

Additional File 1 – Interview Guide

Hi, this is [name] from the [NAME] study team. Is now still a good time to talk?

[if no → reschedule for another time or tell them someone else will call back to reschedule]

[if yes → proceed with consent/interview]

Before we begin, I'd like to record our conversation so I don't miss anything you say. Is it okay if I turn on the recording?

[TURN ON RECORDER] Thank you; I've now started the recording.

Verbal Consent

Thank you for taking the time to talk to me. As a reminder, the goal of this interview is to learn from parents and caretakers of babies who have been in the neonatal intensive care unit, or NICU, about how they would feel about different research studies that a baby in the NICU might be in. You were invited to join the [NAME] study because your child was recently in the NICU at [LOCATION].

During the interview, we will share some examples of different research studies that a baby might be in. These are all just hypothetical examples. Our goal is to learn from families who have experience being in the NICU about what they like or don't like about these examples so that we can make the research process better in the future. We really value your thoughts and opinions and there are no right or wrong answers.

Taking part in this interview is your choice. You can ask me to skip a question or stop the interview at any time. As you know, we are recording this conversation, so we have an accurate recording of what you say. We will transcribe this recording into writing, and we will remove any names or other identifying information from the transcript of the recording before we share any of your responses outside the study team.

Our conversation will last about 30-60 minutes. If we get disconnected for any reason, I'll call you right back. At the end of the interview, I'll confirm your contact information so we can send you a \$50 gift card as a thank you for your time.

What questions do you have for me?

Do I have your permission to start the interview and record our conversation?

Great, now that I've turned on the recording, can you please confirm your permission for me to record this discussion.

****Bracketed comments are prompts and suggestions in case the participant does not know how to answer. Interviewers do not need to ask all of these questions. However, interviewers should make sure participants address the topics of each main question. ****

1. To start, could you tell me something special about your baby?
2. Do you have any experience being asked to be part of a medical research study, for yourself or for a family member including your baby?
 - a. *[if yes]* Please tell me about that experience.
 - b. *[if yes/if not answered]* Did you decide to be part of the study?

In the next sets of questions, I will share with you two imaginary research studies, similar to those that occur in the NICU. We're interested in understanding your reactions to each of these examples. The examples may leave out some details, so if there are certain details that might change your answer one way or another, please feel free to mention those. I'll present one imaginary research study, ask you a set of questions, and then present the other and ask you the same set of questions. I'll start by sharing the first research study.

[Each parent will be assigned to one of 12 options, randomized within site:

1. 1a,2b
2. 1a,3b
3. 1b,2a
4. 1b,3a
5. 2a,1b
6. 2a,3b
7. 2b,1a
8. 2b,3a
9. 3a,1b
10. 3a,2b
11. 3b,1a
12. 3b,2a

Present first study vignette and then go through Questions 1-8. Then present second study vignette and go through Questions 1-8 again.]

1. What is your initial reaction to this research study?
 - a. What do you like about the study?
 - b. What concerns do you have about the study?
 - c. Was there anything about the study that was confusing or you don't understand [ability to clarify methods if not understood by parent]

For the next several questions, I'll read a statement then ask you to first rate your agreement with it and then explain why you answered the way you did.

2. On a scale of 1 to 5 where 1 is "strongly disagree" and 5 is "strongly agree", how much do you agree with the following statement: *The researchers in this study are protecting the babies and families enrolled in the study from risk.*
 - a. Tell me more about why you answered that way.
 - b. What risks do you see in this research study?
 - c. How are they managing the risks?
3. On a scale of 1 to 5 where 1 is "strongly disagree" and 5 is "strongly agree", how much do you agree with the following statement: *The researchers in this study are being appropriately transparent.*
 - a. [probe if need guidance] can define transparent as: "appropriately open and clear about this study"
 - b. Tell me more about why you answered that way.
 - c. What additional information would you have wanted to know? When would you have wanted to know it?

