

WOMEN'S INTERAGENCY HIV STUDY

BASELINE VISIT

MEDICAL AND HEALTH HISTORY

FORM 2

SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: ENTER NUMBER HERE ONLY IF ID LABEL IS NOT AVAILABLE

|_|-|_|_|-|_|_|_|_|-|_|

A2. WIHS STUDY VISIT #:

___ ___

A3. FORM VERSION:

0 8 / 1 5 / 9 4
M D Y

A4. DATE OF INTERVIEW:

___ ___ / ___ ___ / ___ ___
M D Y

A5. INTERVIEWER'S INITIALS:

___ ___ ___

A6. TIME MODULE BEGAN:

|_|_| : |_|_| AM..... 1
PM 2

INTRODUCTION TO PARTICIPANT:

Now, I am going to ask you some questions about your health history. I will be asking you a series of questions about diseases, symptoms, and medicines you may have had or taken in the past. If anything is unclear, please stop me and I will try to make the question clearer. If at any point in the interview, you wish to stop, also let me know. Finally, I need to re-emphasize that all your answers are confidential, and the responses you provide will in no way affect your clinical care. These questions may seem very long and detailed. Please remember that this is our time to cover your medical history up until now. For visits in the future, we will only have to cover the 6 months since we last saw you.

SECTION B. SYMPTOMS

In the past six months, have you experienced any of the following:

| | <u>YES</u> | <u>NO</u> | <u>DON'T KNOW</u> | <u>DECLINED</u> |
|--|------------|-----------|-----------------------|-----------------|
| B1. a fever for more than two weeks straight, with a temperature over 100 degrees Fahrenheit..... | 1 | 2 | <-8> | <-7> |
| B2. diarrhea for more than two weeks straight, with more than 3 soft or liquid stools per day | 1 | 2 | <-8> | <-7> |
| B3. major problems with memory or concentration that interfered with your normal, everyday activities, and that lasted for more than two weeks | 1 | 2 | <-8> | <-7> |
| B4. numbness, tingling, or burning sensations in your arms, legs, hands or feet that lasted for more than two weeks. | 1 | 2 | <-8> | <-7> |
| B5. an unexpected weight loss, of 10 pounds or more that lasted more than one month..... | 1 | 2 | <-8> | <-7> |
| B6. confusion, getting lost in a familiar place or inability to perform routine mental tasks | 1 | 2 | <-8> | <-7> |
| B7. drenching night sweats that soak night clothes or bedding..... | 1 | 2 | <-8> | <-7> |

REFER FOR DIFFERENTIAL DIAGNOSIS TO PARTICIPANT'S MEDICAL PROVIDER

**SECTION C: MEDICAL CONDITIONS
AND CONCOMITANT ILLNESSES/SYMPTOMS**

For these 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.

C1. This question pertains to whether a health care provider has ever told you that you had any kind of cancer at any time in your life. Have you ever been told by a health care provider that you had cancer, including skin cancer, lymphoma, Kaposi's sarcoma, Hodgkin's disease, breast cancer or cancer of the female organs -- the cervix, ovaries or uterus?

YES1
 NO2 (C14)
 DON'T KNOW <-8> (C14)
 DECLINED <-7> (C14)

What kind of cancer? Was it: [READ C2 - C11]

(FOR EACH YES, ASK
SUBQUESTION 'a')

