

WIHS ID#

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. 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 ___ ***Epivir** (lamivudine, 3-TC)
- 218 ___ Ziagen (abacavir, 1592U89)
- 092 ___ Retrovir (AZT, zidovudine, ZDV)
- 227 ___ Combivir (AZT + 3TC)
- 159 ___ Zerit (stavudine, d4T)
- 094 ___ Hivid (dideoxycytidine, zalcitabine, ddC)
- 147 ___ Videx / Videx EC (dideoxyinosine, didanosine, ddl)
- 240 ___ Trizivir (abacavir + AZT + 3TC)
- 234 ___ ***Viread** (tenofovir, bis-POC-PMPA)
- 239 ___ ***Emtriva** (Coviracil, emtricitabine, FTC)

Non-nucleoside RTIs

- 194 ___ Rescriptor (delavirdine, U-90)
- 220 ___ Sustiva (efavirenz, DMP266)
- 191 ___ Viramune (nevirapine)

Protease Inhibitors

- 219 ___ Agenerase (amprenavir, 141W94)
- 212 ___ Crixivan (indinavir)
- 217 ___ Kaletra (lopinavir/ritonavir, ABT-378/r)
- 216 ___ Viracept (nelfinavir)
- 211 ___ Norvir (ritonavir)
- 210 ___ Invirase or Fortovase (saquinavir)
- 243 ___ Reyataz (atazanavir, BMS-232632)
- 238 ___ Tipranavir (PNU-140690)
- 249 ___ Lexiva (fosamprenavir)

Entry Inhibitors

- 233 ___ Fuzeon (T-20, enfuviramide, ENF)

Other

- 207 ___ Droxia or Hydrea (hydroxyurea)
- ___ Other antiretroviral(s) (from Drug List 1)

Name of Drug:	
Name of Drug:	

Drug Code: |_|_|_|_|

Drug Code: |_|_|_|_|

END F22MEDS3

***PROMPT: ASK PARTICIPANT IF SHE TAKES [EPIVIR, VIREAD, EMTRIVA] 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.**

PLEASE COMPLETE DRUG FORM 1 FOR EACH MEDICATION MARKED ABOVE IN QUESTION B2A.

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

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

YES1
NO.....2 (GO TO B4)

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

	<u>YES</u>	<u>NO</u>
i. My viral load went up.....	1	2
ii. My CD4 level went down.....	1	2
iii. I was diagnosed with AIDS	1	2
iv. I became sicker, although I wasn't diagnosed with AIDS.....	1	2
v. My doctor recommended I start since my last study visit	1	2
vi. My doctor had previously recommended I start	1	2
vii. I'm pregnant or intend to become pregnant.....	1	2
viii. Other reason.....	1	2

SPECIFY: _____

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

YES1
NO.....2 (GO TO B5)

a. Why did you change your antiretroviral medications? CIRCLE YES FOR ALL THAT APPLY.

	<u>YES</u>	<u>NO</u>
i. My viral load went up.....	1	2
ii. My CD4 level went down.....	1	2
iii. I was diagnosed with AIDS	1	2
iv. I became sicker, although I wasn't diagnosed with AIDS.....	1	2
v. My doctor recommended I change since my last visit.....	1	2
vi. My doctor had previously recommended I change.....	1	2
vii. I was having side effects I couldn't tolerate	1	2
viii. I'm pregnant or intend to become pregnant.....	1	2
ix. To make other medications I take more effective.....	1	2
x. Other reason.....	1	2

SPECIFY: _____

B5. Sometimes patients stop taking all of their antiretroviral medications for planned or prescribed periods of time to try to boost their immune systems. These therapy breaks, also called structured treatment interruptions, are very different from any therapy breaks that were not planned or prescribed, such as forgetting to take your medications, running out of pills, or simply taking a break because you felt like you needed one. In the next series of questions, I want to know **only** about any breaks in your antiretroviral medications that you have taken in the past three months that were **planned by you** or **prescribed by your provider**.

a. In the past three months, was there a **planned** or **prescribed** period of time when you stopped taking **all** of your antiretroviral medications for at least two consecutive days?

