WOMEN'S INTERAGENCY HIV STUDY

MEDICAL AND HEALTH HISTORY

FORM 22

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 4 / 0 1 / 0 0
M D Y

A4. DATE OF INTERVIEW: ___ ___ / ___ ___ / ___ ___
M D Y

A5. INTERVIEWER'S INITIALS: ___ ___ ___

A6. DATE OF LAST STUDY VISIT (FROM VISIT CONTROL SHEET) ___ ___ / ___ ___ / ___ ___
M D Y

A7. 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 since your study visit on __ __ / __ __ / __ __. Also, if at any point in the interview you wish to stop, let me know.
M D Y

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.

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SECTION B. SYMPTOMS

Since your (MONTH) study visit, have you experienced any of the following:

		YES	NO
B1.	a fever for more than one month straight, with a temperature over 100 degrees	**1**	2
B3.	major problems with memory or concentration that interfered with your normal, everyday activities, and that lasted for more than two weeks	**1**	2
B4.	numbness, tingling, or burning sensations in your arms, legs, hands or feet that lasted for more than two weeks.	**1**	2
B5.	an unintentional weight loss, of 10 pounds or more, or have changed to a smaller clothing size, that lasted more than one month	**1**	2
B6.	confusion, getting lost in a familiar place or inability to perform routine mental tasks	**1**	2
B7.	drenching night sweats that soak night clothes or bedding	**1**	2

REFER FOR DIFFERENTIAL DIAGNOSIS TO PARTICIPANT'S MEDICAL PROVIDER

PROMPT: IF ALL OF B1 - B7 = NO, ASK B8; OTHERWISE, SKIP TO B9.

B8. Do you have any symptoms or complaints related to your health?

YES 1
NO ....2 **(B10)**

B9. Do these symptoms affect your ability to carry on normal activities?

YES 1
NO 2

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INTRODUCTION: The next series of questions asks about changes in the shape of your body that you may have noticed since your (MONTH) study visit. When thinking about these changes, please do not include any changes that have occurred due to being pregnant.

B10. Since your (MONTH) study visit, have you noticed any changes in the shape of your body or in the amount of your body fat (either loss or gain)?

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

To help me understand these changes, please tell me if you have noticed any of the following body changes since your (MONTH) study visit:

Have you noticed…	YES	NO	Was this change in size an increase or a decrease? INCREASE	DECREASE
a) a change in your breast or bra size?	1	2 **(b)**	1	2
b) a change in the size of your belly or waist?	1	2 **(c)**	1	2
c) any changes in the size of your face such as a thinner face or fuller cheeks?	1	2 **(d)**	1	2
d) a lump or bump at the back of your neck, sometimes called a "fat pad"?	1	2		

Since your (MONTH) study visit, have you noticed a change in the amount of fat in any of the following places on your body:

A change in your…	YES	NO	Was this change a fat gain or a fat loss? GAIN	LOSS
e) arms?	1	2 **(f)**	1	2
f) legs?	1	2 **(g)**	1	2
g) buttocks?	1	2 **(B11)**	1	2

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B11. Now I am going to ask you about actions you may have intentionally taken to change the shape of your body. Since your (MONTH) study visit, have you taken any of the following actions to influence your body shape or fat distribution:

Have you…	YES	NO	
a) changed your diet?	1	2	
b) changed your HIV medications?	1	2	
c) changed your exercise habits?	1	2	
d) taken nutritional supplements?	1	2	
e) taken growth hormone or steroids?	1	2	
f) had cosmetic surgery such as liposuction, breast reduction or breast enlargement?	1	2	
g) Done anything else to influence your body shape?	1	2 **(B12)**	Specify: ________________________ ________________________ ________________________

B12. What is your current bra size? I need both the chest and the cup size (for example, 36C.) **NOTE: If participant does not wear a bra or reports wearing a sports bra, code "CHEST SIZE" as 99 and enter –1 in "CUP SIZE."**

a. CHEST SIZE

|__|__|
(e.g., 36)

b. CUP SIZE

|__|__|__|
(e.g., C, DD ,etc…)

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SECTION C: MEDICAL CONDITIONS AND CONCOMITANT ILLNESSES/SYMPTOMS

For the following 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. a. Since your (MONTH) study visit, have you been told by a health care provider that you had cervical cancer?

