Responses of Medical Schools to Institutional Conflicts of Interest

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Institutional Academic-Industry relationships exist when academic institutions or their senior officials have a financial relationship with or a financial interest in a public or private company.1-4 Institutional conflicts of interest (ICOI) occur when these financial interests affect or reasonably appear to affect institutional processes.1,2,5 These potential conflicts are a matter of concern because they severely compromise the integrity of the institution and the public's confidence in that integrity.1 Reports of the 2007 scandal in the university financial aid community illustrate how the self-interest of institutions and of institutional officials can create conflicts of interest and compromise institutional values.6 Conflicts of interest in the academic community have attracted the attention of Congress, the media, and the public.7-9

In the realm of life science research, the effects of individual conflicts of interest have been well documented.10 The potential dangers of unaddressed financial conflicts of interest affecting the proposal or conduct of federally funded research is referenced in the preface of the 1995 federal regulations governing objectivity and conflicts of interest in Public Health Service-fund research, although these regulations focused exclusively on financial interests held by individuals, specifically investigators.11 These regulations resulted in strong national policy recommendations from the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC)12 and in extensive university- and medical school-based policy development addressing conflicts of interest held by individual researchers.12

Although the 1995 federal regulations addressed only individual con-
flicts of interest, the recommendations from the AAU, the AAMC, and the 2004 guidance from the US Department of Health and Human Services regarding conflicts of interest in human subjects research included a separate area of concern—ICOI. “The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the institution. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or values of the university.” These recommendations urged institutions to address ICOI, both institutionally held financial interests in research, such as royalties or equity holdings, as well as the financial interests of institutional officials.

Despite these references to ICOI and increasing skepticism about the integrity of research in the presence of institutional financial interests, anecdotal reports suggest that academic institutions have struggled with the development and adoption of policies governing their own ICOI. Five years after the issue of ICOI was emphasized by the AAU and AAMC and 3 years after the US Department of Health and Human Services guidance, there are no national data on the extent to which potential threats to research integrity and human subjects by ICOI have been addressed by policy responses and administrative practices from medical schools. The adoption of policies and administrative structures are not the only ways to address ICOI; however, they may be seen as among the most significant expressions of institutional values as well as the customary means of communicating expected standards in academic communities.

The purpose of this study was to determine the extent to which medical schools have adopted ICOI policies and to describe their scope and the administrative practices that have been implemented to address financial relationships with industry. The survey instrument was based on a similar 2004 AAMC survey of medical schools, in which adoption of the AAMC’s national recommendations (2001) on individual financial conflicts of interest was tracked. Our study measured the degree to which AAU and AAMC national recommendations on ICOI policies (rather than individual conflicts of interest policies) have been adopted by the schools, including examining the officers, financial interests, and administrative practices that were central to the national recommendations.

The instrument was pretested by 2 former associate deans of medical schools to ensure that the questions were reasonable and answerable by the respondents. The study was deemed exempt from human subjects approval by the institutional review boards (IRBs) of Massachusetts General Hospital and the AAMC.

**Data Collection**

The survey was administered between February 2006 and December 2006. Initially, survey recipients (the dean [or designee], acting dean, or interim dean of each medical school, as applicable) received a letter by e-mail from the president of the AAMC explaining the survey and its importance. The list of deans was obtained from AAMC databases. A follow-up e-mail provided details about the survey and included a password-protected link for online survey completion. All deans received a first reminder letter by e-mail approximately 1 month after the initial contact and a second reminder 3 weeks later. In June 2006, nonrespondents received a reminder letter with a paper copy of the survey for completion. In August 2006, the administrative assistants of the deans of the remaining nonresponder institutions were sent a letter that included a paper copy of the survey for forwarding to the official identified by the dean for survey response. No financial incentives were offered for survey completion.

