

**WOMEN'S INTERAGENCY HIV STUDY
NEW RECRUITS SCREENING FORM (SCR)**

SECTION A: GENERAL INFORMATION

- A1. SCREENING ID: _____
- A2. WIHSID (if enrolled): |__|_|-|__|_|-|__|_|-|__|_|-|__|_|
- A3. VISIT NUMBER: |__|_|
- A4. FORM VERSION: **0 5 / 22 / 1 3**
- A5. DATE OF SCREENING: |__|_|/|__|_|/|__|_|
M D Y
- A6. INTERVIEWER'S INITIALS: |__|_|_|

NOTE: QUESTIONS A1 AND A7 THROUGH A15 WILL NOT BE DATA ENTERED.

- A7. Would you prefer to be interviewed in English or Spanish?
- ENGLISH 1
SPANISH..... 2

IF PREFERRED LANGUAGE IS ENGLISH, READ SCREENING INTRODUCTION BELOW. USE SPANISH VERSION OF FORM IF SPANISH INTERVIEW IS PREFERRED.

Thank you for your interest in the Women’s Interagency HIV Study and for helping us out by coming here today. The purpose of the Women’s Interagency HIV Study, also called the WIHS, is to learn about how HIV infection affects women’s health. The results of this study are used to help in the development and delivery of services to improve the health of women.

The WIHS started in 1994, and has enrolled a total of 4,124 women. The majority of these women is still involved in the WIHS, and still attends WIHS visits every six months. We recently decided to enroll additional women into the WIHS to improve our ability to learn about the health of women in the South.

In order to participate in this study, you must be willing to:

- Be HIV tested (**UNLESS SITE HAS A DOCUMENTED HIV+ TEST RESULT**)
- Complete an interview, which may last as long as two hours
- Receive a physical and gynecological (pelvic) exam, which may also take another forty minutes
- Have blood drawn for laboratory tests
- Agree to have some of your blood stored in a national repository
- And participate in follow-up visits every six months.

Do you have any questions about the study or what you may be asked to do as part of this study?

As with any research study, we need to be sure that we have a diverse group of women in the study. To do that, we will first ask you some questions. It is important for you to understand that right now we may not be able to take everyone into the study who answers our questions. However, whether or not you are asked to participate, we can refer you to places where you can find health care or other services you feel you need at this time.

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A8. IS CONSENT NEEDED TO PROCEED?

YES..... 1 (PROMPT BELOW)
NO..... 2 (A9)

READ INTRODUCTION BELOW:

Before we continue, I must obtain permission to ask you these next few questions. Here is the consent form that explains the screening procedures. I will read it to you; feel free to follow along and ask me any questions.

HAND PARTICIPANT SCREENING CONSENT FORM AND READ IT ALOUD.

IF SITE PROCEDURES REQUIRE THAT YOU GAIN CONSENT FOR ENROLLMENT BEFORE SCREENING, HAND PARTICIPANT ENROLLMENT CONSENT FORM AND READ IT ALOUD.

A9. Are you willing to continue?

YES 1
NO 2 (END)

a. DATE OF CONSENT |__|__|/|__|__|/|__|__|
M D Y

A10. Are you willing to have your specimens stored in the WIHS national repository?

YES 1
NO 2 (END)

a. DATE OF CONSENT |__|__|/|__|__|/|__|__|
M D Y

A11. What is your date of birth? I need the month, day and the year.

|__|__|/|__|__|/|__|__|
M D Y

PROMPT: VERIFY PARTICIPANT'S DOB THROUGH A SOURCE SUCH AS A DRIVER'S LICENSE, A PASSPORT, OR SOME OTHER TYPE OF ID CARD.

A12. Do you plan to move out of the area within the next 12 months?

YES 1 (END)
NO 2

A13. Are you of Hispanic (Spanish) or Latina origin?

YES..... 1
NO..... 2

A14. Do you consider yourself Black/African American, White/Caucasian, American Indian/Alaskan Native, Asian, Native Hawaiian/Other Pacific Islander or another race?

