Table 1. Summary of the Development Process for Model Disclosure Language

I. Develop descriptions of financial interests
   A. Create draft descriptions based on literature review
   B. Expert panel reviews and revises descriptions
   C. Present descriptions as part of focus groups with potential research participants
   D. Revise descriptions

II. Develop draft disclosure statements
   A. Develop conceptual model for disclosure
   B. Write draft disclosure statements
   C. Conduct cognitive pretesting to evaluate participants’ understanding
   D. Revise disclosure statements
   E. Expert panel reviews and revises disclosures
   F. Revise descriptions
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 running this study might 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.