WOMEN'S INTERAGENCY HIV STUDY

MEDICATION HISTORY

FORM 22 MED

SECTION A: GENERAL INFORMATION

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

A2. WIHS STUDY VISIT NUMBER: ____ ____

A3. FORM VERSION: **0 4 / 0 1 / 0 7**

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 a series of questions about medicines you may have had or taken since your study visit on ___ ___ / ___ ___ / ___ ___.
M D Y

Also, if at any point in the interview you wish to stop, 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.

SECTION B. ANTIRETROVIRAL HISTORY

B1. 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

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START F22MEDS3

B2. 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 ANTIRETROVIRAL 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.

IF PARTICIPANT REPORTS USE OF A DRUG MARKED WITH "*," FOLLOW PROMPT AT BOTTOM OF PAGE BEFORE READING OTHER DRUG NAMES TO PARTICIPANT.

CHECK THE DRUG(S) THE PARTICIPANT HAS TAKEN FOR HIV SINCE HER LAST STUDY VISIT. 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…

Combination Medications

262 __ Atripla (Sustiva + Viread + Emtriva)
227 __ Combivir (AZT + 3TC)
254 __ Epzicom (Ziagen + Epivir)
240 __ Trizivir (abacavir + AZT + 3TC)
253 __ ***Truvada** (Viread + Emtriva)

Entry Inhibitors

233 __ Fuzeon (T-20, enfuvirtide)
265 __ Selzentry (maraviroc)

Nucleoside/Nucleotide RTIs

239 __ ***Emtriva** (emtricitabine, FTC)
204 __ ***Epivir** (lamivudine, 3-TC)
094 __ Hivid (zalcitabine, ddC)
092 __ Retrovir (AZT, zidovudine, ZDV)
147 __ Videx / Videx EC (didanosine, ddI)
234 __ ***Viread** (tenofovir)
159 __ Zerit (stavudine, d4T)
218 __ Ziagen (abacavir)

Non-Nucleoside RTIs

194 __ Rescriptor (delavirdine)
220 __ Sustiva (efavirenz)
191 __ Viramune (nevirapine)

Protease Inhibitors

219 __ Agenerase (amprenavir)
238 __ Aptivus (tipranavir)
212 __ Crixivan (indinavir)
210 __ Invirase or Fortovase (saquinavir)
217 __ Kaletra (lopinavir + ritonavir)
249 __ Lexiva (fosamprenavir)
211 __ Norvir (ritonavir)
256 __ Prezista (TMC-114, darunavir)
243 __ Reyataz (atazanavir)
216 __ Viracept (nelfinavir)

Other

207 __ Droxia or Hydrea (hydroxyurea)
__ Other anti-viral(s) (from Drug List 1)

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

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

END F22MEDS3

PROMPT: CHECK ARV HISTORY FROM LAST VISIT ON VISIT CONTROL SHEET. IF MEDICATIONS REPORTED AT LAST VISIT ARE NOT REPORTED AS BEING USED SINCE THE PARTICIPANT'S LAST VISIT, PLEASE PROMPT: "Last visit you said you were taking [DRUG], have you stopped taking that since your (MONTH) study visit or are you still taking it?" AMEND RESPONSE TO QUESTION B2a AS NECESSARY BASED ON PARTICIPANT'S RESPONSE AND PROCEED WITH THE REST OF THE INTERVIEW.

***PROMPT: ASK PARTICIPANT IF SHE TAKES [*EPIVIR, VIREAD, EMTRIVA, TRUVADA*] TO TREAT HIV ONLY, HEPATITIS (B OR C) ONLY, OR BOTH. IF HIV ONLY (OR PARTICIPANT IS UNSURE OF REASON), RECORD MEDICATION IN QUESTION B2A AND PROCEED WITH ADMINISTRATION OF DRUG FORM 1. IF HEPATITIS ONLY, DO NOT RECORD MEDICATION IN QUESTION B2A AND DO NOT ADMINISTER DRUG FORM 1. IF HIV AND HEPATITIS, RECORD MEDICATION IN QUESTIONS B2A AND D1A AND COMPLETE BOTH DRUG FORMS 1 AND 3.**

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PLEASE COMLPETE THE DOSAGE FORM IF PARTICIPANT REPORTS HAVING TAKEN ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT IN QUESTION B2a.

b. IF PARTICIPANT HAS NOT TAKEN **ANY** ANTIRETROVIRAL MEDICATION SINCE HER (MONTH) STUDY VISIT, CHECK HERE: ____ **(GO TO B10)**

c. ENTER THE TOTAL NUMBER OF ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION B2a: |___|___|

B3. Is this the first time you have taken any antiretroviral medication(s)?

