

**WOMEN'S INTERAGENCY HIV STUDY
FORM 22 MED: MEDICATION HISTORY**

SECTION A: GENERAL INFORMATION

- A1. PARTICIPANT ID: ENTER NUMBER HERE ONLY IF ID LABEL IS NOT AVAILABLE |_|-|_|_|-|_|_|_|_|-|_|
- A2. WIHS STUDY VISIT #: |_|_|
- A3. FORM VERSION: **04/01/10**
- 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: REVIEW QXQS FOR INSTRUCTIONS ON HOW TO COLLECT ARV DATA.

PROMPT: HAND PARTICIPANT ANTIRETROVIRAL PHOTO MEDICATION CARDS.

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 + Efavirenz)
- 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)
- 092 ___ Retrovir (AZT, zidovudine, ZDV)
- 147 ___ Videx / Videx EC (didanosine, ddI)
- 234 ___ ***Viread** (tenofovir)
- 159 ___ Zerit (stavudine, d4T)
- 218 ___ Ziagen (abacavir)

Integrase Inhibitors

- 264 ___ ISENTRESS (raltegravir, MK 0518)

Non-Nucleoside RTIs

- 255 ___ Intelence (etravirine, TMC 125)
- 194 ___ Rescriptor (delavirdine)
- 220 ___ Sustiva (efavirenz)
- 191 ___ Viramune (nevirapine)

Protease Inhibitors

- 238 ___ Aptivus (tipranavir)
- 212 ___ Crixivan (indinavir)
- 210 ___ Invirase (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 "other" antiviral: |
| Specify name of "other" antiviral: |

→ Drug Code: |_|_|_|_|

→ Drug Code: |_|_|_|_|

END F22MEDS3

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

b. PARTICIPANT HAS NOT TAKEN ANY ART SLV1 (B10)
 PARTICIPANT HAS TAKEN AT LEAST ONE ART SLV2

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

WIHS ID#

B3. FROM VCS AND DSG, HAS PARTICIPANT STARTED ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT?

YES1
NO2 (B4)

a. Is this the first time you have taken any antiretroviral medications(s)?

YES1
NO2 (B4)

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

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

SPECIFY: _____

B4. FROM VCS AND DSG, HAS PARTICIPANT CHANGED OR STOPPED ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT?

YES1
NO2 (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 antiretroviral medicines:

| | <u>YES</u> | <u>NO</u> |
|--|------------|-----------|
| 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 |
| i. My medicines were too complicated to take, or there were too many pills, or they were hard to swallow | 1 | 2 |

| | <u>YES</u> | <u>NO</u> |
|--|------------|---------------|
| 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. In general, over the past six months, how often did you take your antiretrovirals as prescribed?

| | |
|--|----------------------|
| 100% of the time..... | 1 (SECTION C) |
| 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. Since your (MONTH) study visit, how often have you missed taking your antiretroviral medications because you...

| | <u>Never</u> | <u>Rarely</u> | <u>Sometimes</u> | <u>Often</u> |
|---|--------------|---------------|------------------|--------------|
| 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 |

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| | <u>Never</u> | <u>Rarely</u> | <u>Sometimes</u> | <u>Often</u> |
|--|--------------|---------------|------------------|--------------|
| 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: _____

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 low2
- I feel too healthy3
- 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 resistance9
- I'm having a baby10
- Personal decision to wait11
- They didn't work for my friends.....12
- Liver problems14
- Any other reason.....13

SPECIFY: _____

SECTION C. OI MEDICATION HISTORY

START F22MEDS4

C1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4.

- a. Since your (MONTH) study visit, have you taken the following inhaled medication?
114 ___ Pentamidine (aerosolized)

- 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) or **Interferon alfa-2a** (Roferon-A)
124 ___ Amphotericin B (Ampho B)
242 ___ ***Pegylated interferon** (PEGASYS, PEG-Intron, Peginterferon alfa-2a, Peginterferon alfa-2b)

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

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

- i. PARTICIPANT HAS NOT TAKEN ANY MEDS IN C1a, C1b OR C1c.....1 (SECT. D)
 PARTICIPANT HAS TAKEN AT LEAST ONE MED IN C1a, C1b OR C1c2

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:

WIHS ID#

[Empty box for WIHS ID#]

SECTION D. HEPATITIS MEDICATION HISTORY

START F22MEDS9

D1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4a.

a. Since your (MONTH) study visit, have you taken any of the following medications for Hepatitis B or C?

