General Instructions

Read out the following section:

“Next I would like to update our records for any health issues you may have experienced. Some are questions we asked before, but we want to make sure we don’t miss anything.

I will ask you some questions that may make you feel uncomfortable. You may not feel like answering them completely or at all. Please, take your time to think through your answers. We want to understand these aspects of your health, and at the same time we want you to feel respected and comfortable. You are important to us, and your participation in the study is extremely valuable.”

Question by Question Instructions

A. Women’s Health Questions

Q1. Have your natural periods stopped PERMANENTLY? (No periods in the last 12 months) [If YES] do you have periods from taking hormones?

This question determines if the woman’s menstrual periods have stopped permanently (i.e. no periods in the last 12 months).

- If Q5=0 No, go to Q1a.
- If Q5=1 Yes, I have no menstrual periods, Go to Q2. Choose this answer IF YES to the first question, but NO to ‘do you have periods from taking hormones?’
- If Q5=2 Yes, but I have periods induced by hormones, Go to Q2. Choose this answer IF YES to the first question, and YES to ‘do you have periods from taking hormones?’
- If Q5=7 Refused or =9 Unsure, Go to Q1a.

Q1a. If Unsure, Refused, or NO: What was the date that your most recent menstrual period started? [Prompt for month and year, even if day is unknown.]

Q2. At what age did your natural periods stop?

Enter age in years. Round up if they provide a fraction of a year. Enter “99” if they are unsure and click Override to retain the 99 (validation box will pop up).

Q3. Why did you periods stop (check one)?

Check one only. If they provide more than one reason then ask them to choose the one most likely the cause.
1 = Naturally means spontaneous/not stopped by medications or surgery; 
2 = Surgery to remove ovaries or uterus 
3 = Endometrial ablation is a procedure that a gynecologist performs to make the interior lining of the womb (endometrium) thinner or removes the endometrium. There are several types of endometrial ablation, including electrosurgery, balloon ablation, bipolar radiofrequency ablation, and cryoablation. 
4 = Radiation/chemotherapy 
5 = If other reason, ask for specification, and fill in the blank 
7 = Refused 
9 = Unsure

Q4. Since your last study Visit, have you had a hysterectomy? (This is an operation to take out your uterus or womb)

This is an operation to take out the uterus or womb. If they report having a partial hysterectomy then answer YES. With a partial hysterectomy, the uterus is removed but the cervix remains. A hysterectomy is performed in an operating room, and may be done with an incision in the abdomen, or through several small incisions with a camera (laparoscopy or robotic surgery), or through the vagina.

Q4a. If “Yes,” ask and enter at what age this was done. Round up if they provide a fraction of a year. Enter “99” if they are unsure and click Override to retain the 99 (validation box will pop up).

Q5. Since your last study Visit 2, have you used hormonal birth control treatments or medications? 
If No, Refused or Unsure, skip to Q7.

The goal of this question is to document whether the participant has used hormonal medications for birth control or for other reasons. We are interested in whether women have taken birth control pills or other hormones for any reason, even if they were not used to prevent pregnancy.

Q6. Since your last study Visit 2, which of the following hormonal preparations have you ever used for birth control or for other medical purposes? Tell us whether you have ever used them or you are currently using these treatments.

Read the list to the participant and give them time to respond if they have not used it (Never=0), if used it in the past (Ever=1), if they are currently using (Current=2), or if they are unsure (=9).

Select all that apply. Clarify the formulations if necessary.

Q6a. Birth control pills, oral contraceptive pills, or OCPs
Q6b. The birth control ring (or Nuvaring) is a vaginal contraceptive ring that is inserted into the vagina once a month. The Patch is applied once a week.
Q6c. Depo-Provera shots. Consider current use for Depo-Provera to mean a shot received anytime within the last 3 months.
Q6d. Birth control implant (Norplant, Implanon, or Nexplanon) is implanted in the upper arm. Norplant is usually removed within 5 years, and Implanon or Nexplanon is removed within 3 years. If still in place then answer “Current”.