YES 1
NO .... 2 **(C2)**

. b. Have you had surgery (been admitted to the hospital and had surgery in an operating room) to treat the cervical cancer?

YES 1
NO 2

c. Have you had a CAT or MRI scan of your abdomen (a big donut-shaped machine that takes special pictures)?

YES 1
NO 2

d. Have you been told that you need to have either surgery or radiation therapy?

YES 1
NO 2

C2. Since your (MONTH) study visit, have you been told by a health care provider that you had any other type of cancer, including skin cancer, lymphoma, Kaposi's sarcoma, Hodgkin's disease, breast cancer or cancer of the female organs – the ovaries or uterus?

YES 1
NO .... 2 **(C27)**

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What kind of cancer? Was it: **[READ C3 - C11]**

	YES	NO/NEVER HEARD OF IT
C3. Breast cancer	1	2 **(C4)**

a. Have you had a lump removed by a surgeon (not a needle biopsy, but an incision resulting in stitches)?

Yes……………….…1
No………………..2

b. Have you had a mastectomy (removal of entire breast)?

Yes……….…….…1
No………………..2

	YES	NO/NEVER HEARD OF IT
C4. Cancer of the ovary	1	2
C5. Cancer of the uterus	1	2
C6. Kaposi's Sarcoma (KS)	1	2
C7. Lymphoma	1	2
C8. Lymphoma in the brain	1	2
C9. Hodgkin's disease	1	2
C10. Skin cancer (not KS)	1	2
C11. Other	1	2 **(C12)**

____

(SPECIFY)

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

		YES	NO
C12.	Since your (MONTH) study visit have you received cancer chemotherapies?	1	2
C13.	Since your (MONTH) study visit have you received radiation treatments?	1	2

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C27. Since your (MONTH) study visit, have you had a new diagnosis of asthma, or a worsening of your asthma?

YES 1
NO 2

C28. The next few questions are about tuberculosis. I will refer to tuberculosis as TB for short. Since your (MONTH) study visit, as far as you know, has anyone in your family or anyone you lived with, had TB?

YES 1
NO 2

C29. Since your (MONTH) study visit, have you had TB?

YES 1
NO .... 2 **(C30)**

Was it in your:	YES	NO
a. Lungs?	1	2
b. Other Location?	1	2
______________________ **(SPECIFY)**		
c. Did you have a chest X-ray?	1	2
d. Did you take medications for 3 months or more?	1	2

PROMPT:	**IF ANY OF C29a–d = YES, THEN COMPLETE ASCERTAINMENT TRACKING CHECKLIST FOR EACH ILLNESS AND OBTAIN MEDICAL RECORD RELEASE.**

C30. Not including the test you had for this study, since your (MONTH) study visit, have you had a skin test for TB?

YES 1
NO ....2 **(C31)**
DON'T KNOW ....<-8> **(C31)**
DECLINED ....<-7> **(C31)**

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 told that the test was positive or showed that you had been exposed to TB?

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

PROMPT:	**IF C30b = YES, THEN COMPLETE ASCERTAINMENT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.**

C31. Now I'm going to ask you about some other medical conditions that may require medical care. Have you had any of the following conditions, since your (MONTH) study visit?

