
Eric G. Campbell, PhD; Christine Vogeli, PhD; Sowmya R. Rao, PhD; Melissa Abraham, PhD; Roz Pierson, PhD; Sandra Applebaum, MA

IMPORTANCE For the past decade, more attention and concern has been directed toward financial relationships between the life science industry and physicians. Relationships between industry and institutional review board (IRB) members represent an important subclass that has the potential to broadly influence decisions regarding medical research.

OBJECTIVES To study the nature, extent, and perceived consequences of industry relationships among IRB members in academic health centers and to compare our results with findings from 2005.

DESIGN, SETTING, AND PARTICIPANTS A survey mailed to IRB members from the 115 most research-intensive medical schools and teaching hospitals in the United States from January 16 through May 16, 2014. The survey included questions identical to those used in 2005. Data analysis was conducted from June through October 2014.

MAIN OUTCOMES AND MEASURES The frequency of industry relationships among IRB members and the perceived effect of those relationships on IRB-related activities.

RESULTS We found no significant change in the percentage of IRB members with an industry relationship from 2005 through 2014 (2005: 37.2%; 95% CI, 32.7%-42.0%; 2014: 32.1%; 95% CI, 28.0%-36.4%; P = .09). However, since 2005, the percentage of members who felt another member did not properly disclose a financial relationship decreased from 10.8% (95% CI, 8.0%-14.4%) to 6.7% (95% CI, 4.7%-9.4%) (P = .04), as did the percentage who felt pressure from their institution or department to approve a protocol (2005: 18.6%; 95% CI, 15.0%-22.9%; 2014: 10.0%; 95% CI, 7.6%-13.0%; P < .001). The percentage of members with a conflict of interest who voted on protocols with which they have a conflict has not changed, although the percentage who said they always disclose relationships increased significantly from 54.9% in 2005 (95% CI, 42.2%-66.9%) to 80.0% in 2014 (95% CI, 65.3%-89.4%) (P = .01). We also found evidence of anti-industry bias in the presentation of protocols to the IRB.

CONCLUSIONS AND RELEVANCE The results show significant positive progress in the reporting and management of conflicts of interest among IRB members in academic health centers since 2005 after adjusting for other factors. Additional attention should be focused on deterring IRB members from inappropriately voting on or presenting protocols in a biased manner.

JAMA Intern Med. 2015;175(9):1500-1506. doi:10.1001/jamainternmed.2015.3167
Published online July 13, 2015.

Author Affiliations: Author affiliations are listed at the end of this article.
Corresponding Author: Eric G. Campbell, PhD, Mongan Institute for Health Policy, Massachusetts General Hospital, 50 Staniford St, Ste 901, Ninth Floor, Boston, MA 02114 (ecampbell@partners.org).
For the past 3 decades, much has been written regarding academic-industry relationships in medicine and research. Academic-industry research relationships are often defined as academics who provide life science companies (e.g., biotechnology, drug, and device companies) with access to their knowledge, skills, services, or intellectual property in exchange for payment to the scientist or his or her institution. Most articles have focused on the role of individual researchers, while relatively little has focused on other academic organizational representatives, such as institutional review board (IRB) members.

In 2005, members of our group conducted the first national survey of IRB members in academic health centers regarding their industry relationships. We found that more than one-third of the IRB members had at least 1 industry relationship and 15% admitted that their industry relationship inappropriately affected their IRB-related decisions. Also, among members with industry relationships, 35% reported that in the past year they had voted on at least 1 protocol with which they had a conflict of interest (COI)—a clear violation of federal regulations.

Despite calls for greater regulation of industry relationships, no new national policies or guidelines have been implemented to address these issues among IRB members. Some institutions, such as the University of Washington, have adopted new policies that prohibit IRB members from participating in the review of protocols from companies with which they have financial relationships. Unfortunately, we do not know how frequently other institutions have taken such actions. To address this lack of data, we replicated the 2005 study, seeking to understand changes in the nature, extent, and consequences of industry relationships among IRB members in academic health centers.

