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Disclosing Conflicts of Interest in Clinical Research: Views of Institutional Review Boards, Conflict of Interest Committees, and Investigators

Kevin P. Weinfurt
Associate Professor of Psychiatry and Behavioral Sciences in the Duke University School of Medicine and Deputy Director of the Center for Clinical and Genetic Economics in the Duke Clinical Research Institute. He holds a doctoral degree in psychology from Georgetown University.

Joëlle Y. Friedman
project leader in the Center for Clinical and Genetic Economics. She holds a master's degree in public administration from Columbia University.

Michaela A. Dinan
Research assistants, University of Virginia.

Jennifer S. Allsbrook
project planner in the Center for Clinical and Genetic Economics.

Mark A. Hall
The Fred D. and Elizabeth L. Turnage Professor of Law in the Wake Forest University School of Law. He holds a law degree from the University of Chicago.

Jatinder K. Dhillon
Research assistants, University of North Carolina at Chapel Hill

Jeremy Sugarman
The Harvey M. Meyerhoff Professor of Bioethics and Medicine in The Phoebe R. Berman Institute of Ethics, The Johns Hopkins University. He holds a medical degree from Duke University, an M.A. in Public Health from The Johns Hopkins University, and M.A. in Philosophy from Georgetown University.

Investigator and institutional financial conflicts of interest have raised concerns about both the integrity of clinical research and protecting the rights and welfare of research participants.[1] In response, professional groups and governmental bodies have issued guidance for managing conflicts of interest to minimize their potential untoward effects. Although a variety of approaches have been offered, a common protection is to disclose financial interests in research to potential research participants as part of the recruitment and informed consent process.[2] This approach reinforces a basic norm of candor, ideally allowing potential research participants to evaluate whether financial interests should affect their decision to participate in research. Disclosure to potential research participants is viewed as an alternative to having regulators or research institutions limit or prohibit all financial interests in research, assuming that not all such interests are unacceptable.

Authoritative recommendations for disclosing investigators' financial interests to potential research participants have existed for several years, and these recommendations have been adopted in some fashion by many academic and other research institutions.[3] However, little is known about how decisions are made regarding disclosures of conflicts of interests to

potential research participants, including what is disclosed and the rationale for making these determinations in the context of actual research. It may be that day-to-day practices differ from formal policies, or that adopted policies are resisted by various institutional actors. An understanding of real-world decision making and practices regarding disclosing financial interests to potential research participants is required in order to fully evaluate the successes and limitations of disclosure as a management strategy for conflicts of interest in research.

In this study, we sought to understand the attitudes, beliefs, and practices of institutional review board (IRB) chairs, conflict of interest committee (COIC) chairs, and investigators regarding disclosure of financial interests to potential research participants. IRBs have oversight responsibility for protecting the rights and interests of research participants and for the informed consent process.[4] Therefore, they have an oversight role with regard to disclosures of financial conflicts of interest in research. In addition, many institutions that conduct clinical research have established COICs or similar bodies to provide a somewhat independent review of financial interests in research and to suggest appropriate management strategies, including what should be disclosed to potential research participants. Finally, clinical investigators who are subject to these oversight bodies and may have responsibility for disclosing financial interests to potential research participants should have accumulated experiences and formed opinions that shed light on the appropriateness and effectiveness of disclosure policies. In short, the views of each of these key players are critical to understanding how disclosure to research participants is actually carried out in clinical research settings and how well disclosure enhances the protection of the rights and interests of potential research participants.

Methods

Participants

We selected ten academic medical centers, ten independent hospitals, ten independent IRBs, and ten unaffiliated research entities from which to recruit respondents. At each institution, we attempted to interview the chairpersons of the IRB and the COIC - or officials with similar positions or responsibilities - and a clinical investigator, except in the case of independent IRBs, because they would not be expected to have clinical investigators in house. We interviewed members of each of the IRB and COIC chair groups until we reached saturation in each group (i.e., no new information or insights were being gleaned from subsequent interviews).[5] Although we reached saturation, we interviewed a smaller than expected number of clinical investigators due to difficulties in recruiting investigators to participate, as described below.

To identify institutions with different volumes of work in clinical research, we used a combination of resources, including expert opinion and the ranking in National Institutes of Health (NIH) funding (http:// grants1.nih.gov/grants/award/rank/medttl04.htm). Specifically, we selected institutions that were in the top ten of NIH funding and some institutions that had less NIH funding.

