## WOMEN'S INTERAGENCY HIV STUDY QUESTION BY QUESTION SPECIFICATIONS FORM 22MED: MEDICATION HISTORY

Guidelines for completing Form 22MED, "Medication History."

#### **General Instructions:**

- **NOTE:** If this form is being administered to the participant AFTER her physical exam, be sure to remind her that the findings from her exam conducted today do NOT apply to the questions you are about to ask her.
- 1. Before beginning this section, interviewers should make sure that they have at least eight blank copies of **Drug Form 1, Drug Form 2** and **Drug Form 3** available in case they are needed.
- 2. Use the form version dated **04/01/04**.
- 3. NOTE: No VRS visits will be conducted during visit 20. Thus all F22hx forms completed during visit 20 should indicate that the interview was administered as part of the "WIHS core visit." Interviewers should indicate on the form whether or not the interview is associated with a participant's regular WIHS visit or a 3-month Viral Resistance Study (VRS) visit. In the general information section at the beginning of the form, there is a place to indicate "WIHS Core Visit" or "3 Month VRS Visit." The appropriate visit type should be selected and the corresponding number circled. If there is any confusion as to what type of visit the participant is attending, interviewers should bring this to the attention of the project director for clarification before circling the appropriate response on the form.
- 4. All dates should be recorded in the MM/DD/YY format unless otherwise noted. For dates that must be completed on the form, if the participant cannot remember the exact month (and day), probe for the season. Use "15" for the day if the specific day cannot be recorded. Probe for the season and assign the month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have available an appropriate calendar to aid the participant in determining dates. Years in response to questions inquiring about occurrences "since last visit" should be 1995 and thereafter.

- 5. Times should be recorded in the HH:MM format. Remember to use leading zeros, e.g., 08:00.
- 6. For questions containing an open-ended specify box linked to the response "other," interviewers should <u>print</u> responses exactly in the words of the respondent.
- 7. Obtain the date of the participant's previous visit from the Visit Control Sheet (VCS). The month in this date should be used in the questions wherever (MONTH) appears. For both WIHS core visits and 3-month VRS visits, enter the date of the participant's **last completed core visit**, regardless of whether she has attended an interim VRS visit.
- 8. Interviewers SHOULD IGNORE the three-digit numbers listed next to each box in Questions B2a, C1a-C1c, D1a and F1b. These numbers are necessary for data entry, but should be ignored during the actual interview. Additionally, interviewers should ignore any markings related to data entry such as "START F22MEDS3." These indicators mark the beginning and end of all subforms; they have been added for data entry purposes only and will not affect how the form is completed.
- 9. Follow the skip patterns as they appear on the form.

### READ THE INTRODUCTION TO THE PARTICIPANT.

#### SECTION B: ANTIRETROVIRAL HISTORY

The time frame for questions (e.g., last three months, last six months, last three days) shifts a number of times throughout this section. The interviewer should pay particularly close attention to the time frame to which each question refers and stress this time frame to the participant while reading each question.

B1. A vaccine against HIV-1 can include vaccines that prevent infection with HIV or therapeutic vaccines (those that prevent progression of the infection).

# B2. a. HAND THE PARTICIPANT THE CURRENT ANTIRETROVIRAL PHOTO MEDICATION CARDS.

Go through each card with the participant. For EACH medication, ask the participant "Since your (MONTH) study visit, have you taken (DRUG NAME)?" Ensure that, in addition to her prescribed antiretrovirals, she includes all antiretroviral medications that may have been taken as part of a research study, including those in which she may have been blinded (**PROBE:** unaware of whether you were taking the actual medication or a placebo) to the treatment. However, if the participant is HIV-negative, you do not need to read through the entire list of antiretroviral medications and can skip to question **B2b**.

Mark each drug to which the participant responds with a "YES" by placing an "X" in the corresponding box. Do not concern yourself with the three-digit numbers listed next to each box. These numbers are necessary for data entry purposes only.

If the participant reports using one of the three antiretroviral medications marked with "\*" (i.e., Epivir, Viread, Emtriva), the interviewer should read the prompt at the bottom of page 2 to determine how to proceed with form completion. The interviewer should ask the participant if she takes [EPIVIR, VIREAD, EMTRIVA] (read name of appropriate medication only) to treat HIV only, hepatitis (B or C) only, or to treat both HIV and hepatitis.

