Financial conflicts of interest present enormous challenges for the clinical research enterprise. Managing these conflicts can be critical in protecting the rights and welfare of human research participants and to preserving the scientific integrity of the data being collected.1 2 Several studies have examined the manner in which academic medical centers (AMCs) approach the management of conflicts of interest,3–5 as well as the attitudes of investigators and potential research participants toward conflicts of interest and their management.6–9

A variety of professional societies, governmental bodies, and others have recommended that conflicts of interest be managed, in part, by requiring investigators to disclose financial conflicts to potential research participants.10 For example, in 2001, a task force of the Association of American Medical Colleges (AAMC) recommended that:

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research. Furthermore, the information should be conveyed clearly so that the person can actually use the information in making his or her decision. That is, the information should allow the potential research participant to understand the nature and likely consequences of the financial conflicts of interest in the research under consideration.

A second goal is to respond to perceived regulatory requirements or protect against legal threats. While there is currently no federal regulation requiring disclosure of financial conflicts of interest to research participants, there is precedent in tort law for suing investigators or research institutions for insufficient disclosure of conflicts (Grimes v. Kennedy Krieger, Inc.,15 Moore v. Regents of the University of California14). In general, failure to disclose financial conflicts of interest could put investigators at risk of being charged with battery, negligence, or breach of fiduciary responsibility.10,17 As opposed to the first goal, this goal is less concerned with ensuring that potential research participants understand what information about conflicts means for their decision making, and is more concerned with meeting whatever legal or regulatory requirements might exist without harming the research enterprise. Accordingly, one might expect such disclosures to place conflicts of interest in a relatively more positive light and to be less informative—at least from the potential participant’s perspective.

A third goal of disclosure to potential research participants is to deter investigators and institutions from having significant conflicts of interest.18 The rationale for this goal is that the prospect of disclosing such conflicts to potential research participants would itself discourage investigators from having conflicting interests. To achieve this goal, investigators would have to believe that the required disclosure would paint an unfavorable picture of the financial arrangement and the proposed research. Therefore, such disclosures would likely require direct statements about the potential negative consequences of the investigator or institution having such financial interests.

In this study, we reviewed the publicly available policies of AMCs in the United States regarding disclosure of financial conflicts of interest to potential research participants. Our first objective was to document the current state of IRB and COIC policies regarding such disclosures, with particular attention to any specific language recommended for disclosure. Our second objective was to use this information to identify and share models for how disclosure to potential research participants might be achieved effectively. This information is vital as IRBs and COICs struggle to implement the general guidelines and recommendations regarding disclosure of conflicts of interest.

**Method**

**Sample and procedures**

We identified 123 AMCs in the United States that have IRBs, and we sought their IRB and institutional policies regarding financial conflicts of interest. In February and March 2004, we searched each institution’s Web site to identify documents containing information regarding the disclosure of financial conflicts of interest. We used manual searches and keyword searches (keywords: conflict of interest, financial disclosure, informed consent form, informed consent document) on each institution’s Web site. The desired information was typically found in the institution’s IRB policies, templates of informed consent documents, the institution’s COIC policies, the institution’s conflict of interest policy, and/or financial disclosure forms. In March 2004, we sent letters to 24 institutions that had either no information or incomplete information posted on their Web sites. Institutions that did not respond to this query were sent an e-mail with the same request for information. Institutions that again did not respond were sent the same request by e-mail and/or telephone by August 2004.

**Content coding**

To assess institutions’ guidelines for disclosing financial conflicts of interest to potential research participants, we extracted and coded each institution’s information on disclosure. A checklist (see List 1) was developed using a combination of a priori and empirically generated items that best described the key elements of each institution’s information regarding disclosure. A research assistant coded all documents. Another member of the team reviewed the code assignments, and disagreements about coding were resolved through discussion with the research team.

**Results**

We obtained relevant information from 120 (98%) of the 123 AMCs. Of these, 57 (48%) explicitly mentioned disclosing financial conflicts of interest to potential research participants as a possible strategy for managing conflicts. These statements were contained most often in informed consent document templates (41/57) but were also found in some institutions’ conflict of interest policies (16/57). Table 2 shows the content of the material regarding disclosure from these 57 institutions. Disclosure materials from 33 (58%) institutions required or suggested verbatim language for the informed consent documents. Below we review AMCs’ recommendations and requirements for disclosure, including details of the financial arrangement, administrative management of conflicts of interest, encouragement of dialogue between the investigator and the potential research participant, and nonfinancial conflicts of interest.

