

ATTACHMENT D4: INITIAL INFANT INTERVIEW

APPROVED

OMB# 0920 -XXXX

OMB EXP. DATE / /

SUBJECT ID# _____

DATE OF INTERVIEW / /

Ask these questions only if the enrollment and pregnancy interviews were completed on a previous date.

Note: Read only the wording that appears in regular font when conducting the interview. Wording in italics contains instructions to the interviewer and should not be read.

If this interview is being conducted on the same day as the pregnancy follow-up interview, skip the paragraphs below and begin with Section A.

Hello. May I speak with <Name of the woman>? This is <Project coordinator's name> from the <Name of teratology information service>. I am calling about the project to learn about the safety of medicines during pregnancy and breastfeeding that we are conducting with the Centers for Disease Control and Prevention. You completed the most recent interview for this study on <Date of last interview>. It is now time for the next interview. This will take about 20 minutes. Is now a convenient time for me to conduct that interview? *(Circle one)*

Yes

No

If no, go to tracking form.

I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer. I also want to remind you that whether or not you complete the entire study will not affect the medical care you receive or your use of the <Name of teratology information service>. You can call the service at any time to obtain information and counseling about medicines or other exposures while you are pregnant or breastfeeding regardless of whether you participate in the study.

Before we begin, do you have any questions for me about the study?

Section A

I'd like to ask some questions about your baby's health. All of your answers will be kept private and you can choose not to answer any question you do not want to answer.

1. Is your baby a boy or a girl?
 - a. Boy
 - b. Girl
 - c. Don't know or refused

2. When was he/she born? ____/____/____ ____ Don't know or refused

3. How much did he/she weigh at birth?
_____ pounds _____ ounces ____ Don't know or refused

4. Is your baby alive now?
 - a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 7 in this section.

5. When did your baby die?
 - A. Date ____/____/____
 - B. Baby's age at death _____
 - C. Other response _____
 - D. Don't know or refused

6. Did your baby die while in the hospital nursery after birth or after he/she went home from the nursery?
 - a. In hospital nursery
 - b. After going home from hospital nursery
 - c. Other response _____
 - d. Don't know or refused

Go to question 9 in this section.

7. How much did he/she weigh the last time he/she was weighed?
_____ pounds _____ ounces ____ Don't know or refused

8. When was that? (*Complete the one that best reflects the answer given; probe for specifics if she is unsure*)
- a. Date ____/____/____
 - b. Number of days ago _____
 - c. Number of weeks ago _____
 - d. Number of months ago _____
 - e. Baby's age _____
 - f. Other response _____
 - g. Don't know or refused

9. Did your baby have any (other) complications during the delivery or any (other) complications or illnesses while in the hospital after birth?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 13 in this section.

10. What complications did he/she have? List all the complications you can think of.

_____ Don't know or refused

(If she doesn't know the name of the condition, ask her to describe it and its symptoms)

11. First/Next, let's talk about (name of the first/next complication). How old was your baby when the (name of complication) developed?

_____ Don't know or refused

12. What treatment was he/she given? _____ Don't know or refused

*If there are more complications on the list, go to Question 11 for the next complication.
If there are no more complications on the list, proceed with Question 13.*

13. Was your baby admitted to a neonatal intensive care unit or special care nursery after he/she was born?

- a. Yes
- b. No
- c. Don't know or refused

If no or don't know/refused, go to Section B.

14. How long was he/she in the intensive or special care nursery?

_____ Don't know or refused

15. What treatment was he/she given while there? Examples include a ventilator or respirator to help with breathing, an oxygen hood, intravenous or IV antibiotics, other medicines or fluids through a vein in the arm, leg, or umbilical cord. _____
_____ Don't know or refused

Section B

Note: If the baby has been in the hospital nursery continuously since birth or if the baby died while in the hospital nursery after birth, begin with Question 6 in this section.

Next, I'd like to ask about your baby's health since coming home from the hospital. Again, I want to remind you that all of your answers will be kept private and that you can choose not to answer any question you do not want to answer.