YES 1
NO .....2 **(GO TO B4)**

Why did you start taking antiretroviral medication(s) now? **CIRCLE YES FOR ALL THAT APPLY.**

		YES	**NO**
a.	My viral load went up	1	2
b.	My CD4 level went down	1	2
c.	I was diagnosed with AIDS	1	2
d.	I became sicker, although I wasn't diagnosed with AIDS	1	2
e.	My doctor recommended I start since my last study visit	1	2
f.	My doctor had previously recommended I start	1	2
g.	I'm pregnant or intend to become pregnant	1	2
h.	Other reason	1	2

SPECIFY: _____

B4. Since your (MONTH) study visit, have you changed or stopped **any** of your antiretroviral medications?

YES 1
NO .....2 **(GO TO B7)**

You have reported a change in the antiretroviral medications you are taking. We want to understand the reasons for this change, so please tell me which of these reasons contributed to the decision to change or stop your ART medicines:

		YES	**NO**
a.	My provider changed/stopped my medicines and I don't know why	1	2
b.	My medicines weren't working – my CD4 count was lower or my viral load was higher	1	2
c.	My virus was resistant	1	2
d.	I was not taking my medicines any way	1	2
e.	I am pregnant, or I am trying to become pregnant, or I changed after giving birth	1	2
f.	I was tired of taking the medicines	1	2
g.	I could not pay for the medicines	1	2
h.	My prescription ran out	1	2

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		YES	NO	
i.	My medicines were too complicated to take, or there were too many pills, or they were hard to swallow	1	2	
j.	Family or friends wanted me to change/stop my medicines	1	2	
k.	I heard about better medicines on TV, the radio, in a magazine or the newspaper	1	2	
l.	I had side effects or the medicines made me sick	1	2	**(m)**
i.	I got a skin rash or had skin problems	1	2	
ii.	I got headaches	1	2	
iii.	I had gastrointestinal problems (nausea, vomiting, diarrhea, cramping)	1	2	
iv.	My body shape or body fat changed	1	2	
v.	I became depressed, moody, or had trouble with sleep	1	2	
vi.	My blood count tests weren't normal (anemia, low blood, low white count)	1	2	
vii.	My liver tests weren't normal	1	2	
viii.	My kidney tests weren't normal	1	2	
ix.	I developed diabetes or high blood sugar	1	2	
x.	My blood tests for lipids/fat/cholesterol became abnormal	1	2	
xi.	I became allergic or hypersensitive to a medication	1	2	
xii.	I had some kind of side effect, but do not know what kind	1	2	
m.	Any other reasons for changing/stopping medicines	1	2	**(B7)**

SPECIFY: _____

B7. a. For the remaining questions, I want you to focus on how you have taken your medications over the past six months. In general, over the past six months, how often did you take your antiretrovirals as prescribed?

100% of the time.....1 **(GO TO B8)**
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

b. **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 antiretroviral medications because you…

		Never	Rarely	Sometimes	Often
i.	Simply forgot?	0	1	2	3
ii.	Had a change in daily routine (e.g., vacation, holiday, non-workday)?	0	1	2	3
iii.	Fell asleep or slept through dose time?	0	1	2	3
iv.	Had too many pills to take?	0	1	2	3
v.	Ran out of pills?	0	1	2	3

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		Never	Rarely	Sometimes	Often
vi.	Did not feel like taking any pills?	0	1	2	3
vii.	Did not want others to notice you taking medications?	0	1	2	3
viii.	Were on drugs or drank too much?	0	1	2	3
ix.	Wanted to avoid side effects?	0	1	2	3
x.	Felt like the drug was toxic or harmful?	0	1	2	3
xi.	Felt too sick to take medications?	0	1	2	3
xii.	Felt too depressed to take medications?	0	1	2	3
xiii.	Had difficulty following special instructions (e.g., take with meals or on empty stomach)?	0	1	2	3
xiv.	Other reason?	0	1	2	3

SPECIFY: _____

B8. **PROMPT: HAND PARTICIPANT RESPONSE CARD D2.**

a. 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

b. 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 B9)**

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

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

B9. IS PARTICIPANT CURRENTLY TAKING COMBINATION THERAPY?

