

Draft Topic Guide

Parental decision-making about enrolling children in pediatric clinical trials for antibiotics or other medications:

An in-depth interview study

I. Introduction

Hello, I'm [_____] and I'm calling to conduct the interview we scheduled. Is now still a good time?

Today we'll be talking about clinical trials for children. We will be talking both to parents/ caregivers of children who took part in a pediatric clinical trial as well as parents or caregivers of children who didn't take part in a trial.

We wanted to talk to you because you recently had the experience of considering whether to have your child/ward take part in a clinical trial. I am interested in hearing all about that experience and decision-making process. There has not been a lot research on this topic, so your input will be extremely valuable as doctors and researchers try to better understand how parents and caregivers think about pediatric clinical trials, and the kinds of information they would like in order to make a decision about whether to enroll their child/ward. Ultimately, your input will help provide guidance and information to parents and caregivers who are considering enrolling their child/ward in a trial.

I will be interested in hearing what you have to say, about each of the topics we will be discussing. I will be audio taping our discussion, because everything you say is important to us and I want to make sure I don't miss anything. But I want to assure you that all of your comments will be confidential and that nothing you say will be connected with your name or shared with your healthcare providers.

Before continuing with the interview, I will read you the statement of consent.

STATEMENT OF CONSENT

"The purpose of this interview study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this interview study, with the

understanding that I may withdraw at any time. I am giving my verbal consent to participate in this interview study.”

Do you consent to participate in the interview?

II. Warm up

- A. Could you begin by telling me a little about yourself and your family?
- B. Can you tell me about any recent serious illnesses or hospitalizations that your child/ward has had? What was that like?

III. Questions about experiences and decision-making about taking part in the pediatric clinical trial

Now I'd like to hear about how it was that you were asked about the possibility of your child/ward participating in a clinical trial.

- 1. Under what circumstances were you offered the opportunity for your child/ward to take part in a pediatric clinical trial for an antibiotic or other medication -- that is, how did that come about?

PROBE:

- Did your child/ward have an infection at that time?
 - If so, what kind of infection? Can you tell me a little about that?
 - Had the child been admitted to the hospital, or was he/she an outpatient?
- 2. Can you tell me a little about how you were approached about the possibility of enrolling the child in the trial? What was that process like? (open-ended)
 - 3. Who approached you about the trial? What did that person tell you about the trial?
 - 4. Were you given a consent form to read and sign? Tell me about that. What was the consent form like? What did it say about possible side-effects or risks? What did the (study coordinator) say about the possible risks and side-effects of the drug under investigation?
 - 5. Think back to when you were first approached for consent to have the child take part in the trial. Think aloud for a moment and tell me all your thoughts, good, bad and indifferent. (open-ended at first)

THEN PROBE:

- What questions did you have?

- What did you see as reasons to enroll the child in the clinical trial?
 - What did you see as reasons not to enroll the child in the clinical trial?
 - What concerns did you have?
 - Was there anyone who you looked to guide you through the decision about whether to participate?
 - Who else was involved in making the decision about whether to have the child participate in the trial? The child's father/mother? If so, were you equally involved in the decision-making, or was one of you more involved than the other in making the decision? [Have them elaborate]
6. What kinds of information did you want to see when you were presented with the possibility of enrolling the child in a pediatric clinical trial? What information was helpful? What kinds of information that you didn't receive would you have wanted to have?
 7. At that time, did you want to hear all of the possible side-effects or risks, even those which would be extremely rare, or did you only want to hear the risks and side-effects that would be most likely to occur?
 8. How, if at all, could the process of approaching you about a clinical trial for the child have been different or better as far as you are concerned?
 9. **(For those who DID NOT enroll their child/ward)** Who was involved in the decision about whether to have the child participate in the clinical trial?
 10. Can you walk me through your thinking as you made the decision not to enroll the child in the pediatric clinical trial? (open-ended first)

THEN PROBE:

- What was the child's (father's/mother's) thinking about participation in the trial? Were you both on the same page or did you have different opinions about it? [Have them elaborate]
 - Looking back, how do you feel about the decision not to have the child participate? Would you make the same decision again? Why or why not?
 - What, if anything, might have been different that would have led you to have enrolled the child in the trial? **(SKIP TO #15)**
11. **(For those who DID enroll their child/ward)**
 - Who was involved in the decision about whether or not to enroll your/the child in the clinical trial?

- Tell me about how **you** made the decision to enroll the child in the pediatric clinical trial? What did you see as the most compelling reasons to have the child participate in the trial?
- (If the other parent was involved): What was the child's mother/father's thinking about participation in the trial? Was he/she on the same page as you about participation in the trial?

12. What was your experience and that of the child like in the clinical trial?

13. In what ways could your experience and the child's experiences have been different or better as far as you are concerned?

14. Looking back, how do you feel about having enrolled your/the child in the trial? (open-ended) Would you make the same decision again? Why or why not?

15. If you were on the committee charged with deciding the best ways to approach parents about enrolling their children in pediatric clinical trials what kind of approach would you recommend? (open-ended first)

PROBE:

- How should parents/caregivers be approached?
- What should the study coordinator tell parents/caregivers?
- What kind of information should be given to the parents/caregivers?
- What kinds of information on risks and benefits should be presented to the parents/caregivers?
- What else would be important in communicating to the parents/caregivers about a clinical trial?
- What would be the most compelling reasons for parents/caregivers to enroll their child/ward in the clinical trials?
- What would be the biggest barriers to enrolling their children/wards in a clinical trial? (for each barrier mentioned): What could overcome/address each of these barriers?

16. What other suggestions would you make to improve the parent or caregiver /child experience of the clinical trial itself?

17. What would you advise a friend who is considering having her child take part in a clinical trial for antibiotics or other drugs?

18. Is there anything else that we haven't talked about that you think is important for us to know?

Thank you so much for taking part in this interview. The information you gave us will be extremely valuable to researchers and physicians.