### Methods

#### Sample

We developed the sample using a method identical to that used in 2005. First, we identified the 100 medical schools and the 15 independent hospitals that received the most funding from the National Institutes of Health in 2012. Second, using the Office for Human Research Protections Database, we identified the Institutional Organization Number for each institution and their linked IRB numbers. Third, for each institution, we sought lists of IRB members from the Office for Human Research Protections. This process resulted in a list of 4901 IRB members. From this list, we drew a simple random sample of 1016 members.

#### Development and Testing of the Survey

The survey was informed by a focus group of 8 IRB members from 4 institutions in New York City. The data from the focus groups were used to develop new survey items, which were added to the existing survey items from the 2005 study. Once completed, the survey was pretested with 25 IRB members who were selected randomly from our sampling frame.

#### Survey Administration

Similar to 2005, a survey was mailed to IRB members from the 115 most research-intensive medical schools and teaching hospitals in the United States from January 16 through May 16, 2014. Participants were sent a packet containing a cover letter, a URL so respondents could complete the survey online if desired, a $10 cash incentive, an 8-page questionnaire, a postage-paid confirmation postcard, and a postage-paid return envelope. Participants were asked to complete the online or paper survey and mail a confirmation postcard separately from the completed survey. Participants who did not respond to the initial mailing were sent up to 2 more packets and received follow-up telephone calls. This study was approved by the IRB at Partners HealthCare, Massachusetts General Hospital.

#### Key Outcome Measures and Variables

All the survey items and variables are summarized in eTable 1 in the Supplement. We discuss the IRB member relationships with industry variables and the COI variables.

### Relationships With the Life Science Industry

Using survey questions identical to those from 2005, we asked IRB members:

*In your most recent year of IRB service, were you involved with industry in any of the following ways: officer/executive or paid employee of a company, member of a board of directors of a company, paid consultant for a company, member of a scientific advisory board of a company, recipient of royalties (e.g., licenses or milestones), or member of the speakers bureau of a company.*

Similarly, we also asked:

*In your most recent year of IRB service, did you receive any funding for university/hospital based research from an industry source, support for students or post doctoral fellows from an industry source, equity in a company in exchange for professional services or intellectual property, or compensation for participation in meetings, conferences, or other activities.*

The response categories were yes or no for each.

#### Conflicts of Interest

Using survey items identical to the 2005 survey, we asked IRB members with industry relationships, “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 following responses were possible: 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 a COI. Respondents who had a COI were then 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 or 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?

For each of these questions, we created the following dichotomous variables: always disclosing, always leaving the room, never participating fully in the discussion, and voting on the protocol for which the member had a conflict. All the survey questions are available in eTable 1 and eTable 2 in the Supplement.

Statistical Analysis
Data analysis was conducted from June through October 2014. We pooled the data from 2005 and 2014 and considered them as samples coming from 2 independent strata. We computed weights as a product of the inverse of the sampling fractions and the response rate because the sampling fraction and the response rate were slightly different in the 2 survey years. We then conducted multivariable analysis by fitting separate logistic regression models to assess the relationship of the survey year with the various outcomes, adjusting for sex (male or female), underrepresented minority race or ethnic group (white or Asian and all others), academic rank (instructor or lecturer or other, assistant professor, associate professor, or full professor), having an MD degree (yes or no), and having a PhD degree (yes or no). Owing to small sample sizes, the analysis among persons with a COI were only adjusted for sex and academic rank. From the regression models, we obtained adjusted percentages and associated standard errors or 95% CIs.

Results
Of the 1016 IRB members in our 2014 sample, 150 were considered ineligible because they were deceased (n = 2), had never been a member of an IRB (n = 6), were no longer at the institution (n = 67), could not be located at the institution (n = 73), or were retired (n = 2). Of the remaining 866 eligible persons, 593 completed a survey, yielding an overall response rate of 68.5%.

