

WOMEN'S INTERAGENCY HIV STUDY

FOLLOW-UP VISIT

QUESTION BY QUESTION SPECIFICATIONS

FORM 23: OB/GYN AND CONTRACEPTIVE HISTORY

Guidelines for completing Form 23, "OB/GYN and Contraceptive History."

The Follow-up Obstetric, Gynecological and Contraceptive History is designed to obtain the participant's pregnancy, contraceptive, and gynecological history, as well as the participant's contraceptive intentions and reproductive decisions. For this module, the participant's pregnancy history will be obtained first, in part, because the information is generally the easiest for most women to recall. In addition, other researchers have found that women are more likely to remember why they used contraceptives or had gynecological infections if they think of them in terms of when they were pregnant.

General Instructions:

NOTE: If this form is being administered to the participant AFTER her physical exam, be sure to remind her that the findings from her exam conducted today do NOT apply to the questions you are about to ask her.

1. Use the form version dated 10/01/04.
2. All dates should be recorded in the MM/DD/YY format unless otherwise noted. For dates that must be completed on the form, if the participant cannot remember the exact month (and day), probe for the season. Use "15" for the day if the specific day cannot be recorded. Probe for the season and assign the month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates. Years in response to questions inquiring about occurrences "since last visit" should be 1995 and thereafter.

3. Times should be recorded in the HH:MM format. Remember to use leading zeros, e.g., 08:00.
4. For questions containing an open-ended specify box linked to the response "other," interviewers should print responses exactly in the words of the respondent.
5. Obtain the date of the participant's previous visit from the Visit Control Sheet (VCS). This month should be used in the questions wherever (MONTH) appears.
6. Interviewers should ignore any markings related to data entry such as "START F23S1." These indicators mark the beginning and end of all subforms; they have been added for data entry purposes only and will not affect how the form is completed.

Follow the skip patterns as they appear on the form.

READ THE INTRODUCTION TO THE PARTICIPANT.

SECTION B: GYNECOLOGIC HISTORY, PREGNANCY AND MENSTRUATION

- B2. Indicate whether or not the participant has had one or both of her ovaries removed since her (MONTH) study visit. If the participant has had both ovaries removed, note the prompt at the bottom of the page.
- B3. Indicate whether or not the participant had a tubal ligation since her (MONTH) study visit? **PROBE: “Were your tubes tied?”** If the participant responds “YES,” note the prompt at the bottom of the page.
- B5. Indicate whether or not the participant has had a hysterectomy (partial or total) since her (MONTH) study visit. If participant does not understand the difference between a partial or total hysterectomy, read the probe in parentheses. **PROBE: “A partial hysterectomy includes removal of the uterus, or womb, only. A total hysterectomy includes removal of the cervix in addition to the uterus or womb.”** If “YES,” skip to the prompt at the bottom of the page; if “NO,” proceed to question B7.
- B6. Indicate whether or not the participant has ever had a hysterectomy. If “YES,” skip to question B20; if “NO,” proceed to the prompt at the bottom of the page.

PROMPT: IF PARTICIPANT HAS HAD BOTH OVARIES REMOVED (B2 = 3) OR A TUBAL LIGATION (B3 = 1) OR A PARTIAL OR TOTAL HYSTERECTOMY (B5 = 1), SKIP TO QUESTION B8. OTHERWISE, PROCEED TO QUESTION B7.

- B7. The purpose of this question is to learn if the participant is **currently** pregnant. If the participant suspects she is pregnant because her period is late, repeat the question. A positive home pregnancy test as well as confirmation by a physician are to be coded as “1” (YES).

PROMPT: IF PARTICIPANT IS CURRENTLY PREGNANT (B7 = 1), THEN PARTICIPANT IS ELIGIBLE FOR ENROLLMENT INTO THE PREGNANCY PROTOCOL. PLEASE NOTIFY THE PROPER WIHS STAFF AT YOUR SITE.

- b. If the participant has not already scheduled an appointment to see a health care provider for prenatal care, refer her for prenatal care at the end of the interview.
- c. Enter the total number of confirmed pregnancies the participant reports since her (MONTH) study visit **excluding her current pregnancy**. This question is asked only of women who are currently pregnant because a similar question (B8) is asked of women who are not currently pregnant. If she has had no other pregnancies, CODE “00,” then skip to question B13. Do not leave question blank. **PROBE: “I mean all of your pregnancies regardless of outcome.” PROMPT: IF B8c ≥ 1, SKIP TO B9.**
- B8. Enter the total number of confirmed pregnancies the participant reports since her (MONTH) study visit. Please include all pregnancies regardless of outcome. This question is asked only of women who are not currently pregnant because a similar question (B7c) is asked of women who are currently pregnant.

