



## HCHS/SOL Visit 2- Reproductive and Medical History Questionnaire

### RME/RMS- QxQ

### General Instructions

Read out the following section:

*“This particular interview includes questions about hormones that you may have used or are using, your menstrual periods, and pregnancy. You wonder why we are asking these questions. There is still a lot to discover and learn about women and cardiovascular disease; what puts them at risk and what protects them. There are many unknowns about how some hormones, pregnancy, as well as positive or negative events during and after pregnancy may affect women’s health throughout her life.”*

If the participant needs reassurance, read the following:

*“I will ask you some questions that may make you feel uncomfortable. You may feel like not answering them completely or at all. Please, take your time to think your answers, and let me know whether you would like to answer them or not. We want to understand these aspects of women’s health, and we also want you to feel respected and comfortable. Your desire to not answer any or all questions will not affect your participation in the rest of the interviews or measurements of the study. You are important to us, and your participation in the study is extremely valuable.”*

### Question by Question Instructions

#### A. Hormone and Menstrual History

Q1. Have you ever used a birth control method, including birth control pills or other hormonal methods?

The goal of this question is to document whether the participant ever used birth control methods. The question is read emphasizing the phrase “ever used”, and “birth control method” to broadly to mean any birth control method they have used in the past and/or still using in the present. Because participants may have received care in multiple countries, the interviewer may need to re-emphasize the term “birth control method” and allow the participant time to respond in their own words. 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.

If **No=0** or **Refuse=** skip to Q4.

Q2. 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 not sure (**=9**).

Select all that apply. Clarify the formulas if necessary.

2a. Birth control pills, oral contraceptive pills, or OCPs

2b. 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.

2c. Depo-Provera shots. Consider current use for depo-provera to mean a shot received anytime within the last 3 months.

2d. Birth control implant (Norplant etc...) 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”.

2e. 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 without hormones can stay in place for 10 years. If the participant has an IUD without hormones, the answer is "No."

Q3. [If current or ever to any hormonal preparations], why have you used this/these hormonal preparations? What was it [were they] indicated for? Birth control / to prevent pregnancy? Acne? Menstrual cramps or painful periods? To regulate periods? To treat vaginal bleeding? Or for some other reason, if so, what? Answer each question as Yes, No, or unsure. If for some other reason, then fill in the blank to specify reason.

Q4. Have you ever tried to become pregnant for more than 1 year without success?

The words "without success" means not being able to get pregnant. If the participant had tried to become pregnant for more than a year without success, then ask Q4a. If answer No(0) or Refused or was Unsure, then Go to Q5. Note that this question is asking about fertility, or the ability to become pregnant, defined as having a positive pregnancy test, not the outcome of the pregnancy (miscarriage or stillbirth).

Q4.a. What was the cause for not becoming pregnant? Was it because of a medical problem with you, a medical problem with your partner, or a medical problem with both you and your partner, or you are not sure?

Read the answers provided on the form, for the participant to choose from. If the participant has difficulty answering the question, use the explanations provided with each option.

**Medical problem with you?=0**, can be explained:

*Do you have a medical problem that does not allow you to become pregnant, such as blocked tube or hormone problems that prevent you from producing eggs? Medical problems include diseases, physical conditions, intake of certain medications or surgeries.*

**Medical problem with your partner?=1**, can be explained:

*Does your partner have a medical problem that does not allow you to become pregnant, such as a low sperm count or abnormal sperm? Medical problems include diseases, physical, intake of certain medications or surgeries.*

**Medical problems with both you and your partner?=2**, can be explained:

*Do both your partner and you have medical problems that do not allow you to become pregnant? Medical problems include diseases, physical conditions, intake of certain medications or surgeries.*

Q5. Have your natural periods stopped PERMANENTLY? [If YES] do you have periods from taking hormones?

This question determines if the woman's menstrual periods have stopped permanently.

If Q5=1, "yes, I have no menstrual periods", Go to Q6. 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 Q9. Choose this answer IF YES to the first question, but YES to do you have periods from taking hormones.

