SPECIAL ARTICLE

Financial Relationships between Institutional Review Board Members and Industry

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ABSTRACT

BACKGROUND

Little is known about the nature, extent, and consequences of financial relationships between industry and institutional review board (IRB) members in academic institutions. We surveyed IRB members about such relationships.

METHODS

We surveyed a random sample of 893 IRB members at 100 academic institutions (response rate, 67.2%). The questionnaire focused on the financial relationships that the members had with industry (e.g., employment, membership on boards, consulting, receipt of royalties, and paid speaking).

RESULTS

We found that 36% of IRB members had had at least one relationship with industry in the past year. Of the respondents, 85.5% said they never thought that the relationships that another IRB member had with industry affected his or her IRB-related decisions in an inappropriate way, 11.9% said they thought this occurred rarely, 2.4% thought it occurred sometimes, and 0.2% thought it occurred often. Seventy-eight respondents (15.1%) reported that at least one protocol came before their IRB during the previous year that was sponsored either by a company with which they had a relationship or by a competitor of that company, both of which could be considered conflicts of interest. Of these 78 members (62 voting members and 16 nonvoting members), 57.7% reported that they always disclosed the relationship to an IRB official, 7.7% said they sometimes did, 11.5% said they rarely did, and 23.1% said they never did. Of the 62 voting members who reported conflicts, 64.5% reported that they never voted on the protocol, 4.8% said they rarely did, 11.3% said they sometimes did, and 19.4% said they always did. Most respondents reported that the views of IRB members who had experience working with industry were beneficial in reviewing industry-sponsored protocols.

CONCLUSIONS

Relationships between IRB members and industry are common, and members sometimes participate in decisions about protocols sponsored by companies with which they have a financial relationship. Current regulations and policies should be examined to be sure that there is an appropriate way to handle conflicts of interest stemming from relationships with industry.

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The clinical research enterprise rests on a belief in the integrity of both researchers and the results of their research. Relationships with industry at the level of the individual and the institution have the potential to undermine this confidence.[1-9]

The focus of concern has been on academic investigators and their relationships with industry.[10,11] However, the relationships between academic institutions and industry are also being scrutinized.[12] Of additional interest is the extent to which relationships with industry may affect members of institutional review boards (IRBs). Because IRBs are responsible for overseeing and protecting the safety and well-being of research participants, they should be free of undue influence by financial interests or by the appearance of such interests.[12,13]

Federal regulations anticipated the potential for conflicts of interest among IRB members and require that ". . . no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."[14] Close and remunerative associations between IRB members and industry raise questions about conflicting interests, yet little is known about the extent of these relationships or whether they influence the attitudes and behaviors of IRB members.[15]

METHODS

SAMPLE

We developed our sample in two steps. First, as in our previous research, we identified the 100 medical schools and the 15 independent hospitals that received the most funding from the National Institutes of Health (NIH) in 2003.[16] Second, at each institution we sought lists of IRB members from the Office for Human Research Protections (OHRP) and from the institutions themselves. Of the 115 institutions, 15 were excluded because a list of IRB members was not received within a year (5 institutions), the list of names provided was more than 2 years out of date (8 institutions), or the list of names was for an IRB that did not review medical research (2 institutions).

This process resulted in a list of 3946 IRB members at 100 institutions. From this list we drew a simple random sample of 893 IRB members. The resulting sample was self-weighting and therefore reflected the underlying distribution of the population of IRB members across institutions.

DEVELOPMENT OF THE SURVEY INSTRUMENT AND TESTING

The questionnaire was informed by four focus groups of IRB members. Seven cognitive interviews were used to test for uniformity in comprehension and for the comfort of the respondent with the response tasks.[17] In addition, we mailed a pretest of the questionnaire to 52 IRB members. When completed, the final questionnaire was eight pages long and took approximately 20 minutes to complete (see the Supplementary Appendix, available with the full text of this article at www.nejm.org).

ADMINISTRATION OF THE SURVEY

The survey was administered by mail between April and June 2005. Subjects were sent the questionnaire, an introductory letter, a fact sheet, a confidentiality statement, a postage-paid return envelope, and a postcard. They were asked to return the survey (which contained no identifying information) separately from the postcard (which included the subject's name), to indicate that they had completed the questionnaire. This process simultaneously preserved the anonymity of the responses and identified those subjects who did not respond.

Approximately 2 to 3 weeks after the initial mailing, subjects who had not responded were contacted by telephone and encouraged to complete the questionnaire. A second set of survey materials was mailed to subjects who indicated that they would complete the questionnaire. Additional telephone contact was made with nonrespondents.