- If use is for HIV treatment only, interviewer should mark medication in question B2a and proceed with administration of Drug Form 1.
- If use is for hepatitis treatment only, interviewer should mark medication in question D1a only and complete Drug Form 3 at the appropriate point in the interview.
- If use is for HIV <u>and</u> hepatitis treatment (or participant is unsure of reason for use), interviewer should mark medication in both B2a and D1a and complete both a Drug Form 1 and a Drug Form 3.

The antiretroviral drug listing in question **B2a** is not complete. However, it does contain currently used medications to the best of our knowledge. This list is updated every six months. For any other antiretroviral medication used by the participant against HIV-1 that is not on the list in question **B2a**, check *"Other antiretroviral(s)"* and print the name of the drug in the specify box. Check **Drug List 1** to see if it is on this list. If so, record the three-digit code in the space allotted next to the "Specify" box. If the drug is not on Drug List 1, **CHECK THE DRUGS LISTED IN QUESTIONS C1a–C1c** TO SEE IF IT IS ON ONE OF THESE LISTS. If the drug is listed in question **F1b**. Otherwise, bring this to the attention of the clinic coordinator/director. If the drug is not on the coding list, the center's director should contact the coordinator at WDMAC to inquire about the applicability of getting a new drug code assigned. Use the drug code obtained from WDMAC. Complete a **Drug Form 1**.

If a participant indicates that she is taking an antiretroviral medication, but does not know or cannot remember the name of the medication, check "*Other antiretroviral(s)*" and print "unknown" in the specify box. Enter "999" in the space provided for the three-digit drug code. If the participant reports more than one unknown antiretroviral medication, please list them as *unknown1*, *unknown2*, etc., for tracking purposes.

If the participant indicates that she is taking "Combivir," mark the "Combivir" box (code 227). The individual boxes for AZT and 3TC <u>should not</u> be checked. If the participant indicates that she is taking "Trizivir," mark the "Trizivir" box (code 240). The individual boxes for abacavir, AZT and 3TC <u>should not</u> be checked.

For <u>EACH</u> medication reported, complete a **Drug Form 1**. If the participant is taking multiple antiretrovirals, mark each drug and complete a separate **Drug Form 1** for each medication.

#### **EXAMPLES for Participant "X":**

- X is taking AZT, 3TC and ritonavir. Mark the three boxes corresponding to AZT, 3TC and ritonavir and complete a separate **Drug Form 1** for each drug.
- X was taking AZT and ddI. She recently changed her regimen to AZT, ddC and saquinavir. Mark the boxes corresponding to AZT, ddI, ddC and saquinavir and complete a separate **Drug Form 1** for each drug.
- X is in an AZT/ddI/nelfinavir trial, and knows that she is taking AZT and ddI, but is not sure whether she is receiving nelfinavir or a placebo (i.e., she is <u>blinded</u> to the treatment). Complete a separate **Drug Form 1** for each drug. When filling out the drug form related to nelfinavir, be sure to follow the specific directions on **Drug Form 1** for blinded treatments.
- X reports taking lobucavir in a research trial. Mark "*Other antiretroviral*," print "*lobucavir*" in the specify box. Go to **Drug List 1** and get the 3-digit code for lobucavir (222). Write code "222" in the boxes for 3-digit drug code. Fill out a **Drug Form 1** for lobucavir.
- b. If the participant reports that she has not taken <u>any</u> antiretroviral medications since her (MONTH) study visit, check the box in this question and skip to question **B10**.
- B3. If the participant has taken antiretroviral medications since her (MONTH) study visit, ask her if this is the first time she ever has taken any antiretroviral medications. The participant should only answer "YES" if she has never taken any antiretroviral medication. If she replies "NO," skip to question B4. If she replies "YES," ask subquestions B3a i viii to determine why she has just begun taking antiretroviral medications. Circle "YES" or "NO" for each subquestion.
- B4. Ask the participant if she has changed any of her antiretroviral medications since her (MONTH) study visit. The participant should answer "YES" if she has changed even one of her antiretroviral medications. If she replies "NO," skip to question **B5.** If she replies "YES," ask subquestions **B3a i-viii** to determine why she changed her antiretroviral medications. Circle "YES" or "NO" for each subquestion.
- B5. Questions B5a B5f are designed to capture information on structured treatment interruptions. These treatment interruptions *do not* have to be physician prescribed, but can be planned in advance by the participant on her own.

It is also important to note and stress the timeframe change here – this question is referring to the past <u>three</u> months rather than since the participant's (MONTH) study visit.