**Details of the financial arrangement**

All policies required disclosure of the study sponsor, but there was great variability regarding the requirement for disclosing other details about financial arrangements. Twenty-two (38%) AMCs...
Information Used to Assess Academic Medical Centers’ Guidelines for Disclosing Financial Conflicts of Interest to Potential Research Participants

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Whether disclosure of financial interests to potential research participants was mentioned explicitly in any document or policy</td>
</tr>
<tr>
<td>2.</td>
<td>Where the explicit information regarding disclosure was found</td>
</tr>
<tr>
<td>3.</td>
<td>Whether specific language for informed consent documents was proposed (for example, in a guideline or template for creating informed consent documents)</td>
</tr>
<tr>
<td>4.</td>
<td>Whether the informed consent document guideline specified how funds are allocated</td>
</tr>
<tr>
<td>5.</td>
<td>Whether the informed consent document guideline required a specific description of the relationship between the investigator and sponsor</td>
</tr>
<tr>
<td>6.</td>
<td>Whether the informed consent document guideline required stating that an administrative body (for example, a conflict of interest committee) has reviewed the conflict of interest</td>
</tr>
<tr>
<td>7.</td>
<td>Whether the informed consent document guideline required stating the source of funding</td>
</tr>
<tr>
<td>8.</td>
<td>Whether the informed consent document guideline required stating the amount of funding</td>
</tr>
<tr>
<td>9.</td>
<td>Whether the informed consent document guideline mentioned nonfinancial conflicts of interest</td>
</tr>
<tr>
<td>10.</td>
<td>Whether the informed consent document guideline encouraged discussion between investigators and participants about the financial relationship</td>
</tr>
</tbody>
</table>

Another institution gave a more detailed account of how research funds would be used:

(Insert doctor’s name) is being paid by the sponsor of the study, (Insert sponsor’s name), to conduct this research study. This payment will be used to pay for the costs of the study, which may include such things as tests, medications, physical exams etc. Also, a portion of the money will be given to [the medical center]. One example of what this payment will cover would be the cost of rent for office space within the medical center. [Example 3]

Another detailed approach was identified in an AMCs’s conflict of interest policy:

An institution conducting research that is sponsored by a pharmaceutical company is usually paid in accordance with the reasonable costs of conducting the study. This may include being paid on a “per enrolled subject” basis. These funds may be used to support research work in the investigator’s laboratory. This, in and of itself, does not constitute a conflict of interest, but the subject has the right to disclosure of this relationship. A section should be added to the informed consent document as follows: Payment to Institution: This project is funded, in part, by a grant or contract from (the pharmaceutical company) to the Research Foundation of [the university], in support of the Investigators’ work on this study. [Example 4]

The preceding example is also noteworthy for its comment on whether such relationships constitute a conflict of interest. A related comment about what type of arrangement constitutes a conflict of interest was the following statement from a different institution: “Salary or compensation received for the % effort invested for the performance of this research project is not considered a conflict and they need not be mentioned” [Example 5].

One policy was unusual in that the nature of the financial relationship was not required to be disclosed, but the potential consequences for the investigator or AMC were. In this case, only a single statement was required: “The research(er) and/or (foundation) may earn money from results of this study” [Example 6].

Administrative management of financial conflicts of interest

Template disclosure statements from two AMCs included a statement that the research protocol had been reviewed by an administrative body and that the financial arrangement in question was deemed acceptable:

(Name of researcher) (then describe the nature of the financial interest, e.g., is a paid consultant, owns stock in, is an officer of) a company called (name). (Name of researcher’s) financial relationship with this company has been reviewed by (the university’s) Conflict of Interest in Research Committee (CIRC). The CIRC has developed and implemented a plan to ensure that the research is conducted objectively. [Example 7]

Dialogue between investigators and potential research participants

Two institutions encouraged or required a discussion between investigators and potential research participants regarding financial conflicts of interest. The first example was from template language in the informed consent document:

This study involves a conflict of interest because the institution and/or (choose one) the investigator will be compensated for your participation in it. You should ask the investigator how the institution and/or (choose one) she (he) will benefit by your participation in the study. [Example 9]

The second example was a guidance statement that stated simply, “The investigator should encourage dialogue
related to conflicts of interest” [Example 10]. No additional guidance as to how or when this should occur was provided.