- 090 ___ Interferon alfa-2b (Intron A) or Interferon alfa-2a (Roferon-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. PARTICIPANT HAS NOT TAKEN **ANY** MEDS IN D1a.....1 (SECT. E)
 PARTICIPANT HAS TAKEN **AT LEAST ONE** MED IN D1a.....2

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?

| | <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. HPV (human papillomavirus)..... | 1 | 2 | -8 |

WIHS ID#

[Empty box for WIHS ID#]

PROMPT: IF ODD-NUMBERED VISIT (E.G., 31, 33, ETC.), SKIP TO QUESTION E11.

E2. During the last flu season, did you get the **regular** flu vaccine?

YES 1 (b)

NO 2

a. What was the reason you did not get the **regular** flu vaccine?

_____ (E3)

b. Which type of **regular** flu vaccine did you have?

Flu shot 1

Nose spray 2

c. When did you receive the **regular** flu vaccine?

____|____| / |____|____|____|____|
M Y

d. Where did you receive the **regular** flu vaccine?

At the WIHS/MACS clinic 1

A doctor's office other than the WIHS/MACS clinic 2

Hospital 3

Health Department 4

Supermarket, grocery store, or a superstore like Wal-Mart 5

Pharmacy, like CVS, Walgreens or Rite Aid 6

Other place 7

SPECIFY: _____

PROMPT: IF A PARTICIPANT DESCRIBES RECEIVING THE VACCINATION AT THE TARGET PHARMACY OR CLINIC, PLEASE CLASSIFY THE LOCATION AS "SUPERMARKET, GROCERY STORE, OR SUPERSTORE, LIKE WAL-MART." IF YOU HAVE A QUESTION REGARDING HOW TO CLASSIFY THE LOCATION OF THE VACCINATION, SELECT "OTHER" AND SPECIFY THE LOCATION.

E3. During the last flu season, did you get the **H1N1** flu vaccine?

YES 1 (b)

NO 2

a. What was the reason you did not get the **H1N1** flu vaccine?

_____ (E4)

b. Which type of **H1N1** flu vaccine did you have?

Flu shot 1

Nose spray 2

WIHS ID#

[Empty box for WIHS ID#]

c. When did you receive the **H1N1** flu vaccine?

____/____/____
M Y

d. Where did you receive the **H1N1** flu vaccine?

- At the WIHS/MACS clinic1
- A doctor’s office other than the WIHS/MACS clinic.....2
- Hospital3
- Health Department4
- Supermarket, grocery store, or a superstore like Wal-Mart.....5
- Pharmacy, like CVS, Walgreens or Rite Aid.....6
- Other place7

SPECIFY: _____

PROMPT: IF A PARTICIPANT DESCRIBES RECEIVING THE VACCINATION AT THE TARGET PHARMACY OR CLINIC, PLEASE CLASSIFY THE LOCATION AS “SUPERMARKET, GROCERY STORE, OR SUPERSTORE, LIKE WAL-MART.” IF YOU HAVE A QUESTION REGARDING HOW TO CLASSIFY THE LOCATION OF THE VACCINATION, SELECT “OTHER” AND SPECIFY THE LOCATION.

Now I’m going to ask you about having the flu. Common symptoms of the flu are a high fever and a bad cough. Some people also have muscle or body aches, sore throat and runny or stuffy nose when they have the flu. Some people were who were sick with the H1N1 flu have also reported vomiting and diarrhea. The flu is different from a cold; however it can be difficult to tell the flu from a cold. In general, flu symptoms are much worse and last longer than cold symptoms. The flu can last a few days to a week or longer.

The H1N1 flu started making people sick in May of 2009, so for these questions about flu illness, please think about your flu illness experiences during the summer of 2009 (May through August 2009) and during last flu season.

E4. During the summer of 2009 or the last flu season, did you have any of the following flu symptoms?

| | <u>YES</u> | <u>NO</u> |
|--------------------------------------|------------|-----------|
| a. Fever | 1 | 2 |
| b. Dry cough..... | 1 | 2 |
| c. Sore throat..... | 1 | 2 |
| d. Muscle or body aches..... | 1 | 2 |
| e. Nausea, vomiting or diarrhea..... | 1 | 2 |
| f. Headache..... | 1 | 2 |

PROMPT: IF THE PARTICIPANT RESPONDS “NO” TO ALL SYMPTOMS, GO TO QUESTION E9.

g. What was the date of your worst flu symptoms?