- BLACK/AFRICAN AMERICAN 1
- WHITE/CAUCASIAN 2
- AMERICAN INDIAN/ALASKAN NATIVE ... 3
- ASIAN 4
- NATIVE HAWAIIAN/OTHER PACIFIC ISLANDER 5
- OTHER 6

SPECIFY: _____

A15. How did you find out about this study? (**CIRCLE ONLY ONE**):

- From an enrolled participant..... 1
- From a flier, advertisement, or posting..... 2
 - a. SPECIFY: _____
- From a WIHS staff member..... 3
- From a Community Advisory Board (CAB) member..... 4
- From a clinic provider..... 5
 - b. SPECIFY PROVIDER/CLINIC: _____
- Don't know, don't remember..... 6
- Other source 7
 - c. SPECIFY: _____

SECTION B: HIV STATUS AND MEDICAL CONDITIONS

B1. Have you ever been tested for HIV, the AIDS virus?

- YES 1
- NO..... 2 (**B4**)

B2. Have you ever tested positive (infected) for HIV?

- YES 1
- NO..... 2 (**B3**)

a. What was the date of your first positive test? |_|_|/|_|_|
M Y

B3. Have you ever tested negative (not infected) for HIV?

- YES 1
- NO..... 2 (**B4**)

a. What was the date of your last negative test? |_|_|/|_|_|
M Y

B4. INTERVIEWER: IS PARTICIPANT HIV-POSITIVE OR HIV-NEGATIVE?

- HIV-POSITIVE 1
- HIV-NEGATIVE..... 2 (SECTION C)
- UNKNOWN <-8>

PROMPT (READ TO PARTICIPANTS):

For the next set of questions, I am going to use the words “health care provider” to mean any doctor, nurse, physician’s assistant or nurse practitioner you go to for medical care. Many of the terms in this section are very technical and you may not have heard of them. If you’ve never heard of a term just say so.

B5. Have you ever been told by a health care provider that you had Kaposi’s sarcoma, or KS?

- YES..... 1
- NO/NEVER HEARD OF IT 2

B6. Have you ever been told by a health care provider that you had non-Hodgkin’s lymphoma?

- YES..... 1
- NO/NEVER HEARD OF IT 2

B7. Has a health care provider ever told you that you had herpes simplex with ulcers or sores lasting longer than one month?

- YES..... 1
- NO/NEVER HEARD OF IT 2

B8. Has a health care provider told you that you had herpes simplex infection of the lungs or esophagus, (the tube between your mouth and your stomach)?

- YES..... 1
- NO/NEVER HEARD OF IT 2

B9. Have you ever had diarrhea (three or more soft or liquid stools per day) that lasted for more than one month?

- YES..... 1
- NO 2 (B11)

B10. Has a health care provider ever told you that any diarrhea you may have had was caused by:

	YES	NO/NEVER HEARD OF IT
a. Cryptosporidia?	1	2
b. Microsporidia?	1	2
c. Isospora?	1	2
d. C-M-V?	1	2
e. M-A-I?	1	2

B11. Has a health care provider ever told you that you had PCP, pneumocystis carinii pneumonia?

YES..... 1
 NO/NEVER HEARD OF IT 2

B12. Has a health care provider ever told you that you had another type of pneumonia, lung infection? Do not answer yes if you were diagnosed only with bronchitis.

YES..... 1
 NO/NEVER HEARD OF IT 2 (B13)

a. Have you ever had more than one episode of pneumonia within a one-year period?

YES..... 1
 NO 2

B13. (Has a health care provider ever told you that you had) Candida or thrush, a yeast infection of the esophagus (the tube between your mouth and stomach) not just in your mouth?

YES..... 1
 NO/NEVER HEARD OF IT 2

B14. (Has a health care provider ever told you that you had) Candida or thrush, a yeast infection of the lungs or airways (trachea or bronchi)?

YES..... 1
 NO/NEVER HEARD OF IT 2

B15. (Has a health care provider ever told you that you had) an M-A-I infection, which is sometimes called M-A-C or MAC?

YES..... 1
 NO/NEVER HEARD OF IT 2

B16. (Has a health care provider ever told you that you had) Toxo infection, or toxoplasmosis of the brain?

YES..... 1
 NO/NEVER HEARD OF IT 2

B17. (Has a health care provider ever told you that you had) C-M-V, cytomegalovirus:

	<u>YES</u>	<u>NO</u>
a. in either eye (retinitis)?	1	2
b. in your blood?	1	2
c. in your intestine?.....	1	2
d. in your liver?	1	2
e. elsewhere in your body?.....	1	2 (B18)

SPECIFY: _____

B18. Has a health care provider ever told you that you had meningitis related to HIV?

