Growing concern over financial interests in clinical research has provoked greater efforts to identify effective management strategies. Among the strategies discussed is the disclosure of financial interests to potential research participants. However, there is little guidance available concerning such disclosures. The Conflict of Interest Notification Study, funded by the National Heart, Lung, and Blood Institute, was initiated to provide data to Institutional Review Boards (IRBs), conflict of interest committees (COICs), and other policy makers to assist them in deciding how, when, and what to disclose to potential research participants. This effort necessitated developing disclosure language concerning different financial interests commonly found in clinical research. We used qualitative data to develop, evaluate, and improve disclosure statements in an effort to create model language. Specifically, we collected data and feedback from 1) IRB and COIC officials to identify the most relevant financial interests; 2) small groups of people with and without health conditions; 3) individual patients seen in a general medicine primary care clinic; and 4) a multidisciplinary panel of experts. This article presents the model language for disclosing financial interests in written materials and describes the empirical basis and theoretical assumptions used in developing the language. Table 1 summarizes the steps in our development process, which we now review in detail.

Developing the Descriptions of Financial Interests

We developed descriptions of nine specific financial interests to address the major types of financial interest encountered in clinical research. Our judgments regarding the most relevant relationships and interests were informed by previous research in this area, as well as our own interviews with officials of IRBs and COICs. The specific descriptions we developed and tested were salary support, money received outside of the study, per capita payments, finders’ fees restricted to research uses, unrestricted finders’ fees, researcher holding a patent, university holding a patent, researcher owning equity, and university owning equity (see Appendix for descriptions of each
We sent the draft descriptions of financial interests to a panel of experts in bioethics, law, pharmaceuticals, biotechnology, clinical research, IRBs, and academic medicine for comment and revision. Once revised, the descriptions were presented to potential research participants via focus groups.

Focus Groups with Potential Research Participants. Sixteen focus groups were composed of four types of participants: healthy adults; adults with mild chronic illness (e.g., allergies, hypertension); adults with serious illness (e.g., cancer, heart failure); parents of healthy children; and parents of seriously ill children (e.g., leukemia, brain tumor). The same moderator conducted each two-hour focus group session. In addition, each group had either white participants or nonwhite participants. Participants varied with respect to other demographic characteristics such as gender, education, and income. The focus groups were conducted as part of a larger study of attitudes toward financial interests in clinical trials. As part of the focus group discussion, participants were presented with definitions of nine financial interests and were given the opportunity to ask questions about those interests to clarify their understanding. Each group also reacted to one or two sample generic disclosure statements that were early drafts of the disclosure statements in the Appendix.

We were interested in whether brief statements about financial interests would suffice in the interest of minimizing additions to a consent document. However, few focus group participants understood the financial interests based on brief descriptions (e.g., “Researcher holds a patent.”). Even after we provided longer descriptions about financial interests, many participants required discussion with the group to understand the meaning of the descriptions. Some participants volunteered that they were unclear about various parts of the definitions, whereas others intimated their uncertainty by hesitating to say something about the financial interests. Even when participants did understand the definitions, they did not always understand why the information was relevant to them. This finding highlighted the need to make such implications clear in the disclosure statements.

Developing the Draft Disclosure Statements

Conceptual Model for Disclosure. Based on coded comments from the focus groups, the research team refined the descriptions of the financial interests for use in the draft disclosure statements. In designing the disclosure statements, we had to make some assumptions about how and when different types of disclosures might be used. We adopted the framework suggested by the National Human Research Protections Advisory Committee (NHRPAC), in which two types of disclosure are considered. For situations in which the IRB or COIC determines that a financial interest presents no risk to the research participant or the scientific integrity of the study, a generic disclosure is used (see Appendix). For situations in which there is some question about the risk to the participant or the scientific integrity of the study, or in which institutions want to provide more information, a specific disclosure is used to provide information about the particular financial interest (see Appendix). Consistent with the recommendations of NHRPAC and the Association of American Medical Colleges, our disclosures also include a statement encouraging the participant to ask questions of the researcher or study coordinator if s/he would like more details.

Several assumptions motivate this approach. First, what is material to a person’s decision to participate is whatever the person considers material, regardless of how the information actually affects the decision. Second, people vary in their informational needs. Thus, to provide adequate disclosure to all people, we adopt a core disclosure—information that is made available to everyone—plus an explicit invitation to ask questions for more details. Third, core disclosures should con-
tain more information when there is a greater risk that the financial interest will compromise participants’ safety or the scientific integrity of the study. It is unclear how financial risk is calculated. Risk is subjective, and each IRB uses different algorithms to determine if a financial interest poses a risk to participants’ safety or the scientific integrity of the study. Furthermore, determinations of risk are complex, and calculations of the risk of financial interests warrant further study. Fourth, this approach recognizes that potential research participants can be burdened with too much information. In other words, information might be unhelpful by causing undue concern or by drawing attention to financial interests at the neglect of other important issues. Based on these considerations, we modified the financial interest disclosures to generate draft disclosure statements.

- **Cognitive Pretesting.** The draft disclosure statements were presented to participants in a modified cognitive interview to assess participants’ understanding. A typical cognitive interview is used to evaluate survey questions. We used the same probing methods to evaluate understanding of the disclosure statements.

  A member of the study team approached potential participants from a primary care clinic and asked them to participate in a 45-minute interview. After giving written informed consent and completing a short demographic questionnaire, participants were taken to a private conference room for an interview. Ten participants were interviewed and all interviews were audiotaped and transcribed for analysis. After the first three participants completed the cognitive interviews, it was clear that a discussion of all disclosure statements (one generic disclosure and nine specific disclosures) was too burdensome. Therefore, we split the disclosure statements into two sets and alternated the sets between research participants. As a result, interview time for each participant decreased to about 20 minutes.