**Methods**

**Population**

We conducted a national survey of the deans or their duly designated proxies in the 125 accredited allopathic US medical schools. Each dean received an explanation of the survey and was asked to forward the survey to the official most familiar with the institution’s conflicts of interest policies (eg, the dean/vice provost for research or the general counsel) with the dean’s request that it be given careful and prompt attention. We based this contact on the premise that the dean would have final and comprehensive authority within the medical school and be the individual most likely to reliably identify the most knowledgeable respondent for survey completion.

**Survey Design and Testing**

The survey instrument was based on a similar 2004 AAMC survey of medical schools, in which adoption of the AAMC’s national recommendations (2001) on individual financial conflicts of interest was tracked. Our study measured the degree to which AAU and AAMC national recommendations on ICOI policies (rather than individual conflicts of interest policies) have been adopted by the schools, including examining the officers, financial interests, and administrative practices that were central to the national recommendations.
Adoption of ICOI Policies: Covered Entities and Offices. The survey asked whether or not the institution had adopted an ICOI policy covering financial interests held by the institution, and if not, whether the institution was working on such a policy. Similarly, respondents were asked whether or not the institution had adopted an ICOI policy covering financial interests held by senior institutional officials (presidents/chancellors, provosts/vice presidents/vice chancellors, and deans), and if not, whether the institution was working on such a policy. We asked the same questions regarding financial interests held by midlevel institutional officials (department chairs, directors, and division heads), by IRB members, and by governing board members.

Scope of ICOI Policies: Covered Financial Interests. In order to assess the scope of covered financial relationships, the survey asked: “Which of the following financial interests held by your institution are considered potential ICOIs?” The series of responses included: “types of institutionally held financial interests that could be affected by research results, ie, royalties, milestone payments, equity in a publicly held company, equity in a privately held company, and receipt of substantial gifts.” Respondents were asked to select all that apply. These interests were selected because they were explicitly recommended to be considered potential ICOI by AAMC recommendations.

Because personal financial interests of institutional officials can constitute institutional conflicts of interest, we asked whether a financial interest in a commercial sponsor of research at the institution that is held by an institutional official with research oversight/management responsibility (including management of faculty engaged in research) is considered a potential ICOI. We asked a similar question regarding a financial interest that is held by an institutional official in an investigational product that is the subject of research at the institution. Such direct financial stakes in potential research outcomes are identical to those recognized as potential conflicts in the case of investigators in Public Health Service–funded research.

Implementation of Separation Strategies. ICOI policy recommendations from the AAU and AAMC articulate that “institutions should ensure that in practice, the functions and administrative responsibilities related to human subjects research are separate from those related to investment management and technology licensing.” Therefore, we asked a series of questions regarding the extent to which the institutions had accepted this fundamental organizational principle. This administrative separation of organizational function as a strategy for addressing ICOI is not dependent on the existence of a codified ICOI policy. The national recommendations regarding management separation are distinct from those that recommend particular policy provisions. Accordingly, they serve as an important indicator of institutional sensitivity to potential ICOI, independent from any indicators relating to codified ICOI policies.

Regarding investment management, we asked respondents whether the duties of research oversight/management and investment management “reside in the same individual.” We also asked whether “any official with investment management responsibility serve(s) as a member of an IRB at your institution,” whether “any official with investment management responsibility [has] any institutional role in COI [conflict of interest] evaluation,” and whether “your institution [uses] a separate, university-affiliated organization or foundation for investment management purposes.” The same set of questions was asked with respect to the administrative separation of licensing/technology transfer functions from research functions.

Regarding those institutions that use separate, affiliated organizations or foundations for either investment management purposes or for licensing/technology transfer functions, we asked whether university officials also serve on the separate entity’s governing board.

Linkages of ICOI to IRBs. We asked whether the IRB is informed of potential ICOI when it reviews proposals to conduct human subjects research, independent of whether or not the institution had particular elements of a formal ICOI policy. With respect to IRB members, we asked whether disclosure to the IRB or IRB chair was required of any significant financial interest held by the member in human subject research under review by the IRB.