Nonfinancial conflicts of interest

Three institutions made reference to nonfinancial interests, although these references were vague:

A physician and/or investigator must disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment; a physician’s failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of confidentiality. [Example 11]

The language of Example 11 is taken from the ruling in Moore v. Regents of the University of California.16 The other two references to nonfinancial conflicts of interest were:

Conflict of interest is a situation where a person or an organization has a financial or other interest large enough to appear as if it could influence their judgment. The investigator in this study has a conflict of interest in connection with this study and the following paragraph(s) tell(s) you about it. (Insert specific information on the conflict of interest(s).) [Example 12]

(If the investigator has any personal interest, unrelated to the patient’s health, whether research or economic in the research study, include the following language): Your investigator has a financial interest in this research and may benefit monetarily from this investigation. [Example 13]

In Example 13, the language in parentheses appears to include nonfinancial interests, but the subsequent template language was for a disclosure only about financial interests, making it somewhat unclear.

### Discussion

There is little agreement about how financial conflicts of interest should be disclosed to potential research participants or how that process should be accomplished. Our review of the conflict of interest disclosure policies of AMCs documents the current state of affairs and identifies the variety of approaches taken by their IRBs and COICs as they respond to the call to disclose financial conflicts of interest to potential research participants. About half of AMCs’ IRB or COIC policies made explicit reference to disclosing financial conflicts of interest to potential research participants. This lack of guidance at many AMCs is troubling, given the challenges of disclosing conflicts of interest to research participants and evidence that suggests that potential research participants want to know about financial interests.8 It should be noted, however, that some of these AMCs might not have explicit guidance because they do not endorse disclosure to potential research participants as an acceptable management strategy. Of those AMCs that explicitly addressed disclosure to potential participants, most guidance was found in the informed consent document template. Just over half of the explicit instances of guidance included verbatim language that investigators could use in designing their informed consent documents. Where guidance existed, there was considerable variability among AMCs concerning the amount and type of information that should be disclosed.

With regard to the detail found in disclosures, our data suggest that most AMCs that explicitly discussed disclosure of conflicts did not recommend or require a great deal of information beyond the name of the sponsor. Even statements that included information about the nature of the relationship were brief, mentioning only that a sponsor supports the research. In terms of the three goals of disclosure, it is possible that the lack of detail required for disclosures is consistent with the goal of protecting against legal liability without affecting meaningfully the research enterprise.

In contrast, if the goal is to allow people to make informed decisions about participation, it seems reasonable that more information would have to be provided regarding the nature of the financial relationships and perhaps even the way in which funds are allocated. More important, it may be necessary to inform potential research participants of the possible consequences of these relationships. A small minority of AMCs made statements indicating that the investigator or AMC could benefit financially from the results of the study. Without such statements, it is not clear whether or how people understand information about financial relationships in clinical research and the implications of such relationships for their desire to participate. With regard to the goal of deterring financial conflicts of interest, it is highly questionable whether the sparse detail required by most AMCs would serve as a disincentive for investigators to have substantial financial conflicts of interest. Exceptions to this majority include AMCs that required potential research participants to be told that the investigator might benefit financially and those that encouraged discussion between the investigator and the potential participant.

Thus, it appears that the majority of AMCs’ policies were most consistent with the goal of avoiding legal liability. Whether or not this was the intent of

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### Table 2

**Content of Material Regarding Disclosure of Financial Conflicts of Interest to Potential Research Participants for 57 U.S. Academic Medical Centers (AMCs), 2004**

<table>
<thead>
<tr>
<th>Content of disclosure</th>
<th>No. (%) AMCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required or suggested verbatim language for informed consent document</td>
<td>33 (58)</td>
</tr>
<tr>
<td>Required disclosure to include</td>
<td></td>
</tr>
<tr>
<td>Identity of sponsor</td>
<td>57 (100)</td>
</tr>
<tr>
<td>Nature of relationship</td>
<td>22 (38)</td>
</tr>
<tr>
<td>How funds are allocated</td>
<td>10 (18)</td>
</tr>
<tr>
<td>Notification that protocol has been reviewed by conflict of interest committee or other administrative body</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Encouragement of discussion between investigators and potential research participants regarding financial relationship</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Amount of money involved</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Referred to nonfinancial interests</td>
<td>3 (5)</td>
</tr>
</tbody>
</table>

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**3 (5)**
those framing the guidelines, the resulting template language appeared to serve this legalistic goal better than the goals of ensuring an informed decision or of deterrence. Whether the recommended language would actually protect individuals and AMCs from liability of course remains to be seen.