RELATIONSHIPS WITH INDUSTRY

We asked IRB members whether, in the past year, they had held any of the following positions with a company: officer or paid employee, member of a board of directors, paid consultant, member of a scientific advisory board, recipient of royalties (e.g., patent licenses or milestone payments), or member of a speakers bureau. Similarly, we asked whether, in the past year, they had received from an industry source any funding for university or hospital research, support for students or postdoctoral fellows, equity in exchange for professional services or intellectual property, or compensation for participation in meetings, conferences, or other activities.

To measure the potential positive consequenc-

es of the relationships between IRB members and industry, we asked members to estimate the benefits of the relationships with industry in terms of conveying the scientific superiority of the drug, device, or other product in comparison with others currently on the market, as well as providing an understanding of industry standards for data management, the effect of industry regulations on study design, the use by industry of multiphase or multisite trials, and industry requirements for secrecy. To measure the potential negative consequences of the relationships between members and industry, we asked members how often in the past year of IRB service they thought an IRB member's relationship with a company inappropriately affected his or her IRB-related decisions. We also asked how frequently they thought a protocol was presented in a biased way because of a member's relationship with industry, whether a member did not properly disclose a relationship with industry, and whether they believed that their IRB failed to take appropriate action regarding the relationship of an IRB member with industry.

DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

We asked members whether their IRB had a defined process by which they could disclose their financial and other relationships with industry to the IRB. We also asked them to indicate the actions of their IRB regarding such relationships, including whether "IRB members are specifically asked about or are expected to complete a form documenting their financial and other industry relationships when joining the IRB" or whether "financial and other relationships are openly discussed in IRB meetings or other IRB forums."

CONFLICTS OF INTEREST

Conflicts of interest occur when primary interests may be superseded by a secondary interest.[18] The primary interest of IRBs is to ensure the rights, safety, and welfare of human subjects.[15] All other interests are secondary and may include financial gain, professional status, power, or recognition. These secondary interests, although not improper in and of themselves, can conflict with the primary interest. When the relationship of an IRB member with industry conflicts with the protection of human subjects, a conflict of interest exists. However, not all relationships with industry are conflicts of interest. Rather, conflicts of interest are a subgroup of all relationships with industry that may unduly influence or supersede the primary interest of protecting human subjects. In order to understand how conflicts of interest are identified, we asked, "Does your IRB have a written policy that defines when an IRB member's financial or other industry relationship is a conflict of interest?"

To estimate whether respondents had one specific form of conflict of interest with industry, we asked, "During your most recent year of IRB service, about how many protocols came before your IRB that were either sponsored by a company with which you personally had a relationship . . . or sponsored by a company that was in competition with a firm with which you had a personal relationship?" The possible responses were as follows: none, 1 or 2 protocols, 3 to 5 protocols, 6 to 10 protocols, and more than 10 protocols. Respondents who checked any category other than "none" were considered to have had a conflict of interest, even if their interactions with the company and the protocol under consideration were in different therapeutic areas (e.g., a consultation about antiinfective agents and a protocol for a study of antihypertensive agents). Respondents who had a conflict of interest were asked, "For the protocols involving companies with which you had relationships of these kinds, how often did you [do the following]: disclose the relationship to the IRB and an IRB official, leave the room when the protocol was under consideration, partially participate in the discussion by only responding to specific questions, fully participate in the general discussion, or vote on the protocol?"

STATISTICAL ANALYSIS

The data were analyzed with the use of the frequency and chi-square procedures in SPSS software. Because of the random-sample design, weighting after sampling was not necessary. Furthermore, because responses were anonymous, we could not weight the responses for differential nonresponse, nor were we able to perform analyses within individual IRBs or institutions.

RESULTS

CHARACTERISTICS OF THE RESPONDENTS

Of the 893 IRB members in the survey sample, 39 were ineligible because they either were deceased or were no longer members of the IRB at the institution in which they were sampled. Of the remaining 854 eligible subjects, 574 completed a

Table 1. Characteristics of the Respondents.