If Q5=7, "refused", Go to Q8.

If Q5=7 or =9, Go to Q5a

5a. **IF UNSURE or NO**: What was the date that your **most recent** menstrual period started? [*Prompt for month and year, even if day is unknown.*]

If the participant does not remember exact date prompt for at least a month and year. To help participant remember the date, use probing techniques for remembering dates. Go to Question 8.

Q6. 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.

Q7. Why did your 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.

4 = "Radiation/chemotherapy"

5 = If other reason, ask for specification, and fill in the blank

7 = refused

9 = unsure

Q8. Have you had a hysterectomy? (This is an operation to take out your 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.

Q8a. If "yes" ask what age this was done (Q8a), otherwise Go to Q9. If unsure then enter "99".

Q9. Have you had either of your ovaries surgically removed? If YES, then ask, "have you had one or both ovaries removed?" If they say YES, but are not sure whether one or both were removed, then answer "Yes, unsure if one or both removed".

Q9a. If "yes" that one or both ovaries were removed (Q9=1 or =2), then ask what age in years this was done (Q9a), otherwise Go to Q10. If each ovary removed in different years, then ask the age that the last ovary was removed. Enter "99" if they are unsure.

**For the next question,** *I would like to ask you to think about your menstrual periods when you were 20 to 40 years old. Think about what your periods were like when you were not using birth control pills or other hormone medications, and were not pregnant or breastfeeding. Think carefully; take your time.*

Q10. How many days did your typical menstrual cycle last, that is, how many days were between the beginning of one menstrual period to the beginning of bleeding of the next period? If the woman is under age 40, ask her to think of her periods since she turned 20; if she is 40 or older, ask her to think of her periods when she was in her 20s or 30s.

This question will get information about how long the participant's menstrual cycle typically lasts when the participant was not using birth control pills, or other hormone medications, when they were not pregnant, or breastfeeding.

Read each option: Less than 24 days, 24-35 days, >35 days, or too variable or irregular

Q11. Has a health care provider ever told you that you have polycystic ovary syndrome or PCOS?

PCOS is a common hormonal disorder in which the ovaries can be seen to have small cysts. PCOS can cause acne, unwanted excess hair growth [in areas such as face, and on chest], and obesity. If she has a history of ovarian cysts, but she was not told that she had PCOS, then answer NO.

## B. Pregnancy History Questions

This section will ask about all pregnancies the participant has had. Remember that these are sensitive questions. Allow the participant time to think about the answer and wait for her response. Remind the participant that there is no right or wrong answer.

Q12. Lead with:

*"Next, I will be asking you about any pregnancies you have had. We would like to understand your pregnancy history for before your SOL Visit 1 date and after your SOL visit1 date."*

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 not like to answer them. You are important to us. "*

For all questions 12a-12b, enter "99" if they are unsure.

12a-12b. How many times have you been pregnant before VISIT 1? And after Visit 1? [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 1 pregnancy.

If no pregnancies at all were reported (12a=00 and 12b=00), then **End the Questionnaire**. If no pregnancies at all (12a=00 and 12b=00), If no pregnancies at one of the time points, but pregnancies at the other time point then continue to ask the questions for the time period for which there are pregnancies, skipping the other time period. So, if no pregnancies after VISIT 1, then proceed to ask the questions 13a-16a for before VISIT 1, but do not ask 13b-16b for *after* VISIT 1.

13a. How many pregnancies have you had that lasted 6 months or longer before VISIT 1? And after VISIT 1?

14a. How many miscarriages have you had before VISIT 1? Miscarriages are pregnancy losses that happen before 24 weeks. If they had a pregnancy loss at 24 weeks or longer then this is a considered a stillbirth rather than a miscarriage. For those with a miscarriage consider condolences of "I am sorry that you had this experience." Further if felt needed then, "Is it OK if we continue with the questionnaire?"

15a. How many tubal or ectopic pregnancies have you had before VISIT 1? Ectopic pregnancies are when the embryo or fetus implant somewhere outside of the uterus, usually in the fallopian tube.