		YES	NO	DON'T KNOW
a.	Sinusitis, a sinus infection that required antibiotics..	1	2	<-8>
b.	UTI, a urinary tract infection or an infection in your bladder or kidneys that required antibiotics..	1	2	<-8>
c.	High blood pressure or hypertension............	1	2	<-8>
d.	High blood sugar, diabetes, or sugar diabetes	1	2 **(e)**	<-8> **(e)**
	1. Are you taking insulin?..............................	1	2	<-8>
e.	High blood cholesterol, triglyceride or blood lipid level	1	2 **(f)**	<-8> **(f)**
	1. Are you taking any medications to lower your cholesterol, triglyceride or blood lipid level?	1	2	<-8>
f.	Lupus or rheumatoid arthritis or any rheumatologic disease...................................	1	2	<-8>
g.	Depression	1	2	<-8>
h.	Hepatitis...	1	2 **(Sec. D)**	<-8> **(Sec. D)**
	1. Hepatitis C	1	2	<-8>

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SECTION D: SKIN AND ORAL CONDITIONS

ASK QUESTIONS D1 AND D3 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-D3 Since your (MONTH) study visit, has a health care provider, either a doctor, dentist, nurse practitioner, nurse, or physician's assistant, told you that you had **(CONDITION)?**			D1a –D3a How many different times in the past 6 months did you have this?
D1. Shingles (Herpes Zoster)?	YES .... 1 NO .... 2 DON'T KNOW .... <-8> DECLINED .... <-7>	 **(D3)** **(D3)** **(D3)**	a. |__|__| # TIMES
b. Have you had 2 or more separate areas with shingles at the same time?	YES .... 1 NO 2		
D3. Candida or thrush, yeast inside your mouth?	YES .... 1 NO .... 2 DON'T KNOW .... <-8> DECLINED .... <-7>	 **(E1)** **(E1)** **(E1)**	a. |__|__| # TIMES

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SECTION E: AIDS DEFINING ILLNESSES

We are now interested in finding out about diseases that some women experience. These diseases are rare and 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. 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.

E1. Since your (MONTH) study visit, has a health care provider 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

E2. Since your (MONTH) study visit, has a health care provider told you that you had herpes simplex with ulcers or sores lasting longer than one month?

YES 1
NO/NEVER HEARD OF IT 2

E3. Since your (MONTH) study visit, have you had diarrhea (3 or more soft or liquid stools per day), that lasted for more than one month?

YES 1
NO ....2 **(E5)**

E4. Since your (MONTH) study visit, has a health care provider told you that any diarrhea you may have had was caused by:

	YES	NO/NEVER HEARD OF IT
i. Cryptosporidia?	1	2
ii. Microsporidia?	1	2
iii. Isospora?	1	2
iv. C-M-V?	1	2
v. M-A-I?	1	2

E5. Since your (MONTH) study visit, 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

PROMPT: IF THE PARTICIPANT RESPONDED "YES" TO ANY OF QUESTIONS E4–E20, COMPLETE ASCERTAINMENT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.

E6. Since your (MONTH) study visit, has a health care provider told you that you had PCP, pneumocystis carinii pneumonia?

YES 1
NO/NEVER HEARD OF IT 2

E7. Since your (MONTH) study visit, has a health care provider told you that you had another type of pneumonia, lung infection?

YES 1
NO/NEVER HEARD OF IT ....2 **(E8)**

a. In the **past 12 months**, how many times has a health care provider told you that you had pneumonia, that required antibiotics, not counting PCP?

|___|___|
TIMES

b. **Since your (MONTH) study visit**, 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

E8. (Since your (MONTH) study visit, has a health care provider 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

START F22p1

E9. (Since your (MONTH) study visit, has a health care provider 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

E10. (Since your (MONTH) study visit, has a health care provider 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

PROMPT: IF THE PARTICIPANT RESPONDED "YES" TO ANY OF QUESTIONS E4–E20, COMPLETE ASCERTAINMENT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.

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E11. (Since your (MONTH) study visit, has a health care provider told you that you had) Toxo infection, or toxoplasmosis of the brain?

YES 1
NO/NEVER HEARD OF IT 2

E12. (Since your (MONTH) study visit, has a health care provider told you that you had) C-M-V, cytomegalovirus:

		YES	NO	
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	**(E13)**

____
(SPECIFY)

E13. Since your (MONTH) study visit, has a health care provider told you that you had meningitis related to HIV?