Characteristic	All Respondents*
	no. (%)
Male sex	313 (55.6)
Female sex	250 (44.4)
Race or ethnic group	
American Indian or Alaskan Native	7 (1.3)
Asian or Pacific Islander	26 (4.7)
Black	22 (3.9)
Hispanic	27 (4.8)
White	486 (87.1)
Other	4 (0.7)
Professional	
Holds faculty appointment	
Yes	395 (69.5)
No	173 (30.5)
Academic rank	
None	135 (25.8)
Instructor or lecturer	23 (4.4)
Assistant professor	107 (20.5)
Associate professor	138 (26.4)
Professor	120 (22.9)
Conducts clinical research involving living human subjects	
Yes	440 (77.6)
No	127 (22.4)
IRB	
Voting member of IRB	
Yes	439 (78.7)
No	119 (21.3)
Member type	
Member affiliated with the institution	473 (87.1)
Member not affiliated with the institution or a community member	70 (12.9)
Use of primary review system†	
Yes	544 (97.7)
No	13 (2.3)
Attended meetings (mean % of meetings attended)	555 (79.3)
Was the primary reviewer for protocols	551
Median no. of protocols	13

* The number of respondents varies among categories because of missing data.

† The actual survey item read, "In your most recent year of IRB service, did your IRB use a primary reviewing system, where certain individuals were assigned primary or 'in-depth' review responsibilities for the group?"

questionnaire, for a response rate of 67.2%. The characteristics of the respondents are shown in Table 1.

RELATIONSHIPS OF THE IRB MEMBERS WITH INDUSTRY

Of the respondents, 22.6% had received funding for research from industry in the previous year; 17.4% had received compensation for participation in meetings and conferences; 14.5% had served as a consultant; 14.2% had served as a member of a speakers bureau; 10.0% had been members of a scientific advisory board; 2.0% had served as an officer, an executive, or a paid employee; 1.2% had received royalties or equity; and 1.1% had served on a board of directors (Table 2). Altogether, 36.2% of IRB members had had at least one of these types of relationship with industry.

Some members reported multiple relationships with industry. Of all IRB members who responded to the questionnaire, 12.8% said they had had one type of relationship with industry in the previous year, 13.7% said they had had two or three types, and 9.8% reported four or more types.

EFFECTS OF RELATIONSHIPS WITH INDUSTRY

Most of the IRB members (85.5%) reported that in the past year they never thought that the relationship between another member and industry inappropriately affected his or her IRB-related decisions. However, 11.9% thought this happened rarely, 2.4% thought it happened sometimes, and 0.2% thought it happened often (Table 3). Similar rates were reported for questions about whether the respondent thought that a protocol had been presented in a biased manner because of a member's relationship with industry (sometimes, 2.7%; often, 0.4%) and about lack of proper disclosure by another member of his or her relationship with industry (sometimes, 1.8%; often, 0.2%).

Respondents also reported potential benefits of the relationships between IRB members and industry. According to 27.2% of the respondents, it was a large benefit to have members who had experience working with industry and who could convey the scientific benefit of a drug or medical device or product in comparison with others currently on the market.

DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

Of the respondents, 67.0% said that their IRB had a formal process for members to disclose their

relationships with industry. The remaining 33.0% said no such process existed or they did not know of one. When asked what their IRB did regarding the disclosure of relationships with industry, 49.1% of the respondents reported that when joining the IRB, they were required to fill out a form documenting their relationships, and 45.6% said that the relationships were openly discussed by their IRB.

CONFLICTS OF INTEREST

Almost half of all IRB members (45.8%) reported that their IRB had a formal written definition of what constituted a conflict of interest, 12.1% said no such definition existed, and 42.2% did not know. Table 4 provides the percentages of members who reported that at least one protocol came before their IRB for review in the previous year that was sponsored either by a company with which they had a relationship or by a company in competition with a firm with which they had a relationship. Of all respondents, 15.1% had this type of conflict of interest at least once in the previous year.

Table 4 also shows the actions that were taken when such a conflict of interest occurred. For example, in the year before the survey, 3.4% of all respondents reported that they had had a conflict of interest and never disclosed it, 1.6% reported that they had rarely disclosed it, and 1.1% reported that they had sometimes disclosed it. Taken together, 6.1% of all IRB members had had a conflict of interest at least once in the previous year but had not disclosed it. As a second example, 10.4% of all respondents reported that they had had a conflict of interest but never voted on the protocol, whereas 5.1% had voted on at least one protocol with which they had had a conflict of interest in the previous year.