Twenty-three IRB chairs and fourteen COIC chairs participated in the study. In one case, we interviewed the IRB administrator in lieu of the chair. Also, many of the nonacademic medical institutions did not have a COIC chair, but rather an individual(s) who was responsible for these issues. Three institutions required us to interview two people together.

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Clinical investigators were identified using the investigator relations database of the Duke Clinical Research Institute (Duke University, Durham, N.C.) for each of the selected institutions. In instances where institutions were not in the database, we used expert opinion and queried the IRB and COIC chairs we interviewed to identify clinical investigators at their institutions. We also asked clinical investigators who declined participation to recommend other potential participants. Investigators who had IRB or COIC service since 2000 were excluded from participation so that we could focus the interviews on the views of investigators not currently involved with oversight. Despite these efforts, only eight investigators agreed to be interviewed.

Interview Design

The interview was designed to elicit respondents' understandings of how disclosure of financial interests is currently done at their institutions, as well as their thoughts about whether and how disclosure should be done. We also elicited opinions about the definition of conflicts of interest, potential consequences of financial relationships in research, risks and benefits of disclosure, and colleagues' attitudes about conflicts of interest in research. In addition, we asked IRB and COIC chairs about how their respective committees relate to one another. The script (available on request) was pilot-tested with six people at Duke University and subsequently revised. All interviews were recorded digitally, transcribed verbatim, and verified to confirm the accuracy of the transcription. The interviewer then re-dacted identifiable information regarding respondents and institutions.

Procedures

The interviews were conducted from October 2004 to March 2005. All potential participants were initially sent an invitation by e-mail to participate in the study. We confirmed the roles of all interested participants (i.e., confirmed the accuracy of publicly available information that listed them as IRB chair, no recent IRB service, etc.) and scheduled a time to conduct the interview. We attempted to contact nonresponders by e-mail and telephone a minimum of five times. All respondents gave oral consent to participate and received $100 for their participation.

Three interviewers received standardized training in conducting qualitative research interviews. One interviewer was assigned to each group of participants (COIC chairs, IRB chairs, and investigators). The study team jointly reviewed three to four randomly selected interviews in each group to ensure quality. Each interview was conducted over the telephone and lasted approximately forty-five minutes. This study was approved by the institutional review boards of the Duke University Health System and the Johns Hopkins Medical Institutions and deemed exempt from the requirement for review by the institutional review board at Wake Forest University.

Data Analysis

Interview transcripts were entered into N6 (QSR International Pty. Ltd., Doncaster, Victoria, Australia) for qualitative analyses. All interviews were read, content-coded, and reconciled by two members of the study team. Initial content codes were developed based on the first two interviews in each group and were refined iteratively for the rest of the interviews. The Appendix lists the final content codes used in the analysis.

Results

Several salient themes emerged in the interviews, including general attitudes toward conflicts of interest, circumstances in which financial interests should be disclosed, the rationale and benefits of disclosure, what information should be disclosed, negative effects of and barriers to disclosure, and the timing and presentation of disclosure. We discuss each in turn. Table 1

shows the prevalence of the various themes separately for IRB chairs, COIC chairs, and investigators. All quotations in the following section remain anonymous to protect respondent's identities.

Some respondents suggested that concerns about conflicts of interest were unwarranted.

General Attitudes

Respondents held one of three basic attitudes toward financial conflicts of interest and their management, which we categorized as believing that attention to conflicts of interests is either overblown or important or that conflicts of interest are unavoidable. Some respondents suggested that concerns about conflicts of interest were unwarranted. For example, an investigator dismissed the idea that an equity holding could bias the conduct of a study:

> As far as I am concerned, the conflict of interest thing is blown way, way, way out of proportion. I honestly believe that with the ability to affect a stock you may own or a pharmaceutical company that you may be involved with in any manner by doing a simple drug study, the amount of money therein is so incontestably small. Let's say...we do a dozen studies for [Company X]...and it is a $2 billion company. I mean, you know, how could I possibly...Let's say that I owned a lot of stock in [Company X]. I mean, the application of a new drug to the company, let alone our ability to participate in that drug, would not affect that one iota. So, as far as I am concerned, conflict of interest is overblown.

In contrast, others felt that conflicts of interest are a serious problem. One COIC chair remarked, "The future of academic health centers depends on [COIC oversight] being done right." Finally, others indicated that conflicts of interests were a necessary part of life that can not be avoided entirely. One IRB chair's comments are representative:

> Well, I think conflicts of interest are an important part of practically every human transaction. ... The only way we can remove conflict of interest is to all live in individual cages and not have any interactions with each other. The institutions obviously have to balance that with the incentives that they provide for their members, as well as their interactions with society as a whole.