YES 1
NO ..... 2 **(GO TO SECTION C)**

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PROMPT: HAND PARTICIPANT RESPONSE CARD 12.

I am going to read to you some things that people taking combination drug treatments believe about the transmission of HIV. We realize that some people might find these questions offensive, or that you may be tired of answering them since they're asked at every visit. We apologize for the repetition, but need to ask these questions at every visit to be able to tell if people's attitudes toward HIV transmission change when they change medications. Please tell me if you strongly agree, agree, if you are uncertain, or if you disagree or strongly disagree with each of these statements.

	STRONGLY AGREE	AGREE	UNCERTAIN	DISAGREE	STRONGLY DISAGREE
a. Since starting combination drug treatments, I worry less about passing HIV to other people during sex	1	2	3	4	5
b. I worry less about always using condoms since I started combination drug treatments	1	2	3	4	5
c. I think that it is less likely that I could infect other people during sex now that I am on combination drug treatments	1	2	3	4	5
d. I would be less worried about a new partner's HIV serostatus now that I am on combination drug treatments	1	2	3	4	5

PROMPT: GO TO SECTION C.

B10. **PROMPT: HAND PARTICIPANT RESPONSE CARD D3.**

What is your **main** reason for not taking any antiretroviral medications or treatments? **CIRCLE ONE ANSWER ONLY.**

I am HIV negative.....1
My CD4+ was too high / viral load too low 2
I feel too healthy 3
I am taking alternative treatments.....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
I am concerned about resistance 9
I'm having a baby 10
Personal decision to wait 11
They didn't work for my friends.....12
Liver problems.....14
Any other reason.....13

SPECIFY: _____

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SECTION C. OI MEDICATION HISTORY

START F22MEDS4

C1. **PROMPT: HAND PARTICIPANT RESPONSE CARD D4. READ THE NAME OF EACH MEDICATION ALOUD. ASK THE PARTICIPANT IF SHE IS TAKING THIS MEDICATION. IF SHE ANSWERS "YES," CHECK NEXT TO THE DRUG NAME.**

IF PARTICIPANT REPORTS USE OF A DRUG MARKED WITH "*," FOLLOW PROMPT AFTER EACH QUESTION BEFORE READING OTHER DRUG NAMES TO PARTICIPANT.

a. Since your (MONTH) study visit, have you taken the following inhaled medication?

114 ___ Pentamidine (aerosolized)

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION IN C1a SINCE HER (MONTH) STUDY VISIT, CHECK HERE: ____ **(GO TO C1b)**

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

091 ___ Foscarnet (Foscavir)
125 ___ Ganciclovir (DHPG, Cytovene IV)
232 ___ Nandrolone (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 alfa-2b** (Intron A)
124 ___ Amphotericin B (Ampho B)
242 ___ ***Pegylated interferon** (PEGASYS, PEG-Intron, Peginterferon alfa-2a, Peginterferon alfa-2b)

***PROMPT: ASK PARTICIPANT IF SHE TAKES [*INTERFERON, PEGYLATED INTERFERON*] TO TREAT HEPATITIS (B OR C) ONLY, TO PREVENT OR TREAT ANOTHER CONDITION, OR BOTH. IF HEPATITIS ONLY, DO NOT RECORD MEDICATION IN QUESTION C1B AND DO NOT ADMINISTER DRUG FORM 2. IF ANOTHER CONDITION ONLY, RECORD MEDICATION IN QUESTION C1B AND PROCEED WITH ADMINISTRATION OF DRUG FORM 2. IF HEPATITIS AND ANOTHER CONDITION, RECORD MEDICATION IN QUESTIONS C1B AND D1A AND COMPLETE BOTH DRUG FORMS 2 AND 3.**

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION IN C1b SINCE HER (MONTH) STUDY VISIT, CHECK HERE: ____ **(GO TO C1c)**

c. Since your (MONTH) study visit, have you used any of the following pills, liquids or creams?