YES..... 1
 NO/NEVER HEARD OF IT 2 (B19)

a. Were you told that this was Crypto, Cryptococcal meningitis?

YES..... 1
 NO/NEVER HEARD OF IT 2

B19. (Has a health care provider ever told you that you had) Cryptococcal infection:

	<u>YES</u>	<u>NO</u>
a. in your blood?	1	2
b. elsewhere in your body?.....	1	2 (B20)

(SPECIFY)

B20. (Has a health care provider ever told you that you had) Histoplasmosis infection or Histo?

YES..... 1
 NO/NEVER HEARD OF IT 2 (B21)

a. Where in your body? _____

(SPECIFY)

B21. (Has a health care provider ever told you that you had) Cocci, coccidioidomycosis infection or Valley Fever?

YES..... 1
 NO/NEVER HEARD OF IT 2

B22. (Has a health care provider ever told you that you had) wasting syndrome, in other words, severe weight loss?

YES..... 1
 NO/NEVER HEARD OF IT 2 (B23)

Have you had any of the following conditions that lasted for at least one month, during the same time that you experienced severe weight loss?

	<u>YES</u>	<u>NO</u>
a. chronic diarrhea (at least 3 loose stools per day for greater than or equal to 30 days?)	1	2
b. chronic weakness and documented fever (for greater than or equal to 30 days?)	1	2
c. were you told that [this symptom/these symptoms] [was/were] due to HIV/AIDS?	1	2

B23. (Has a health care provider ever told you that you had) dementia or encephalopathy, or that you had a memory problem or confusion caused by HIV?

YES..... 1
 NO/NEVER HEARD OF IT 2

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B24. (Has a health care provider ever told you that you had) an infection in the blood with a bacterium called salmonella?

YES..... 1
NO/NEVER HEARD OF IT 2

B25. (Has a health care provider ever told you that you had) PML, progressive multifocal leukoencephalopathy, a disease of the brain?

YES..... 1
NO/NEVER HEARD OF IT 2

B26. The next few questions are about tuberculosis or TB. To see if a person has TB a doctor or nurse will give a blood or a skin test – sometimes called a PPD test. If the skin test shows the person has been exposed to or infected with TB, more tests are done to see if they are sick from the TB. A person might get an X-ray or be asked to cough into a machine. If they are sick, then we say they have “tuberculosis disease.” Sometimes this is called “active” or “infectious tuberculosis.” Usually, if a person has tuberculosis disease, people who lived or worked with the person will be tested for tuberculosis too.

Have you ever...

- | | | |
|--|--------------------------|-----------|
| | <u>YES</u> | <u>NO</u> |
| a. Had a positive blood or skin test for TB, sometimes called a PPD? | <input type="checkbox"/> | 2 (b) |
| i. When was your <u>last</u> positive test (month / year)? | | |

|_|_|/|_|_|
M Y

- | | | |
|--|--------------------------|---------------|
| | <u>YES</u> | <u>NO</u> |
| b. Been told you had tuberculosis disease? | <input type="checkbox"/> | 2 (SECTION C) |
| i. Where were you told that the TB was? Was it in your lungs or some other location? | | |

LUNGS 1
OTHER LOCATION 2
UNKNOWN..... 3

PROMPT: IF AN ENROLLED PARTICIPANT RESPONDS “YES” TO EITHER B26a or B26b, COMPLETE AN ATC FOR EACH ILLNESS.

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SECTION C. ANTIRETROVIRAL MEDICATION HISTORY

Now I'm going to ask about any antiretroviral medications you may have ever taken.

PROMPT: HAND PARTICIPANT ANTIVIRAL PHOTO MEDICATION CARDS AS A REFERENCE.

C1. Have you ever taken any HIV-related medications or treatments? (That is, any medications or treatments to suppress or prevent getting sick because of HIV or to treat the sickness related to HIV or AIDS.)

- YES..... 1 (C3)
- NO.....2
- DON'T KNOW <-8>

C2. What is your main reason for not taking any antiretroviral medications or treatments?

- I am HIV-negative 1
- My CD4+ was too high or my viral load was too low.....2
- I feel too healthy3
- I am taking alternative medications4
- I don't want side effects.....5
- They are too hard to swallow.....6
- My doctor did not prescribe them.....7
- I can't afford them or have no insurance coverage.....8
- I'm concerned about resistance9
- I'm having a baby10
- It was a personal decision to wait11
- They didn't work for my friends or family.....12
- Any other reason.....13

SPECIFY other reason: _____

PROMPT: IF PARTICIPANT HAS NEVER TAKEN ANY ANTIRETROVIRAL MEDICATIONS, GO TO SECTION D.