Disclosure of Financial Interests

Most respondents suggested that disclosure should occur under all circumstances in which a financial interest exists. Close to half of the sample indicated that the disclosure itself depended on the type of financial relationship: I guess the most common [financial relationship] is everybody gets support from pharmaceutical companies to do the trial. But those are usually based on sort of a fee per patient going through....And in that sense I do not really see that as a financial disclosure that is necessary, because those budgets are, at least in my institution, very tightly regulated and very much fee-for-service type thing. So, I do not really think that there is a lot of need for saying Company XYZ is paying me $6,000 for every patient we enroll on this, and those costs are going to pay for extra lab and time of people who do extra exams and fill out paperwork and submit things to the IRB.

An IRB chair mentioned that risks to the research participants would also factor into decisions about disclosure:

> I do not know if [disclosure] is a requirement, but probably obliquely, or explicitly, and it depends on how large the incentive is and how it might adverse or increase the risk, or induce the investigator to put the patient at greater risk.

No respondent indicated that disclosure of financial interests should never take place.

Rationale and Benefits of Disclosure

Despite their agreement about the need to disclose financial interests to potential research participants, the respondents offered a variety of justifications for doing so. These included better informed decision making regarding participation, trust and transparency, reducing the risk of liability, and others, such as the role of disclosure in managing public perceptions and the institution's management of particular financial interests.

Informed Decision Making

The most frequently discussed justification for disclosing financial interests was to enable potential research participants to make better informed decisions. One respondent said, "If people are going to do this ethically and morally you should give them as much information as you can so that they can make reasonable decisions." However, some respondents expressed strong negative views about the possibility of better informed decisions through the disclosure of financial benefits: "I do not think it adds any piece of information that would help them judge being in the study or the quality of the data that will come out of the study." Others expressed ambivalence about the rationale for disclosure:

> I do not think it is the kind of information that patients use to make decisions about which trial they will participate in. But when they are asked that bottom-line question - you know, "Will you participate?" - it is at that point that they really do require this type of full disclosure. In other words, I do not want to load up the consent form and consent process with even more forms that are just going to get in the way of the patients making decisions.

Trust and Transparency

Another prominent reason for disclosing financial interests in research involved engendering participants' trust in investigators, the research institution, and the research enterprise in general. One COIC chair was particularly passionate:

> The benefits of disclosure obviously is we develop a culture where people increasingly realize and trust academic health centers as working in their best interest, and partnering with, and that word is sort of en vogue, but I think it is a very important word, but that they are a part of our team. That benefit is tremendous.

Some respondents underscored the need for disclosure to prevent a later reaction of distrust if research participants learned about a previously undisclosed conflict of interest. Several respondents said that whether disclosure would build trust depended on the individual situation and that in some cases such disclosures could decrease trust in the researchers or research institution.

Closely related to trust was the notion that disclosure is important to maintain an environment of transparency. However, one IRB chair noted the difficulty in determining what aspects of the study should be transparent to potential research participants:

> We make decisions all the time about what we are going to put in a consent form. You know, if 5,000 people have received a drug for 10,000 patient-years, and one person dropped dead of a cardiac arrhythmia, do we put that risk in the consent form? No, we do not. Because we have to make some decisions about what is material and germane to the decision. And I guess that we have decided that those are not material and germane to a decision.

Reducing the Risk of Liability

Several respondents in each group stated that disclosure of conflicts of interest was necessary to avoid legal liability if something went wrong with the trial or if a research participant later became upset about the presence of a financial interest. Among the IRB chairs, however, some disagreed that reducing liability should be a rationale for disclosure.

Other Justifications

Less frequently cited reasons for disclosure included potential research participants' basic right to know this information and the need for institutions to manage the public's perceptions of conflicts of interest. Regarding the latter, several respondents noted that disclosure would be important to avoid a newspaper headline about their institution's conflicts of interest.

While no respondent mentioned deterrence (i.e., discouraging investigators from holding questionable financial interests) as a rationale for disclosure, one COIC chair felt that disclosure could help investigators and institutions police themselves:

> And also, by declaring it, I think the institution and the investigators appropriately keep under their nose[s] the issues that...may be influencing them, and it continually alerts them to the possibility of potential for hidden bias in their studies. And it is important because they are training the next level of investigators. So this is something that is important to have, I think, always in front of us, because we do this [research] as a privilege and not as a right.