112 ___ Bactrim (Septra, cotrimoxazole, trimethoprim-sulfamethoxazole, TMP/SMZ)
184 ___ Biaxin (clarithromycin)
153 ___ Cipro (ciprofloxacin)
113 ___ Dapsone
116 ___ Diflucan (fluconazole)
213 ___ ***Famvir** (famciclovir)
125 ___ Ganciclovir (Cytovene, valganciclovir, Valcyte)
138 ___ INH (isoniazid)
154 ___ Lamprene (clofazimine)
190 ___ Mepron (atovaquone)
540 ___ Methadone
705 ___ Methyl-prednisolone (Medrol)
229 ___ Monistat (miconazole)
137 ___ Myambutol (ethambutol)
145 ___ Mycelex or Lotrimin (clotrimazole)
127 ___ Nizoral (ketoconazole)
144 ___ Nystatin (Mycostatin)
228 ___ Oxandrin (oxandrolone)
706 ___ Orapred
707 ___ Prednisolone (Prelone)
704 ___ Prednisone (Deltasone)
182 ___ PZA (pyrazinamide)
235 ___ ***Rebetron** (Ribavirin & Interferon alfa-2b)
093 ___ Rifabutin (mycobutin)
139 ___ Rifadin (rifampin)
169 ___ Sporanox (itraconazole)
230 ___ Terazol (terconazole)
198 ___ Valtrex (valacyclovir)
247 ___ Vfend (voriconazole)
152 ___ Zithromax (azithromycin)
146 ___ Zovirax (acyclovir)

***PROMPT: ASK PARTICIPANT IF SHE TAKES [*FAMVIR, REBETRON*] TO TREAT HEPATITIS (B OR C) ONLY, TO PREVENT OR TREAT ANOTHER CONDITION, OR BOTH. IF HEPATITIS ONLY, DO NOT RECORD MEDICATION IN QUESTION C1C AND DO NOT ADMINISTER DRUG FORM 2. IF ANOTHER CONDITION ONLY, RECORD MEDICATION IN QUESTION C1C AND PROCEED WITH ADMINISTRATION OF DRUG FORM 2. IF HEPATITIS AND ANOTHER CONDITION, RECORD MEDICATION IN QUESTIONS C1C AND D1A AND COMPLETE BOTH DRUG FORMS 2 AND 3.**

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION IN C1c SINCE HER (MONTH) STUDY VISIT, CHECK HERE: ____ **(GO TO PROMPT)**

END F22MEDS4

PLEASE COMPLETE DRUG FORM 2 FOR EACH MEDICATION MARKED ABOVE IN QUESTION C1a – C1c. IF NO MEDICATIONS ARE MARKED, GO TO SECTION D.

d. ENTER THE TOTAL NUMBER OF NON-ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTIONS C1a, C1b and C1c: |___|___|

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SECTION D. HEPATITIS MEDICATION HISTORY

START F22MEDS9

D1. **PROMPT: HAND PARTICIPANT RESPONSE CARD D4a. READ THE NAME OF EACH MEDICATION ALOUD. ASK THE PARTICIPANT IF SHE HAS TAKEN THIS MEDICATION FOR HEPATITIS. IF SHE ANSWERS "YES," CHECK THE DRUG NAME.**

a. Since your (MONTH) study visit, have you taken (MEDICATION) for Hepatitis (B or C)?

090 ___ Interferon alfa-2b (Intron A)
242 ___ Pegylated interferon (PEGASYS or Peginterferon alfa-2a)
(PEG-Intron or Peginterferon alfa-2b)
058 ___ Ribavirin (Virazole, Rebetrol, Copegus)
235 ___ Rebetron (Ribavirin and interferon alfa-2b)
204 ___ Epivir (lamivudine, 3-TC)
234 ___ Viread (tenofovir, bis-POC-PMPA)
224 ___ Hespera (adefovir, Preveon, bis-POM PMPA, GS 840)
239 ___ Emtriva (emtricitabine, Coviracil, FTC)
708 ___ Infergen (Interferon alfacon-1)
213 ___ Famvir (famciclovir)
253 ___ Truvada (Viread + Emtriva)
709 ___ Baraclude (entecavir, BMS-200475)
710 ___ Tyzeka (telbivudine)

b. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION IN D1a SINCE HER (MONTH) STUDY VISIT, CHECK HERE: ____ **(GO TO SECTION E)**

END F22MEDS9

PLEASE COMPLETE DRUG FORM 3 FOR EACH MEDICATION MARKED ABOVE IN QUESTION D1a.

c. ENTER THE TOTAL NUMBER OF HEPATITIS MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION D1a: |___|___|

SECTION E. OTHER PRESCRIPTION MEDICATION USE

E1. Since your (MONTH) study visit, have you received any of the following vaccinations?