| | <u>YES</u> | <u>NO</u> | <u>DON'T KNOW</u> | <u>DECLINED</u> | a. When was the first time you were told that? I just need the year. |
|----------------------------------|------------|------------|-----------------------|-----------------|--|
| C2. Cervical cancer.....1 | 2 (C3) | <-8> (C3) | <-7> (C3) | 1 9 ___ ___ | |
| C3. Kaposi's Sarcoma1 | 2 (C4) | <-8> (C4) | <-7> (C4) | 1 9 ___ ___ | |
| C4. Lymphoma1 | 2 (C5) | <-8> (C5) | <-7> (C5) | 1 9 ___ ___ | |
| C5. Lymphoma in the brain1 | 2 (C6) | <-8> (C6) | <-7> (C6) | 1 9 ___ ___ | |
| C6. Hodgkin's disease.....1 | 2 (C7) | <-8> (C7) | <-7> (C7) | 1 9 ___ ___ | |
| C7. Breast cancer.....1 | 2 (C8) | <-8> (C8) | <-7> (C8) | 1 9 ___ ___ | |
| C8. Ovarian cancer1 | 2 (C9) | <-8> (C9) | <-7> (C9) | 1 9 ___ ___ | |
| C9. Endometrial cancer.....1 | 2 (C10) | <-8> (C10) | <-7> (C10) | 1 9 ___ ___ | |
| C10. Skin cancer.....1 | 2 (C11) | <-8> (C11) | <-7> (C11) | 1 9 ___ ___ | |
| C11. Other1 | 2 (C12) | <-8> (C12) | <-7> (C12) | 1 9 ___ ___ | |

(SPECIFY)

PROMPT: IF ANY OF C1 - C11 = YES, THEN COMPLETE ABSTRACT TRACKING CHECKLIST FOR EACH ILLNESS AND OBTAIN MEDICAL RECORD RELEASE.

| | <u>YES</u> | <u>NO</u> | <u>DON'T KNOW</u> | <u>DECLINED</u> |
|--|------------|------------|-------------------|-----------------|
| C12. Have you ever received cancer chemotherapies? 1 | 2 (C13) | <-8> (C13) | <-7> (C13) | |
| a. Was this in the past month?..... 1 | 2 | <-8> | <-7> | |
| C13. Have you ever received radiation treatments?..... 1 | 2 (C14) | <-8> (C14) | <-7> (C14) | |
| a. Was this in the past month?..... 1 | 2 | <-8> | <-7> | |

C14. Have you ever had asthma?

| | | |
|-----------------|------|-------|
| YES | 1 | |
| NO | 2 | (C15) |
| DON'T KNOW..... | <-8> | (C15) |
| DECLINED | <-7> | (C15) |

a. Approximately how many years ago did your asthma start?

|_|_|
YEARS AGO

C15. The next few questions are about Tuberculosis. I will refer to tuberculosis as TB for short. As far as you know, has anyone in your family or anyone you lived with, ever had TB?

| | | |
|-----------------|------|--|
| YES | 1 | |
| NO | 2 | |
| DON'T KNOW..... | <-8> | |
| DECLINED | <-7> | |

C16. Have you ever had TB?

| | | |
|-----------------|------|-------|
| YES | 1 | |
| NO | 2 | (C17) |
| DON'T KNOW..... | <-8> | (C17) |
| DECLINED | <-7> | (C17) |

a. Was the TB in your lungs?

| | | |
|-----------------|------|--|
| YES | 1 | |
| NO | 2 | |
| DON'T KNOW..... | <-8> | |
| DECLINED | <-7> | |

b. Was the TB in any part of your body, other than your lungs?

- YES1
- NO2
- DON'T KNOW.....<-8>
- DECLINED.....<-7>

c. Did you ever receive treatment for tuberculosis?

- YES1
- NO2 (C17)
- DON'T KNOW.....<-8> (C17)
- DECLINED.....<-7> (C17)

d. What medications did you take?

(LIST MEDICATIONS IN SPACES BELOW)

| | | | |
|------|-------|-------|-------|
| i. | _____ | v. | _____ |
| ii. | _____ | vi. | _____ |
| iii. | _____ | vii. | _____ |
| iv. | _____ | viii. | _____ |

C17. Have you ever had a skin test for TB?

- YES1
- NO2 (C18)
- DON'T KNOW.....<-8> (C18)
- DECLINED.....<-7> (C18)

a. When was the last time (most recent) you had a skin test for TB? I need the month and the year.

_____ / _____
 M Y

b. Were you ever told the test was positive or showed that you had been exposed to TB?

