAMC and other organizations[3-9] suggest that policy should more clearly guide practice. In this study, considerable differences in understanding of conflict of interest policies were observed between IRB and COIC officials, suggesting that clear, comprehensive, and well-disseminated policies may lead to more consistent practice within institutions. Although written policies were for the most part readily available on the Internet, it is unknown whether the policies are publicized to committee members. Limited and imprecise policies may result when institutions place priority on risk management but wish to avoid overly prescriptive policies and poor compliance. Written policies that are vague and general may also afford institutions flexibility in adapting practices to changing needs and varying circumstances. This is especially likely in a relatively new field, such as conflict of interest management, in which best practices are still emerging and evolving. An additional area of interest is how the potential research participants view disclosure of conflicts of interest and whether their ability to understand these disclosures have potential implications for how policies should be developed and implemented. We explored this topic in a recent study.[19]

As institutions grapple with formulating new policies or revising their existing policies in light of evolving and increasing concerns about financial conflicts of interests in research, they should take into account the findings reported here. Specifically, they should consider reviewing concurrently their IRB and COIC policies; involve IRB and COIC officials in the process; use explicit language in policies to describe processes such as communication of conflicts of interest to the IRB; and vet draft policies not only with the leadership of these committees, but also with their members. Such an approach promises to bring coherence to the important process of managing conflicts of interest in research.

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References

1. Christensen JA, Orlowski JP. Bounty-hunting and finder's fees. IRB 2005;27:16–19. [PubMed: 16021797]
2. Moses H 3d, Dorsey ER, Matheson DH, Thier SO. Financial anatomy of biomedical research. JAMA 2005;294:1333–1342. [PubMed: 16174691]
3. Financial Conflict of Interest: Objectivity in Research. Office of Extramural Research, National Institutes of Health. 2002 [May 9, 2006]. Available at: http://grants.nih.gov/grants/policy/coi/nih_review.htm.
4. Chapter V: Grantee Standards. National Science Foundation. 2002 [May 9, 2006]. Available at http://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp.
5. Guidance: Financial Disclosure By Clinical Investigators. Food and Drug Administration. 2001 [May 9, 2006]. Available at: http://www.fda.gov/oc/guidance/financialdis.html.
6. NHRPAC Recommendations on HHS's Draft Interim Guidance on Financial Relationships in Clinical Research. National Human Research Protections Advisory Committee, US Department of Health and Human Services. Oct2001 [May 9, 2006]. Available at: http://www.hhs.gov/ohrp/nhrpac/documents/aug01a.pdf.
7. Task Force on Financial Conflicts of Interest in Clinical Research. Protecting Subjects, Preserving Trust, Promoting Progress—Policy and Guidelines for the Oversight of Individual Financial Interests

in Human Subjects Research. Association of American Medical Colleges; Washington, DC: 2001. p. 1-23.

8. American Society of Clinical Oncology. American Society of Clinical Oncology: revised conflict of interest policy. J Clin Oncol 2003;21:2394–2396. [PubMed: 12721282]
9. Financial Conflict of Interest in Clinical Research. American Society of Gene Therapy. 2000 [May 9, 2006]. Available at: http://www.asgt.org/position_statements/conflict_of_interest.html.
10. Boyd EA, Lipton S, Bero LA. Implementation of financial disclosure policies to manage conflicts of interest. Health Aff 2004;23:206–214.
11. Lo B, Wolf LE, Berkeley A. Conflict-of-interest policies for investigators in clinical trials. N Engl J Med 2000;343:1616–1620. [PubMed: 11096170]
12. McCrary SV, Anderson CB, Jakovljevic J, et al. A national survey of policies on disclosure of conflicts of interest in biomedical research. N Engl J Med 2000;343:1621–1626. [PubMed: 11096171]
13. Boyd EA, Cho MK, Bero LA. Financial conflict-of-interest policies in clinical research: issues for clinical investigators. Acad Med 2003;78:769–774. [PubMed: 12915362]
14. Weinfurt KP, Dinan MA, Allsbrook JS, et al. Policies of academic medical centers for disclosing conflicts of interest to potential research participants. Acad Med 2006;81:113–118. [PubMed: 16436571]
15. Weinfurt KP, Friedman JY, Dinan MA, et al. Disclosing conflicts of interest in clinical research: views of institutional review boards, conflict of interest committees, and investigators. J Law Med Ethics. In press
16. Ehringhaus, S.; Korn, D. U.S. medical school policies on individual financial conflicts of interest: results of a AAMC survey. Association of American Medical Colleges; Washington, DC: 2004 [June 8, 2006]. Available at: http://www.aamc.org/research/coi/coiresults2003.pdf.
17. Kassirer JP. Financial conflict of interest: an unresolved ethical frontier. Am J Law Med 2001;27:149–162. [PubMed: 11467107]
18. Martin JB, Kasper DL. In whose best interest? Breaching the academic-industrial wall. N Eng J Med 2000;343:1646–1649.
19. Weinfurt KP, Friedman JY, Allsbrook JA, et al. Views of potential research participants on financial conflicts of interest: barriers and opportunities for effective disclosure. J Gen Intern Med 2006;21:901–6. [PubMed: 16918732]