YES1
 NO2 (GO TO B6)

b. How many **planned** breaks in your antiretroviral therapy did you take over the past three months? # BREAKS

c. Were these planned breaks prescribed by your doctor or health care provider?

YES1
 NO2 (GO TO B5e)

d. What was the main reason that your doctor or health care provider told you to interrupt your treatment? **CIRCLE ONLY ONE ANSWER.**

- To strengthen your immunity to HIV1
- Because your viral load was going up or your CD4 count was falling2
- Because you were having side effects3
- Because you were pregnant4
- Because you had another illness5
- Other reason6

SPECIFY: _____

e. When was the last time that you interrupted or took a planned break in all of your antiretroviral medications for at least two days? I just need to know the month. **INTERVIEWER FILL IN YEAR.**

____ / ____
 M Y

f. During this last therapy interruption in (MONTH), how long did you go without taking any of your antiretroviral medications? You can tell me in days or weeks, whichever is easiest for you.

DAYS1
 WEEKS2

B6. Now I am going to ask you about any therapy breaks you may have taken that were **unplanned**.

a. In the past three months, was there a time when you took any **unplanned** breaks in all of your prescribed antiretroviral therapy for at least one full day?

YES1
 NO2 (GO TO B7)

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b. How many **unplanned** breaks in your antiretroviral therapy did you take over the past three months? |_|_|
#BREAKS

c. When was the last time that you skipped or took an unplanned break in all your antiretroviral medications for at least one full day? I just need to know the month.
INTERVIEWER FILL IN YEAR.

_ _ / _ _
M Y

d. During this last unplanned therapy break in (MONTH), how long did you go without taking any of your antiretroviral medications? You can tell me in days or weeks, whichever is easiest for you.

|_|_| DAYS1
WEEKS2

For the remaining questions, I want you to focus on how you have taken your medications over the past six months.

B7. a. In general, over the past six months, how often did you take your antiretrovirals as prescribed?

- 100% of the time1 **(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 medications5

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
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)

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.

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)

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)**

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

- | | |
|--|--|
| 112 ___ Bactrim (Septra, TMP/SMX) | 127 ___ Nizoral (ketoconazole) |
| 184 ___ Biaxin (clarithromycin) | 144 ___ Nystatin (Mycostatin) |
| 153 ___ Cipro (ciprofloxacin) | 228 ___ Oxandrin (oxandralone) |
| 113 ___ Dapsone | 702 ___ Prednisone (Deltasone) |
| 116 ___ Diflucan (fluconazole) | 182 ___ PZA (pyrazinamide) |
| 213 ___ *Famvir (famcyclovir) | 235 ___ *Rebetron (Ribavirin & Interferon alfa-2b) |
| 138 ___ INH (isoniazid) | 093 ___ Rifabutin (mycobutin) |
| 154 ___ Lamprene (clofazimine) | 139 ___ Rifadin (rifampin) |
| 190 ___ Mepron (atovaquone) | 169 ___ Sporanox (itraconazole) |
| 540 ___ Methadone | 230 ___ Terazol (terconazole) |
| 229 ___ Monistat (miconazole) | 198 ___ Valtrex (valacyclovir) |
| 137 ___ Myambutol (ethambutol) | 152 ___ Zithromax (azithromycin) |
| 145 ___ Mycelex or Lotrimin (clotrimazole) | 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.

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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)
- 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)

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.

SECTION E. OTHER PRESCRIPTION MEDICATION USE

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

	<u>YES</u>	<u>NO</u>	<u>DON'T KNOW</u>
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. Smallpox	1	2	-8

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E2. Since your (MONTH) study visit, have you taken any medication for blood pressure or your heart?

YES1
NO2 (GO TO E3)

a. How many blood pressure or heart medications are you taking now?

PROMPT: HAND PARTICIPANT RESONSE CARD D4b: HEART AND BLOOD PRESSURE MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
b. Amiodarone (Cordarone, Pacerone)	1	2 (c)	1	2
c. Quinidine (Cardioquin, Quin-Tab, Quinadure, Quinaglute, Quinidex)	1	2 (d)	1	2
d. Verapamil (Calan, Verelan, Covera, Isoptin)	1	2 (e)	1	2
e. Diltiazem (Cardizem, Cartia, Dilacor, Tiamate, Tiazac)	1	2 (f)	1	2
f. Nicardipine (Cardene)	1	2 (g)	1	2
g. Nifedipine (Procardia, Adalat)	1	2 (h)	1	2
h. Felodipine (Plendil)	1	2 (E3)	1	2

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E3. Since your (MONTH) study visit, have you taken any medication to lower your cholesterol, tryglyceride, or blood lipid level?