- YES1
- NO2 (C18)
- DON'T KNOW.....<-8> (C18)
- DECLINED.....<-7> (C18)

c. Were you ever treated as a result of having a positive skin test?

YES1
 NO2 (C18)
 DON'T KNOW..... <-8> (C18)
 DECLINED..... <-7> (C18)

d. What did you take?

(LIST IN SPACES BELOW)

| | |
|------------|-------------|
| i. _____ | v. _____ |
| ii. _____ | vi. _____ |
| iii. _____ | vii. _____ |
| iv. _____ | viii. _____ |

C18. Now I'm going to ask you about some other medical conditions that may require medical care. Have you ever had any of the following conditions that required medical care:

| | <u>YES</u> | <u>NO</u> | <u>DON'T KNOW</u> | <u>DECLINED</u> |
|--|------------|-----------|-------------------|-----------------|
| a. High blood pressure or hypertension | 1 | 2 | <-8> | <-7> |
| b. High blood sugar or Diabetes | 1 | 2 | <-8> | <-7> |
| c. Lupus or rheumatoid arthritis or any rheumatologic disease | 1 | 2 | <-8> | <-7> |
| d. An operation to remove your spleen | 1 | 2 | <-8> | <-7> |
| e. Sinusitis, a sinus infection that required antibiotics..... | 1 | 2 | <-8> | <-7> |
| f. UTI, a urinary tract infection or an infection in your bladder or kidneys that required antibiotics..... | 1 | 2 | <-8> | <-7> |
| g. Any other major chronic illness, that required medical care or hospitalization, excluding HIV infection | 1 | 2 (D1) | <-8> (D1) | <-7> (D1) |

(PROBE: Any others?)

(LIST ILLNESSES IN SPACES BELOW)

| | |
|------------|-------------|
| i. _____ | v. _____ |
| ii. _____ | vi. _____ |
| iii. _____ | vii. _____ |
| iv. _____ | viii. _____ |

PROMPT: IF ANY OF C16, C17 OR C18g = YES, THEN COMPLETE ABSTRACT TRACKING CHECKLIST FOR EACH ILLNESS AND OBTAIN MEDICAL RECORD RELEASE.

SECTION D. SKIN AND ORAL CONDITIONS

ASK QUESTIONS D1-D4 FOR EACH CONDITION BELOW. EACH TIME A PARTICIPANT RESPONDS THAT SHE HAS HAD THE CONDITION, ASK SUBQUESTION "a" BEFORE PROCEEDING TO THE NEXT CONDITION.

D1-D4

Has a health care provider (doctor, dentist, nurse practitioner, nurse, or physician's assistant) ever told you that you had (CONDITION)?

D1a -D4a

How many different times in the past 6 months were you told that you had this?

- | | | |
|---|--|---|
| <p>D1. Shingles (Herpes Zoster)?</p> | <p>YES..... 1 NO 2 (D2) DON'T KNOW <-8> (D2) DECLINED <-7> (D2)</p> | <p>a. __ # TIMES</p> |
| <p>D2. Skin rashes?</p> | <p>YES..... 1 NO 2 (D3) DON'T KNOW <-8> (D3) DECLINED <-7> (D3)</p> | <p>a. __ # TIMES</p> |
| <p>D3. Candida or thrush, yeast inside your mouth?</p> | <p>YES..... 1 NO..... 2 (D4) DON'T KNOW <-8> (D4) DECLINED <-7> (D4)</p> | <p>a. __ # TIMES</p> |
| <p>D4. Herpes in or around your mouth (cold sores)?</p> | <p>YES..... 1 NO..... 2 (SECTION E) DON'T KNOW <-8> (SECTION E) DECLINED <-7> (SECTION E)</p> | <p>a. __ # TIMES</p> |

SECTION E: AIDS DEFINING ILLNESSES

We are now interested in finding out about diseases that some women experience. These diseases are rare. They may occur in women who are HIV negative, however, they tend to occur more often in HIV positive women. As I read this list of diseases, please let me know whether or not you have had any of them.