We performed an analysis of the 6.9% of IRB members who had a conflict of interest who either freely participated in the general discussion of a protocol or voted on a protocol from companies with which they had relationships. We found that these members were significantly more likely to be consultants to industry than were the following: IRB members who had relationships with industry but who did not engage in these activities (56.4% vs. 35.0%, $P=0.01$), members of speakers bureaus (66.7% vs. 32.7%, $P<0.001$), recipients of reimbursements for participation in conferences (74.4% vs. 41.8%, $P<0.001$), and members of a scientific advisory board (41.0% vs. 24.4%, $P=0.03$).

Table 2. Frequency of Relationships with Industry in the Previous Year of IRB Service.*

Item	Respondents (N=563)†
	%
Received any funding for university or hospital research from any industry source	22.6
Received compensation from industry for participation in meetings, conferences, or other activities	17.4
Was a paid consultant for a company	14.5
Was a member of the speakers bureau for a company	14.2
Was a member of a scientific advisory board for a company	10.0
Received any support for his or her students or postdoctoral fellows from an industry source	6.9
Was an officer, executive, or paid employee of a company	2.0
Received royalties (e.g., patent licenses or milestone payments) from a company	1.2
Received equity in a company in exchange for professional services or intellectual property	1.2
Was a member of a board of directors for a company	1.1
Had any of the relationships described above	36.2
Number of relationships with industry	
0	63.8
1	12.8
2 or 3	13.7
4 or more	9.8

* See the Supplementary Appendix for the actual wording of the questions.
† The number of respondents varies among categories because of missing data.

DISCUSSION

These results raise several important issues regarding relationships between industry and IRB members at universities and independent hospitals. Clearly, such relationships occur frequently and multiple relationships exist, suggesting that IRBs need to attend to the disclosure and management of relationships between industry and their members in much the same way that during the past two decades, medical schools and universities have given attention to relationships between industry and faculty members. In addition, a small percentage of IRB members with conflicts of interest report having participated in discussions or voted

Table 3. Effects of Relationships with Industry on IRBs.*

Question	No. of Respondents	Response			
		Never	Rarely	Sometimes	Often
		percent			
In the most recent year of IRB service, how often have you . . .					
Thought an IRB member's relationship with a company inappropriately affected his or her IRB-related decisions?	553	85.5	11.9	2.4	0.2
Thought that a protocol was presented in a biased manner because of a member's relationship with a company?	553	84.4	12.5	2.7	0.4
Thought that a member did not properly disclose a financial relationship?	543	86.9	11.0	1.8	0.2
Believed that your IRB failed to take appropriate action regarding a member's relationships with a company?	547	92.9	5.5	1.5	0.2
		No Benefit	Small Benefit	Large Benefit	
			percent		
Of what added benefit are the views of IRB members who have previous or ongoing experience working with industry on the following:					
Conveying the scientific benefit of the drug, device, or product in comparison with others currently on the market?	544	28.5	44.3	27.2	
Understanding industry standards for data management?	543	23.9	43.8	32.2	
Understanding the effect of industry regulations on study design?	542	22.7	40.8	36.5	
Understanding industry's use of multiphase or multisite trials?	542	27.3	39.1	33.6	
Understanding industry requirements for secrecy?	543	46.2	35.4	18.4	

* The number of respondents varies among categories because of missing data. Percentages may not total 100 because of rounding. See the Supplementary Appendix for the actual wording of the questions.

on proposals, suggesting possible violations of federal regulations.

More than half the IRB members reported that their IRB did not have a formal process for disclosure of relationships with industry or that they did not know of one (which is the functional equivalent of not having a process). This may be viewed as problematic and suggests that current policies and practices regarding the disclosure of such relationships among IRB members should be examined.

The results were similar for the identification of conflicts of interest. Twelve percent of members said that their IRB had no formal definition of a conflict of interest, but more than 40% did not know whether such a definition existed for their IRB, suggesting that a large number of members are unfamiliar with their IRB's policies. These findings suggest a relative lack of clear policies and guidance, which if true, could lead to variation within and among IRBs and institutions regarding which relationships are considered conflicts of interest and which are not. Such variation may make it difficult for institutions and policymakers to measure the frequency with which conflicts of interest occur and what, if anything, is done about them.