Q6e. The IUD (intra-uterine device) with hormones is placed in the uterus and can last five years, and it usually makes a woman’s periods lighter. If still in place then answer “Current”. We are only interested in IUDs with hormones, and these need to be distinguished from IUDs without hormones. If it is an IUD that makes periods heavier, then it is likely an IUD without hormones. This is called a Copper IUD or a Paraguard. These non-hormonal IUDs can stay in place for 10 years. If the participant has an IUD without hormones, the answer is “No.”

B. PREGNANCY HISTORY QUESTIONS

Read out the following section:

“Now, we would like to ask you some more detailed questions about pregnancies that occurred AFTER your visit to our center on [Last SOL Visit DATE].”

Q7. Have you been pregnant since the last Visit? 0=No, 1=Yes. If NO, skip to Q13.

The pregnancy questions could be difficult for some participants. If the participant needs reassurance, read the following:

“I would like to assure you that I understand that some of the questions are sensitive. You may not want to answer them completely or at all. There is no right or wrong answer. Please, take your time to think about the answers and let me know whether you would prefer to not answer them. You are important to us.”

Q8. How many times have you been pregnant since the last Visit?
[If none, enter 00] Please include all pregnancies including losses. Note we are counting pregnancies here, so if there were twin babies in a single pregnancy then this is counted as one pregnancy.

Q9. How many pregnancies have you had that lasted 24 weeks or longer since the last Visit?
[If none, enter 00]

Q10. How many miscarriages have you had since the last Visit?
[If none, enter 00] A miscarriage is a pregnancy loss before 24 weeks. Miscarriage is when a pregnancy isn’t viable, that is the embryo or fetus dies in the uterus within the early stages of pregnancy.

Q11. How many babies were born alive since the last Visit?
[If none, enter 00]

Q12. How many babies were stillborn since the last Visit?
[If none, enter 00] A stillbirth would be loss of a baby at 24 weeks or later in a pregnancy. Still birth is the death of the fetus after week 24 when the fetus is viable. Still birth (or Still born) is also used to describe an infant dead at birth. Include IUFD (intrauterine fetal death) at or after 24 weeks with no signs of life on delivery.
Q13. Did you ever have any of these illnesses or conditions during any of your pregnancies after the last study Visit on [date]?

Q13a. High blood pressure first diagnosed during pregnancy?
   Ask if the participant was told by her health care provider that she had high blood pressure or hypertension during this pregnancy. If they had high blood pressure before this pregnancy then answer NO. Do not include high blood pressure from an earlier pregnancy. If only prior high blood pressure from a prior pregnancy before their last visit then answer NO. If they report that they had high blood pressure during this pregnancy that was not treated with medication or lifestyle then answer YES.

Q13b. Preeclampsia or toxemia?
   Ask if the participant was told by her health care provider that she had preeclampsia or toxemia (if unclear mention that this is typically identified through an increase in blood pressure and/or protein in urine). If they had pre-eclampsia then developed eclampsia then answer YES.

Q13c. Seizures, convulsions or eclampsia?
   Ask if the participant if she had a seizure or was told by her health care provider that she had eclampsia during this pregnancy (if unclear then mention that eclampsia is typically identified through convulsions and seizures during pregnancy).

Q13d. Diabetes first diagnosed during pregnancy?
   Ask if the participant was told by her health care provider that she had diabetes during this pregnancy, or that her blood sugar was high? (if unclear mention that this is typically identified through high blood sugar, usually after drinking a sweet drink at a prenatal visit). If she had diabetes before the pregnancy then answer NO. Do not include gestational diabetes from an earlier pregnancy. If they report that they had high blood sugar before this pregnancy that was not treated with medication (diet controlled diabetes) then answer NO.

Q13e. Birth of an infant weighing less than 5.5 lbs (2.5 kg)?
Q13f. Birth of an infant weighing more than 9 lbs (4.09 kg)?
Q13g. Birth of a premature infant, or infant born earlier than 37 weeks?
   The pregnancy due date is 40 weeks, so a premature infant is an infant born more than 3 weeks before the due date.

Q13h. Birth of twins, triplets or more babies?

Each question should be answered separately with No, Yes, Refused, or Not Sure.