

ATTACHMENT D3: FOLLOW-UP PREGNANCY INTERVIEW

APPROVED
OMB# 0920 -XXXX
OMB EXP. DATE / /

SUBJECT ID# _____
DATE OF INTERVIEW / /

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

Before beginning the interview, obtain the following information from the last pregnancy interview:

Date of the last interview _____

Section A:

Due date from the last interview _____

Gestational age at the last interview (calculated from the due date) _____

Section B:

List of all medications she reported at the last interview _____

Section C:

List of all medical conditions she reported at the last interview _____

Section D:

List of all injuries or traumas she reported at the last interview _____

Section E:

List of all prenatal tests she reported at the last interview _____

Section F:

List of all other exposures she reported at the last interview _____

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.

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 first 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

First, I'd like to ask some questions to update our information about your pregnancy. As a reminder, your last interview was on <Date of the last pregnancy interview> and at that time you were approximately <Calculated gestational age> weeks pregnant.

1. Are you still pregnant now?
 - a. Yes
 - b. No

If no, go to Question 5 in this section.

2. Is your baby still due on or about <Date from the last pregnancy interview>?
 - a. Yes
 - b. No
 - c. Don't know or refused

If yes or don't know/refused, go to Section B.

3. When is your baby due?
- Date ____/____/____
 - Other response _____
 - Don't know or refused

If don't know or refused, go to Section B.

4. How did your health care provider decide when your baby is due? Was it by:
(*Read all choices except Don't know or refused; Circle all that apply*)
- The date of your last menstrual period
 - An ultrasound
 - The date of an embryo transfer
 - Another method What method was it? _____
 - Don't know or refused

Go to Section B.

5. When did your pregnancy end?
- Date ____/____/____
 - Number of weeks or months ago _____
 - Other response _____
 - Don't know or refused

6. Did your pregnancy end in a (*Read all choices except Other and Don't know or refused*)
- Live birth
 - Stillbirth or miscarriage
 - Elective termination
 - Other
 - Don't know or refused

If ended in other than a live birth or if don't know/refused, go to Section B.

If ended in a live birth, continue with Question 7 in this section.

7. Is your baby alive now?
- Yes
 - No
 - Don't know or refused

Go to Section B.

Section B

Next, I'd like to update our information about medicines you took at any time between your last interview and <now/the end of your pregnancy>. 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 dietary supplements. I'll be asking about how much medicine you took and how often you took it (them).

Sometimes it is helpful to have the medicine bottles, or a calendar or other reminder, in front of you when answering these questions. Do you want to take a minute to collect these items?
(If yes, wait for her to collect the items, then continue)

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. During your last interview, you said you had taken the medicine(s) *(read list of medications from the last interview)*. Did you take this/any of these medicine(s) at any time between your last interview and <now/the end of your pregnancy>?
 - a. Yes
 - b. No
 - c. Don't know or refused

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

If yes but only one medicine is listed from the last pregnancy interview, go to Question 3 in this section.

2. Which of these medicines did you take? _____
_____ Don't know or refused
3. First/Next, let's talk about (name of the first/next medicine). When between your last interview and <now/the end of your pregnancy> did you first/next take (name of the first/next medicine)? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
 - a. Date ____/____/_____
 - b. Weeks or months of gestation _____
 - c. Taking it continuously since the last interview _____
 - d. Other response _____
 - e. Don't know or refused
4. How many (name of the medicine) pills/teaspoons did you take at a time the first/next time you took it? _____ Don't know or refused
5. How many milligrams were in each pill/teaspoon?
_____ Don't know or refused
6. How often did you take that dose? For example, how many times per day, per week, or per month? *(Complete the one that best reflects the answer given)*

- a. Number of times per day _____
- b. Number of times per week _____
- c. Number of times per month _____
- d. Other response _____
- e. Don't know or refused

7. Did the dose of (name of the medicine) or how often you took it change (again) while you were taking it that time?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 9 in this section.

8. When did the dose of (name of medicine) change? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- a. Date ____/____/____
 - b. If before conception, days or weeks before _____
 - c. If during pregnancy, weeks or months of gestation _____
 - d. Number of days or weeks after starting the medicine _____
 - e. Other response _____
 - f. Don't know or refused

Go to Question 4 in this section.