Because some of our outcome variables examined key IRB activities (such as voting), we excluded 235 respondents who indicated on the 2005 or 2014 survey that they were not voting members of their IRB at the time of the survey. This exclusion resulted in a final analytic data set of survey responses from 439 members in 2005 and 493 members in 2014, for a total analytic sample of 932 IRB members.

Characteristics of Respondents
Compared with 2005, respondents in 2014 were less likely to hold a faculty appointment (77.2% in 2005 vs 69.3% in 2014; P = .007) (Table 1). Among those with a faculty appointment, we found significant differences in rank between study years. We found no significant differences in any other respondent characteristics.

Relationships of IRB Members With the Life Science Industry
After adjusting for all other variables, we found that the percentage of IRB members who served on speakers bureaus decreased from 13.8% in 2005 to 4.2% in 2014 (P < .001). Also, the percentage who received payment from industry sources decreased significantly from 16.4% in 2005 to 9.4% in 2014 (P = .002). However, the percentage of members with an industry relationship of any type did not change significantly from 2005 to 2014 (37.2% vs 32.1%; P = .09) (Table 2).

Table 3 shows the independent characteristics of IRB members associated with having an industry relationship in 2005 and 2014. Men were significantly more likely than women to have had an industry relationship (37.2% vs 30.3%, P = .03). In addition, IRB members with more advanced academic status (primarily at the associate or full professor level) were more likely to have industry relationships.

IRB Policies and Practices Regarding Industry Relationships
Institutional review board members were more likely to report that their IRB had a formal written definition of what constituted a COI in 2014 compared with 2005 (45.6% in 2005 vs 63.1% in 2014; overall P < .001). The percentage of members who reported that no such policy existed decreased significantly (13.8% in 2005 vs 5.1% in 2014), as

| Table 1. Unadjusted Characteristics of Current IRB Voting Members |
|---------------------------------|----------------|----------------|-----------|
| Characteristic | All Respondents, % | | |
| | 2005 (n = 439) | 2014 (n = 493) | P Value |
| Sex | | | |
| Male | 53.9 | 51.6 | .49 |
| Female | 46.1 | 48.4 | |
| Race or ethnicity | | | |
| Non-URM | 91.6 | 88.8 | .15 |
| URM | 8.4 | 11.2 | |
| Holds faculty appointment | 77.2 | 69.3 | .007 |
| Academic rank | | | |
| None | 23.3 | 31.3 | |
| Instructor, lecturer, or other | 11.4 | 3.7 | |
| Assistant professor | 18.5 | 19.7 | <.001 |
| Associate professor | 25.1 | 20.5 | |
| Professor | 21.7 | 24.7 | |
| Academic degree held | | | |
| MD | 42.4 | 41.4 | .77 |
| PhD | 32.8 | 33.9 | .74 |
| Conducts clinical research | 78.4 | 80.7 | .39 |

Abbreviations: IRB, institutional review board; URM, underrepresented minority.
did the percentage who did not know if such a policy existed (40.6% in 2005 vs 31.8% in 2014).

### Perceived Effect of Industry Relationships
Since 2005, the percentage of IRB members who felt another member did not properly disclose their financial relationships in the past year decreased significantly (10.8% in 2005 vs 6.7% in 2014; \( P = .04 \)) (Table 4). In addition, the percentage who felt pressure from their institution or department to approve a protocol they felt was not ready for approval decreased significantly from 18.6% in 2005 to 10.0% in 2014 (\( P < .001 \)).

### Bias in Presentation
The percentage of members who felt another IRB member had presented a protocol in a biased manner because of his or her industry relationship decreased from 13.5% in 2005 to 8.4% in 2014 (\( P = .02 \)). On the 2014 survey, we asked 2 new items to assess the direction of the bias. We found that 7.8% of IRB members felt that in the past year a protocol was presented with a proindustry bias. At the same time, 14.2% felt a protocol was presented with an anti-industry bias. Anti-industry bias was significantly more common than proindustry bias in presentation (\( P = .002 \)).