YES 1
NO/NEVER HEARD OF IT ....2 **(E14)**

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

YES 1
NO/NEVER HEARD OF IT 2

E14. (Since your (MONTH) study visit, has a health care provider told you that you had) Cryptococcal infection:

		YES	NO	
a.	in your blood?	1	2	
b.	elsewhere in your body?	1	2	**(E15)**

____
(SPECIFY)

E15. (Since your (MONTH) study visit, has a health care provider told you that you had) Histoplasmosis infection or Histo?

YES 1
NO/NEVER HEARD OF IT ....2 **(E16)**

a. Where in your body? ______________________________________
(SPECIFY)

PROMPT: IF THE PARTICIPANT RESPONDED "YES" TO ANY OF QUESTIONS E4–E20, COMPLETE ASCERTAINMENT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.

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E16. (Since your (MONTH) study visit, has a health care provider told you that you had) Cocci, coccidioidomycosis infection or Valley Fever?

YES 1
NO/NEVER HEARD OF IT 2

E17. (Since your (MONTH) study visit, has a health care provider told you that you had) wasting syndrome, in other words, severe weight loss?

YES 1
NO/NEVER HEARD OF IT ....2 **(E18)**

Have you had (CONDITION) that lasted for at least one month, during the same time that you experienced severe weight loss?

	YES	NO
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

E18. (Since your (MONTH) study visit, has a health care provider 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

E19. (Since your (MONTH) study visit, has a health care provider told you that you had) an infection in the blood with a bacteria called salmonella?

YES 1
NO/NEVER HEARD OF IT ....2 **(E20)**

a. Have you had this more than once, since your (MONTH) study visit?

YES 1
NO 2

E20. (Since your (MONTH) study visit, has a health care provider told you that you had) PML, progressive multifocal leukoencephalopathy, a disease of the brain?

YES 1
NO/NEVER HEARD OF IT 2

PROMPT: IF THE PARTICIPANT RESPONDED “YES” TO ANY OF QUESTIONS E4–E20, COMPLETE ASCERTAINMENT TRACKING CHECKLIST AND OBTAIN MEDICAL RECORD RELEASE.

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E21. (Since your (MONTH) study visit, has a health care provider told you that you had) AIDS?

YES 1
NO 2

E22. Since your (MONTH) study visit, have you had a biopsy? A biopsy is when tissue, sometimes a lump or a mass, is removed with a needle or by making an incision. (DO NOT include biopsies that have been taken at WIHS gynecologic exams, including WIHS colposcopic examinations.)

YES 1
NO ....2 **(E23)**

Where in your body? Was it a:	YES	NO
a. Lung biopsy?	1	2
b. Skin biopsy?	1	2
c. Bone marrow biopsy?	1	2
d. Cervical biopsy?	1	2
e. Other biopsy?	1	2

____
(SPECIFY)

PROMPT: IF THE PARTICIPANT RESPONDED "YES" TO ANY OF QUESTIONS E22a–e, COMPLETE AN AIDS MALIGNANCY BANK ASCERTAINMENT TRACKING CHECKLIST (AMB ATC) FOR EACH REPORTED BIOPSY AND OBTAIN MEDICAL RECORD RELEASE.

E23. Since your (MONTH) study visit, 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.

YES 1
NO ....2 **(Section F)**
DON'T KNOW ....<-8> **(Section F)**

a. How many times since your (MONTH) study visit?

|___|___|
TIMES

END F22p1
START F22p2

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SECTION F. MEDICATION HISTORY

F1. Since your (MONTH) study visit, have you had a vaccine injection against HIV or participated in a vaccine trial? A vaccine against HIV can include vaccines which prevent infection with HIV or therapeutic vaccines (those which prevent progression of the infection).

YES..1
NO..2

START F22p2s1

F2. Now I'm going to ask about any antiretroviral medications you may have taken since your (MONTH) study visit. In addition to all your prescribed medications, please include any antiretroviral medications you have taken as part of a research study including those in which you may have been blinded to the study medication.