YES1
 NO2 (GO TO E4)

PROMPT: HAND PARTICIPANT RESONSE CARD D4c: CHOLESTEROL MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Lescol (Fluvastatin)	1	2 (b)	1	2
b. Lipitor (Atorvastatin)	1	2 (c)	1	2
c. Mevacor (Lovastatin)	1	2 (d)	1	2
d. Pravachol (Pravastatin)	1	2 (e)	1	2
e. Zocor (Simvastatin)	1	2 (f)	1	2
f. Lipid (Gemfibrozil)	1	2 (g)	1	2
g. TriCor (Fenofibrate)	1	2 (h)	1	2
h. Colestid (Colestipol)	1	2 (i)	1	2
i. Questran (Cholestyramine)	1	2 (j)	1	2
j. Welchol (Colesevelam)	1	2 (k)	1	2
k. Niaspan (Niacin)	1	2 (E4)	1	2

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E4. Since your (MONTH) study visit, have you taken any medication to lower your blood sugar?

YES1
 NO.....2 **(GO TO E5)**

PROMPT: HAND PARTICIPANT RESONSE CARD D4d: BLOOD SUGAR MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Insulin (injection)	1	2 (b)	1	2
b. Acarbose (Precose)	1	2 (c)	1	2
c. Chlorpropamide (Diabinese)	1	2 (d)	1	2
d. Glimepiride (Amaryl)	1	2 (e)	1	2
e. Glipizide (Glucotrol)	1	2 (f)	1	2
f. Glyburide (Micronase, Diabeta)	1	2 (g)	1	2
g. Metformin (Glucophage)	1	2 (h)	1	2
h. Miglitol (Glyset)	1	2 (i)	1	2
i. Orlistat (Xenical)	1	2 (j)	1	2
j. Pioglitazone (Actos)	1	2 (k)	1	2
k. Repaglinide (Prandin)	1	2 (l)	1	2
l. Rosiglitazone (Avandia)	1	2 (m)	1	2
m. Starlix (Nateglinide)	1	2 (E5)	1	2

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E5. Since your (MONTH) study visit, have you taken any medication to prevent or treat osteoporosis?

YES.....1
NO.....2 (GO TO E6)

PROMPT: HAND PARTICIPANT RESONSE CARD D4e: OSTEOPOROSIS MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Vitamin D supplements	1	2 (b)	1	2
b. Calcium supplements	1	2 (c)	1	2
c. Estrogen replacement therapy	1	2 (d)	1	2
d. Fosimax (Alendronate)	1	2 (e)	1	2
e. Evista (Raloxifene)	1	2 (f)	1	2
f. Forteo (Teriparatide)	1	2 (E6)	1	2

E6. Since your (MONTH) study visit, have you taken any medication for seizures?

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

PROMPT: HAND PARTICIPANT RESONSE CARD D4f: SEIZURE MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Tegretol (Carbamazepine)	1	2 (b)	1	2
b. Dilantin (Phenytoin)	1	2 (c)	1	2
c. Felbatol (Felbamate)	1	2 (d)	1	2
d. Mysoline (Primidone)	1	2 (e)	1	2
e. Topamax (Topiramate)	1	2 (f)	1	2
f. Mebaral (Mephobarbital)	1	2 (g)	1	2
g. Phenobarbital (Luminal, Solfoton)	1	2 (h)	1	2
h. Depakote	1	2 (E7)	1	2

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E7. Since your (MONTH) study visit, have you taken any medication for psychological conditions or depression?

YES1
NO2 (GO TO E8)

PROMPT: HAND PARTICIPANT RESONSE CARD D4g: PSYCH MEDICATIONS.