Information to Disclose

Funding Source

Respondents in all three groups remarked that the disclosure should be as simple as possible to avoid confusion. Many indicated that the funding source should be disclosed, although not all IRB chairs thought that disclosing the name of the sponsor was necessary. For example:

> Well, I do not really know if it matters too much if you necessarily disclose the particular brand name or the company name. But I think that the positions that have been taken on our board are that the important thing is to disclose to people that, if they are participating in research, what kind of an organization is sponsoring this study. Is it an organization that makes products? Is it a government agency? Is it a nonprofit organization that is funded by others, presumably nonindustrial backers, or what sort of an organization is it? And so our position would be that that should be disclosed to study subjects as part of the informed consent.

Amount of Financial Interest

None of the investigators thought the amount of the financial interest should be disclosed. Investigators' reasons for not wanting to disclose the amount included the complexity such a disclosure would require, the idea that the amount might "detract attention away from what really needs to be decided," the potential effects of this disclosure, and the concern that participants would attach greater importance to a particular amount than would physicians. One investigator's concerns about the effects of disclosing specific amounts of financial interests are clear: "[It] could become an inflammatory issue if someone says they are getting $100,000 to sponsor [sic] this particular form of research."

Implicit in statements about the relative implications of money was the idea that potential research participants would overestimate the influence that particular amounts of money would have on the investigator's behavior. Among IRB and COIC chairs, some remarks were

consistent with the notion that researchers and potential research participants would value the money differently, but this led to different conclusions. For example, one COIC chair observed:

> Well, I actually think they should be told not only whether a financial relationship exists, but also the amount. One thing we have on our [COIC] is lay members, which a lot of [COICs] don't have. They always bring an interesting perspective, because the amount of money that a surgeon thinks is not much our lay members think is quite a bit.

Thus, this COIC chair appeared to believe that disclosing the amount would allow potential research participants to exercise their right to disagree that the amount is too small to be influential. One IRB chair echoed the notion that any amount might be influential, and for that reason the amount should not be relevant for the disclosure: "Now, to this point, we have not ever asked anyone to express the amount of money involved, really thinking that $1,000 may be as bad as $20,000."

Among the ways to disclose the amount, IRB and COIC chairs suggested using a range, an adjective (e.g., "substantial investment," where "substantial" was defined using a threshold), or an explicitly stated threshold. One COIC chair's comments illustrated the tension between providing material information and respecting the privacy of investigators:

> My own feeling - I think I am sort of like 55/45 on this one - I think just to indicate that there is a significant financial interest derived from intellectual property interest or consulting arrangements is an adequate way. And, if the person says, "Well, I am thinking about it, but I want to get more information," if they want more information, the disclosure in the consent form at least gives them the possibility to ask additional questions. And if they really want to know the amount, then they can ask for it. If the investigator does not want to reveal it, then the person has the option not to be in the study. I think this is a way in which you can provide still some privacy on both sides, in doing it that way.

Finally, there was great variability and uncertainty among the respondents regarding what would be a reasonable threshold amount. Some respondents offered examples from $1 to $50,000, and other respondents simply acknowledged that the threshold is something they struggle with.

Nature and Implications of the Relationship

Most respondents seemed to agree that information about financial ties between the investigator and the sponsor - the nature of the relationship - was important to disclose, but that such disclosures should be kept simple. There was disagreement, however, about whether the disclosure should highlight the potential consequences of financial relationships. Some respondents indicated that one should not tell potential research participants how to think about the information, but simply provide them with the information. These respondents sometimes referred to the tension between wanting to provide the requisite information for informed decision making, but without making the risk of harm due to the financial interest more salient than it ought to be. For example, when asked whether participants ought to be told that a financial interest might influence an investigator to interpret study results with some bias, one COIC chair remarked:

> I do not think I would say that, because I think that that is sort of leading the subject to where they might think that this is what is going to happen. I think that if the relationship between the risk and the study was not clear, you might need to spell that out. But to some degree I think you are just informing the subject. You are not trying to tell them what they should think about it.