		YES	NO	DON'T KNOW
a.	Hepatitis A	1	2	-8
b.	Hepatitis B	1	2	-8
c.	Pneumovax	1	2	-8
d.	Varicella (chicken pox)	1	2	-8
e.	Tetanus	1	2	-8
f.	HPV (human papillomavirus)	1	2	-8

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E2. Since your (MONTH) study visit, have you had a routine flu vaccine? A flu vaccine is usually given in the fall and protects against influenza for the flu season. **(PROBE: A flu shot is injected. The FluMist vaccine is sprayed into the nose.)**

YES 1
NO.....2 **(GO TO E3)**

PROMPT: ASK THE PARTICIPANT TO DISPLAY HER VACCINATION CARD.

IF INFORMATION REGARDING FLU VACCINATION IS ON THE CARD, COMPLETE QUESTION E2a AND THEN SKIP TO QUESTION E3. RECORD FLU VACCINATION INFORMATION ON THE VACCINATION HISTORY (VAC) FORM.

IF INFORMATION REGARDING FLU VACCINATION IS <u>NOT</u> ON THE CARD, COMPLETE QUESTION E2a AND THEN ASK PARTICIPANT QUESTIONS E2b – E2d.

a. IS INFORMATION REGARDING FLU VACCINATION ON THE PARTICIPANT'S VACCINATION CARD?

YES .....1 **(GO TO E3)**
NO.....2

b. Which did you have?

Flu shot.....1
Nose spray.....2

c. When did you receive the flu vaccine? __ __ / __ __ __ __
M Y

d. Where did you receive your flu vaccine?

Same clinic as the WIHS study visit. 1
Other doctor's office 2
Hospital 3
Supermarket or a grocery store 4
Superstore, such as Wal-Mart 5
Pharmacy..... 6
Health Department 7
Shelter 8
Other (Specify below)..... 9

SPECIFY: _____

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E3. Since your (MONTH) study visit, have you had a vaccine for bird flu? This is also called avian flu or H5N1 influenza.

YES 1
NO .....2 **(GO TO E4)**

a. When did you receive the bird flu vaccine? __ __ / __ __ __ __
M Y

PROMPT: IF PARTICIPANT SAYS "NO" AND ASKS IF THIS IS AVAILABLE, SAY THAT THIS QUESTION IS INCLUDED IN CASE A BIRD FLU VACCINE IS OFFERED IN THE FUTURE.

E4. Since your (MONTH) study visit, did you have a discussion with a health care provider about receiving a flu shot?

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

a. During that discussion, did your health care provider recommend you receive a flu shot? (**PROBE:** By recommend, I mean did your provider want you to get a flu shot?)

YES 1
NO 2

E5. Do you know where you can get a free-of-charge flu shot (**PROBE:** meaning it does not cost you any money out of your pocket)?

YES 1
NO 2

E6. Did you receive a prescription medication from your provider to **prevent** getting flu, or to **treat** flu since your (MONTH) study visit?

YES 1
NO .....2 **(GO TO E7)**

a. Did you receive Tamiflu (oseltamivir), a capsule that you swallow?

YES 1
NO 2

b. Did you receive Relenza (zanamivir), a powder that is inhaled?

YES 1
NO 2

c. Did you receive amantadine (Symmetrel) or rimantadine (Flumadine), pills that you swallow?

YES 1
NO 2

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E7. Now I'm going to ask you about any time you might have had flu since your (MONTH) study visit. The word "flu" is used for several illnesses. For example, people may say they have "stomach flu" for gastrointestinal illnesses (vomiting and diarrhea) that are caused by viruses other than influenza. Our questions are about influenza flu. Common symptoms are fever and a dry, hacking cough. Influenza flu is different from a cold; however, it can be very difficult to tell flu from a cold. In general, flu symptoms are much worse and last longer than cold symptoms. Since your (MONTH) study visit, did you have an illness that you think was the "flu" (but not stomach flu)?

YES 1
NO .....2 **(GO TO E10)**

a. How many times did you have flu since your (MONTH) study visit? |___|___|
TIMES

b. When did you have flu? __ __ / __ __ __ __
M Y

PROMPT: IF THE PARTICIPANT HAD FLU MORE THAN ONCE SINCE HER (MONTH) STUDY VISIT (I.E., E7a > 1), READ: "Please give me the month and year of the time it was most serious, or the time when a doctor or other healthcare practitioner said you had the flu."