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Zyprexa (Olanzapine)	1	2 (b)	1	2
b. Serzone (Nefezodone)	1	2 (c)	1	2
c. Luvox (Fluvoxamine)	1	2 (d)	1	2
d. Zoloft (Sertraline)	1	2 (e)	1	2
e. Celexa (Citalpram)	1	2 (f)	1	2
f. Depakote	1	2 (E8)	1	2

E8. **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.

ESTROGEN:

Premarin, Estrace, Estratab, Menest, Ogen, Cenestin, Estraderm, Climera

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

YES1
NO2 (GO TO E9)

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a. INTERVIEWERS: BASED ON PARTICIPANT RESPONSE IN E8, CODE BELOW THE TYPE OF HRT PARTICIPANT REPORTED ABOVE:

- ESTROGEN.....1
- PROGESTERONE2
- COMBINATION3
- OTHER HRT4

SPECIFY: _____

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

	<u>YES</u>	<u>NO</u>
i. Menopause related symptoms (the change, hot flashes, vaginal dryness, sweating).....1	1	2
ii. Depression, anxiety or emotional distress1	1	2
iii. Replacement after hysterectomy or removal of ovaries1	1	2
iv. Osteoporosis, or to prevent or treat bone loss.....1	1	2
v. Prevention of heart disease1	1	2
vi. Irregular menstrual periods (spotting)1	1	2
vii. Other reason.....1	1	2 (E9)

SPECIFY: _____

E9. Since your (MONTH) study visit, have you been treated with radioactive iodine or any other medication for an overactive thyroid (hyperthyroidism)?

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

PROMPT: HAND PARTICIPANT RESPONSE CARD D4i: HYPERTHYROID MEDICATIONS

Did these include any of the following:	i) Have you taken this in the past 6 months?		ii) Have you taken this in the past 5 days?	
	YES	NO	YES	NO
a. Propylthiouracil (PTU)	1	2 (b)	1	2
b. Beta blockers (propranolol, Inderal)	1	2 (c)	1	2
c. Methimazole (Tapazole)	1	2 (d)	1	2
d. Radioactive iodine (RAI)	1	2 (E10)	1	2

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E10. Since your (MONTH) study visit, have you taken any other **prescribed** medications **not** previously mentioned?

YES1
 NO2 **(GO TO SECTION F)**

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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 visit4 Record obtained directly from pharmacy5 Other6 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 visit4 Record obtained directly from pharmacy5 Other6 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 visit4 Record obtained directly from pharmacy5 Other6 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 visit4 Record obtained directly from pharmacy5 Other6 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.

YES1
 NO.....2 **(GO TO F5)**

START F22MEDS5

WIHS ID#

b. Please name those complementary and alternative medications that you have taken.

PROMPT: CHECK THE COMPLEMENTARY AND/OR 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		Currently taking?		MAIN reason for taking?
		Every or almost every day	Only as needed			
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	
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: <input type="text"/>	1	2	Y	N	
Specify:	→Drug code: <input type="text"/>	1	2	Y	N	
Specify:	→Drug code: <input type="text"/>	1	2	Y	N	
Specify:	→Drug code: <input type="text"/>	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

- 05 = for general health
- 06 = beneficial without causing side effects
- 07 = standard HIV medications don’t work
- 99 = other

END F22MEDS5

F2. Who prescribes or guides your use of these alternative medications? **CIRCLE ONE ANSWER ONLY.**

- Primary care provider (non-C/A practitioner)1 (GO TO F5)
- Self-medicated2
- Complementary/Alternative practitioner
(homeopath, herbalist, naturopath)3
- Health store staff4
- Other5

F3. Have you discussed your use of this medication with your primary care provider?

- YES1 (GO TO F5)
- NO2
- DON'T HAVE A PRIMARY CARE PROVIDER3 (GO TO F5)

F4. **PROMPT: HAND PARTICIPANT RESPONSE CARD D7.**

What is the **main** reason you have not told him/her? **CIRCLE ONE ANSWER ONLY.**

- He/she didn't ask1
- I didn't think it was important2
- I don't think he/she would approve of its use3
- I think he/she would ask me to stop taking it4
- He/she is not knowledgeable about alternative
medications5
- Other6

F5. In the last six months, have you eaten powdered cornstarch for your health?

- YES1
- NO2 (GO TO SECTION G)

a. On average how often do you eat cornstarch?