Other respondents felt it was important to help potential research participants understand the implications of a conflict of interest. One IRB chair explained the reasoning for this, while also expressing doubt that potential research participants would consider such disclosures seriously enough:

> I think they need to understand that there is a way in which an investigator - and, I will put parenthetically, a less than scrupulous investigator - could potentially alter or in some way affect or influence the results of the research that is being done for strictly personal, private reasons that would often but not always be fiscal and that that would be potentially prostituting - sorry to use the word - the scientific process and that subject's contribution to science. And that is a theoretical fault in the system for which there are potential safeguards within the system and potential remedies. To me it is not unlike the statements that are put on cigarette packets, that smoking can cause cancer and birth defects and all those things. It is a very minute statement when you consider the seriousness of the concern. No one takes any notice of it. It more, I think, satisfies the needs of the Surgeon General and who he represents than any health interest. That may be a skeptical, cynical view of that. But perhaps there is some analogy between the two that is relevant.

Many respondents from all groups mentioned the risk of potential research participants not having the background and education required to understand a conflict of interest in the context of the informed consent process.

One COIC chair described possible misunderstandings that could occur if potential research participants were left to draw their own conclusions about the implications of a financial interest, noting the importance of trust in the investigator:

> Another risk might be is, the subject might not understand what is meant, what the statement means, and just cause confusion that maybe is not necessary. I have heard stories that subjects might actually think that because the investigator is invested in the company that they might have more reason to trust that the drug would work, because they trust the investigator and they think that they might be more apt to join the study. Because they think that the investigator is invested because it is such a great drug or something like that. ... I would say that that would be a risk because we do not want the subject to misunderstand. It might influence their opinion of - get their hopes up short of saying that this drug is going to work, more so than without the statement in the consent form.

Some respondents in each group discussed the importance of having potential research participants ask questions about the financial interest. There was some variation, however, regarding whether one should assume that participants will ask questions if necessary, or whether the disclosure must include a specific invitation to ask questions.

Negative Effects and Barriers to Disclosure

Lower Enrollment

When asked about the potential risks associated with disclosing financial interests, many respondents mentioned the possibility that disclosure would affect potential research participants' decisions to enroll. The majority of remarks, however, dismissed concerns about lower enrollment, citing participants' desire to get better or to find a novel treatment as more powerful factors in potential research participants' decisions to enroll.

Decreasing Trust

All groups of respondents mentioned that disclosure might undermine the trust of potential research participants in the investigators. One COIC chair noted that, although disclosure might make some people more wary, this was not necessarily a bad thing: "Subjects do have a right to be wary of participating in research and of the motives of investigators." Still others maintained that disclosures could increase trust in individual researchers, as well as in the overall clinical research enterprise.

Burdening the Informed Consent Process

Several respondents in all three groups were concerned about burdening the consent process and documents with additional disclosures. One investigator discussed the relative importance of the financial disclosures in the consent process as follows:

> I think what we have right now is too detailed. I think that the less detail would be better. I think there is enough to read about the actual mechanism of the study itself, as far as the drug, the side effects, this, that, and the other - the disease, the side effects. I think we should low-key this as much as possible. I think, if anything, the law should be liberalized. I do not see any advantage to the patient. So, I really think we are going down the wrong side of this mountain.

Inability to Understand

Many respondents from all groups mentioned the risk of potential research participants not having the background and education required to understand a conflict of interest in the context of the informed consent process. Others disagreed, including this IRB chair, who cited the ubiquity of conflicts of interest in daily life: "I think most people understand what a conflict of interest means. They see the news. You could say if you do not understand what the term conflict of interest is, please ask."

Violating Investigators' Privacy

Some respondents were concerned that financial disclosures might harm investigators. One COIC chair from an independent IRB provided an example of how disclosure of a financial interest did in fact create a problem related to privacy for the investigator:

> We did have an interesting case where [an] investigator who wanted to do a [study]...and he was getting substantial consulting fees from this manufacturer. And so when we wrote that in the letter that the conflict of interest was very large...the school fired him. He was pretty mad at us. So in that case there was a risk to the investigator, and I guess we just figured, or it did not occur to us that he might not have been straight with the school in applying for this research.

Several IRB chairs recognized that investigators were concerned about protecting their financial privacy but questioned sarcastically whether such a risk was a legitimate concern: "One principal risk I have heard comes from investigators, which is an invasion of their privacy. I always enjoy that one."

A small number of respondents said they believed that disclosure of financial interests would not pose any risks whatsoever.