PROMPT: HAND PARTICIPANT ANTIVIRAL PHOTO MEDICATION CARDS. GO THROUGH THE CARDS WITH THE PARTICIPANT, SAYING THE NAME OF EACH DRUG ALOUD AND ASKING HER TO TELL YOU "YES" OR "NO" WHETHER SHE HAS TAKEN THIS DRUG SINCE HER LAST VISIT.

CHECK THE BOX NEXT TO THE DRUG(S) THE PARTICIPANT HAS TAKEN. FOR DRUGS NOT ON THE LIST, RECORD THE NAME UNDER "OTHER" AS STATED BY THE PARTICIPANT AND FILL IN THE CORRESPONDING THREE-DIGIT DRUG CODE FROM DRUG LIST 1.

A. Since your (MONTH) study visit, have you taken…

Nucleoside/Nucleotide RTIs

204 ~ 3-TC (lamivudine, Epivir)
218 ~ Abacavir (Ziagen, 1592U89)
224 ~ Adefovir (Preveon, bis-POM PMPA, GS 840)
092 ~ AZT (Retrovir, zidovudine, ZDV)
227 ~ Combivir (AZT + 3TC)
159 ~ d4T (stavudine, Zerit)
094 ~ ddC (dideoxycytidine, Zalcitabine, Hivid)
147 ~ ddI (dideoxyinosine, Didanosine, Videx)

Protease Inhibitors

219 ~ Amprenavir (Agenerase, 141W94)
212 ~ Indinavir (Crixivan)
216 ~ Nelfinavir (Viracept)
211 ~ Ritonavir (Norvir)
210 ~ Saquinavir (Invirase, Fortovase)

Non-Nucleoside RTIs

194 ~ Delavirdine (Rescriptor, U-90)
220 ~ Efavirenz (Sustiva, DMP266)
191 ~ Nevirapine (Viramune)

Other

207 ~ Hydroxyurea (Hydrea)
~ Other anti-viral(s) (from Drug List 1)

Name of Drug:	Drug Code: |__|__|__|
Name of Drug:	Drug Code: |__|__|__|

END F22p2s1

PLEASE COMPLETE DRUG FORM 1 FOR EACH MEDICATION MARKED ABOVE IN QUESTION F2.A.

WIHS ID#

B. If the participant is not taking ANY antiviral medication, check here: ~⎞ **GO TO QF8**

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F3. In general, over the past 6 months, how often did you take your antiretrovirals as prescribed?

100% of the time 1
95-99% of the time..2
75-94% of the time..3
< 75% of the time..4
I haven't taken any of my prescribed medications 5

F4. A. Since your [MONTH] study visit, was there a time when you skipped at least two consecutive days of prescribed anti-retroviral therapy?

YES..1
NO..2 → **GO TO QF5**

B. Was this skip in medication prescribed by your physician?

YES..1
NO..2

C. How many days did you go without taking any antiretroviral medications during your last break?

|__|__|__| days

F5. **PROMPT: HAND PARTICIPANT RESPONSE CARD D1.**

People skip or miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Since your (MONTH) study visit, how often have you missed taking your anti-retroviral medications because you:

	Never	Rarely	Sometimes	Often
Were told to take a break by your physician?	0	1	2	3
Simply forgot?	0	1	2	3
Had a change in daily routine (e.g., vacation, holiday, non-workday)?	0	1	2	3
Fell asleep or slept through dose time?	0	1	2	3
Had too many pills to take?	0	1	2	3
Ran out of pills?	0	1	2	3
Did not feel like taking any pills?	0	1	2	3
Did not want others to notice you taking medication?	0	1	2	3
Were on drugs or drank too much?	0	1	2	3
Wanted to avoid side effects?	0	1	2	3
Felt like the drug was toxic or harmful?	0	1	2	3
Felt too sick to take medications?	0	1	2	3
Felt too depressed to take medications?	0	1	2	3
Had difficulty following special instructions (e.g., take with meals or on empty stomach)?	0	1	2	3
Other reason	0	1	2	3

Specify reason:

WIHS ID#

F6. **PROMPT: HAND PARTICIPANT RESPONSE CARD D2.**

Most anti-HIV medications need to be taken on a schedule, such as "every 12 hours" or "every 8 hours." In general, how closely do you follow your specific schedule?