- a. If the participant responds that there was never a planned or prescribed period of time of two or more days during which she stopped all of her antiretroviral medications, skip to question **B6**.
- b. If the participant does not know the exact number of breaks, ask her to give her best estimate.
- c. If the participant responds that the breaks were not prescribed by a health care provider, skip to question **B5e**.
- d. Circle only one answer to this question. If the participant does not know the main reason that her health care provider prescribed the breaks, write in "-8," as per WIHS interviewing convention.
- e. Since the time frame for this question is in the past three months, the interviewer should fill in the year rather than asking the participant to state the year.

f. This question asks for the length of time (in days or weeks) that the participant skipped taking her antiretroviral medications the last time she had a planned or prescribed treatment interruption that lasted at least two days or longer. By the nature of this question, **B5f** must be at least two days or greater. Circle the corresponding days/weeks indicator based on the participant's response.

If the participant answers in both days and weeks (e.g., "My last interruption in therapy lasted three weeks and four days"), convert this response to days (e.g., convert three weeks, four days to 25 days).

- B6. Questions B6a B6d are designed to capture breaks in therapy caused by non-adherence. These breaks are very different than the structured therapy breaks that are captured in B5, and you should be sure that the participant understands the distinction while administering these questions.
  - a. If the participant responds that she never took any unplanned breaks of at least one full day in her prescribed antiretroviral therapy, skip to question **B7**.
  - b. If the participant does not know the exact number of breaks, ask her to give her best estimate.
  - c. Since the time frame for this question is in the past three months, the interviewer should fill in the year rather than asking the participant to state the year.
  - d. This question asks for the length of time (in days or weeks) that the participant skipped taking her antiretroviral meds the last time she had an unplanned or non-adherent break in treatment. Circle the corresponding days/weeks indicator based on the participant's response.

If the participant responds in hours greater than 24 hours, convert this to the closest number of days (e.g., convert a response of "45 hours" to two days). If the participant answers in both days and weeks (e.g., "My last interruption in therapy lasted three weeks and four days"), convert this response to days (e.g., convert three weeks, four days to 25 days).

The remaining questions focus on how the participant has taken her medications in the past six months.

B7. a. This question is designed to assess the participant's <u>general</u> level of adherence to <u>all</u> of her prescribed antiretroviral medications.

If the participant responds that she took her antiretroviral meds 100% of the time, skip to question B8.

b. Hand the participant **Response Card D1**. This question asks a series of reasons for missing medications and how often each reason applies. Read each reason to the participant and mark how frequently this reason causes her to miss her medications. At the end, ask the participant if there is any other reason that causes her to miss her medications. Print her response in the specify box and indicate how often this reason causes her to miss taking her medications.

Since questions on structured treatment interruptions are now asked in a different section of the form, "Prescribed by physician" is no longer a valid response for this question.

- B8. a. Hand the participant Response Card D2 before asking her question B8. All participants reporting use of antiretrovirals in question B2 should answer this question related to general adherence to their medication schedules.
  - b. If the participant was never given special instructions for any of her antiretroviral medications, skip to question **B9**.
  - c. Hand the participant **Response Card D2** before asking her question **B8c.**
- B9. If the participant is <u>currently taking at least two</u> antiretroviral medications, circle "YES" to indicate that she is on combination therapy and proceed to ask her questions **B9a–d**. If she is on mono therapy (currently taking only one antiretroviral medication), or she has taken more than one antiretroviral medication since her (MONTH) study visit but is not <u>currently</u> taking at least two antiretroviral medications, circle "NO" and skip to **Section C.**

**NOTE:** You may need to refer to the Drug Form 1's completed after question **B2a** in order to determine whether the participant is currently taking at least two antiretroviral medications.

a-d: Hand the participant **Response Card 12** before asking her questions **B9a–B9d**. These questions ask about the participant's attitude towards transmission of HIV while on combination therapy. For each question, record whether she strongly agrees, agrees, is uncertain, disagrees or strongly disagrees. If the participant is hesitant to answer, **PROBE** for a response by saying, "We are interested how you feel on this question," or, "Which choice do you think is closest to how you feel?" If the participant has difficulty choosing a category, the interviewer should re-focus the participant by re-asking the question. If the participant has questions about the question you are asking, respond with, "Whatever you think the question means," or, "However you understand it." If the participant remains hesitant, **PROBE** further by saying, "Remember, there are no right or wrong answers. We are interested in your feelings on this." These questions will only be asked of women on antiretroviral therapy.

As question **B10** is asked only of women not taking antiretroviral therapy, skip to **Section C** after asking question **B9d** regardless of the participant's response.