16a. How many C-sections have you had before VISIT 1?

[Sum answers to 13a, 14a, and 15a. If the sum of these three is greater than 12a, prompt the participant and reconcile the discrepancy: "This adds up to more than the total number of times you said you have been pregnant before visit 1. May we go over these questions again?" If the total number is smaller than 12a, we assume that the other pregnancies ended with abortions. Do not prompt the participant.]

Question 17 and 18 are for all pregnancies, both before and after visit1.

Q17. During any of your pregnancies (or "during your pregnancy"), did you feel sad, miserable, or very anxious? By this, we mean a period of at least 2 weeks when you were not yourself and which was worse than the normal ups and downs of life? By "two weeks," I mean most the day, nearly every day.

This question determines if the participant was ever depressed for 2 weeks or more during a pregnancy. Enter 77 for a refusal.

Q18. After any of your pregnancies (or "After your pregnancy"), within the first 6 months after delivery [or postpartum], did you feel sad, miserable, or very anxious? By this, we mean a period of at least 2 weeks, when you were not yourself and which was worse than the normal ups and downs of life? By "for two weeks," I mean most of the day, nearly every day.

This question determines if the participant was ever depressed for 2 weeks or more for the time period of 6 months after delivery of the baby. Enter 77 for a refusal.

*Now for the remaining questions on this form, we would like to ask you questions about pregnancies that happened before visit 1 on [date].*

Q19. How many babies (or baby) were born alive before VISIT 1? [If none, enter 00].

Q19.a. And how many babies (or baby) were stillborn before VISIT 1? [If none, enter 00].

Q20. Did you ever have any of these illnesses or complications during [your pregnancy before VISIT 1] any of your pregnancies before VISIT 1?

Read the options in the table and ask the participant if any of the illnesses or complications occurred during her pregnancy.

For high blood pressure (20a) and diabetes (20d), we are interested in whether these conditions were noticed *for the first time* during a pregnancy. If the participant was found to have high blood pressure or diabetes before a pregnancy, and then had the conditions in the pregnancy, mark "No."

Women who are diagnosed with high blood sugar or blood pressure during pregnancy often go on to have these conditions outside of pregnancy. If the condition was *first* detected during a pregnancy, and persisted or was found again after the pregnancy, mark "Yes."

For 20g, a premature infant is any birth that occurred more than 3 weeks before the due date or earlier than 37 weeks.

Q21. For pregnancies that were less than 6 months and before VISIT 1, how many of these pregnancies (or for this pregnancy) did you receive prenatal care, and if so was care received both inside and outside of the United States, in the United States only, or outside the United States only? Enter the number of pregnancies for each location of prenatal care. This question determines the location(s) that prenatal care was given for pregnancies that resulted in a miscarriage.

*[sum 21a, b, c and d. If this sum is greater than (12a-13a), prompt the patient to reconcile: "That adds up to xx pregnancies lasting less than 6 months, which is more than (12a-13a) – may I go over these questions with you again?" ]*

Q22. For pregnancies that were 6 months or longer and before VISIT 1, did you receive prenatal care, and if so was care received both inside and outside of the United States, in the United States only, or outside the United States only? Enter the number of pregnancies for each location of prenatal care. This question determines the location(s) that prenatal care was given for pregnancies that made it 6 months or longer.

*[sum 22a, b, c and d. If this sum is greater than (13a), prompt the patient to reconcile: "That adds up to xx pregnancies lasting less than 6 months, which is more than (13a) – may I go over these questions with you again?" ]*

### **End of Questionnaire**

If the number reported for Q12b is "00", then do not fill out a PCE/PCS form. If the number reported for Q12b is 1 or greater, then fill out a PCE/PCS form for each pregnancy; and you may say, "***Now, we would like to ask you some more detailed questions about the pregnancies [pregnancy] that occurred after SOL Visit 1 on [DATE] ."***"

<b>GO to PREGNANCY COMPLICATIONS Form to collect details of each pregnancy after SOL Visit 1.</b>
---