Never..1
Some of the time...................................2
About half of the time............................3
Most of the time.....................................4
All of the time..5

F7. A. Do any of your anti-HIV medications have special instructions such as "take with food" or "take on an empty stomach" or "take with plenty of fluids?"

Yes...1
No..2 **GO TO QF9**

PROMPT: HAND PARTICIPANT RESPONSE CARD D2.

B. In general, how often do you follow these special instructions?

Never..1
Some of the time...................................2
About half of the time............................3
Most of the time.....................................4
All of the time..5

GO TO QF9

F8. **PROMPT: HAND PARTICIPANT RESPONSE CARD D3.**

What is your MAIN reason for not taking any antiviral medications or treatments?

CIRCLE ONE ANSWER ONLY.

I am HIV negative...1
My CD4+ was too high / viral load was too low..............2
I feel too healthy...3
I am taking alternative medications.................................4
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/have no insurance coverage...............8
Concerned about resistance...9
I'm having a baby...10
Personal decision to wait...11
They didn't work for my friends......................................12
Any other reason...13

Specify reason:

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START F22p2s2

F9. PROMPT: HAND PARTICIPANT RESPONSE CARDS D4a and D4b.

PROMPT: READ THE NAME OF EACH MEDICATION ALOUD. ASK THE PARTICIPANT IF SHE IS TAKING THIS MEDICATION. IF SHE ANSWERS YES, CHECK THE BOX NEXT TO THE DRUG NAME.

A. Since your (MONTH) visit, have you taken either of the following inhaled medications?

124 ~ Amphotericin B (Ampho B)
114 ~ Pentamidine (aerosolized)

If the participant is not taking ANY medication in F9A, check here: ~ ⎫ **GO TO QF9B**

B. Since your (MONTH) visit, have you taken any of the following injected or infused drugs?

091 ~ Foscarnet (Foscavir)
125 ~ Ganciclovir (DHPG, Cytovene)
232 ~ Nandralone (Deca-Durabolin)
157 ~ Medication to increase white blood cell count (G-CSF, GM-CSF, Neupogen)
117 ~ Medication to increase red blood cell count (Erythropoietin, Epogen, Procrit, EPO)
090 ~ Interferon

If the participant is not taking ANY medication in F9B, check here: ~ ⎫ **GO TO QF9C**

C. Since your (MONTH) visit, have you taken any of the following pills or liquids?

112 ~ Bactrim (Septra, SMP/TMX)
184 ~ Biaxin (Clarithromycin)
153 ~ Cipro (Ciprofloxacin)
113 ~ Dapsone
116 ~ Diflucan (Fluconazole)
213 ~ Famvir (Famcyclovir)
138 ~ INH (Isoniazid)
154 ~ Lamprene (Clofazimine)
190 ~ Mepron (Atovaquone)
540 ~ Methadone
229 ~ Monistat (Miconazole)
137 ~ Myambutol (Ethambutol)
145 ~ Mycelex or Lotrimin (Clotrimazole)
127 ~ Nizoral (Ketoconazole)
144 ~ Nystatin (Mycostatin)
228 ~ Oxandrin (Oxandralone)
702 ~ Prednisone (Deltasone)
182 ~ PZA (Pyrazinamide)
235 ~ Rebetron (Ribavirin & Alpha Interferon)
093 ~ Rifabutin (Mycobutin)
139 ~ Rifadin (Rifampin)
169 ~ Sporanox (Itraconazole)
230 ~ Terazol (Terconazole)
198 ~ Valtrex (Valacyclovir)
152 ~ Zithromax (Azithromycin)
146 ~ Zovirax (Acyclovir)

If the participant is not taking ANY medication in F9C, check here: ~ ⎫ **GO TO QF10**

END F22p2s2

PLEASE COMPLETE DRUG FORM 2 FOR EACH MEDICATION MARKED ABOVE IN QUESTION F9.