Our survey suggests that the relationships of

Table 4. Conflicts of Interest among IRB Members Who Have Relationships with Industry.*

Question and Response	All Respondents (N=558)	Respondents with at Least One Relationship with Industry (N=202)
	percent	
During your most recent year of IRB service, how many protocols were reviewed by your IRB that were sponsored by a company with which you personally had a relationship or sponsored by a company that was in competition with a firm with which you had a personal relationship?		
None	84.9	61.9
1 or 2 protocols	9.1	22.3
3–5 protocols	3.4	9.4
6–10 protocols	1.3	3.5
More than 10 protocols	1.3	2.5
	All Respondents (N=560)	**Respondents with at Least One Conflict of Interest (N=78)**
	percent	
For the protocols involving companies with which you had a relationship or with which you had a relationship with a competitor, how often did you . . .		
Disclose the relationship to the IRB or to an IRB official?†		
Never	3.4	23.1
Rarely	1.6	11.5
Sometimes	1.1	7.7
Always	9.3	57.7
Leave the room while the protocol was under consideration?†		
Never	5.0	34.6
Rarely	2.1	15.4
Sometimes	1.4	10.3
Always	6.8	39.7
Limit participation in the discussion by responding only to specific questions?†		
Never	8.0	51.3
Rarely	2.7	17.9
Sometimes	3.0	21.8
Always	1.6	9.0
Fully participate in the general discussion?†		
Never	8.4	51.3
Rarely	2.3	16.7
Sometimes	2.0	14.1
Always	2.7	17.9
Vote on the protocol†‡		
Never	10.4	64.5
Rarely	0.7	4.8
Sometimes	1.6	11.3
Always	2.8	19.4

* See the Supplementary Appendix for the actual wording of the questions.
† Of all the respondents, 84.6% did not answer the question because they had had no conflicts of interest.
‡ This category was restricted to voting members (432 of all respondents and 62 of the respondents with at least one conflict of interest).

IRB members with industry have both positive and negative effects on IRBs. Although 15.6% of the respondents reported that they thought at least one protocol may have been presented in a biased way because of a member's relationships with industry, only 2.7% thought this happened "sometimes," and 0.4% thought it happened often. This finding suggests that the primary reviewer system, which IRBs depend on heavily, is functioning largely independently of the influence of the relationships between members and industry.

However, our data regarding the percentage of members who fully participate in discussions or vote on protocols with which they have a conflict of interest, even though these events are rare, suggest that additional scrutiny of IRB policy and practices related to the relationships between members and industry is warranted, since such behavior is in violation of federal regulations. Despite these concerns, it is reassuring that 92.9% of all respondents believe that their IRB always took appropriate action regarding a member's relationships with industry.

At the same time, many IRB members perceived beneficial effects of relationships with industry, including the conveyance of the scientific superiority of an investigational drug or medical device or product in comparison with others currently on the market, and improved understanding of industry standards for data management. The extent to which these benefits can be derived from sources outside the IRB is unknown, but it is likely that banning members from having industry relationships would have a deleterious effect on IRBs.

These perceived benefits may reflect the dependence of IRBs on investigators who have experience in clinical research and may also have relationships with industry. This causes a predicament — namely, that those who are most knowledgeable are also most likely to have relationships with industry that create conflicts of interest. Suggestions for balancing these perceived benefits and risks include encouraging experienced investigators who have no relationships with industry to serve on the IRB and consulting with experts who do not have industry relationships and who are not IRB members.

This research has several limitations. First, subjects may have been unwilling to admit to engaging in behaviors that might be viewed by others as undesirable, such as having relationships with industry or conflicts of interest. Thus, our data may underestimate the actual frequency of such behaviors. It is also possible that the conflicts we identified were de minimis and that our data overestimate their effect. For example, by our definition, a person who served as a consultant to industry once in the previous year and received a modest honorarium (e.g., $1,000) is treated similarly to a person who had a significant ongoing relationship with a commercial entity and who received substantially larger payments as a result of equity relationships.

Second, our results may not apply to IRBs at institutions that are not research intensive. Because most of the respondents in our study are members of IRBs that operate under institutional assurances of compliance to federal agencies and are subject to oversight and enforcement by the OHRP, it is possible that policies and practices are better developed at the institutions included in our sample than at many other institutions. Third, we were unable to determine how certain findings, such as reports of conflicts of interest, were distributed among the institutions we surveyed as a result of the procedures we used to protect the anonymity of the respondents.

Despite these limitations, our study provides both positive and negative findings with regard to relationships between industry and IRB members. Such relationships are not universally bad or good. Rather, they have risks and benefits. The goal from a public policy perspective is to encourage disclosure of these relationships and to identify conflicts of interest by means of clearly identified standards. When problematic relationships are discovered, IRBs must identify the steps that should be taken to eliminate or ameliorate the conflict. Failure to do so could call into question the ability of the IRB system to discharge its duty as the overseer of the safety and protection of human subjects in a fair and unbiased manner.

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