Statistical Analysis
We were interested in comparing whether ICOI policies and practices varied between public medical schools vs private medical schools; and schools ranked among the top 25 National Institutes of Health (NIH)–funded medical schools vs those ranked 26 or lower. We compared our respondent sample to the overall population of 125 institutions due to concerns that there might be a response bias by their status. We found that 63% (54) of the 86 responding institutions were public as compared with 60% (75) of the overall population. We also found that 22% (19) of the responding institutions were among the top 25 NIH-funded medical schools, which is similar to the 20% (25) among the overall population. We did not have differential response within subgroups and as a result, we did not weight by either public vs private status or by NIH ranking.

We obtained the distributions of whether ICOI policies were adopted or whether policies were in the process of being adopted covering the financial interests of the institution, of senior officials, of midlevel officials, of IRB members, and of governing board members. We further obtained the distributions of the type of financial relationships that might cause ICOI among institutions that had adopted policies and those that were working on them. We examined whether or not administrative responsibility for research within an institution was separated from that relating to financial management and technology transfer.
We hypothesized that more research-intensive institutions, as assessed by NIH funding rank, would be more likely to have more comprehensive policies because of the volume of their research portfolios and the attention given to conflict of interest by federal regulations, federal guidance, and by national higher education organizations. We also hypothesized that public institutions would be more likely than private institutions to have policies covering ICOI because of the existence of state laws that address linkages between public decision making and conflicts of interest.

We used χ² tests to assess whether subgroups (public vs private and top 25 NIH ranking vs those ranked 26 and lower) differed significantly in their responses. A 2-sided P value of .05 was used to test significance. We used SPSS statistical software version 15.0 (SPSS Inc, Chicago, Illinois) to conduct our analysis. No statistically significant differences were observed among subgroups due to the small number of institutions studied.

RESULTS

Adoption and Scope of ICOI Policies: Covered Entities and Offices

Responses were received from 86 (69%) of 125 accredited US allopathic medical schools surveyed. Table 1 shows the extent of adoption of ICOI policies applicable to medical schools, by coverage of the institution and of institutional officials. Thirty (38%) survey respondents have adopted an ICOI policy covering financial interests held by the institution, 29 (37%) are working on adopting an ICOI policy covering financial interests held by the institution, and 20 (25%) are not working on adopting such a policy or do not know. Much higher numbers are reflected for ICOI policies that cover the individual financial interests of officials: with adoption of policies for senior officials (55 [71%]), midlevel officials (55 [69%]), IRB members (62 [81%]), and governing board members (51 [66%]); and with adoption of policies being worked on for senior officials (9 [12%]), midlevel officials (12 [15%]), IRB members (6 [8%]), and governing board members (2 [3%]).

We examined the rates of adoption of ICOI policies by covered entities and offices separately for public and private institutions and for the top 25 and the remaining NIH-ranked medical schools. No statistically significant differences were observed.

Scope of ICOI Policies: Covered Financial Interests

Table 2 shows those types of financial interests held by respondent institutions that have adopted potential ICOI separately by institutions that have adopted ICOI policies covering financial interests of the institutions, and by those that have not but are working on such policies. Of the institutions that have adopted policies covering the institution’s own financial interests, 24 (80%) respondents have adopted policies that cover royalties, 22 (73%) cover milestone payments, 27 (90%) cover equity in publicly held companies (51 [66%]), and 22 (73%) cover equity in nonpublicly held companies, 23 (77%) cover equity in publicly held companies, and 22 (73%) cover receipt of substantial gifts from potential commercial sponsors of research. We examined those adopting ICOI policies covering the institution’s own financial interests separately by public and private status and by NIH rank. No statistically significant differences were observed.

