Institutional Conflict of Interest in Research
By Jere M. Boyer, Maria Schimer, Heather Holmes and Patricia Heilmann

Abstract
We conducted a survey of institutional research administrators to determine if research administrators in smaller, non-collegiate institutions (< 500 total active protocols) considered institutional conflict of interest (ICOI) in research to be an issue at their institution and, if so, did policies exist to address ICOI in research. If such policies did not exist, were they perceived to be needed?

All but one respondent indicated that their institution had general ICOI policies. However, only four respondents indicated that their policies made any reference to institutional conflicts of interest related to research. Over half of the 28 respondents indicated that higher administrators or influential researchers had exerted undue pressure on them to inappropriately act upon research protocols. They experienced such pressure, on average, 2.4 times over the past year. 93% of respondents stated that their institutions should develop ICOI policies. The authors propose an institutional research conflict-of-interest policy to assist institutions in developing their own internal policies.

Introduction
A conflict of interest may be defined as any instance in which financial or other interests may bias, or is perceived by others to bias, actions or judgments. (Association of American Medical Colleges [AAMC], 1993) In sponsored research, such conflicts may involve investigators, institutional review board (IRB) members, data and safety monitoring committee (DSMC) members, institutions and other personnel involved in a clinical trial. Managing such conflicts, regardless of the source or potential source, is imperative to maintain data integrity and protect the rights and welfare of research subjects (Weinfurt, 2006) as well as staff members. One way to manage these conflicts is to establish policies. For example, an institution may decide to prioritize certain categories of clinical trials over others; it is one thing if there are clearly defined rules for prioritization, and quite another if anyone with power can change a study's priority.

Many organizations and federal agencies have developed guidance documents (Brody, Anderson, McCrary, McCullough, Morgan, et al., 2004; Weinfurt, 2006) and policies (Boyd, Lipton, & Bero, 2004; Ehringhaus & Korn, 2004) to provide guidance for appropriately handling the conflicts of investigators, IRB members and DSMC members. Almost all institutions have conflict-of-interest policies. Indeed, depending upon their status, such as being a not-for-profit organization, they may be required by state law to have such policies. However, only recently has institutional conflict of interest (ICOI) in research been recognized as an issue.

An important concern of ICOI in research is any undue influence that is placed on IRB members, research administrators, coordinators or others involved in research by senior administrators or influential investigators to inappropriately deal with a research study or give such a study favorable treatment contrary to institutional policy or regulations. Few institutions, even those with significant research activity, have ICOI policies specifically for research. Those that have such policies are large, high-profile research institutions and...
The purpose of the study presented in this article was to answer three questions:

- Do smaller hospitals or research organizations that conduct sponsored research also have ICOI policies for research?
- If they do, are they effective?
- If they do not, would such policies be perceived as helpful for research administrators?

**Methods**

This study and the questionnaire used were approved by the Summa Health System Institutional Review Board. All data sources were kept confidential and the source information was destroyed after de-identified data was recorded.

**Survey Method**

A survey and request for demographic information was sent via email to a convenience sample of persons administering human subjects’ research protection programs with no more than 500 currently active protocols. Demographic information requested included the number of active protocols and title of the respondent. 28 of the 35 institutional representatives surveyed returned the questionnaire, resulting in an 80% response rate.

**Presentation and Statistics**

Data was analyzed by Chi-Square analysis as described by Siegel (1956) using a statistical package (SPSS, 2004). Results are presented with p-values unless all respondents indicated “yes” or “no” to a question.

**Results**

<table>
<thead>
<tr>
<th>Question</th>
<th>Number</th>
<th>Percent</th>
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<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
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<td>________</td>
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<tr>
<td>Question 1. Does your institution have a general institution-wide conflict of interest policy?</td>
<td>0</td>
<td>27</td>
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<tr>
<td>Question 2. Does this policy specifically state that it covers institutional conflicts related to research?</td>
<td>24</td>
<td>4</td>
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<tr>
<td>Question 3. Do you feel that you are protected from undue influence placed upon you by the institution?</td>
<td>15</td>
<td>13</td>
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<td>Question 4. Have you ever felt pressure to obtain an outcome preferential to the institution?</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>Question 5. Do you feel a specific institutional COI policy for research is needed?</td>
<td>2</td>
<td>26</td>
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Question 1

Question 1 asked whether the respondent institution had general conflict of interest policies. All but one respondent answered “yes.” The single respondent who did not answer the question indicated that he/she was too new in the position and was not aware of all the institutional policies. The remaining respondents indicated that ICOI policies were in place. This result is highly significant. Because all evaluable respondents answered “yes”, statistical analysis was not required.

Question 2

Question 2 asked if their ICOI policies contained specific references addressing research. Only 4 of 28 respondents (14%) answered “yes,” that their policies did have such references to research. Chi-Square results are statistically significant (p < .000).

Question 3

Question 3 asked the respondents if they felt protected from undue influence placed on them by institutional officials. 15 of the 28 respondents (54%) indicated that they did not feel protected.

Question 4

Question 4 asked the respondents if they actually had been pressured to provide inappropriate or preferential actions regarding IRB review of a protocol. Of the 28 respondents, 19 (68%) indicated that they had felt such pressure from senior management or influential investigators.

Examples of ICOI reported by respondents included:

- Senior officials asked that projects with potentially high income value to the institution be approved, even if designed inappropriately.
- A high-income-generating physician placed pressure on research administration personnel to push through a study without proper review.
- A high-volume physician who repeatedly mismanaged his research placed pressure on institutional administration to have the IRB remove suspension of his research. He deemed the suspension to be detrimental to his reputation and his practice.
- An institutional official tried to have IRB members disapprove a study, apparently because the principal investigator was a competing physician.