9. Are you still taking <name of the medicine> now?
- a. Yes
 - b. No
 - c. Don't know or refused

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

10. And are you still taking *(read the dose and frequency from the last response to Questions 4 and 5)*?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes or don't know/refused, go to Question 3 in this section for the next medicine on the list. If there are no more medicines on the list, go to Question 13 in this section.

If no, ask her to clarify when she started taking her current dose. Then go to Question 3 in this section for the next medicine on the list. If there are no more medicines on the list, go to Question 13 in this section.

11. When did you stop taking <name of medicine> that time? For example, how many days or weeks did you take it, or how many weeks pregnant were you when you stopped?
- a. Number of days _____
 - b. Number of weeks _____
 - c. Number of months _____
 - d. Weeks or months of gestation _____
 - e. Other response _____
 - f. Don't know or refused

12. Have you taken <name of the medicine> again since then?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 3 in this section.

If no or don't know/refused, go to Question 3 in this section for the next medicine on the list. If there are no more medicines on the list, continue with Question 13 in this section.

13. Did you take any other medicines at any time between your last interview and <now/the end of your pregnancy> that we haven't talked about? This includes things like Tylenol, cold medicine, extra vitamins, or dietary supplements.
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 17 in this section.

14. What other medicines did you take between your last interview and <now/the end of your pregnancy>? List all the medicines you can think of even if you took them for a short time or only occasionally when needed.
(Ask for both trade and generic names of each medicine; If the medicine has a name that is common to multiple preparations, such as Tylenol, ask her for the exact name of the preparation, e.g., Tylenol PM, Tylenol Sinus, Tylenol Arthritis, etc.)

If the medicine is a prenatal vitamin, go to Question 3 in this section.

15. First/Next, let's talk about (name of the first/next medicine). What condition did you take (name of the medicine) for?
_____ Don't know or refused

16. When did you first have (the condition)? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- a. Date ____/____/____
- b. If before conception, days, weeks, months, or years before _____
- c. If during pregnancy, weeks or months of gestation _____
- d. Mother's age at onset _____
- e. Other response _____
- f. Don't know or refused

Go to Question 3 in this section.

17. *If prenatal vitamins have already been mentioned, go to Question 18 in this section.*
Still thinking about the time between your last interview and <now/the end of your pregnancy>, did you take any prenatal vitamins?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 3 in this section .

18. *If a folic acid supplement not contained in a multivitamin has already been mentioned, go to Section C.*
Still thinking about the time between your last interview and <now/the end of your pregnancy>, did you take a folic acid supplement between your last interview and <now/the end of your pregnancy> that was not part of a prenatal or other vitamin that we've already talked about?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 3 in this section.

Section C

Next, I'd like to update our information about any other medical conditions you had at any time between your last interview and <now/the end of your pregnancy>. 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.

If she reported having no other medical conditions at the last interview, go to Question 6 in this section.

1. During your last interview, you said you had had (*read list of medical conditions from last interview*). Have you had this (any of these) condition(s) at any time between your last interview and <now/the end of your pregnancy>?
 - a. Yes

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

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

If yes but only one condition is listed from the last interview, go to Question 3 in this section.

2. Which conditions have you had? _____
_____ Don't know or refused
3. First/Next, let's talk about (name of the first/next condition). When since your last interview did you first have <name of the first/next condition> again? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- A. Date ____/____/____
 - B. Weeks or months of gestation _____
 - C. Had it continuously since the last interview _____
 - D. Other response _____
 - E. Don't know or refused
4. Did you take any medicine for <name of the condition> at any time between your last interview and <now/the end of your pregnancy> that we haven't already talked about?
- a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused and there are more conditions on the list, go to Question 3 in this section. If there are no more conditions on the list, go to Question 6 in this section.

5. What medicine did you take for <name of the condition>?
(Ask for both trade and generic names of each medicine; If the medicine has a name that is common to multiple preparations, such as Tylenol, ask her for the exact name of the preparation, e.g., Tylenol PM, Tylenol Sinus, Tylenol Arthritis, etc.)
- _____
- _____
- _____

Go to Section B, Question 3.