Table 1. Policy Adoption Status and Scope

<table>
<thead>
<tr>
<th>Responding Institutions, No. (%)</th>
<th>Policy Not Adopted</th>
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<tbody>
<tr>
<td></td>
<td>Policy Adopted</td>
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<tr>
<td></td>
<td>Working on a Policy</td>
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<tr>
<td></td>
<td>Not Working on a Policy/Don’t Know</td>
</tr>
<tr>
<td>Total, No.a</td>
<td></td>
</tr>
</tbody>
</table>
| Has your institution adopted a conflicts policy covering the financial interests held by:
  The institution                | 30 (38)           |
  Senior institutional officials  | 55 (71)           |
  Midlevel institutional officials| 55 (69)           |
  Institutional review board members| 62 (81)     |
  Governing board members        | 51 (66)           |
  respondents, numbers of total responding institutions vary due to nonresponse to specific questions.

Table 2. Financial Relationships by Type, Consideration, and Status

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Policy Adopted</th>
<th>Policy Not Adopted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalties</td>
<td>24/30 (80)</td>
<td>23/29 (79)</td>
</tr>
<tr>
<td>Milestone payments</td>
<td>22/30 (73)</td>
<td>22/29 (76)</td>
</tr>
<tr>
<td>Equity in nonpublicly traded research sponsor</td>
<td>27/30 (90)</td>
<td>24/29 (83)</td>
</tr>
<tr>
<td>Equity in publicly traded research sponsor</td>
<td>23/30 (77)</td>
<td>20/29 (69)</td>
</tr>
<tr>
<td>Receipt of substantial gifts from research sponsor</td>
<td>22/30 (73)</td>
<td>20/29 (69)</td>
</tr>
<tr>
<td>Research sponsor with research oversight/management responsibility considered potential ICOI?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior officials</td>
<td>43/55 (78)</td>
<td>6/9 (67)</td>
</tr>
<tr>
<td>Midlevel officials</td>
<td>43/55 (78)</td>
<td>8/12 (67)</td>
</tr>
<tr>
<td>Investigational product with research oversight/management responsibility considered potential ICOI?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senior officials</td>
<td>43/55 (78)</td>
<td>7/9 (78)</td>
</tr>
<tr>
<td>Midlevel officials</td>
<td>42/55 (76)</td>
<td>10/12 (83)</td>
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Abbreviation: ICOI, institutional conflicts of interest.

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Forty-three (78%) institutions that have adopted ICOI policies covering their own senior and midlevel officials considered the significant financial interest of an institutional research official in a commercial sponsor of research at that institution to be a potential ICOI. Forty-three (78%) take the position that a significant financial interest held by a senior official in a product that is the subject of research at that institution and 42 (76%) for such an interest held by a midlevel official presents a potential ICOI. For institutions that had adopted ICOI policies covering their senior and midlevel officials, public and private institutions were evaluated separately and according to NIH ranking. No statistically significant differences were found.

Implementation of Management Separation
Seventy-four institutions (94%) place the final authority for investment management duties in an official who is different from the official with final authority for research functions (excluding the governing board and the president/chancellor of the institution; [TABLE 3]). Two institutions (3%) do not. In 73 (92%) institutions, no investment management official serves as a member of an IRB. In 63 (79%) institutions, no investment management official has any role in the evaluation of conflicts. However, in 72 (91%) institutions, no licensing/technology transfer official serves as a member of an IRB.

Some institutions have elected to use separate organizations to assist with either or both investment management and licensing/technology transfer. Thirty-five (44%) use a separate, university-affiliated organization or foundation for investment management purposes. Forty-three (53%) use both a separate, university-affiliated organization or foundation for licensing/technology transfer. Of the institutions reporting the use of separate foundations for investment management purposes, licensing/technology transfer purposes, or both, 29 (56%) report that senior institutional officials (ie, president/chancellor, provost/vice chancellors/deans) serve on the governing board of such separate entities and 18 (36%) report that midlevel officials serve on such boards.