PROMPT: IF PARTICIPANT HAS BEEN PREGNANT SINCE HER LAST STUDY VISIT (B8 > 0), THEN PARTICIPANT IS ELIGIBLE FOR ENROLLMENT INTO THE PREGNANCY PROTOCOL. PLEASE NOTIFY THE PROPER WIHS STAFF AT YOUR SITE.

PROMPT: IF B8 = 00 AND IF B2, B3 OR 5 = YES, SKIP TO B13. IF B8 = 00 AND IF NONE OF B2, B3 OR B5 = YES, SKIP TO B12.

- B9–B11: **Hand participant Response Card 8.** For these questions, it is important to read all the categories the first time you ask the question. The interviewer does not need to read the categories for the following pregnancies unless the participant has difficulty remembering all the choices.

Indicate the outcome of each pregnancy and the month and the year when it occurred. These questions determine the number of live births, multiple births, miscarriages, therapeutic or elective abortions, stillbirths and tubal pregnancies a woman has had since her (MONTH) study visit.

NOTE: MAKE SURE TO COLLECT THE MONTH AND THE YEAR FOR EACH PREGNANCY. Interviewers should have a calendar available to aid the participant in determining the date of each pregnancy.

PREGNANCY OUTCOME DEFINITIONS:

- **Livebirth:** By livebirth we mean a baby that was born alive.
 - **Stillbirth:** By stillbirth we mean a baby that was born dead.
 - **Abortion:** By abortion we mean a pregnancy in which the participant chose to end the pregnancy and did so by having a procedure performed.
 - **Miscarriage:** By miscarriage we mean a pregnancy where the participant lost the baby before she was 20 weeks or five months pregnant.
 - **Ectopic Pregnancy:** By ectopic pregnancy we mean a tubal pregnancy that occurred in the woman's fallopian tubes.
- a. If the pregnancy outcome is coded as “ABORTION,” “MISCARRIAGE,” “ECTOPIC PREGNANCY,” “OTHER” (**SPECIFY**) or “DON'T KNOW,” skip to “**c**” to obtain the month and the year of the event.
- c. Record the month and the year of that pregnancy outcome. If the participant cannot remember the month and/or the year, after probing, follow general instruction #2 on the first page of these QxQs to estimate the date. Interviewers should have a calendar available to aid the participant in determining the date of the outcome. **DO NOT LEAVE BLANK.**

NOTE: The number of pregnancies recorded in question B7c or question B8 should be consistent with the number of pregnancy outcomes listed in questions B9–B11.

NOTE: After recording the last pregnancy outcome, if the women is currently pregnant, skip to question **B13**.

- B14. Record the month, day, and year the participant's last menstrual period began excluding the participant's current menstrual cycle. **PROBE: “Please try to remember as best you can.”** If the participant gives a date within the past seven days, ask: “Are you currently menstruating?” If the participant says “YES,” say: “I need the month and day of the period before this one.” Interviewers should have a calendar available to aid the participant in determining the date her last menstrual period began.
- B15. Record the number of days bleeding occurred during the participant's most recent period. We want to know how many days of bleeding the participant experienced. **PROBE: “How many days did you use a tampon or pad for bleeding?”** **PROBE: “Please remember as best you can.”**
- B16. Record the number of days the participant experienced monthly bleeding, on average, over the past six months. We want to know how many days bleeding lasted on average during her menstrual cycle over the past six months. If the participant had only one period in the past six months, enter the number of days that period lasted. Do not enter zero. **PROBE: “Please estimate as best you can.”**
- B17. Indicate whether or not the participant's periods were regular over the past six months. By regular, we mean there are about the same number of days between each of the participant's menstrual cycles in the past six months.

- B18. Indicate whether or not the participant has skipped any periods in the last six months when she was not pregnant or breast feeding. Skipped periods can be defined as 40 days without usual menstrual bleeding.
- B19. If the participant has experienced any spotting or bleeding between periods during the past six months, refer for follow up to her health care provider.
- B20. We are interested in knowing whether or not the participant has been through menopause or the change of life. By menopause we mean cessation of menstrual activity for twelve months, (not during or immediately after pregnancy or due to medication).
- B21. If the participant has had bleeding after sexual intercourse or use of toys when she was not having her period in the past six months, refer for follow up to her health care provider.