PROMPT: GO THROUGH THE PHOTO MEDICATION CARDS WITH THE PARTICIPANT, SAYING THE NAME OF EACH DRUG ALOUD AND ASKING HER WHETHER SHE HAS EVER TAKEN EACH DRUG. CHECK THE BOX NEXT TO EACH DRUG THE PARTICIPANT REPORTS EVER HAVING TAKEN.

C3. Have you ever taken any of the following protease inhibitors, or PIs?

- 238 Aptivus (tipranavir)
- 212 Crixivan (indinavir)
- 210 Invirase (saquinavir)
- 217 Kaletra (lopinavir + ritonavir)
- 249 Lexiva (fosamprenavir)
- 211 Norvir (ritonavir)
- 256 Prezista (darunavir)
- 243 Reyataz (atazanavir)
- 216 Viracept (nelfinavir)
- Reported taking a protease inhibitor, but can't remember the name of the medication
- Other, specify: _____
- Don't know

IF NONE OF THE ABOVE MEDICATIONS ARE CHECKED, SKIP TO C4.

a. Of the PIs you have taken, which did you take first? (enter drug code)

- i.
- ii.
- iii.

b. When did you first take it? /
M Y

C4. Have you ever taken any of the following non-nucleoside reverse transcriptase inhibitors, or NNRTIs?

- 276 Edurant (rilpivirine)
- 255 Intelence (etravirine)
- 194 Rescriptor (delavirdine)
- 220 Sustiva (efavirenz)
- 191 Viramune (nevirapine)
- Reported taking an NNRTI, but can't remember the name of the medication
- Other, specify: _____
- Don't know

IF NONE OF THE ABOVE MEDICATIONS ARE CHECKED, SKIP TO C5.

a. Of the NNRTIs you have taken, which did you take first? (enter drug code)

- i.
- ii.
- iii.

b. When did you first take it? /
M Y

C5. Have you ever taken any of the following nucleoside reverse transcriptase inhibitors, or NRTIs?

- 239 Emtriva (emtricitabine, FTC)
- 204 Epivir (lamivudine, 3-TC)
- 092 Retrovir (AZT, zidovudine, ZDV)
- 147 Videx / Videx EC (didanosine, ddI)
- 234 Viread (tenofovir)
- 159 Zerit (stavudine, d4T)
- 218 Ziagen (abacavir)
- Reported taking an NRTI, but can't remember the name of the medication
- Other, specify: _____
- Don't know

IF NONE OF THE ABOVE MEDICATIONS ARE CHECKED, SKIP TO C6.

a. Of the NRTIs you have taken, which did you take first? (enter drug code)

- i. |_|_|_|_|
- ii. |_|_|_|_|
- iii. |_|_|_|_|

b. When did you first take it? |_|_|_|_|/|_|_|_|_|
M Y

C6. Have you ever taken any of the following combination HIV medications?

- 262 Atripla (Sustiva + Viread + Emtriva)
- 227 Combivir (AZT + 3TC)
- 254 Epzicom (Ziagen + Epivir)
- 240 Trizivir (abacavir + AZT + 3TC)
- 253 Truvada (Viread + Emtriva)
- 280 Complera (FTC + RPV + TDF)
- 287 Stribild (FTC + Viread + EVG + cobicistat)
- Reported taking a combination HIV medication, but can't remember the name of the medication
- Other, specify: _____
- Don't know

IF NONE OF THE ABOVE MEDICATIONS ARE CHECKED, SKIP TO C7.

a. Of the combination HIV medications you have taken, which did you take first? (enter drug code)

- i. |_|_|_|_|
- ii. |_|_|_|_|
- iii. |_|_|_|_|

b. When did you first take it? |_|_|_|_|/|_|_|_|_|
M Y

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C7. Have you ever taken any other HIV medications?