WIHS ID#

F10. **PROMPT: HAND PARTICIPANT RESPONSE CARDS D5.**

In addition to standard medication therapies, we are interested in collecting information on complementary and alternative therapies.

A. Since your (MONTH) visit, have you used any complementary or alternative medications that you take by mouth either as a pill or liquid, that you apply to your skin, or that you insert in your rectum or vagina. Please include any enzyme therapies, flower remedies, herbs, homeopathic remedies and nutritional supplements such as vitamins or minerals you may have taken. Do not include commercial herbal tea preparations (i.e., tea bags), but please include tea remedies made from fresh bulk herbs.

YES..1
NO..2 ⎫ **GO TO QF14**

START F22p2s3

WIHS ID#

B. Please name those complementary and alternative medications that you have taken.
PROMPT: CHECK THE BOX NEXT TO THE COMPLEMENTARY AND/OR ALTERNATIVE MEDICATION(S) NAMED. SPECIFY THOSE NOT ON THE LIST UNDER "OTHER" AND FILL IN THE CORRESPONDING THREE-DIGIT DRUG CODE FROM DRUG LIST 3.

	Treatments		Frequency of Use: Every or almost every day	Frequency of Use: Only as needed	Currently taking?	MAIN reason for taking?
621 ~	**Enzyme Therapies (plant or pancreatic)**		1	2	Y N	
622 ~	**Flower Remedies**		1	2	Y N	
	Herbs (Chinese/Asian, Native American, South American, Indian/Ayurvedic)					
	613 ~ Cat claw		1	2	Y N	
	615 ~ Chinese herbs in combination		1	2	Y N	
	620 ~ Echinacea (with or without Goldenseal)		1	2	Y N	
	624 ~ Garlic		1	2	Y N	
	632 ~ Milk thistle		1	2	Y N	
	167 ~ St. John's Wort (Hypericin)		1	2	Y N	
	539 ~ Other herbs, unspecified		1	2	Y N	
629 ~	**Homeopathic Remedies**		1	2	Y N	
	Nutritional Supplements (such as vitamins, minerals)					
	602 ~ Acidophilus		1	2	Y N	
	601 ~ A-Vitamins		1	2	Y N	
	610 ~ Beta-carotene		1	2	Y N	
	607 ~ B-Complex		1	2	Y N	
	608 ~ B-Vitamins (B1 Thiamine, B2 Riboflavin, B5 Pantothenic Acid, B6 Pyridoxine, B12)		1	2	Y N	
	612 ~ C-Vitamins (Rosehips)		1	2	Y N	
	196 ~ Coenzyme Q-10		1	2	Y N	
	161 ~ DHEA		1	2	Y N	
	619 ~ E-Vitamins		1	2	Y N	
	623 ~ Folic Acid		1	2	Y N	
	630 ~ Multivitamin / Mineral		1	2	Y N	
	631 ~ Megadose Vitamins		1	2	Y N	
	633 ~ Omega-3 Type Oils		1	2	Y N	
	634 ~ Protein Powder		1	2	Y N	
	640 ~ Zinc		1	2	Y N	
	503 ~ Other nutritional supplements, unspecified		1	2	Y N	
188 ~	**NAC (N-acetyl-cysteine)**		1	2	Y N	
173 ~	**Ozone**		1	2	Y N	
635 ~	**SPV-30**		1	2	Y N	
637 ~	**Thymus Glandular**		1	2	Y N	
~	**Other treatment(s) (from Drug List 3)**					
Specify:		→Drug code: |__|__|__|	1	2	Y N	
Specify:		→Drug code: |__|__|__|	1	2	Y N	
Specify:		→Drug code: |__|__|__|	1	2	Y N	

HAND PARTICIPANT RESPONSE CARD D6. ***Reasons for taking complementary/alternative medications:***

WIHS ID#

01=to treat or reduce side effects from "standard" medications	05=for general health
02=to boost immune system	06=beneficial without causing side effects
03=to prevent opportunistic and general infections	07=standard HIV medications don't work
04=to treat HIV infection	99=other

WIHS ID#

END F22p2s3

F11. Who prescribes or guides your use of these alternative medications? **CIRCLE ONE ANSWER.**

- Primary care provider (non-C/A practitioner) .... 1 **GO TO QF14**
- Self-medicated 2
- Complementary/Alternative practitioner (Homeopath, Herbalist, Naturopath).... 3
- Health Store Staff.......... 4
- Other 5

F12. Have you discussed your use of this medication with your primary care provider?