Timing and Presentation of Disclosure

With regard to how the disclosure should take place, most respondents believed the disclosure should occur at the beginning of the informed consent process. For most respondents, this referred to the time when information about the risks and benefits of participation were

presented, usually in the informed consent document. Some respondents suggested that the disclosure be highlighted in some way, as in this investigator's comment: "It should not be hidden, but it should not be overwhelming. I say a good paragraph, maybe one good paragraph in heavy print. So that the patient would recall seeing it." A COIC chair described how one institution highlights the disclosure:

> We request that the statement on the consent form be placed up at the top, at the beginning of the consent form. So I guess if during the enrollment process or the informed consent process the investigator is going through the consent form from front to back, he or she would start with the statement of conflict of interest.

Some respondents, such as this IRB chair, emphasized that it is important to distinguish between the informed consent document and the informed consent process:

> [I] also think the consent form, reading it and finding it, is not really consent. It is really the discussion between the investigator or people involved in the research team and the participant to make them fully aware of all issues related to that particular study. And conflict of interest is one of them.

Discussion

Interviews with IRB chairs, COIC chairs, and investigators revealed a considerable amount about how conflicts of interest are or are not being disclosed to potential research participants, including what is disclosed and the rationale for making these determinations in the context of actual research. Despite apparent consensus regarding some aspects of this process, several issues warrant attention.

Rationale for Disclosure

The motivation or rationale for disclosure of financial interests in research is critical, because it determines how one evaluates the effectiveness of disclosures and determines, in part, how disclosure ought to occur. Our respondents cited a number of rationales, including enabling informed decision making, promoting trust in researchers and research institutions, and reducing the risk of legal liability. Enabling informed decision making about enrollment was the most frequently discussed rationale, with some respondents supporting this goal and others questioning it. This finding begs the question, however, of what it means to make an "informed decision" about enrollment. Two aspects of informed decision making that surfaced in the interviews were materiality and substantial understanding.[6]

Materiality refers generally to whether the information will have implications for the decision making process. While most respondents agreed that disclosing conflicts of interest would not affect enrollment, many respondents disagreed about whether information about financial interests still might be "material" to the decision to enroll. Some suggested that there was little point in disclosing financial interests if the information would not affect enrollment decisions. Others implicitly agreed with the conceptual model of informed consent articulated by Faden and Beauchamp,[7] in which materiality depends not on whether the information influences decisions, but rather on the value that potential research participants place on having the information. More conceptual work is needed to clarify what constitutes materiality in this context.

Our data also suggest that it will be difficult to achieve agreement on the issue of substantial understanding of financial interests. Before we can resolve what counts as substantial understanding, there must be agreement about what risks are important for potential research participants to understand. Implicit in guidance documents and regulations is the notion that potential research participants should be able to evaluate the risks that conflicts of interest pose to them or to the integrity of the science. Curiously, few respondents explicitly mentioned

protecting the welfare of research participants or the integrity of the science when discussing reasons for disclosure. It was not clear whether the respondents assumed these considerations in their comments (e.g., this was implicit in making "better decisions") or did not think primarily in terms of risk to participants and scientific integrity. Not believing that these risks are salient might explain, in part, some respondents' reluctance to include statements about the implications of financial interests in the disclosure. This finding might also relate to some respondents' belief that concerns about conflicts of interest are "overblown."

Strategies for Disclosure and Potential Barriers

Consistent with our previous review of disclosure policies in academic medical centers,[8] the current study identified a variety of practices for disclosing financial interests. There was some agreement that the financial disclosure should occur early in the consent process, and some respondents suggested that a disclosure statement should appear near the top of the consent document. There was also support for highlighting the disclosure in some way, but this suggestion raises the concern that such highlighting might communicate to potential research participants that the financial disclosure is more important than other components of the consent document. Bringing consent-related information to the potential research participant's attention while not artificially inflating the salience of that information is a challenge that applies to all disclosed information. If disclosure to potential research participants is to be an effective strategy for managing conflicts of interest, more work is needed to determine how to ensure that potential research participants are aware of the disclosure but do not overemphasize its relative importance.

Respondents also agreed about disclosing the name of the sponsor. However, one IRB chair suggested describing what kind of organization is sponsoring the trial (e.g., government agency, company that manufactures the product under study, etc.) It is possible that potential research participants would find such a disclosure more helpful than the name of the sponsoring agency or company.

In contrast, there was much disagreement about whether to disclose the amount of the financial interest. At the foundation of these disagreements was a difference of views on who is in the best position to judge the value and potential influence of a particular amount of money on investigators or institutions. Respondents who opposed disclosing the amount believed that potential research participants were likely to overestimate the value and influence of specific amounts of money. Interestingly, recent research on disclosing financial conflicts of interest in financial advising suggests that consumers do not know how to evaluate the information and likely underestimate the degree of influence.[9] An alternative view found in our data was that no one can determine the influence of a given amount of money or stock, and so the amount is not helpful information to disclose. This belief is consistent with many respondents' difficulty with determining a threshold amount, with values ranging from $1 to $50,000.