____/____/____
M Y

WIHS ID#

E5. Did you go to the emergency room because you had flu symptoms?

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

E6. Did you talk to a health care provider on the phone or during a clinic visit because you had flu symptoms?

YES.....1
NO.....2 (E9)

E7. Were you **told** by a health care provider that you had the flu?

YES.....1
NO.....2 (E9)

a. Did the health care provider tell you it was **H1N1** flu that made you sick?

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

b. Were you admitted to a hospital because you had the flu?

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

E8. When you had the flu, how many days were you not able to do your usual activities or how many days of work did you miss?

DAYS

E9. Now I am going to ask you about some of your beliefs about the **regular** flu vaccine and illness. I am asking for your personal opinions and beliefs, so please answer the questions honestly. There are no right answers. Please answer these questions with regard to your personal opinions and beliefs **today**. 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 regular flu shot protects me from getting the flu. | 1 | 2 | 3 | 4 | 5 |
| b. The regular flu shot made me sick in the past. | 1 | 2 | 3 | 4 | 5 |
| c. I do not like to be stuck by needles during my health care visits. | 1 | 2 | 3 | 4 | 5 |
| d. I do not believe the regular flu can cause serious illness for me. | 1 | 2 | 3 | 4 | 5 |
| e. I do not think I am at high risk for catching the regular flu. | 1 | 2 | 3 | 4 | 5 |
| f. I do not trust the medicine in the regular flu shot. | 1 | 2 | 3 | 4 | 5 |
| g. I do not think the regular flu shot is safe. | 1 | 2 | 3 | 4 | 5 |

h. During the last flu season, did you have a discussion with a health care provider about receiving the **regular** flu vaccine?

- YES1
- NO, and I spoke to my provider during last flu season3 (i)
- NO, but I did not speak to my provider during last flu season4 (i)

1. During that discussion, did your health care provider want you to receive the **regular** flu vaccine?

- YES1
- NO.....2

i. Do you think your beliefs about the **regular** flu vaccine changed during the last flu season?

- YES1
- NO.....2 (E10)

1. Which statement best describes your beliefs about the **regular** flu vaccine at the **beginning** of the last flu season?

- I did not believe I should get the regular flu vaccine.....1
- I did not have a belief about whether or not to get the regular flu vaccine ...2
- I believed I should get the regular flu vaccine3

2. Which statement best describes your beliefs about the **regular** flu vaccine at the **end** of the last flu season?

- I did not believe I should get the regular flu vaccine.....1
- I did not have a belief about whether or not to get the regular flu vaccine ...2
- I believed I should get the regular flu vaccine3

E10. Now I am going to ask you about some of your beliefs about the **H1N1** flu vaccine and illness. Again, I am asking for your personal opinions and beliefs, so please answer the questions honestly. There are no right answers. Please answer these questions with regard to your personal opinions and beliefs **at the end of the last flu season**. 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 H1N1 flu shot protected me from getting the flu. | 1 | 2 | 3 | 4 | 5 |
| b. The H1N1 flu shot made me sick. | 1 | 2 | 3 | 4 | 5 |
| c. I did not believe the H1N1 flu could cause serious illness for me. | 1 | 2 | 3 | 4 | 5 |
| d. I did not think I was at high risk for catching the H1N1 flu. | 1 | 2 | 3 | 4 | 5 |
| e. I did not trust the medicine in the H1N1 flu shot. | 1 | 2 | 3 | 4 | 5 |
| f. I did not think the H1N1 flu shot was safe. | 1 | 2 | 3 | 4 | 5 |

g. During the last flu season, did you have a discussion with a health care provider about receiving the **H1N1** flu vaccine?

- YES1
- NO, and I spoke to my provider during last flu season2 **(h)**
- NO, but I did not speak to my provider during last flu season3 **(h)**

1. During that discussion, did your health care provider want you to receive the **H1N1** flu vaccine?

- YES1
- NO.....2

h. Do you think your beliefs about the **H1N1** flu vaccine changed during the last flu season?

