WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS
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. 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.

2. Times should be recorded in the HH:MM format. Remember to use leading zeros, e.g., 08:00.

3. For questions containing an open-ended specify box, interviewers should neatly print responses exactly in the words of the respondent.

4. 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.

5. 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.

READ THE INTRODUCTION TO THE PARTICIPANT.

SECTION B: GYNECOLOGIC HISTORY, PREGNANCY AND MENSTRUATION

B1 a. Indicate whether or not the participant has had a Pap test **(PROBE: *"Pap smear, Papanicolaou test, a test for early detection of cancer of the cervix"*)** since her (MONTH) study visit. Do not include Pap tests that the participant has received as part of her WIHS visit. If the participant answers "NO," the interviewer should skip to **Question B1c.**

b. Indicate whether this Pap test was abnormal.

c. Indicate whether or not the participant has had a colposcopy since her (MONTH) study visit. (**PROBE: *"Colposcopy uses an instrument like binoculars to examine the cervix, and a biopsy may or may not be taken."***) Do not include any colposcopies that the participant has received as part of her WIHS visit.

d. Indicate whether or not the participant was treated for any cervical abnormality since her (MONTH) study visit. If the participant answers "NO," the interviewer should skip to **Question B1f.**

e. Indicate the type of treatment that was utilized.

f. Indicate if the participant was treated for any other gynecological conditions since her (MONTH) study visit. If the participant answers "NO," the interviewer should skip to **Question B2.**

d. Specify verbatim for what gynecological condition the participant was treated in **Question B1g.**

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, the response to **Question B6a** should be "2."

a. Indicate whether or not the participant has <u>ever</u> had both of her ovaries removed. If the participant responds "YES," the response to **Question B6a** should be "2."

B3. Indicate whether or not the participant had a permanent sterilization procedure, such as tubal ligation (tubes tied) or Essure procedure <u>since her (MONTH) study visit</u>. If the participant responds "YES," the response to **Question B6a** should be "2."

a. Indicate whether or not the participant has <u>ever</u> had a permanent sterilization procedure, such as tubal ligation (tubes tied) or Essure procedure. If the participant responds "YES," the response to **Question B6a** should be "2."

B5. Indicate whether or not the participant has had a hysterectomy (partial or total) <u>since her (MONTH) study visit</u>. 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 **Question B6a** and circle response "2"; if "NO," proceed to **Question B6**.

B6. Indicate whether or not the participant has <u>ever</u> had a hysterectomy, either partial or total. If "YES," skip to **Question B20**; if "NO," proceed to **Question B6a**.

PROMPT: IF PARTICIPANT REPORTS "EVER" HAVING A BILATERAL OOPHERECTOMY (QUESTION B2a=1), THEN SKIP TO QUESTON B20.

a. Review the participant's responses to the following questions: **B1e, B2, B3, B3a,** and **B5**. If participant reports having had a ***<u>hysterectomy</u>*** since her (MONTH) study visit (B1e = 4 or B5 = 1), circle "2" and skip to **Question B8**. If participant reports having had a ***<u>permanent sterilization procedure</u>*** since her (MONTH) study visit or ever (B3 = 1 or B3a = 1), circle "2" and skip to **Question B8**. If participant reports having had a ***<u>bilateral oopherectomy</u>*** (removal of *both* ovaries) since her (MONTH) study visit (B2 = 3), circle "2" and skip to **Question B8**. If participant reports having had ***<u>no gynecological surgery</u>*** (i.e., responses to all above listed questions are "NO"), circle "1" and then proceed to **Question B7**. NOTE: Do not circle "2" if the participant reports only a dilation and curettage (Question B4 = 1).

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). If the participant answers "NO," the interviewer should skip to **Question B8.**

a. Ask the participant if she has seen a prenatal health care provider, doctor, nurse, nurse practitioner, midwife, or physician's assistant for the pregnancy she reported in **Question B7.** If the participant answers "YES," the interviewer should skip to **Question B7c.**

b. If the participant has not already scheduled an appointment to see a health care provider for prenatal care, refer her for prenatal care <u>at the end of the interview</u>.

c. Enter the total number of confirmed pregnancies the participant reports having experienced 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 the participant 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 B7c ≥ 1, SKIP TO B9.

B8. Enter the total number of confirmed pregnancies the participant reports having experienced 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 B8 = 00 AND IF B6a = 2, SKIP TO B13.

IF B8 = 00 AND IF B6a = 1, 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 pregnancies subsequent to the first one unless the participant has difficulty remembering all the choices.

For each pregnancy reported, indicate the outcome and the month and the year when the outcome 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:

- **Live birth:** Live birth means a baby that was born alive.
- **Stillbirth:** Stillbirth means a baby that was born dead.
- **Abortion:** Abortion means a pregnancy in which the participant chose to end the pregnancy and did so by having a procedure performed.
- **Miscarriage:** Miscarriage means a pregnancy where the participant lost the baby before she was 20 weeks, or five months, pregnant. This is sometimes called a "spontaneous abortion."
- **Ectopic Pregnancy:** Ectopic pregnancy means a tubal pregnancy that occurred in the woman's fallopian tubes. Ectopic pregnancies usually result in surgery to save the mother's life.

a. If the pregnancy outcome is coded as "abortion," "miscarriage," "ectopic pregnancy," "other," or "don't know," skip to **Question B9c** to obtain the month and the year of the event.

c. Record the month and the year of the pregnancy outcome. If the participant cannot remember the month and/or the year, after probing, follow general instruction #1 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 THROUGH B11.

PROMPT: IF CURRENTLY PREGNANT (B7=1), OR IF PARTICIPANT REPORTS GYNECOLOGICAL SURGERY (B6a=2), SKIP TO QUESTION B13.