One potential barrier for effective disclosure might be the attitudes expressed by some respondents about the management of conflicts of interest in general. Some investigators clearly felt that calls for disclosure were unwarranted. Others expressed fears of reducing trust in researchers or concerns about compromising investigators' privacy. These data complement findings reported by Boyd, et. al,[10] who conducted a survey of investigators at the University of California, San Francisco, and Stanford University. Many investigators in that study recognized the general risk of conflicts of interest, but felt they were personally not at risk. It is possible that such attitudes might affect how some investigators disclose financial interests to potential research participants. For example, an investigator might skip over the financial disclosure when discussing the consent document with a potential research participant. If a participant were to ask a question about a disclosed financial interest, an investigator with a negative attitude toward disclosure might provide vague or dismissive answers. This is an

important barrier that must be considered when IRBs and other oversight bodies consider whether disclosure will be an effective management strategy in individual cases.

Conclusion

Although there are strong arguments for disclosing financial interests in research to potential research participants, officials currently charged with performing this task, as well as those involved in its oversight, are struggling to do so appropriately and effectively. Part of this struggle relates to a lack of clarity regarding the ultimate goals of disclosure.[11] There also is a lack of systematic data regarding how potential research participants can and will use such information in their decision making. Mitigating the first problem will require more explicit articulation and greater consensus regarding the goals of disclosure. The second shortcoming requires the collection of empirical information from potential research participants. Both of these endeavors will be critical in efforts to ensure that the integrity of the research enterprise and the rights and interests of research participants are protected appropriately.

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Appendix

Content Codes

(Note: Each code description is preceded by the code's index number in parentheses.)

(1) Circumstances under which conflicts of interest should be disclosed

- **(1 1)** Under all circumstances
- **(1 2)** Degree of financial relationship involvement
- **(1 3)** Risk to subjects
- **(1 4)** Never
- **(1 5)** Other

(2) Rationale or benefits for disclosure (Why?)*

- **(2 1)** Right to know.
- **(2 2)** More informed decision
- **(2 3)** Liability
- **(2 4)** Regulations
- **(2 5)** General warning to participants
- **(2 6)** Building trust
- **(2 7)** Transparency / honesty
- **(2 8)** Public perception
- **(2 9)** Other

(3) Information to be disclosed (level of detail)*

*These codes were given additional subcodes indicating the direction of the in terviewee's remark as full agreement, qualified agreement, full disagreement, qualified disagreement, spilt, uninterpretable, maybe, or don't know.

- **(3 1)** Funding source (i.e. sponsor)
- **(3 2)** Amount of funding
- **(3 3)** Ties between investigator and sponsor
- **(3 4)** Potential consequences of ties between investigator and sponsor
- **(3 5)** Patient can ask questions
- **(3 6)** Other

(4) Negative effects of or barriers to disclosure (Risks)*

- **(4 1)** Enrollment
- **(4 2)** Breaks down trust
- **(4 3)** Lengthen ICD
- **(4 4)** Lengthen IC process
- **(4 5)** Investigators think unnecessary
- **(4 6)** Investigator privacy
- **(4 7)** COIs difficult to understand
- **(4 8)** None
- **(4 9)** Other

(5) Timing of disclosure*

- **(5 1)** Recruitment/Explanation of the study
- **(5 2)** Informed consent document
- **(5 3)** Educational brochure
- **(5 4)** Informed consent process
- **(5 5)** Other

(6) Attitudes

- **(6 1)** Interviewees
  - **(6 1 1)** Positive
  - **(6 1 2)** Neutral
  - **(6 1 3)** Negative
  - **(6 1 4)** Other
- **(6 2)** Colleagues
  - **(6 2 1)** Positive
  - **(6 2 2)** Neutral
  - **(6 2 3)** Negative
  - **(6 2 4)** Other
- **(6 3)** Patients
  - **(6 3 1)** Do Care