- YES1
- NO.....2 **(E11)**

1. Which statement best describes your beliefs about the **H1N1** flu vaccine at the **beginning** of the last flu season?

- I did not believe I should get the H1N1 flu vaccine1
- I did not have a belief about whether or not to get the H1N1 flu vaccine2
- I believed I should get the H1N1 flu vaccine3

2. Which statement best describes your beliefs about the **H1N1** flu vaccine at the **end** of the last flu season?

- I did not believe I should get the H1N1 flu vaccine1
- I did not have a belief about whether or not to get the H1N1 flu vaccine2
- I believed I should get the H1N1 flu vaccine3

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)

YES1
 NO2 **(E12a)**

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

ESTROGEN1
 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 reason1 | 1 | 2 (E12a) |

SPECIFY: _____

WIHS ID#

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.**

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

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

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

E12c. (Since your (MONTH) study visit), have you taken any medication to lower your blood sugar, such as insulin injections or any oral medications? **SHOW PARTICIPANT RESPONSE CARD D4d. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

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

E12d. (Since your (MONTH) study visit), have you taken any medication to prevent or treat osteoporosis or fracture, such as calcium or vitamin D supplements, hormone replacement therapy, or bisphosphonates (e.g., Fosamax, Actonel, Reclast, Boniva, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4e. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**

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

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.**

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

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.**

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

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.**

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

WIHS ID#

[Empty box for WIHS ID#]

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.**

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

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

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

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” AND COMPLETE COLUMNS “b” AND “c” FOR EACH MEDICATION.

PROMPT: PHOTOCOPY PAGE 12 AND INSERT IF PARTICIPANT REPORTS USING MORE THAN 10 OTHER PRESCRIPTION MEDICATIONS.

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: _____ |
| 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: _____ |

WIHS ID#

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

PROMPT: HAND PARTICIPANT RESPONSE CARD D5.

- 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)

WIHS ID#

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

PROMPT: CIRCLE THE DRUG CODE FOR CAM NAMED. SPECIFY THOSE NOT LISTED UNDER "OTHER" AND FILL IN THE THREE-DIGIT DRUG CODE FROM DRUG LIST 3.

START F22MEDS5

| Treatments | i. Frequency of Use | | ii. Currently Taking | | iii. MAIN Reason for Taking | |
|------------|--|----------------|----------------------|----|-----------------------------|-----|
| | Every or Almost Every Day | Only as Needed | YES | NO | | |
| 602 | Acidophilus | 1 | 2 | 1 | 2 | ___ |
| 607 | B-complex | 1 | 2 | 1 | 2 | ___ |
| 608 | B-vitamins (B1 thiamine, B2 riboflavin, B5 pantothenic acid, B6 pyridoxine, B12) | 1 | 2 | 1 | 2 | ___ |
| 612 | C-vitamins (rosehips) | 1 | 2 | 1 | 2 | ___ |
| 646 | Calcium | 1 | 2 | 1 | 2 | ___ |
| 615 | Chinese herbs in combination | 1 | 2 | 1 | 2 | ___ |
| 196 | Co-enzyme Q-10 | 1 | 2 | 1 | 2 | ___ |
| 657 | D-vitamins | 1 | 2 | 1 | 2 | ___ |
| 619 | E-vitamins | 1 | 2 | 1 | 2 | ___ |
| 620 | Echinacea (with or without goldenseal) | 1 | 2 | 1 | 2 | ___ |
| 623 | Folic Acid | 1 | 2 | 1 | 2 | ___ |
| 624 | Garlic | 1 | 2 | 1 | 2 | ___ |
| 652 | Glucosamine/Chondroitin | 1 | 2 | 1 | 2 | ___ |
| 641 | Iron | 1 | 2 | 1 | 2 | ___ |
| 630 | Multi- or Prenatal vitamins / Minerals | 1 | 2 | 1 | 2 | ___ |
| 633 | Omega-3 Type or Fish Oils | 1 | 2 | 1 | 2 | ___ |
| 640 | Zinc | 1 | 2 | 1 | 2 | ___ |
| ___ | Specify: | 1 | 2 | 1 | 2 | ___ |
| ___ | Specify: | 1 | 2 | 1 | 2 | ___ |
| ___ | Specify: | 1 | 2 | 1 | 2 | ___ |
| ___ | Specify: | 1 | 2 | 1 | 2 | ___ |

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

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