4. On a scale of 1 to 5 where 1 is “strongly disagree” and 5 is “strongly agree”, how much do you agree with the following statement: *The researchers in this study are giving families the right amount of control about being in the study.*
 - a. Tell me more about why you answered that way.
 - b. In what ways could a more appropriate amount of control be given?
5. On a scale of 1 to 5 where 1 is “strongly disagree” and 5 is “strongly agree”, how much do you agree with the following statement: *The researchers in this study are allowing families to make decisions about being in the study that are in line with their family’s values.*
 - a. Tell me more about why you answered that way.
 - b. In what ways could they better support families’ values?
6. On a scale of 1 to 5 where 1 is “strongly disagree” and 5 is “strongly agree”, how much do you agree with the following statement: *The research described in this study seems trustworthy.*
 - a. Tell me more about why you answered that way.
 - b. What makes it seem trustworthy?
 - c. What makes it not seem trustworthy?
 - d. Do you think others you know, like your family or friends, would find the research trustworthy? Why or why not?
7. On a scale of 1 to 5 where 1 is “strongly disagree” and 5 is “strongly agree”, how much do you agree with the following statement: *The researchers in this study seem to respect the babies and families they are working with.*
 - a. Tell me more about why you answered that way.
 - b. What assumptions did the researchers in this example seem to be making? What made you think that?
8. On a scale of 1 to 5 where 1 is “strongly disagree” and 5 is “strongly agree”, how much do you agree with the following statement: *If my baby were eligible for a study like this, I would want them to be in it.*
 - a. Tell me more about why you answered that way.

Thank you for sharing your thoughts on the first imaginary research study. I’m now going to share information about a different imaginary study, and then I’ll ask you the same questions as before.

[Present second vignette and repeat questions 1-8]

Thank you for sharing your perspectives.

9. Each of these examples used a different approach to how they asked families about whether they wanted to be in the research study.
 - a. For both of these studies, researchers are comparing two interventions that are both already being used for babies in this clinical condition, and doctors don't know which is best.

- b. In the [full consent] example, parents are asked if their baby can join and if they agree then their baby is part of the study and receives one of the interventions.
 - c. In the [alternative consent] example, babies first receive one of the interventions, then later parents are asked for permission to allow the researchers to use their data and for continued participation in the study.
 - d. How did each way feel to you?
 - e. [probe] Tell me more about why you answered that way.
 - f. [probe] Is there anything that feels better about one or the other?
10. Comparing the two cases, can you tell us about any differences in how they may have felt to parents?
- a. [probe if different] What might make this type of approach feel better?
11. One reason why researchers may wait to have the full consent discussion until later is that it can avoid asking parents to enroll during a time of high stress. How does that change how you think about this, if at all?
- a. [probe] Tell me more about why you answered that way.
12. Before we wrap up, is there anything else you would like to add about these examples or any of the topics we've covered?

Before we finish, I'll ask a few questions about you. We ask these so we can make sure we're talking to people with different experiences and perspectives.

13. What is your Gender?
14. Are you Hispanic, Latino, or of Spanish origin?
15. How would you describe your race, using the following categories? You can pick more than one.
- a. American Indian or Alaska Native
 - b. Asian
 - c. Black or African American
 - d. Native Hawaiian or Pacific Islander
 - e. White
16. Within the last year, have you or any of your children been on Medicaid (such as "Medi-Cal" in California, "New York Medicaid Choice" in New York, "Medical Assistance" in Pennsylvania, and "Apple Health" in Washington State)??

Thank you again for taking the time to talk to me today. We really appreciate your feedback and your help thinking about how to make the experience of research better for families and babies in the NICU.

I'm now going to turn off the recorder. [TURN OFF RECORDER]

As I mentioned earlier, we'll be sending you a \$50 gift card as a thank you for your time.
[CONFIRM EMAIL ADDRESS]

If you have any questions or want to follow up about anything, I also want to make sure you have our study team contact information. [CONFIRM THEY HAVE CONTACT INFORMATION]