### COIs Among IRB Members
Since 2005, the percentage of members with COIs in the most recent year of IRB service has not changed significantly (38.7% in 2005 vs 30.4% in 2014; \( P = .13 \)) (Table 5). However, from 2005 through 2014, a significantly greater percentage of IRB members with COIs reported always disclosing their industry relationships (54.9% vs 80.0%; \( P = .01 \)) and always leaving the room when a protocol with which they had a conflict was under discussion (37.7% vs 68.1%; \( P = .002 \)). However, the percentage of members who voted on a protocol with which they had a COI did not decrease significantly (35.2% in 2005 vs 24.9% in 2014; \( P = .24 \)).
Discussion

These results provide the most comprehensive empirical portrait of COIs among IRB members in academic health centers. Overall, the results show significant improvements since 2005 in the frequency of disclosure of industry relationships and management of COIs among academic IRB members.

Unlike studies involving researchers and practicing physicians, we did not find a statistically significant decrease in the percentage of members with any type of industry relationship from 2005 through 2014. However, we did find declines in the percentage of IRB members serving on speakers bureaus or receiving payments for attending meetings—relationships that are sometimes viewed as unacceptable in academic settings. These declines may reflect changes in the marketing practices of the life science industry or changes in institutional policies. Furthermore, it is encouraging that relationships such as research funding and support for students have not decreased—indicating that medical schools and teaching hospitals did not seek to discourage all types of industry relationships. These findings, taken together, suggest that academic institutions have been successful at limiting problematic relationships without restricting participation in...

Table 4. Changes in Members’ Benefit and Risk Perceptions by Survey Year

<table>
<thead>
<tr>
<th>Questiona</th>
<th>Response by Year, Adjusted % (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the most recent year of IRB service, how often have you...b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt an IRB member’s relationship with a company inappropriately affected his or her IRB-related decisions?</td>
<td>12.9 (9.9-16.8)</td>
<td>10.3 (7.8-13.5)</td>
</tr>
<tr>
<td>Felt that a protocol was presented in a biased manner because of a member’s relationship with a company?</td>
<td>13.5 (10.4-17.4)</td>
<td>8.4 (6.2-11.3)</td>
</tr>
<tr>
<td>Felt that a member did not properly disclose a financial relationship?</td>
<td>10.8 (8.0-14.4)</td>
<td>6.7 (4.7-9.4)</td>
</tr>
<tr>
<td>Felt pressure from your institution or department to approve a protocol that you felt was not ready for approval?</td>
<td>18.6 (15.0-22.9)</td>
<td>10.0 (7.6-13.0)</td>
</tr>
<tr>
<td>Bias questionsc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt that a protocol was presented in a biased manner because of a member’s proindustry bias?</td>
<td>NAc</td>
<td>7.8 (5.7-10.6)</td>
</tr>
<tr>
<td>Felt that a protocol was presented in a biased manner because of a member’s anti-industry bias?</td>
<td>NAc</td>
<td>14.2 (11.3-17.6)</td>
</tr>
</tbody>
</table>

Abbreviations: IRB, institutional review board; NA, not applicable.

a Questions are quoted directly from the survey.
b Adjusted for sex, underrepresented minority status, academic rank, and academic degree.
c These questions were only asked in the 2014 survey.
d P value for the difference is based on a 2-sample z test to compare proportions reporting pro-industry vs anti-industry bias in 2014.