SECTION C: HORMONES, BIRTH CONTROL AND BARRIER METHODS

Read the introductory statement to the participant so she understands we would like to know about hormones, birth control and barrier methods that she uses or has used in the last six months and if she uses them for reasons other than pregnancy prevention. That is why all women are asked these questions regardless of whether they are capable of becoming pregnant.

PROMPT: IF PARTICIPANT HAD TUBAL LIGATION (B3=1) OR HYSTERECTOMY PRIOR TO HER (MONTH) STUDY VISIT (B1=1), THEN SKIP TO C6.

C1–C13: These questions are about different types of hormones, birth control and barrier methods. We want to know if each study participant has used these methods in the past six months. If she has used the method during the past six months, read the questions in the right column, otherwise skip to the next method.

We want to know the reason or reasons the participant uses or has used this method in the past six months. Read each reason in the right box. Please code each item "YES" or "NO", as it is possible the participant may be using the (METHOD) for more than one reason. If the participant gives a reason other than those listed, record the response verbatim in the space provided.

- C1. Indicate whether or not the participant has used the Pill/Oral contraceptives in the past six months. If the participant answers “NO” or declines to answer, skip to question **C2**.
- a. Enter the total number of months in the past six months that the participant has taken the pill (oral contraceptives).
 - b-d: Indicate the reason or reasons the participant used the Pill/Oral Contraceptives in the past six months, whether it was for birth control, to regulate her period, or for any other reason (which the participant must specify).
- C2. Indicate whether or not the participant has used Norplant in the past six months. If the participant answers “NO” or declines to answer, skip to question **C3**.
- a. We would like to know the month and year the participant had Norplant inserted. **PROBE: “Please try and remember as best you can.”** Interviewers should have a calendar available to aid the participant in determining the date her Norplant was inserted.
 - b. Indicate whether or not the participant's Norplant is still in place. Then, proceed to the right column, **C2c–e**.
 - c–e: Indicate the reason or reasons the participant used Norplant in the past six months.

- C3. Indicate whether or not the participant has used Depo/Depo Provera/Lunelle/Other Contraceptive Injection in the past six months. If the participant answers “NO” or declines to answer, skip to question C4.
- a. Enter the month and year the participant had received her most recent injection. **PROBE: “Please try and remember as best you can.”** Interviewers should have a calendar available to aid the participant in determining the date of her last Depo/Depo Provera/Lunelle/Other Contraceptive injection.
- b–d: Indicate the reason or reasons the participant used Depo/Depo Provera/Lunelle/Other Contraceptive Injection in the past six months.
- C4. Indicate whether or not the participant has used an IUD in the past six months. Examples of IUDs include Paragard, Progestasert, and Mirena. If the participant answers “NO” or declines to answer, skip to question C5.
- a: Indicate the type of IUD used by the participant, i.e., with hormone or without hormone.
- C5. Indicate whether or not the participant used Ortho Evra, the once-a-week birth control patch, in the past six months. Ortho Evra is marketed by Ortho-McNeil a subsidiary of Johnson & Johnson. Currently, it is the only brand name patch on the market.
- C6. Indicate whether or not the participant used NuvaRing, a vaginal ring containing hormone, which is inserted once-a-month.
- C7. Indicate whether or not the participant used emergency contraception (emergency hormonal contraceptive pills) in the past six months. If the participant answers “NO” or declines to answer, skip to question C8.
- a: Enter the total number of times in the past six months that the participant has taken emergency contraceptives. **NOTE: Taking emergency contraception one time entails; 2 doses taken with in a twelve hour period.**
- C8. Indicate whether or not the participant has used a diaphragm or cervical cap in the past six months. If the participant answers “NO” or declines to answer, skip to question C9.
- a–c: Indicate the reason or reasons the participant used a diaphragm or cervical cap in the past six months.
- C9. Indicate whether or not the participant has used vaginal creams/jellies/foams/sponge in the last six months. If the participant answers “NO” or declines to answer, skip to question C10.
- a–c: Indicate the reason or reasons the participant used vaginal creams/jellies/foams/sponge in the past six months.
- C10. Indicate whether or not the participant or her partner has used the rhythm method or withdrawal in the past six months.
- C11. Indicate whether or not the participant's partner has used male condoms in the past six months while having sex with her. If the participant answers “NO” or declines to answer, skip to question C12. **NOTE: Female condoms are asked about in question C12.**
- a–c: Indicate the reason or reasons the participant used male condoms in the last six months.
- C12. Indicate whether or not the participant used a female condom while having sex in the last six months. If participant answers “NO” or declines to answer, skip to question C13.
- a-c: Indicate the reason or reasons that participant used female condoms in the last six months.