Question 5

Question 5 asked the respondents if they felt that a separate ICOI policy for research was needed. Overwhelmingly, 93% of respondents indicated that a specific ICOI policy would be useful in the performance of their duties and to protect them from undue institutional influence. (Chi-Square test shows that this result is statistically significant, p < .000.)

Discussion

Support for Clinical Research

Sponsored clinical research in the United States is funded at a level near $90 billion per year (Angell, 2004; National Institutes of Health [NIH], 2006). This figure does not include support from private foundations. Although most COI policies for research focus on the investigator’s financial conflicts, the levels of funding available to institutions for research have led to concerns about institutional conflicts (Hasselmo, 2002).
The Perceived Need for ICOI in Research

This study has examined the need for ICOI in research at smaller research/academic medical centers. Results indicate that institution-wide COI policies that do not specifically address research appeared inadequate. 68% of the respondents felt pressure at times from superiors to treat protocols inappropriately. These respondents stated that ICOI policies for research were necessary. 93% of respondents, including those who reported not being pressured, stated that ICOI policies for research were necessary, even though all have general institution-wide COI policies.

Two Major Areas of Concern for ICOI in Research

Hasselmo (2002) described two major categories of ICOI in research. The first category involves institutional officials and other influential individuals who, for financial or other reasons, use their position to either make, or pressure others to make, decisions that are inappropriate and may not be in the best interest of the institution. The second category involved equity holdings or royalties by institutions such as those that might occur from institutional research that have resulted in "start-up" or "spin-off" companies. When equity interests are at stake a greater potential for conflict is perceived to exist. Institutional financial gains can be at odds with research integrity.

Smaller institutions are most likely to encounter conflicts of the first type. This type of conflict was addressed in this study. The authors, however, recognize the issues involving patents and "spin-off" companies. (Morris, 2000; Hasselmo, 2002) This area will be addressed in another planned study. Stanford University, among others, has developed ICOI policies regarding research and spin-off companies (Stanford Human Research Protection Program, 2006).

Based on information from this study and using expertise within our institutions, we propose the policy presented below, which may be adapted to each institution’s situation. The policy’s guidelines suggest that research administrators must be aware of pressures from both senior administrators and from investigators or others who might benefit from a research study.

Involvement of Stakeholders

Any successful policy must be consistent with all other institutional policies. An ICOI policy for research must be reviewed by all appropriate institutional officials and approved by the highest authorities in the institution. Otherwise, broad institutional acceptance will not occur. In smaller institutions, physician-researchers conduct most research; thus it is imperative that the medical staff understands and accepts the policy.

No Dollar Thresholds for Administrators

One of the unusual aspects of the proposed policy (Figure 1) is that there are no financial thresholds. COI for individuals often have dollar cutoffs above which reporting must occur. This proposal does not have such ceilings. After much discussion, it was concluded that persons in administrative positions, where power can be exercised, must be held to significantly higher standards. Reporting must occur for any dollar amount or for any equity interest.
Figure 1. Institutional Research Conflict-of-Interest Policy Proposed by the Authors

Not only are investigators potentially subject to conflicts of interest, but so also can the institution and its administrators. This policy addresses aspects of institutional conflict of interest. The following policy relates to research and shall not be in conflict with any other system policy.

**Guidelines**

1. No administrator involved with research shall serve on a board or be a consultant to a research sponsor that is involved with [institution name] in research activities without disclosing such to [appropriate institutional authority]. This disclosure will be made in the form provided for this purpose on an annual basis or, if significant (per institution’s policy), as soon as such a conflict appears.

2. No administrator shall receive any compensation, defined as cash, payment for goods, services, travel expenses, or other valuable compensation from a research sponsor without disclosing such to [appropriate institutional authority].

3. No administrator or physician leader shall receive any remuneration for discounting or reducing the fees for a sponsor of a research protocol. (See [institution name] Policy and Procedure Manual.)

4. No administrator shall interfere with the activities of the [institution name] Institutional Review Board or other research-related committee with the intent to influence any outcome regarding the deliberations of the committee on any subject brought before the committee.

5. No administrator shall interfere with the activities of research administration personnel while performing appropriate oversight duties as indicated elsewhere in these documents and in federal regulations.

6. If a research study is disapproved by the IRB, no administrator may overrule the committee action. However, the administration of [institution name] may decide that an IRB-approved study may not proceed.

7. Appropriate oversight of research administration and grants administration personnel by [institution name] administrators, and especially the Institutional Official (IO) and the Director of Research (or equivalent), shall occur as per [institution name] Policies and Procedures.

**Consequences**

Issues and complaints regarding any of the above listed situations may be reported to the IO, the Director of Research Administration (or equivalent), Director of Institutional Compliance, the President of the Medical Staff, Department Chair, or the CEO of [institution name]. If reported to other than the IO, the person to whom the incident or situation was reported should report the situation to the IO.

The mechanism for follow-up outlined in the Research Compliance Plan shall be followed. Remediation shall occur and is outlined in the Research Compliance Plan.

**Future Studies**

In future studies, the investigators will address the institutional issues of equity in spin-off companies, patents, and intellectual assets, and their effects on ICOI for smaller research institutions.
Acknowledgements

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References


Association of American Medical Colleges (1993). Guidelines for dealing with faculty conflicts of commitment and conflicts of interest in research. (pp. 6-7). Washington, DC: Association of American Medical Colleges


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