B12. Indicate whether or not the participant is currently trying to get pregnant.

B13. Indicate if the participant has had a period within the past six months. If she answers "NO," the interviewer should skip to **Question B20.**

B14. Record the month, day, and year the participant's most recent menstrual period began. If the participant is menstruating at the time of her visit, record the first day she started bleeding for her *current* period. **(PROBE: *"Please try to remember as best you can."*)** Interviewers should have a calendar available to aid the participant in determining the date her last menstrual period began.

NOTE:	IF THE PARTICIPANT IS CURRENTLY MENSTRUATING (OR GIVES A DATE WITHIN THE SEVEN DAYS PRECEDING THE INTERVIEW), DO NOT ASK THE PARTICIPANT FOR THE MONTH AND DAY OF THE PERIOD BEFORE HER CURRENT ONE; RECORD THE START DATE OF HER CURRENT PERIOD.

B17. Indicate whether or not the participant's period has been either three days early or three days late during 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 should 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 or more months, not during or immediately after pregnancy and not due to medication use.

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 that we would like to know about birth control methods, including hormones and barrier methods, that she has used withinin the last six months and if she uses them for reasons other than pregnancy prevention. That is women are asked these questions regardless of whether they are capable of becoming pregnant.

C0. Indicate whether or not the participant has used any form of birth control at all, either to prevent pregnancy, to avoid getting or giving STDs or HIV, or to regulate her periods. Ensure the participant knows that the question refers to **all** types of birth control, including condoms and abstinence. If she answers "NO," the interviewer should skip to **Section E.**

a. Indicate whether or not the participant has ever had a sterilization procedure or bilateral ooperectomy. This question should not be asked of the participant as the answer can be determined from Questions B2a and B3a. If Question B2a or B3a = 1, then answer "YES," and skip to **Question C8.**

b. Indicate whether or not the participant has had a hysterectomy prior to her last study visit. This question should not be asked of the participant as the answer can be determined from Question B6. If Question B6 = 1, then answer "YES," and skip to **Question C8.**

C1–C13: These questions are about different types of hormones, birth control and barrier methods. We want to know if the participant has used any of these methods in the past six months. If she has used a particular 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 a particular 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 C3i.**

a. Enter the total number of months in the past six months that the participant has taken the pill (oral contraceptives).

b. Record whether the type of birth control pill used by the participant is Seasonale or Seasonique, the pill that means you have only four periods per year.

c. Record whether the type of birth control pill used by the participant is Lybrel, the continuous use pill, that means you do not have a period at all.

d-f: 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).

C3i. Indicate whether or not the participant has used Depo/Depo Provera in the past six months. If the participant answers "NO" or declines to answer, skip to **Question C3ii**.

a. Enter the month and year the participant received her most recent Depo 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 injection.

b–d: Indicate the reason or reasons the participant used Depo/Depo Provera in the past six months.

C3ii. Indicate whether or not the participant has used Implanon, an implantable progestin contraceptive, 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 received her most recent implant. **(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 Implanon implant.

b–d: Indicate the reason or reasons the participant used Implanon in the past six months.

C4. Indicate whether or not the participant has used an IUD in the past six months. If the participant answers "NO" or declines to answer, skip to **Question C5**.

a. There are two types of IUD available: (1) the ParaGard, which has a tiny copper wire wrapped around the plastic body and should not be used by anyone who is allergic to copper, and (2) the Mirena, which releases small amounts of a synthetic progesterone hormone. The hormone was added to attempt to decrease the bleeding and cramping that some women have with the IUD. Indicate the type of IUD used by the participant, i.e., with hormone (i.e., Mirena) or without hormone (i.e., ParaGard).

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 **(PROBE: *"emergency hormonal contraceptive pills, Plan B, Ovral, PREVEN"*)** 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 two doses taken within 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 has used male condoms with her partner in the past six months. 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 not mentioned in **Questions C1** through **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 **Section E.**

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. Ensure that the participant knows **not** to include any conditions that she may have been told about during a WIHS visit (either prior WIHS visit, or current WIHS visit if exam order is changed).

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** through **E9** have 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** and **E9b**.

E17–E21: 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."*)** Do not explain further. However, if the participant responds with terms such as tush, behind, vulva, labia, crotch or butt, code "1" (YES).

PROMPT: FOR EACH "YES" RESPONSE IN QUESTIONS E17 THROUGYH E21, 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.

F1. Indicate whether or not the participant has been breast feeding since her (MONTH) study visit. If the participant answers "YES," the interviewer should skip to **Question F4.**

F2. Indicate whether or not the participant has had discharge from either nipple since her (MONTH) study visit. If the participant answers "YES," refer for follow-up to her health care provider.

F3. Indicate whether or not the participant has had pain in either of her breasts since her (MONTH) study visit. If the participant answers "NO," the interviewer should skip to **Question F4.**

a. Ask the participant if the pain in her breast(s) was during the week prior to getting her period. If the participant answers "NO," refer for follow-up to her health care provider.

F4. Indicate whether or not the participant has had a lump in either of her breasts since her (MONTH) study visit. If the participant answers "YES," refer for follow-up to her health care provider.

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.**

F6. Ask the participant the reason that her most recent mammogram was completed.

F7. We would like to know the results of the participant's most recent mammogram. Please circle response "4" (i.e., pending) if she indicates that she has had a mammogram, but has not yet received the results. **(PROBE: *"'Pending' means that the participant has not yet received any results."*)** If the results are reported as "other" by the participant, please ask her to specify. Record the participant's answer verbatim.

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.