- C13. Indicate whether or not the participant purposefully abstained from having sex in the last six months. If participant answers “NO” or declines to answer, skip to question **C14**.
- a-c: Indicate the reason or reasons that the participant purposefully abstained from having sex in the last six months.
- C14. Indicate whether or not the participant has used any other contraceptive method in the past six months that has not been mentioned in questions C1–C13. If the participant answers “NO” or declines to answer, skip to question **C15**.
- a. Please ask the participant to specify any other contraceptive method she may have used during the past six months and record the participant's answer verbatim.
- C15. Indicate whether or not the participant has used any other method, such as dental dams or saran wrap, in the past six months to avoid getting or giving sexually transmitted diseases. If the participant answers “NO” or declines to answer, skip to question **E1**.
- a. Indicate what other method has been used by the participant. Please ask the participant to specify and record her answer verbatim.

SECTION E: GYNECOLOGICAL INFECTIONS

This section obtains information about gynecological infections or abnormalities that a participant may have experienced since her (MONTH) study visit.

- E1–E9: We want to know if the participant remembers being told by a doctor, nurse, nurse practitioner, midwife or physician's assistant that she had any of the conditions listed here since her (MONTH) study visit.
- a. We do not want to include conditions the participant was told she had during her previous WIHS visit. So, this question is asked to verify that the conditions reported in questions E1–E9 occurred since her (MONTH) study visit.
- E5. We would like to know if the participant has been told she had herpes in or around her genital area since her (MONTH) study visit. **PROBE: “your vagina or anus.”** Do not explain further. However, if the participant responds with terms such as: tush, behind, vulva, labia, crotch, or butt, code “1” (YES).
- E6. We would like to know if the participant has been told she had warts in or around her genital area since her (MONTH) study visit. **PROBE: “your vagina or anus.”** Do not explain further. However, if the participant responds with terms such as: tush, behind, vulva, labia, crotch, or butt, code “1” (YES).
- E9. If the participant responds that she has had a vaginal yeast infection, ask questions E9a, E9b and E9c. If she reports taking any medication(s) (either by mouth or in a cream or lotion) for a vaginal yeast infection, record the name of the medication in question E9d. Record the participant’s answer verbatim.
- E10–E14: Questions deleted.
- E15. We would like to know how many days the participant's most recent yeast infection lasted. **PROBE: “Please remember as best you can.” PROBE: “If the infection is still present count from the day it began until today.”** Interviewers should have a calendar available to aid the participant in determining the how many days her last yeast infection lasted.
- E17–E22: The next set of questions asks about symptoms the participant may have experienced since her (MONTH) study visit.

- E20. Indicate whether or not the participant has had a sore or ulcer in or around her genital area since her (MONTH) study visit? **PROBE: “Your vagina or anus.”** However, if the participant responds with terms such as tush, behind, vulva, labia, crotch or butt, code “1” (YES).
- E22. Indicate whether or not the participant has experienced any pain in the lower part of her belly since her (MONTH) study visit? **PROBE: “pain in the lower part of your abdomen.”**

PROMPT: FOR EACH “YES” RESPONSE IN QUESTIONS E17–E22, REFER FOR FOLLOW-UP TO PARTICIPANT’S HEALTH CARE PROVIDER.

SECTION F: MAMMOGRAPHY AND BREAST CONDITIONS

This next set of questions is about breast conditions and mammograms.

- F5. Indicate whether or not the participant has had a mammogram since her (MONTH) study visit.
PROBE: “A mammogram is a special type of x-ray for examining the breast.” If the participant answers “NO,” “DON'T KNOW” or declines to answer, skip to question **F9**.
- F7. We would like to know the results of the participant's most recent mammogram. If the results are reported as “other” by the participant, please ask her to specify. Record the participant's answer verbatim.
- F8. Question deleted.
- F9. Please record the time module ended. Circle the code for AM (Code 1) or PM (Code 2). Remember to use leading zeros. For example: 08:00.