An alternative interpretation of the findings, however, is that AMCs are interested in fostering more informed decision making but are unsure about what or how to disclose with respect to financial conflicts of interest. This uncertainty is understandable, because there are few published data to inform investigators and administrators about the information that is viewed as “material” by different parties involved in research, and how best to communicate that information to potential research participants (see Kim et al.8 for one empirical study). Our review sets the stage for this line of research by identifying several models for disclosure to submit to empirical testing. For example, it would be interesting to know whether a simple disclosure stating that the investigator could benefit financially from the results of the study (Example 6) is better understood and more satisfying to potential research participants than a long description of the nature and possible consequences of the financial relationship. Our current work is focusing on such issues.

Our data also present an opportunity to examine conformity with the 2001 AAMC recommendation11 that disclosure language “should include an explanation of the fact that the financial interest in question has been reviewed by the [conflict of interest] committee, approved subject to committee oversight, and determined by both the committee and the IRB not to pose any additional risk to the welfare of research subjects or the integrity of the research.”11, p.18 Only two of the disclosure templates (Examples 5 and 6) included such language. This small number might result from the fact that the AAMC recommendation assumes that a well-defined process is in place to make determinations regarding the risk of conflicts of interest to research participants or to the integrity of research. The failure of almost every AMC to follow the AAMC recommendation in their policies could be a reflection that such a process is not yet well-established. Our findings also add to the picture of conflict of interest management in AMCs recently presented in a report by the AAMC.4 The authors of the report note that, although progress is being made in many AMCs in the management of financial conflicts of interest, there are still areas requiring attention. Better compliance with AAMC guidelines might be accomplished by incorporating the guidelines into IRB accreditation criteria.

Our conclusions should be qualified by several considerations. First and foremost, our findings apply only to AMCs. The vast majority of industry-sponsored clinical research is conducted outside of AMCs, so the generalizability of our findings is not clear. Second, while we made every effort to identify the relevant policy statements and materials at each AMC, additional information regarding disclosure of financial conflicts of interest may have been contained in unidentified documents. It is interesting to note, however, that our failure to obtain conflict of interest policies from every AMC is itself telling with regard to the AAMC guideline11 that the “policy and the related information should be readily accessible to covered individuals and to the public.” In addition to conventional means of communication, the policy should be placed on the institution’s website, if one exists.”11, p.16 Even for the policies we found, considerable effort was required to identify them. Third, some AMCs’ documented policies might not have kept pace with changes in practice. We are now conducting interviews with IRB and COIC chairpersons to understand current practices. Still, the review of documented policies is important in that, compared to undocumented, informal practices, documented policies should provide a baseline of assurance that financial conflicts of interest will be managed consistently and effectively. It is conceivable that accreditation of human research protection programs can and will play a role in establishing such a baseline in the future. Fourth, our focus on template language in the informed consent documents should not imply that consent forms are the only or even the most important aspect of the informed consent process. Especially given the complexity of the information involved, greater attention is required for other aspects of the consent process that include giving potential research participants adequate and understandable information that is relevant to the research. The AAMC guidelines11 and others,19 for example, recommend explicit statements that encourage participant-investigator dialogue (Examples 9 and 10).

In conclusion, disclosure to potential research participants is a frequently mentioned approach to the management of financial conflicts of interest. Significant questions remain, however, concerning the goals of disclosure and the most effective methods for achieving those goals. We found a variety of recommended disclosure practices among AMCs—the large majority of which were not consistent with key recommendations of the AAMC. We also found a number of promising models for disclosure language that IRB administrators and other policy makers might consider. More work is required to answer several questions: What are the intended goals of disclosing to potential research participants? What are the administrative barriers (e.g., communication between an AMC’s IRB and COIC) to achieving those goals? From the participant’s perspective, how can the informed consent process (including documents and conversations between participants and research staff) be engineered to best meet the goals of disclosure?

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