PROMPT: INTERVIEWER, STATE THE MONTH AND YEAR REPORTED IN QUESTION E7b WHEREVER "[MONTH/YEAR]" APPEARS IN QUESTIONS E7c THROUGH E9.

c. When you had flu in [MONTH/YEAR], were you told by a doctor or other health practitioner that you had flu?

YES 1
NO 2
DID NOT SEE HEALTH PROFESSIONAL 3

d. Were you **admitted** to a hospital to treat your flu when you had it in [MONTH/YEAR]?

YES 1
NO 2

E8. Did you have any of the following symptoms when you had flu in [MONTH/YEAR]?

		YES	NO
a.	Fever	1	2
b.	Dry cough	1	2
c.	Sore throat	1	2
d.	Muscle aches	1	2
e.	Nausea, vomiting or diarrhea	1	2
f.	Headache	1	2

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E9. When you had flu in [MONTH/YEAR], how many days were you not able to do your usual activities or how many days of work did you miss? |___|___| DAYS

E10. **PROMPT: HAND PARTICIPANT RESPONSE CARD D4j.**
Now I am going to ask you about some of your beliefs about the flu vaccine. For each statement, please tell me if you strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree.

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
a. I believe the flu shot protects me from getting the flu.	1	2	3	4	5
b. I do **not** believe flu can cause serious illness.	1	2	3	4	5
c. I do **not** think I am at high risk for catching the flu.	1	2	3	4	5
d. I have gotten sick from the flu shot.	1	2	3	4	5
e. I do **not** like to be stuck by needles during my health care visits.	1	2	3	4	5

E11. **PROMPT: HAND PARTICIPANT RESPONSE CARD D4h.**

Since your (MONTH) study visit, have you taken any of the following hormone replacement therapies (hormones, estrogen, progesterone) for more than one month? These therapies could have been taken in the form of a pill, cream, or patch worn on the skin. Please do not include any hormones taken only to prevent pregnancy; we will discuss those later in the interview.

ESTROGEN: Premarin, Estrace, Estratab, Menest, Ogen, Cenestin, Estraderm, Climera, Menostar, Estrasorb

PROGESTERONE: Provera, Cycrin, Amen, Prometrium, Micronor, Nor-QD

COMBINATION ESTROGEN/PROGESTERONE: Premphase, Prempro, Combipatch

OTHER HRT: Tamoxifen, Raloxifene, testosterone patch or cream, Estratest (combination estrogen/testosterone), birth control pills, Norplant, Ortho Evra (birth control patch), NuvaRing (a vaginal ring containing hormone)

YES.....1
NO.....2 **(GO TO E12a)**

a. INTERVIEWER: BASED ON PARTICIPANT RESPONSE IN E11, CODE BELOW THE TYPE OF HRT PARTICIPANT REPORTED ABOVE:

ESTROGEN.....1
PROGESTERONE 2
COMBINATION 3
OTHER HRT 4

SPECIFY: _____

b. What are the main reasons you are taking hormone replacement therapy? Is it for:

		YES	NO	
i.	Menopause related symptoms (the change, hot flashes, vaginal dryness, sweating)	1	2	
ii.	Depression, anxiety or emotional distress	1	2	
iii.	Replacement after hysterectomy or removal of ovaries	1	2	
iv.	Osteoporosis, or to prevent or treat bone loss	1	2	
v.	Prevention of heart disease	1	2	
vi.	Irregular menstrual periods (spotting)	1	2	
vii.	Other reason	1	2	**(E12a)**