Table 5. Extent and Management of COIs Among IRB Members

<table>
<thead>
<tr>
<th>Question and Responsea</th>
<th>Respondents by Year, % (95% CI)b</th>
<th>2005 (n = 439)</th>
<th>2014 (n = 493)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?c</td>
<td>None</td>
<td>61.3 (53.6-68.5)</td>
<td>69.6 (61.7-76.5)</td>
<td>.13</td>
</tr>
<tr>
<td>For the protocols involving companies with which you had relationships of these kinds, how often did you...d</td>
<td>1 or more</td>
<td>38.7 (31.5-46.4)</td>
<td>30.4 (23.5-38.3)</td>
<td></td>
</tr>
<tr>
<td>Always disclose the relationship to the IRB or an IRB official?</td>
<td>Always</td>
<td>54.9 (42.2-66.9)</td>
<td>80.0 (65.3-89.4)</td>
<td>.01</td>
</tr>
<tr>
<td>Always leave the room while the protocol was under consideration?</td>
<td>Never fully participate in the general discussion?</td>
<td>37.7 (26.1-51.0)</td>
<td>68.1 (53.3-79.9)</td>
<td>.002</td>
</tr>
<tr>
<td>Never fully participate in the general discussion?</td>
<td>Vote on a protocol with a COI?</td>
<td>53.7 (41.2-65.8)</td>
<td>56.0 (40.9-70.1)</td>
<td>.82</td>
</tr>
<tr>
<td>Vote on a protocol with a COI?</td>
<td>35.2 (24.2-48.0)</td>
<td>24.9 (14.5-39.4)</td>
<td>.24</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: COIs, conflicts of interest; IRB, institutional review board.

a Questions and answers are quoted directly from the survey.
b Regression-adjusted percentages for sex and academic rank.
c For this question, n = 163 and n = 148 for 2005 and 2014, respectively; for all others, n = 61 and n = 42 for 2005 and 2014, respectively.
d Of those with 1 or more COIs.
relationships, such as research funding, that are generally viewed as positive.

Among members with industry relationships, the proportion with a COI has not changed significantly since 2005. However, the percentage who report that they always disclose conflicts and always leave the room during discussions has increased significantly. This change could reflect a heightened awareness of industry relationships in academic settings or changes in industry promotional activities. It may also be that IRBs have become more alert to COIs among members and have taken their own actions to address these issues. Regardless of the explanation, this finding is positive and suggests that IRBs have improved their management of COIs among members.

The finding that the percentage of members with COIs who voted on a protocol has not changed is troubling. This behavior is in violation of the Department of Health and Human Services’ federal-wide assurance that prohibits a member’s involvement in the review of protocols with which they have a conflict. It is possible that IRBs are not adequately clear with members about the types of relationships that constitute a COI and/or what members should do when they have a COI. The fact that more than one-third (36.9%) of the IRB members in 2014 did not know if their IRB had a policy defining a COI suggests that a lack of clear policies may, in part, explain this behavior. This finding may also result from a lack of enforcement of federal policy. Regardless of the explanation, it is clear that institutions have failed to limit this behavior, and intervention from the federal government appears necessary.

In terms of bias in the presentation of protocols, we found that anti-industry bias was twice as likely as proindustry bias. Given the declines in research funding from government sources, academic institutions are increasingly relying on the life science industry for support. Thus, the effect of anti-industry bias on IRB-related activities and decisions is particularly relevant in the current funding environment and warrants further investigation.

Several limitations should be kept in mind when considering the results of this study. First, as with all survey studies, our results may be affected by social desirability bias in that people tend to underreport engaging in activities that others might find problematic. It is believed that women are more susceptible to such bias than men. Our results may therefore underestimate the percentage of IRB members (especially women) who report voting on proposals with which they have a COI. However, the anonymous nature of the survey and adjustments for sex likely help to mediate this bias. Second, we only studied academic IRBs associated with medical schools, so our results do not represent IRBs from nonacademic institutions and those that service other parts of the university (eg, schools of engineering, education, and business). Third, because we did not collect institutional identifying information in 2005, we are unable to adjust for institution-level effects. Finally, like all survey studies, our results may be subject to response and/or nonresponse bias. Given that we were not able to compare respondents with nonrespondents and that data on the characteristics of the underlying population of IRB members is not available, we cannot empirically rule out either or both of these biases. However, we are encouraged by our high response rate (68.5%) and similarity in the characteristics of respondents across study years. Also, our analysis controlled for observable characteristics of IRB members in 2005 and 2014 (such as faculty status) to the extent possible. Because we conducted multiple regression analyses, the differences observed between 2005 and 2014 are likely not attributable to changes in IRB composition related to sex, faculty rank, having an MD or PhD degree, race or ethnicity, and whether IRB members conduct clinical research. We were not able to conduct analyses using interaction variables to test this assertion directly.