Linkages of ICOI to IRBs
With respect to the linkages between ICOI review and an institution’s IRBs, 25 (83%) institutions with policies covering its financial interests report that their IRB is informed of potential ICOI when it reviews proposals to conduct human subjects research, ranging through those with policies covering senior officials (35; 64%), midlevel officials (37; 67%), IRB members (44; 71%), and governing board members (31; 61%). Sixty-nine (89%) respondents require an IRB member to disclose to the IRB any significant financial interest held by the member in human subjects research under review by the IRB.

COMMENT
This study provides the first comprehensive view of the state of ICOI policies and practices of US medical schools and can serve as a means for assessing the extent to which the challenges presented by institutional academic/industry relationships have been addressed by institutional policies and procedures.

National recommendations may be used as a measure to weigh these policies and practices and focus on the 2 key dimensions of ICOI: those created by financial interests held by the institutions and those potentially created by the financial interests of institutional officials. Despite strong national recommendations from 2 prominent higher education organizations, adoption of ICOI policies by US medical schools is far from complete on both dimensions.

Anecdotal reports of a variety of difficulties associated with developing and implementing such policies are confirmed by the finding that policies covering institutions’ own financial interests exist at slightly more than one-third of responding institutions. Although it is encouraging that 38% of institutions are in the process of developing policies covering the institutions’ financial interests, wider adoption of ICOI policies covering these interests is imperative in light of the compelling interests of research integrity, protection of human subjects, and preservation of public trust.

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Table 3. Separation of Investment Management and Technology Transfer Functions From Research Functions

<table>
<thead>
<tr>
<th>Separation Methods</th>
<th>Investment Management</th>
<th>Technology Transfer</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Yes/No (%)*</td>
<td>Yes/No (%)*</td>
</tr>
<tr>
<td>Duties reside in same individual</td>
<td>2/79 (3) 74/79 (94)</td>
<td>29/79 (37) 48/79 (61)</td>
</tr>
<tr>
<td>Member of an institutional review board</td>
<td>0 (0) 73/79 (92)</td>
<td>2/79 (3) 72/79 (91)</td>
</tr>
<tr>
<td>Role in conflict of interest evaluations</td>
<td>13/80 (16) 63/80 (79)</td>
<td>30/81 (37) 43/81 (63)</td>
</tr>
</tbody>
</table>

*Numbers for each item vary and percentages do not total 100% due to nonresponse; “don’t know” responses are not reported in this table.
Substantially higher rates of policy adoption are reported for addressing the financial interests of institutional officials, especially the financial interests of IRB members. This finding in particular demonstrates attention to the special status of those who participate in human subjects protection programs. Nevertheless, in approximately one-fifth of medical schools, policies are not reported to be in place to govern key financial interests of officials who have responsibilities for managing the research enterprise, and even this may underrepresent the number of institutions without policies because of social desirability bias. When this survey was administered, it had been 4 years since the issuance of the AAMC recommendations concerning ICOI. While acknowledging that adoption of ICOI policies is not a simple task and is dependent on, among other factors, highly interactive institutional databases and the active involvement of faculty, administrative officials, and the institution's governing board(s), it is problematic that more schools do not have more comprehensive policies in place.

A variety of dynamics could be operating that may delay the development of comprehensive policies on ICOI. Many medical schools are components of universities and, therefore, may not have the authority to adopt such policies independently from their parent universities. Other difficulties with policy adoption may include the accessibility of information on institutional financial holdings as well as the holdings of institutional officials with which to build adequate databases to support comprehensive ICOI evaluation. ICOI identification, assessment, and management are dependent on the timely availability of such information to duly authorized review officials or groups.

In addition, adoption of ICOI policies may be complicated by interests associated with regional, national, and international economic development and pressures to bring quickly to market the discoveries resulting from academic research, especially in the health arena. These interests often involve academic/industry relationships. ICOI policies may be perceived as delaying or inhibiting the realization of these interests. Consequently, in the absence of any requirement that ICOI policies be in place, institutions may not have experienced the same pressure to move forward that they apparently underwent regarding adoption of policies on individual conflicts of interest. Finally, the low percentages of policy adoption may indicate that the national recommendations need attention.