E1. Has a health care provider ever told you that you had a CD4 count (T-cell count) less than 200 or less than 14%?

- YES 1
 NO/NEVER HEARD OF IT 2
 DON'T KNOW <-8>
 DECLINED <-7>

E2. Has a health care provider ever told you that you had PCP, pneumocystis carinii pneumonia?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E3. (Has a health care provider ever told you that you had) another type of pneumonia, lung infection?

- YES1
- NO/NEVER HEARD OF IT2 (E4)
- DON'T KNOW..... <-8> (E4)
- DECLINED <-7> (E4)

a. Has a health care provider ever told you that you had two or more episodes of pneumonia, not counting PCP, in one year?

- YES1
- NO2
- DON'T KNOW..... <-8>
- DECLINED <-7>

b. During the past 6 months, how many times have you had pneumonia, that required antibiotics, not counting PCP?

|_|_|_|
TIMES

c. When was the last time you had pneumonia, not counting PCP? I need the month and the year?

____ / ____
M Y

E4. (Has a health care provider ever told you that you had) Candida or thrush, a yeast of the esophagus, the swallowing tube, not just in your mouth?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E5. (Has a health care provider ever told you that you had) Candida or thrush, a yeast of the lungs or airways (trachea or bronchi)?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW.....<-8>
- DECLINED.....<-7>

E6. (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? They are caused by mycobacterium avium or other atypical mycobacterium.

- YES1
- NO/NEVER HEARD OF IT2 (E7)
- DON'T KNOW.....<-8> (E7)
- DECLINED.....<-7> (E7)

a. Was this in your lungs or found in your sputum or phlegm?

- YES1
- NO2
- DON'T KNOW.....<-8>
- DECLINED.....<-7>

E7. (Has a health care provider ever told you that you had) Toxo infection, or toxoplasmosis of the brain?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW.....<-8>
- DECLINED.....<-7>

E8. (Has a health care provider ever told you that you had) C-M-V, cytomegalovirus infection in the eye (retinitis)?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW.....<-8>
- DECLINED.....<-7>

E9. (Has a health care provider ever told you that you had) C-M-V, cytomegalovirus infection elsewhere in your body?

- YES1
- NO/NEVER HEARD OF IT2 (E10)
- DON'T KNOW.....<-8> (E10)
- DECLINED.....<-7> (E10)

a. Where in your body was the infection? (**PROBE:** Any other place?)
(CIRCLE "1" OR "2" FOR EACH)

| | <u>MENTIONED</u> | |
|---------------------|------------------|-----------|
| | <u>YES</u> | <u>NO</u> |
| i. BLOOD..... | 1 | 2 |
| ii. URINE | 1 | 2 |
| iii. INTESTINE..... | 1 | 2 |
| iv. LIVER..... | 1 | 2 |
| v. OTHER..... | 1 | 2 |

(SPECIFY)

E10. Have you ever had severe, persistent diarrhea?

| | | |
|-----------------|------|--------------|
| YES | 1 | |
| NO | 2 | (E11) |
| DON'T KNOW..... | <-8> | (E11) |
| DECLINED | <-7> | (E11) |

a. Were you told that your diarrhea was caused by:

| | <u>YES</u> | <u>NO/NEVER HEARD OF IT</u> | <u>DON'T KNOW</u> | <u>DECLINED</u> |
|--------------------|------------|---------------------------------|-----------------------|-----------------|
| i. Cryptosporidia? | 1 | 2 | <-8> | <-7> |
| ii. Microsporidia? | 1 | 2 | <-8> | <-7> |
| iii. Isospora | 1 | 2 | <-8> | <-7> |
| iv. C-M-V | 1 | 2 | <-8> | <-7> |
| v. M-A-I | 1 | 2 | <-8> | <-7> |

E11. Has a health care provider ever told you that you had Crypto, Cryptococcal meningitis?

| | |
|----------------------------|------|
| YES | 1 |
| NO/NEVER HEARD OF IT | 2 |
| DON'T KNOW..... | <-8> |
| DECLINED | <-7> |

E12. (Has a health care provider ever told you that you had) Cryptococcal infection in the blood or elsewhere in the body?