- Daily1
- Once a week2
- Several times a month3
- Once a month4
- Less than once a month5

b. When you eat cornstarch, how much do you consume?

- One tablespoon or less1
- Several tablespoons to 1/4 of a cup2
- 1/4 of a cup to one cup3
- More than one cup4

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SECTION G. SYMPTOMS

G1. 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 (MONTH) study 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 PARTICIPANT IS NOT TAKING ANY PRESCRIBED OR ALTERNATIVE MEDICATIONS, CODE SUBQUESTIONS i AND ii AS “N/A.”

Since your (MONTH) study visit, have you had...						Do you feel that this symptom was a side effect of your...					
	Not at all	Not bad	Bad	Very bad	Terrible	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. Chills	0 (d)	1	2	3	4	Y	N	N/A	Y	N	N/A
d. Rash	0 (e)	1	2	3	4	Y	N	N/A	Y	N	N/A
e. Lack of appetite	0 (f)	1	2	3	4	Y	N	N/A	Y	N	N/A
f. Drowsiness / tiredness	0 (g)	1	2	3	4	Y	N	N/A	Y	N	N/A
g. Nausea and/or vomiting	0 (h)	1	2	3	4	Y	N	N/A	Y	N	N/A
h. Pain / tingling in feet or hands	0 (i)	1	2	3	4	Y	N	N/A	Y	N	N/A
i. Dizziness or lack of concentration	0 (j)	1	2	3	4	Y	N	N/A	Y	N	N/A
j. Muscle aches or pains	0 (k)	1	2	3	4	Y	N	N/A	Y	N	N/A
k. Abdominal pains or cramps	0 (l)	1	2	3	4	Y	N	N/A	Y	N	N/A
l. Kidney stones	0 (m)	1	2	3	4	Y	N	N/A	Y	N	N/A
m. Dry mouth	0 (n)	1	2	3	4	Y	N	N/A	Y	N	N/A
n. Shifting of your body fat	0 (o)	1	2	3	4	Y	N	N/A	Y	N	N/A
o. Diarrhea	0 (p)	1	2	3	4	Y	N	N/A	Y	N	N/A
p. Constipation	0 (q)	1	2	3	4	Y	N	N/A	Y	N	N/A
q. Low red blood cell count (anemia)	0 (r)	1	2	3	4	Y	N	N/A	Y	N	N/A
r. Low white blood cell count (leukopenia)	0 (s)	1	2	3	4	Y	N	N/A	Y	N	N/A
s. Other: _____	0 (G2)	1	2	3	4	Y	N	N/A	Y	N	N/A
t. Other: _____	0 (G2)	1	2	3	4	Y	N	N/A	Y	N	N/A

WIHS ID#

G2. PROMPT: HAND PARTICIPANT RESONSE CARD 12.

I am going to read to you some things people say about HIV. Please tell me if you strongly agree, agree, if you are uncertain, or if you disagree or strongly disagree.

	<u>STRONGLY</u> <u>AGREE</u>	<u>AGREE</u>	<u>UNCERTAIN</u>	<u>DISAGREE</u>	<u>STRONGLY</u> <u>DISAGREE</u>
a. HIV is no longer the threat it used to be	1	2	3	4	5
b. A person with a higher viral load is more likely to pass HIV to sexual partners if she has unprotected sex	1	2	3	4	5
c. Because of combination drug treatments for HIV, I am less concerned about getting HIV or infecting someone else	1	2	3	4	5
d. Being on combination drug treatments decreases a person's chances of giving HIV to other people	1	2	3	4	5
e. People who are sicker because of their HIV are more likely to pass the virus on to others	1	2	3	4	5
f. HIV is now a controllable disease, like diabetes	1	2	3	4	5
g. People who always take their combination drug treatments as prescribed are less likely to pass HIV to sexual partners than those who do not take their drugs as prescribed.....	1	2	3	4	5
h. Because of the new combination drug treatments, fewer people in the future will be infected with HIV	1	2	3	4	5
i. Because of the new combination drug treatments, fewer women will give HIV to their babies during pregnancy and childbirth.....	1	2	3	4	5

G3. TIME MODULE ENDED:

□□ : □□

AM 1

PM 2