Conclusions

Overall, the research presented here provides the most recent empirical data on the nature, extent, and perceived consequences of IRB members’ industry relationships. The good news is that during the past decade, significant progress has been made in disclosing and managing COIs among IRB members. Nevertheless, there is still work to be done, including educating members about what constitutes a COI, stopping IRB members with COIs from voting on protocols with which they have a conflict, and researching bias in the presentation of industry-sponsored protocols.

ARTICLE INFORMATION

Accepted for Publication: February 14, 2015.
Published Online: July 13, 2015.

Author Affiliations: Mongan Institute for Health Policy, Massachusetts General Hospital, Boston (Campbell, Vogeli, Abraham); Department of Medicine, Massachusetts General Hospital, Boston (Campbell, Vogeli); Department of Psychiatry, Massachusetts General Hospital, Boston (Abraham); Department of Medicine, Harvard Medical School, Boston, Massachusetts (Campbell, Vogeli); Department of Psychiatry, Harvard Medical School, Boston, Massachusetts (Abraham); Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester (Rao); Center for Healthcare Organization and Implementation Research, Bedford Veterans Affairs Medical Center, Bedford, Massachusetts (Rao); The Nielsen Company, New York, New York (Pierson, Applebaum).

Author Contributions: Drs Campbell and Vogeli had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Campbell, Vogeli, Abraham, Pierson, Applebaum. Acquisition, analysis, or interpretation of data: Vogeli, Rao, Abraham, Pierson, Applebaum.

Drafting of the manuscript: Campbell.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Rao.
Obtained funding: Campbell.
Administrative, technical, or material support: Campbell, Vogeli, Abraham, Pierson, Applebaum.
Study supervision: Campbell, Pierson, Applebaum.
Conflict of Interest Disclosures: None reported.
Funding/Support: This study was funded by grant R01 GM100026-01 from the National Institute of General Medical Sciences, National Institutes of Health (Dr Campbell).

September 2015 Volume 175, Number 9

Copyright 2015 American Medical Association. All rights reserved.
Role of the Funder/Sponsor: The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The opinions expressed in this manuscript do not necessarily represent the official views of the Department of Veterans Affairs.

REFERENCES

Advancing Science in the Service of Humanity Professionalism and Ethical Safeguards

Laura Weiss Roberts, MD, MA

Is human experimentation ever ethically permissible? Are human studies always and inevitably exploitative? Since the release of the Belmont Report in the United States in 1979, the response to these difficult ethical questions has been that people may participate in scientific studies when the following 2 conditions have been met: the research must occur in a context of utmost trust and professionalism, and it must be conducted in a manner that wholly embodies the ethical principles of respect for persons, beneficence, and justice. When these conditions are fulfilled, the person is not used as a “means to an end” by science. Rather, a well-informed and capable person may engage with investigators, accepting freely the risks of research, in the shared pursuit of knowledge that may improve human health.

These ideals are expressed in the actions of professionals and the safeguard practices of institutions that conduct human studies. In this issue of JAMA Internal Medicine, Campbell and colleagues focus precisely on these actions and practices, documenting how issues relating to conflicts of interest (COIs) are handled among those who serve on the institutional review boards (IRBs) of our country’s most research-intensive medical schools and teaching hospitals. Overshadowed by concerns about industry relationships of investigators, COI issues among IRB members have received relatively little attention. This topic is nevertheless an important concern because the protection of human participants in research in the United States relies greatly on local IRB members’ unbiased and objective assessment of protocols. The findings by Campbell et al suggest that actions and safeguards related to IRB oversight have...