  We gave participants each disclosure statement and asked them to read it aloud and then restate the disclosure in their own words. Next, we questioned them about the overall clarity of the disclosure statement. If participants were able to restate the disclosure accurately, then we probed them on how they felt about the financial relationship described in the disclosure. Eight of the ten participants understood the relationships well and were able to restate the disclosure accurately. Two of the participants struggled with understanding; one of these participants also had difficulty reading the disclosure statements aloud. Several of the participants provided comments on how we could clarify the disclosure statements. Although most participants understood the disclosures well, some felt that certain sentences and/or words could be presented more clearly and succinctly for future potential research participants.

- **Expert Panel Revisions.** We incorporated the participants’ recommendations into the next version of the disclosure statements, which were then presented to an expert panel at an in-person meeting for discussion. Following discussion, the expert panel members provided individual feedback in writing for each of the disclosure statements. The feedback generally reflected agreement on the proposed language, with few suggested revisions. This fifth and final version of the generic and specific disclosure statements appears in the Appendix.

**Discussion**

As part of ongoing efforts to understand how best to disclose financial interests to potential research participants, we developed and refined some working disclosure language. The process included data collection and feedback from 1) IRB and COIC officials to identify the most relevant financial interests; 2) small groups of people with and without health conditions; 3) individual patients seen in a general medicine primary care clinic; and 4) a multidisciplinary panel of experts.

Our study team is currently conducting research to test this language on a larger scale in hypothetical and actual clinical research settings.

This empirical process for creating appropriate disclosure language resulted in a generic disclosure statement for cases in which no risk to participants’ welfare or the scientific integrity of the research is expected, and nine specific disclosure statements for cases in which some risk is expected. These disclosure statements are not meant to be canonical, but instead were designed to reflect the typical situations in which disclosure of financial interests might be considered by an IRB or COIC. Individual institutions could modify key phrases to suit their purposes.

The developed language could be used in a variety of ways. First, the disclosure statements might serve as models for wording disclosures in informed consent documents. A previous analysis by Weinfurt et al. of IRB and COIC policies indicated that few academic medical centers had models for disclosing financial interests in research.

Thus, the language presented here might serve to fill this gap. Second, the language we developed could be expanded and presented in alternative formats, such as in stand-alone pamphlets or video programs about clinical research. Third, the language might provide investigators and study personnel with some vocabulary and phrasings that could be effective in discussing financial interests with potential research participants. Fourth, we hope that the language will be used by others in future empirical work on informed consent to better refine the options for disclosing financial interests in clinical
research. Finally, the multistep method we used to develop the language for disclosing financial interests in research might also be used more generally in developing template language for informed consent in research.

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Human Subjects Protection

The IRBs of the Duke University Health System, the Johns Hopkins Medical Institutions, and Wake Forest University approved this work.

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References


10. See ref. 7, Faden and Beauchamp 1986.

Appendix: Final Model Language

Generic Disclosure
The person leading this medical research study might benefit financially from this study. The Institutional Review Board and a committee at ABC University have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Specific Disclosure
The person leading this medical research study might benefit financially from this study. Specifically, [insert appropriate description from below].

The Institutional Review Board and a committee at ABC University have reviewed the possibility of financial benefit. They believe that the possible financial benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Descriptions
The relevant description below should be inserted into the above disclosure as indicated, except for the description of unrestricted finder’s fees, which should be used instead of the “specific disclosure” language given above.

Salary Support
Company XYZ is paying some or all of the salary for the doctors and staff who are working on this research study.

Money Received Outside of the Study
This research study is supported by money from Company XYZ. In addition, the person leading this research study receives extra money from Company XYZ for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports. The person running this research might receive hundreds or thousands of dollars for this work.

Per Capita Payments
Company XYZ pays the hospital/clinic running this research study for study supplies, staff salaries, and for each person who agrees to participate in the study. This amount of money is just enough to cover the cost of running the study.

Finders’ Fees Restricted to Research Uses
Company XYZ pays the hospital/clinic running this research study enough money for study supplies, staff salaries, and for each person who agrees to participate in the study, plus some extra money. The person running this research study can use this extra money for other work-related costs, such as travel to meetings, paying support staff, purchasing new office equipment, or funding other research.

Unrestricted Finders’ Fees
[Note: Substitute this entire paragraph for the “specific disclosure” language given above.]

Your doctor might benefit financially from this medical research study. Company XYZ paid your doctor $XXXX for referring you to this research study. Your doctor can use this money however he or she wishes. The Institutional Review Board and a committee at ABC University have reviewed the study plan and believe it is unlikely that the possible financial benefit to your doctor will affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Researcher Holds a Patent
The person leading this medical research study owns [or has applied for] a patent on the new [test, drug, treatment] being studied. Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment] is safe and effective. If research shows the new [test, drug, treatment] is safe and effective, the person leading this study would receive a part of the profits from any sales of this [test, drug, treatment].

University Holds a Patent
Research studies like the one you are thinking about joining are done to determine whether the new [test, drug, treatment] is safe and effective. ABC University owns [or has applied for] a patent on the new [test, drug, treatment] being studied. If research shows the new [test, drug, treatment] is safe and effective, ABC University would receive a part of the profits from any sales of this [test, drug, treatment].

Researcher Owns Equity
This research study is designed to test a product made by Company XYZ. The person running this study has an investment in Company XYZ, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study.

University Owns Equity
This research study is designed to test a product made by Company XYZ. ABC University has an investment in Company XYZ, such as stock. The financial value of this investment might be affected by the results of this study. This means that ABC University could gain or lose money depending on the results of this study.