6. Did you have any (other) medical conditions at any time between your last interview and <now/the end of your pregnancy> that we haven't already talked about, even if you did not take medicine for them? Examples might be a sore throat or sinus infection, asthma, depression, or a pregnancy-related condition like high blood pressure, gestational diabetes, or too little or too much amniotic fluid.
- a. Yes
 - b. No
 - c. Don't know or refused

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

7. What did you have? 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 condition). When between your last interview and <now/the end of your pregnancy> did you first have <name of the condition>? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- Date _____/_____/_____
 - If before conception, days, weeks, months, or years before _____
 - If during pregnancy, weeks or months of gestation _____
 - Mother's age at onset _____
 - Other response _____
 - Don't know or refused

Go to Question 4 in this section.

Section D

Next, I'd like to update our information about any injuries or traumas, such as falls or accidents, you had at any time between your last interview and <now/the end of your pregnancy>. 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.

If she reported having no injuries at the last interview, go to Question 9 in this section.

1. During your last interview, you said you had had *(read list of injuries from last pregnancy interview)*. Have you had any other injuries or traumas at any time between your last interview and <now/the end of your pregnancy>?
- Yes
 - No
 - Don't know or refused

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

2. What was the first/next injury you had? _____ Don't know or refused
(If she doesn't know what the injury is called, ask her to describe it and its symptoms)

3. When did the injury occur? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*

- A. Date ____/____/____
- B. Weeks or months of gestation _____
- C. Other response _____
- D. Don't know or refused

4. Did you see a doctor or go to the emergency room to receive treatment for this injury?
- a. Yes
 - b. No
 - c. Don't know or refused

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

5. What treatment did you receive? _____
_____ Don't know or refused
(If she doesn't know what the treatment was called, ask her to describe it)

6. Did you take any medicine for this injury 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 9 in this section.

7. What is the brand name of the first/next medicine you took during this period?
_____ Don't know or refused
(If the medicine has a name that is common to multiple preparations, such as Tylenol, ask her for the exact name of the preparation, e.g., Tylenol PM, Tylenol Sinus, Tylenol Arthritis, etc.)

8. What is the generic name of the medicine? _____
_____ Don't know or refused
(If she is unsure, explain where this can be found on a medicine bottle. Record all of the active ingredients)

Go to Section B, Question 3.

9. Did you have any (other) injuries or traumas at any time between your last interview and <now/the end of your pregnancy>?
- a. Yes
 - b. No
 - c. Don't know or refused

If yes, go to Question 2 in this section.

Section E

Next, I'd like to update our information about any prenatal tests or surgery you've had between your last interview and <now/the end of your pregnancy>. 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. Did you have an ultrasound between your last interview and <now/the end of your pregnancy>?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 5 in this section.

2. Did any of the ultrasounds show a problem?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 5 in this section.

3. What was the problem? _____
_____ Don't know or refused
(If she doesn't know what it is called, ask her to describe it and its symptoms)

4. When between your last interview and <now/the end of your pregnancy> did you have the first ultrasound that showed the problem? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
 - A. Date ____/____/____
 - B. Weeks or months of gestation _____
 - C. Other response _____
 - D. Don't know or refused

5. Did you have an amniocentesis, or amnio, between your last interview and <now/the end of your pregnancy>?
 - a. Yes
 - b. No
 - c. Don't know or refused

If no or don't know/refused, go to Question 9 in this section.

6. Did the amnio show a problem?
 - a. Yes
 - b. No

- c. Don't know or refused

If no or don't know/refused, go to Question 9 in this section.

7. What was the problem _____
_____ Don't know or refused
8. When between your last interview and <now/the end of your pregnancy> did you have the first amnio that showed the problem? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- Date ____/____/____
 - Weeks or months of gestation _____
 - Other response _____
 - Don't know or refused
9. Did you have chorionic villus sampling, also known as CVS, between your last interview and <now/the end of your pregnancy>
- Yes
 - No
 - Don't know or refused

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

10. Did the CVS show a problem?
- Yes
 - No
 - Don't know or refused

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

11. What was the problem? _____
_____ Don't know or refused
12. When between your last interview and <now/the end of your pregnancy> did you have the CVS that showed the problem? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- Date ____/____/____
 - Weeks or months of gestation _____
 - Other response _____
 - Don't know or refused
13. Did you have any other prenatal tests between your last interview and <now/the end of your pregnancy> that we haven't talked about, other than a first trimester screen or other maternal serum screening test?
- Yes

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

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

14. What was the first/next other prenatal test that you had? *(If she doesn't know what the test is called, ask her to describe it)* _____
_____ Don't know or refused

15. Did it show a problem?
- a. Yes
 - b. No
 - c. Don't know or refused

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

16. What was the problem? _____
_____ Don't know or refused

17. When between your last interview and <now/the end of your pregnancy> did you have the first test that showed the problem? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- a. Date ____/____/_____
 - b. Weeks or months of gestation _____
 - c. Other response _____
 - d. Don't know or refused

Go to Question 13 in this section.