- 233 Fuzeon (T-20, enfuvirtide)
- 264 Isentress (raltegravir)
- 265 Selzentry (maraviroc)
- 207 Droxia or Hydrea (hydroxyurea)
- Reported taking an other HIV medication, but can't remember the name of the medication
- Other, specify: _____
- Don't know

IF NONE OF THE ABOVE MEDICATIONS ARE CHECKED, SKIP TO C8.

a. Of the other HIV medications you have taken, which did you take first? (enter drug code)

- i.
- ii.
- iii.

b. When did you first take it? /
M Y

C8. Have you ever been on a combination of drugs referred to as highly active antiretroviral therapy, HAART, combination cocktails or three-drug combination therapy?

- YES..... 1
- NO 2 **(PROMPT BELOW)**
- DON'T KNOW-8 **(PROMPT BELOW)**

a. What was the date of the first time you took this type of therapy? /
M Y

PROMPT: IF PARTICIPANT REPORTED USE OF ANY OF THE MEDICATIONS IN QUESTIONS C3 – C7, OR HAART IN QUESTION C8, OBTAIN MEDICAL RECORD RELEASE AND FILL OUT BOX ON FRONT PAGE OF RAB FORM.

SECTION D. BEHAVIORAL INFORMATION

NOTE: SECTION D WILL NOT BE DATA ENTERED.

Now I'm going to ask you some personal questions that may be related to information you have already discussed with others here, but I need to ask about them again. Your answers will be kept confidential and your name will not be reported to anyone. An identification number has been assigned to you, so your name does not appear on any of the study forms.

D1. Have you ever injected (skin popped or shot up with a needle) drugs **OR** used crack, cocaine, heroin or methamphetamine?

YES..... 1
 NO 2 (D2)

a. When was the last time you injected or used these drugs? I just need the month and year.
 (PROBE: If you cannot remember exactly, please estimate as best you can.)

M			Y		

D2. In the past five years, have you been told by a health care provider (doctor, nurse, midwife, physician’s assistant or nurse practitioner) that you had an STD, or sexually transmitted disease, including gonorrhea (GC, the clap), syphilis, chlamydia, PID (pelvic inflammatory disease), herpes in or around your genital area, or warts in or around your genital area?

YES..... 1
 NO 2

D3. These next questions are about different types of sexual behavior, and refer only to sex you may have had with men in the past five years. In this case, “sex” includes vaginal sex and anal sex. I understand that these questions are personal and sometimes difficult to respond to, but please remember that no one is judging you on your answers.

a. How many men have you had sex with, even once, in the past five years?

0 1 (D4)
 1 to 5 2
 6 to 10 3
 11 to 100 4
 Greater than 100 5

b. In the past five years, have you had sex with a man who you knew was HIV-positive?

YES..... 1
 NO..... 2

c. In the past five years, how many men have you had unprotected sex with?

0 1
 1 to 2 2
 3 to 5 3
 6 to 10 4
 Greater than 10 5

d. In the past five years, have you ever had sex for drugs, money, or shelter?

YES..... 1
 NO..... 2

D4. In the past five years, has your sex partner injected (skin popped or shot up with a needle) drugs **OR** used crack, cocaine, heroin or methamphetamine?

YES..... 1
 NO2
 DON'T KNOW-8

D5. In the past five years, has your sex partner been told by a health care provider (doctor, nurse, midwife, physician's assistant or nurse practitioner) that he/she had an STD, or sexually transmitted disease, including gonorrhea (GC, the clap), syphilis, chlamydia, PID (pelvic inflammatory disease), herpes in or around his/her genital area, or warts in or around his/her genital area?

YES..... 1
 NO2
 DON'T KNOW-8

D6. These next questions are about different types of sexual behavior, and refer only to sex your sex partner may have had with women and men in the past five years. In this case, "sex" includes vaginal sex and anal sex. I understand that these questions are personal and sometimes difficult to respond to, but please remember that no one is judging you on your answers.

a. How many women and men has your sex partner had sex with, even once, in the past five years?

0..... 1 **(END)**
 1 to 5 2
 6 to 10 3
 11 to 100 4
 Greater than 100..... 5
 DON'T KNOW -8

b. In the past five years, has your sex partner had sex with a woman or a man who he/she knew was HIV-positive?

YES..... 1
 NO2
 DON'T KNOW-8

c. In the past five years, how many women and men has your sex partner had unprotected sex with?

0..... 1
 1 to 2 2
 3 to 5 3
 6 to 10 4
 Greater than 10..... 5
 DON'T KNOW -8

d. In the past five years, has your sex partner ever had sex for drugs, money, or shelter?

YES..... 1
 NO2
 DON'T KNOW-8