#### B10. Hand the participant **Response Card D3** before asking her question **B10**.

This question asks for the <u>MAIN</u> reason a participant is not taking any antiretroviral medications. Read the responses to the participant and then circle the one answer that matches her response. If the participant's main reason for not taking any antiretroviral medications is not listed as one of the responses, circle "*any other reason*" and print her response in the specify field.

#### SECTION C. OI MEDICATION HISTORY

- C1. Hand the participant **Response Card D4**. In questions **C1b** and **C1c**, if the participant reports using one of the four non-antiretroviral medications marked with "\*" (i.e., interferon alfa-2b, pegylated interferon, Famvir, Rebetron), the interviewer should read the appropriate prompt in **C1b/C1c** to determine how to proceed with form completion. The interviewer should ask the participant if she takes [INTERFERON ALFA-2b, PEGYLATED INTERFERON, FAMVIR, REBETRON] (read name of appropriate medication only) to treat hepatitis (B or C) only, to treat or prevent another condition, or to both treat hepatitis and treat/prevent another condition.
  - If use is for hepatitis treatment only, interviewer should mark medication in question D1a only and complete Drug Form 3 at the appropriate point in the interview.
  - If use is for treatment or prevention of another condition only, interviewer should mark medication in question C1b/C1c (as appropriate) and proceed with administration of Drug Form 2.
  - If use is for hepatitis treatment <u>and</u> to treat/prevent another condition (or participant is unsure of reason for use), interviewer should mark medication in both C1b/C1c and D1a and complete both a Drug Form 2 and a Drug Form 3.
- C1. a. Ask the participant if she has taken the inhaled medication listed in question C1a since her (MONTH) study visit. If "YES," mark an "X" in the appropriate box; if "NO," check the box in C1ai indicating that the participant has not taken the medication listed in question C1a since her (MONTH) study visit and skip to question C1b.
  - b. Ask the participant if she has taken any of the injected or infused medications listed in question C1b since her (MONTH) study visit. If "YES," mark an "X" in the appropriate box(es); if "NO," check the box in C1bi indicating that the participant has not taken ANY of the medications listed in question C1b since her (MONTH) study visit and skip to question C1c. See instructions above if participant is taking a medication marked with "\*."
  - c. Ask the participant if she has used any of the pills, liquids or creams listed in question C1c since her (MONTH) study visit. If "YES," mark an "X" in the appropriate box(es); if "NO," check the box in C1ci indicating that the participant has not taken ANY of the medications listed in question C1c since her (MONTH) study visit and go to PROMPT. See instructions above if participant is taking a medication marked with "\*."

#### PROMPT: COMPLETE A DRUG FORM 2 FOR EACH MEDICATION MARKED IN QUESTIONS C1a THROUGH C1c. IF NO MEDICATIONS ARE MARKED, GO TO SECTION D.

#### SECTION D. HEPATITIS MEDICATION HISTORY

D1. a. Hand the participant **Response Card D4a**. Ask the participant if she has ever taken any of the listed medications <u>for hepatitis</u> (B or C). If "YES," mark an "X" in the appropriate box(es).

**NOTE:** If the participant indicates that she has taken Epivir, Viread or Emtriva; however is uncertain if it was taken for her HIV or hepatitis infection, please complete **Drug Form 3**, in addition to **Drug Form 1**. If participant indicates that she has taken interferon alfa-2b, pegylated interferon, Famvir or Rebetron; however is uncertain if it was taken for her hepatitis infection or for another condition, please complete a **Drug Form 3**, in addition to **Drug Form 2**.

b. If the participant has not taken any of the medications for hepatitis listed in D1a, check the box in question **D1b** and go to **Section E.** 