SPECIFY: _____

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E12a. Since your (MONTH) study visit, have you taken any medication for blood pressure or your heart, such as Amiodarone, Quinidine, Verapamil, etc.? **SHOW PARTICIPANT RESPONSE CARD D4b. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12b. Since your (MONTH) study visit, have you taken any medication to lower your cholesterol, tryglyceride, or blood lipid level, such as Lipitor, Pravachol, Zocor, etc.? **SHOW PARTICIPANT RESONSE CARD D4c. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12c. Since your (MONTH) study visit, have you taken any medication to lower your blood sugar, such as insulin injections, Precose, Diabinese, Glucotrol, etc.? **SHOW PARTICIPANT RESPONSE CARD D4d. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12d. Since your (MONTH) study visit, have you taken any medication to prevent or treat osteoporosis, such as Fosamax, Evista, etc.? **SHOW PARTICIPANT RESPONSE CARD D4e. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12e. Since your (MONTH) study visit, have you taken any medication for seizures, such as Tegretol, Dilantin, Phenobarbital, Depakote, etc.? **SHOW PARTICIPANT RESPONSE CARD D4f. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12f. Since your (MONTH) study visit, have you taken any medication for psychological conditions or depression, such as Zyprexa, Zoloft, Celexa, etc.? **SHOW PARTICIPANT RESPONSE CARD D4g. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12g. Since your (MONTH) study visit, have you taken any medication for HIV lipodystrophy or body fat changes related to HIV, such as growth hormones or steroids? **SHOW PARTICIPANT RESPONSE CARD D4i. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12h. Since your (MONTH) study visit, have you taken any medication for breathing or lung problems, such as Singulair, monteleukast, Accolate, zafirlukast, Zyflo, zileutin, Theodur, theophylline, Slo-phyllin, Slo-bid, or Aerolate? **SHOW PARTICIPANT RESPONSE CARD D4k. IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E12i. Since your (MONTH) study visit, have you taken any other **prescribed** medications **not** previously mentioned? **IF "YES," RECORD MEDICATION IN QUESTION E13a.**

E13. ENTER THE TOTAL NUMBER OF OTHER PRESCRIPTION MEDICATIONS THE PARTICIPANT REPORTS TAKING IN QUESTIONS E12a – E12i: |___|___|

PROMPT: IF E13 = 0, SKIP TO SECTION F. IF E13 ≥ 1, LIST MEDICATIONS IN COLUMN a ON PAGE 16 AND COMPLETE COLUMNS b AND c FOR EACH MEDICATION.

PROMPT: PHOTOCOPY PAGE 16 AND INSERT IF PARTICIPANT REPORTS USING MORE THAN 7 OTHER PRESCRIPTION MEDICATIONS.

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START F22MEDS6

a. Specify Drug Name	b. Have you taken this in the past 5 days? **YES** **NO**	c. INTERVIEWER, RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.
Name of drug:	1 2	Self report....1 Participant brought written list to visit....2 Participant brought medication bottles to visit....3 Participant brought pharmacy record to visit....4 Record obtained directly from pharmacy....5 Other....6 SPECIFY: ________________________
Name of drug:	1 2	Self report....1 Participant brought written list to visit....2 Participant brought medication bottles to visit....3 Participant brought pharmacy record to visit....4 Record obtained directly from pharmacy....5 Other....6 SPECIFY: ________________________
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Name of drug:	1 2	Self report....1 Participant brought written list to visit....2 Participant brought medication bottles to visit....3 Participant brought pharmacy record to visit....4 Record obtained directly from pharmacy....5 Other....6 SPECIFY: ________________________

END F22MEDS6

WIHS ID#

SECTION F. ALTERNATIVE / COMPLEMENTARY MEDICATION USE

F1. **PROMPT: HAND PARTICIPANT RESPONSE CARD D5.**

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

a. Since your (MONTH) study 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 G3)**

START F22MEDS5

b. Please name those complementary and alternative medications that you have taken. **PROMPT: CHECK THE COMPLEMENTARY/ALTERNATIVE MEDICATION(S) NAMED. SPECIFY THOSE NOT LISTED 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	
629 ___	**Homeopathic remedies**	1	2	Y	N	
	Nutritional supplements (such as vitamins or 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	

PROMPT: HAND PARTICIPANT RESPONSE CARD D6. REASONS FOR TAKING COMPLEMENTARY/ALTERNATIVE MEDICATIONS:

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

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Treatments			Frequency of Use: Every or almost every day	Frequency of Use: Only as needed	Currently taking?	MAIN reason for taking?
	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	
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	
Specify:		➔Drug code: |__|__|__|	1	2	Y N	

PROMPT: HAND PARTICIPANT RESPONSE CARD D6. REASONS FOR TAKING COMPLEMENTARY/ALTERNATIVE MEDICATIONS:

01 = to treat or reduce side effects from "standard" medications
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06 = beneficial without causing side effects
07 = standard HIV medications don't work
08 = to gain weight
09 = to lose weight
99 = other

END F22MEDS5

c. ENTER THE TOTAL NUMBER OF ALTERNATIVE/COMPLEMENTARY MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION F1b: |___|___|

G3. TIME MODULE ENDED: |__|__| : |__|__| AM.....1
PM.....2