- YES.......... 1 **GO TO QF14**
- NO 2
- DON'T HAVE A PRIMARY CARE PROVIDER .... 3 **GO TO QF14**

F13. **PROMPT: HAND PARTICIPANT RESPONSE CARD D7.**

If no, what is the MAIN reason you have not told him/her? **CIRCLE ONE ANSWER.**

- He/She didn't ask.......... 1
- I didn't think it was important 2
- I don't think he/she would approve of its use 3
- I think he/she would ask me to stop taking it.......... 4
- He/She is not knowledgeable about alternative medications.......... 5
- Other 6

F14. Since your (MONTH) visit, have you taken any other **PRESCRIBED** medications NOT previously mentioned?

- YES 1
- NO .... 2 **GO TO F15**

START F22p2s4

SPECIFY:

Name of Drug:	Name of Drug:
Name of Drug:	Name of Drug:
Name of Drug:	Name of Drug:
Name of Drug:	Name of Drug:
Name of Drug:	Name of Drug:
Name of Drug:	Name of Drug:

END F22p2s4

WIHS ID#

F15. **PROMPT: HAND PARTICIPANT RESPONSE CARD D8.**
Now I am going to ask you some questions about symptoms that may occur due to the stress of daily life or aging. These symptoms also occur in a small number of people as a result of taking certain medications.

Since your last visit, please tell me if you have experienced any of the following symptoms and, if you have, whether the symptom was not bad, bad, very bad or terrible.

PROMPT: If patient is not taking any prescribed or alternative medications, code part i. and ii. as "N/A."

Since your last visit, have you had…	Not at all	Not bad	Bad	Very bad	Terrible	Do you feel that this symptom was a side effect of your… i. Prescribed medications	ii. Alternative therapies
a. Headaches	0 (**b**)	1	2	3	4	Y N N/A	Y N N/A
b. Fever	0 (**c**)	1	2	3	4	Y N N/A	Y N N/A
c. Rash	0 (**d**)	1	2	3	4	Y N N/A	Y N N/A
d. Lack of appetite	0 (**e**)	1	2	3	4	Y N N/A	Y N N/A
e. Drowsiness / tiredness	0 (**f**)	1	2	3	4	Y N N/A	Y N N/A
f. Nausea and/or vomiting	0 (**g**)	1	2	3	4	Y N N/A	Y N N/A
g. Pain / tingling in feet or hands	0 (**h**)	1	2	3	4	Y N N/A	Y N N/A
h. Dizziness or lack of concentration	0 (**i**)	1	2	3	4	Y N N/A	Y N N/A
i. Muscle aches or pains	0 (**j**)	1	2	3	4	Y N N/A	Y N N/A
j. Abdominal pains or cramps	0 (**k**)	1	2	3	4	Y N N/A	Y N N/A
k. Kidney stones	0 (**l**)	1	2	3	4	Y N N/A	Y N N/A
l. Dry mouth	0 (**m**)	1	2	3	4	Y N N/A	Y N N/A
m. Shifting of your body fat	0 (**n**)	1	2	3	4	Y N N/A	Y N N/A
n. Diarrhea	0 (**o**)	1	2	3	4	Y N N/A	Y N N/A
o. Other: ________________	0 (**F17**)	1	2	3	4	Y N N/A	Y N N/A
p. Other: ________________	0 (**F17**)	1	2	3	4	Y N N/A	Y N N/A

F17. TIME MODULE ENDED |__|__| : |__|__| AM............1
PM 2

STOP HERE