1. How old was your baby when he/she went home from the hospital? *(Complete the one that best reflects the answer given)*
 - a. Number of days _____
 - b. Number of weeks _____
 - c. Number of months _____
 - d. Other response _____
 - e. Don't know or refused
2. Since coming home from the hospital, has your baby had any (other) illnesses or complications that we haven't already talked about?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 6 in this section.

3. What illnesses or complications has your baby had? List all the illnesses you can think of.

_____ Don't know or refused
(If she doesn't know the name of the condition, ask her to describe it and its symptoms)
4. First/Next, let's talk about (name of the first/next illness). How old was your baby when the (name of illness) developed? _____ Don't know or refused
5. What treatment was he/she given? _____
_____ Don't know or refused

*If there are more illnesses on the list, go to Question 4 in this section for the next illness.
If there are no more illnesses on the list, proceed with Question 6 in this section.*

6. Has your baby been diagnosed with any (other) birth defects that we haven't already talked about? This would include physical, internal, or genetic conditions that are not due to a medical complication or illness such as prematurity or infection.
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 11 in this section.

7. What kind of birth defects were they? List all you can think of.

_____ Don't know or refused
(If she doesn't know the name of the condition, ask her to describe it and its symptoms)

8. First/Next, let's talk about (name of the first/next defect). How old was he/she when it was diagnosed? _____ Don't know or refused

9. How was it diagnosed? For example, with an x-ray, MRI or CT scan, blood test, or other procedure. _____ Don't know or refused

10. What treatment was he/she given for it? _____ Don't know or refused

*If there are more defects on the list, go to Question 8 in this section for the next defect.
If there are no more defects on the list, proceed with Question 11 in this section.*

11. Has your baby had any (other) surgery that we haven't already talked about?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 15 in this section.

12. What kind of surgeries has he/she had? List all the surgeries you can think of.

_____ Don't know or refused

13. First/Next, let's talk about (name of the first/next surgery). Why was it done? *(Skip this question if already answered in Question 12)* _____ Don't know or refused

14. How old was your baby when the surgery was done? _____ Don't know or refused

*If there are more surgeries on the list, go to Question 13 in this section for the next surgery.
If there are no more surgeries on the list, proceed with Question 15 in this section.*

15. Has your baby been to see any other doctor or specialist, other than his/her general pediatrician, family physician, or nurse practitioner, that we haven't already talked about? Examples include a geneticist, a cardiologist, an ophthalmologist or eye doctor, a neurologist, a hearing specialist, or other type of provider?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 18 in this section.

16. What kinds of doctors or specialists has he/she seen? List all you can think of.

_____ Don't know or refused

17. First/Next, let's talk about (name of the first/next specialist). Why did your baby see that specialist? _____

_____ Don't know or refused

If there are more specialists on the list, repeat Question 17 in this section for the next specialist.

If there are no more specialists on the list, proceed with Question 18 in this section.

18. Have you, yourself, had any visits with a doctor or health care provider since you went home from the hospital? Examples include visits with an obstetrician, a nurse midwife, family practitioner, lactation consultant, psychologist, or other provider.

- a. Yes
- b. No
- c. Don't know or refused

If no or don't know/refused, go to Question 21 in this section.

19. What kinds of providers have you seen? List all you can think of.

_____ Don't know or refused

20. First/Next, let's talk about (name of the first/next provider). Why did you see that provider? _____

_____ Don't know or refused

If there are more providers on the list, repeat Question 20 in this section for the next provider.

If there are no more providers on the list, proceed with Question 21 in this section.

21. Are you currently breastfeeding?
- Yes
 - No
 - Don't know or refused

If no or don't know/refused, go to End of Interview.

22. Have you taken any medicines at any time while you were breastfeeding? This includes prescription medicines that you got from a doctor or pharmacy, over-the-counter medicines such as Tums or Tylenol, vitamins, herbals, and other supplements.
- Yes
 - No
 - Don't know or refused

If yes, proceed with Initial Breastfeeding Questionnaire.

If no, continue with End of Interview.

End of Interview

That is the end of this interview. I truly want to thank you for taking the time to complete it. Your contribution to this study is very important. Before we hang up, do you have any questions for me? _____

Your next interview is scheduled for when your baby is about 3 months old. That will be approximately <Calculated date the baby reaches 3 months based on the date of birth given in Section A, Question 2>.

Go to tracking form.