- YES1
- NO/NEVER HEARD OF IT2 **(E13)**
- DON'T KNOW..... <-8> **(E13)**
- DECLINED <-7> **(E13)**

a. Where in your body? _____
(SPECIFY)

E13. (Has a health care provider ever told you that you had) Histo, Histoplasmosis infection?

- YES1
- NO/NEVER HEARD OF IT2 **(E14)**
- DON'T KNOW..... <-8> **(E14)**
- DECLINED <-7> **(E14)**

a. Where in your body? _____
(SPECIFY)

E14. (Has a health care provider ever told you that you had) Cocci or coccidioidomycosis infection?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E15. (Has a health care provider ever told you that you had) wasting syndrome, in other words, severe weight loss?

- YES1
- NO/NEVER HEARD OF IT2 **(E16)**
- DON'T KNOW..... <-8> **(E16)**
- DECLINED <-7> **(E16)**

a. Were you told that it was due to HIV or AIDS?

- YES1
- NO2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E16. (Has a health care provider ever told you that you had) dementia or encephalopathy?

- YES1
- NO/NEVER HEARD OF IT2 **(E17)**
- DON'T KNOW..... <-8> **(E17)**
- DECLINED <-7> **(E17)**

a. Were you told it was caused by HIV or AIDS?

- YES1
- NO2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E17. Has a health care provider ever told you that you had herpes simplex with ulcers lasting longer than one month?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E18. (Has a health care provider ever told you that you had) herpes simplex infection of the lungs or esophagus, the swallowing tube?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E19. (Has a health care provider ever told you that you had) an infection in the blood with a bacteria called salmonella?

- YES1
- NO/NEVER HEARD OF IT2 **(E20)**
- DON'T KNOW..... <-8> **(E20)**
- DECLINED <-7> **(E20)**

a. Have you had this more than once?

- YES1
- NO2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E20. (Has a health care provider ever told you that you had) PML, progressive multifocal leukoencephalopathy, a disease of the brain?

- YES1
- NO/NEVER HEARD OF IT2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E21. Has a health care provider ever told you that you had AIDS?

- YES1
- NO2
- DON'T KNOW..... <-8>
- DECLINED <-7>

E22. During the past 6 months, have you been admitted to the hospital for any reason? This would include staying overnight or being admitted for a procedure that was done in one day. Please include all medical and psychiatric hospitalizations. This doesn't include being treated in the emergency room and later released.

- YES1
- NO2 (PROMPT)
- DON'T KNOW..... <-8> (PROMPT)

a. How many times during the past 6 months?

|_|_|_|
TIMES

PROMPT: IF THE PARTICIPANT RESPONDED "YES" TO ANY QUESTION IN SECTION E (E1-E22), COMPLETE ABSTRACT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.

SECTION F. MEDICATION HISTORY

F1. Now, I'm going to ask you some questions about medicines you may have taken. Not including this study, have you ever been part of any research study that related to HIV or AIDS, including studies that involved taking experimental medicines or treatments?

YES1
NO2 (F2)
DON'T KNOW..... <-8> (F2)

a. How many studies were or are you involved in? |_|_|
NUMBER

b. Of these, how many involved taking medicine or treatment? |_|_|
NUMBER

c. Do you know the name of the medicine or treatment you received for (#) study?

d. Do you know the name of the study?

(#1) YES 1

(SPECIFY)
NO 2

YES 1

(SPECIFY)
NO 2

(#2) YES 1

(SPECIFY)
NO 2

YES 1

(SPECIFY)
NO 2

(#3) YES 1

(SPECIFY)
NO 2

YES 1

(SPECIFY)
NO 2