18. Did you have any (other) surgery between your last interview and <now/the end of your pregnancy> for which you had general anesthesia? That is, for which you were put to sleep?
- a. Yes
 - b. No
 - c. Don't know or refused

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

19. What kind of surgery did you have?
(If she doesn't know what the test is called, ask her to describe it)
_____ Don't know or refused

20. When did you have it?
- A. Date ____/____/_____
 - B. Weeks or months of gestation _____

- C. Other response _____
D. Don't know or refused

Go to Question 18 in this section.

Section F

Finally, I'd like to update our information about some other exposures that you might have had between your last interview and <now/the end of your pregnancy>. 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. Did you smoke a cigarette at any time between your last interview and <now/the end of your pregnancy>?
a. Yes
b. No
c. Don't know or refused

If no or don't know/refused, go to Question 4 in this section.

2. On average, how many cigarettes did you smoke per day? (1 pack = 20 cigarettes, half a pack = 10)
a. Number of cigarettes _____
b. Number of packs _____
c. Other response _____
d. Don't know or refused
3. When was the last time you smoked a cigarette? (Complete the one that best reflects the answer given; probe for specifics if she is unsure)
a. Date ____/____/_____
b. Weeks or months of gestation _____
c. Other response _____
e. Don't know or refused
4. Have others in your home or workplace smoked between your last interview and <now/the end of your pregnancy>?
a. Yes
b. No
c. Don't know or refused

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

5. How many people in your home or workplace smoked during this time?
_____ Don't know or refused

6. Thinking about the time between your last interview and <now/the end of your pregnancy>, on average how often did you have a drink of alcohol? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- a. Number of times per day _____
 - b. Number of times per week _____
 - c. Number of times per month _____
 - d. Didn't drink
 - e. Other response _____
 - f. Don't know or refused

If she didn't drink or doesn't know/refused, go to Question 10 in this section.

7. On average, how many drinks did you have at one time? One drink is equal to one glass of wine like you would have at a restaurant, one bottle or can of beer, or 1 ounce of hard liquor either in a mixed drink or straight up. *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- a. Number of drinks per day _____
 - b. Number of drinks per week _____
 - c. Number of drinks per month _____
 - d. Other response _____
 - e. Don't know or refused

8. What was the most number of drinks you had on any one occasion between your last interview and <now/the end of your pregnancy> _____ Don't know or refused

9. When was the last time you had a drink? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- A. Date ____/____/____
 - B. Weeks or months of gestation _____
 - C. Other response _____
 - D. Don't know or refused

10. Have you used any (other) recreational drugs between your last interview and <now/the end of your pregnancy>?
- a. Yes
 - b. No
 - c. Don't know or refused

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

11. What recreational drugs did you use? List all you can think of. _____
_____ Don't know or refused

12. On average, how often did you use <name of the first/next drug>? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- a. Number of times per day _____
 - b. Number of times per week _____
 - c. Number of times per month _____
 - d. Other response _____
 - e. Don't know or refused
13. When was the last time you used <name of the drug>? *(Complete the one that best reflects the answer given; probe for specifics if she is unsure)*
- A. Date ____/____/____
 - B. Weeks or months of gestation _____
 - C. Other response _____
 - D. Don't know or refused

*If there are more drugs on the list, go to Question 12 in this section.
If there are no more drugs on the list, go to Question 10 in this section.*

End of Interview

If her pregnancy has already ended in a live birth (see Section A), go to the Initial Infant Interview.

If her pregnancy has already ended in a stillbirth or elective termination (see Section A), say:

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

Did you find it difficult or burdensome to participate in this study?

- Yes
- No
- Not sure

If yes or not sure, ask

How was it difficult or burdensome? _____

If she is still pregnant (see Section A), say:

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 about 1 months after your due date. That will be
approximately *<Calculated date based on EDD given in Section A, Question 1>*.

Go to tracking form.