Table 1

Type of Communication Between IRB and COIC as Described by Institutions' Formal Policies, IRB Officials, and COIC Officials

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Policy	BD	BD	NS	NS	NS	NS	NS	NS	NS
IRB	BD	BD	BD	BD	BD	BD	ND	None	None
COIC	BD	BD	BD	BD	BD	BD	BD	ND	ND

IRB indicates institutional review board; COIC, conflict of interest committee; BD, bidirectional; NS, not specified; and ND, no data.

* Institutions in order of agreement.

Table 2

Joint Membership Between IRB and COIC as Described by Institutions' Formal Policies, IRB Officials, and COIC Officials

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Policy	NS	NS	NS	NS	NS	NS	NS	NS	NS
IRB	Joint	Liaison	Liaison	None	None	None	ND	None	None
COIC	Joint	Liaison	Liaison	None	ND	ND	None	Liaison	Liaison

IRB indicates institutional review board; COIC, conflict of interest committee; NS, not specified; Joint, joint membership; Liaison, nonvoting liaison membership; and ND, no data.

* Institutions in order of agreement.

Table 3

Committee to Which Conflicts of Interest Are Reported as Described by Institutions' Formal Policies, IRB Officials, and COIC Officials

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Policy	Both	COIC	COIC	COIC	Both	COIC	COIC	NS	COIC
IRB	Both	COIC	COIC	COIC	COIC	ND	IRB	IRB	Med
COIC	Both	COIC	COIC	Both	COIC	COIC	COIC	ND	ND

IRB indicates institutional review board; COIC, conflict of interest committee; NS, not specified; ND, no data; and Med, medical school.

* Institutions in order of agreement.

Table 4

Level of IRB Discretion in the Management of Conflicts of Interest as Described by Institutions' Formal Policies, IRB Officials, and COIC Officials

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Policy	Full	None	None	Full	None	None	None	NS	None
IRB	Full	Full	Full	Shared	Shared	NS	ND	Full	Full
COIC	Full	Full	Full	Shared	Shared	None	Unk	ND	ND

Full indicates IRB has full discretion; Shared, IRB and COIC share discretion; None, IRB has no discretion; NS, not specified; and ND, no data.

* Institutions in order of agreement.

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Table 5

Disclosure Specificity as Described by Institutions' Formal Policies, IRB Officials, and COIC Officials

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Policy	Explicit	Explicit	Vague	None	None	Vague	Vague	Vague	None
Disclosure required according to IRB official?	Yes	Yes	Yes	Yes	Yes	ND	Yes	No	No
Disclosure required according to COIC official?	Yes	Yes	Yes	Yes	Yes	Yes	ND	No	ND

Unk indicates unknown; and ND, no data.

* Institutions in order of agreement.

Table 6

Template Language

	Institution								
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Described by written policy?	Yes	Yes	No	No	No	No	No	No	No
Described by IRB official?	Yes	Yes	No	No	No	No	ND	Yes	Yes
Described by COIC official?	Yes	Yes	No	No	No	ND	No	No	ND

Unk indicates unknown; and ND, no data.

* Institutions in order of agreement.