Regarding the different types of institutionally held financial interests considered to be potential ICOI, those medical schools with policies applicable to institutionally held financial interests report comprehensive coverage of key institutional financial holdings, ranging from a low of 22 (73%) for coverage of receipt of substantial gifts from a research sponsor and for receipt of milestone payments, to a high of 27 (90%) for equity in a nonpublicly traded research sponsor. Similarly, more than three-fourths of institutions with policies applicable to senior and midlevel officials cover their research-related financial interests. These are encouraging numbers and represent appropriate attention to potentially biasing financial positions.

Institutions also report widespread implementation of management separation as a strategy for addressing potential ICOI. Management separation or structure is distinct from and not dependent on the existence of codified policies on ICOI, and is an additional means of addressing ICOI. Management separation is especially evident with respect to the separation of investment management responsibility from responsibility for research oversight. Although management separation does not suffice to prevent negative consequences from an ICOI, separation of management function comprises a key element, in addition to ICOI policy codification and management or elimination of the institutional financial conflicts, in protecting the integrity of the institution's research and the human subjects who participate in it.

Because technology transfer depends on an institution's research, the 2 functions are intertwined and oversight is frequently combined, especially at the senior official level. Predictably, therefore, only 48 (61%) institutions reported a separation of licensing/technology transfer responsibilities from research oversight responsibilities. However, a substantial majority of institutions reported that officials with investment management or technology transfer responsibilities did not serve on or participate in IRB discussions, thus reflecting a healthy “firewall” between economically driven interests and the IRB's ethical and legal focus on protection of human subjects.

Another kind of barrier involves extraorganizational separation of functions. Institutions report that they often use separate foundations or organizations in investment management and in licensing/technology transfer. However, the frequency with which institutional officials serve on the governing boards of these separate organizations suggests that the barrier between the institutions and the external organizations is at least somewhat porous.

The 2004 US Department of Health and Human Services guidance urges institutions to establish policies for conflict of interest committees to provide information, recommendations, and findings to IRBs. Substantial gaps exist in informing institutional IRBs of potential ICOI in research projects under review, other than of those of its own members. This is a disturbing finding, may be contrary to federal guidance, and calls for prompt institutional attention.

This study has a number of limitations. First, the actual policy language was not compared to verify survey responses from those institutions that reported adoption of ICOI policies. Second, respondent institutions that reported not adopting policies in particular areas were asked about the nature of policies that were in progress at their institutions. To the extent we have
reported their responses, they are necessarily imperfect indicators of future policy provisions and may cover a wide variety of facts, from very preliminary drafting to mature policies that lack only formal governing board approval before becoming operational.

Third, some institutions may address ICOI on a case-by-case ad hoc basis, depending on particular facts and circumstances rather than relying on formal policies. While explicit policy provisions represent transparent and systematic evidence of institutional commitment to particular values and behaviors, formal policies can be ignored or not enforced. Conversely, the absence of policies does not necessarily indicate that ICOI are not responsibly addressed, nor does it indicate research bias or problems in the protection of human subjects. Further research should explore the causes for delay in institutional policy development, particular issues or difficulties surrounding the national recommendations, and the extent to which the existence of policies influences the conduct of research. Fourth, like all surveys our results may be subject to social desirability bias in that respondents may be less likely to report engaging in behaviors or holding beliefs perceived to be viewed negatively by others. Thus, the findings of this study related to the volume of institutions with ICOI policies and the coverage of those policies may be upper-bound estimates. Finally, the existence of policy provisions and administrative structures addressing ICOI does not imply effectiveness in addressing potential ICOI at medical schools. Additional research should address these issues as well.

This study provides the first national data on the existence and nature of policies and practices of US medical schools for addressing potential ICOI. The gaps in coverage suggest the need for continuing attention by the academic medical community to more consistently and comprehensively address the challenges presented by ICOI.

Author Contributions: Ms Ehringhaus and Ms Sears had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

REFERENCES


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