(6 3 2) Don't Care

(6 3 3) Other

(6 4) Public

(6 4 1) No Care

(6 4 2) Don't Care

(6 4 3) Other

References

1. Angell M. Is Academic Medicine for Sale? New England Journal of Medicine 2000;342:1516–1518. [PubMed: 10816191]Bodenheimer T. Uneasy Alliance - Clinical Investigators and the Pharmaceutical Industry. New England Journal of Medicine 2000;342:1539–1544. [PubMed: 10816196]Korenman SG. Conflicts of Interest and Commercialization of Research. Academic Medicine 1993;68(9 suppl):S18–S22. [PubMed: 8373487]Shalala D. Protecting Research Subjects-What Must Be Done. New England Journal of Medicine 2000;343:808–810. [PubMed: 10984573]
2. Department of Health and Human Services. Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. Federal Register 2004;69:26393–26397.
3. Weinfurt KP, Dinan MA, Allsbrook JS, et al. Policies of Academic Medical Centers for Disclosing Conflicts of Interest to Potential Research Participants. Academic Medicine 2006;81:113–118. [PubMed: 16436571]
4. 45 C.F.R. § 46 (2005); 21 C.F.R. § 50 (2005); 21 C.F.R. § 56 (2005).
5. Krueger, RA. Focus Groups,. 2nd edition. Sage Publications; Thousand Oaks, CA: 1994.
6. Faden, RR.; Beauchamp, TL. A History and Theory of Informed Consent. Oxford University Press; New York: 1986.
7. Id.
8. See Weinfurt, et al., *supra* note 3.
9. Cain DM, Loewenstein G, Moore DA. The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest. Journal of Legal Studies 2005;34:1–25.
10. Boyd EA, Cho MK, Bero LA. Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators. Academic Medicine 2003;78:769–774. [PubMed: 12915362]
11. Resnik DB. Disclosing Conflicts of Interest to Research Subjects: An Ethical and Legal Analysis. Accountability in Research 2004;11:141–159. [PubMed: 15675055]Id.;Schneider CE. Reaching Disclosure. Hastings Center Report 2005;35:12–13. [PubMed: 15799493]

Table 1

Relative Frequency of Respondents Who Mentioned a Theme by Respondent Type

Theme	Respondents, n (%)*		
Circumstances in which conflicts of interest should be disclosed	Investigators N=8	IRB Chairs N=23	COIC Chairs N=14
In all circumstances	6 (75)	14 (61)	8 (57)
Degree of financial relationship involvement	4 (50)	10 (43)	7 (50)
Risk to subjects	0 (0)	2 (9)	0 (0)
Never	0 (0)	0 (0)	0 (0)
Other	0 (0)	5 (22)	0 (0)
Rationale for or benefits of disclosure			
Right to know	5 (63)	3 (13)	3 (21)
More informed decision	7 (88)	17 (74)	10 (71)
Liability	3 (38)	8 (35)	2 (14)
Regulations	0 (0)	3 (13)	0 (0)
General warning to participants	1 (13)	8 (35)	3 (21)
Building trust	3 (38)	7 (30)	9 (64)
Transparency/honesty	6 (75)	12 (52)	4 (29)
Public perception	1 (13)	4 (17)	3 (21)
Other	3 (37)	4 (17)	2 (14)
Information to be disclosed (level of detail)			
Funding source (i.e., sponsor)	7 (88)	17 (74)	10 (71)
Amount of funding	7 (63)	17 (78)	10 (93)
Ties between investigator and sponsor	6 (75)	21 (91)	13 (93)
Potential consequences of ties between investigator and sponsor	5 (63)	9 (39)	7 (50)
Patient can ask questions	3 (38)	9 (39)	6 (43)
Other	7 (87)	14 (61)	9 (64)
Negative effects or barriers to disclosure (risks)			
Enrollment	5 (63)	18 (78)	11 (79)
Breaks down trust	5 (63)	6 (26)	3 (21)
Lengthen informed consent document	3 (38)	6 (26)	4 (29)
Lengthen informed consent process	3 (38)	2 (9)	0 (0)
Investigators think unnecessary	2 (25)	0 (0)	1 (7)
Investigator privacy	2 (25)	5 (22)	4 (29)
Conflicts of interest difficult to understand	2 (25)	10 (43)	10 (71)
None	1 (13)	1 (4)	4 (29)
Other	5 (62)	8 (35)	2 (14)
Timing of disclosure			
Timing of disclosure	6 (75)	7 (30)	6 (43)
Informed consent document	7 (88)	12 (52)	4 (29)
Educational brochure	2 (25)	1 (4)	0 (0)
Informed consent process	2 (25)	10 (43)	6 (43)

* Respondents could provide more than one coded response for any category