#### PROMPT: COMPLETE A DRUG FORM 3 FOR EACH MEDICATION MARKED IN QUESTION D1a.

#### SECTION E. OTHER PRESCRIPTION MEDICATION USE

- E1a-f: These questions ask about vaccinations that the participant may have received. For each, indicate "YES" or "NO" to indicate whether she has received it since her (MONTH) study visit.
- E2. This question asks if the participant has taken any medication for blood pressure or her heart. If she answers "NO," skip to question E3. If she responds "YES," ask question E2a.
  - a. Indicate the number of blood pressure and heart medications that the participant reports currently taking.
  - b-h: Hand the participant **Response Card D4b**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E2bii–E2hii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E3. This question asks if the participant has taken any medication to lower her cholesterol, triglyceride or blood lipid level. If she answers "NO," skip to question E4. If she responds "YES," ask questions E3a–E3k.
  - a-k: Hand the participant **Response Card D4c**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E3aii–E3kii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E4. This question asks if the participant has taken any medication to lower her blood sugar. If she answers "NO," skip to question E5. If she responds "YES," ask questions E4a–E4m.
  - a-m: Hand the participant **Response Card D4d**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E4aii–E4mii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E5. This question asks if the participant has taken any medication to treat or prevent osteoporosis. If she answers "NO," skip to question E6. If she responds "YES," ask questions E5a–E5f.
  - a-f: Hand the participant **Response Card D4e**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E5aii–E5fii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E6. This question asks if the participant has taken any medication for seizures. If she answers "NO," skip to question E7. If she responds "YES," ask questions E6a–E6h.

- a-h: Hand the participant **Response Card D4f**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E6aii–E6hii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E7. This question asks if the participant has taken any medication for psychological conditions or depression. If she answers "NO," skip to question **E8**. If she responds "YES," ask questions **E7a**–**E7f.** 
  - a-f: Hand the participant **Response Card D4g**. Read each medication aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E7aii–E7fii**. If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E8. Hand the participant **Response Card D4h** before asking her question **E8**. This question should be recorded as "YES" only if the participant took any of the <u>listed</u> therapies for more than one month since her (MONTH) study visit. If the participant reports no use of hormone replacement therapy, skip to question **E9**.
  - a. This question should not be read aloud to the participant. Based on the medications the participant reports taking in question **E8**, the interviewer should record the type of hormone replacement therapy taken by the participant since her (MONTH) study visit. Be sure to specify the therapy taken if "other HRT" was indicated in **E8**. If the participant reports use of both estrogen and progesterone hormone replacement therapies, record this as "combination" in **E8a**.
  - b. Read the participant each reason listed and circle "YES" for each reason she reports that she is taking hormone replacement therapy. If she answers "other," specify the reason where listed on the form. Do not include medications the participant reports taking solely for birth control as their use will be captured on WIHS form F23 Obstetric, Gynecologic and Contraceptive History.
- E9. This question asks if the participant has ever been treated with radioactive iodine or any other medication for the treatment of hyperthyroidism. If the participant received only surgery (with no radioactive iodine or other medication), circle "NO" for this question. If the participant answers "NO" for question E9, skip to question E10. If she answers "YES," ask questions E9a–d.
  - a-d: Hand the participant **Response Card D4h.** Read each drug aloud. If she responds "YES" to having taken any of the listed medications in the past six months, then also ask about use in the last five days in questions **E9aii–E9dii.** If the participant has not taken any medications on the response card, simply circle "NO" for each medication.
- E10. Ask the participant if she has taken any other **PRESCRIBED** medications not previously mentioned since her (MONTH) study visit.
  - a. If question E10 is "YES," list those medications named in the specify fields provided in E10a. If possible, enter the exact name of the medication the participant is taking. However, if the participant knows that she is taking, for example, an anti-depressant or blood pressure medication, but can't remember the medications' specific name(s), record "anti-depressant" or "blood pressure medication."
  - b. For each medication listed in E10a, ask the participant whether she has taken it within the last five days.
  - c. For each medication listed in E10a, the interviewer should record how use of the medication was reported by the participant, i.e., self report, participant brought written list to visit, participant brought medication bottle to visit, participant brought pharmacy record to visit, record obtained directly from pharmacy, or other.

#### SECTION F. ALTERNATIVE/COMPLEMENTARY MEDICATION USE

- F1. a. Hand the participant **Response Card D5**. Ensure that the participant is aware that all enzyme therapies, flower remedies, herbs, homeopathic remedies and nutritional supplements such as vitamins or minerals should be reported in this question. If the participant has not taken any complementary or alternative medications since her last study visit, skip to **question F5**.
  - b. THIS LIST IN F1b IS NOT MEANT TO BE READ TO THE PARTICIPANT. Rather, the participant should read **Response Card D5**. If the participant cannot read or has problems with her vision, read the list of therapies and treatments. For each therapy the participant indicates that she has taken (since last visit), place an "X" in the corresponding box. Once you have placed an "X" in the corresponding box, ask the participant about her frequency of use, if she is currently taking the therapy, and her main reason for taking the therapy. For the participant's main reason, hand the participant **Response Card D6** and record the number the participant indicates in the box corresponding to the therapy under question.

If the participant names a therapy that is not listed in question **F1b**, or if she knows that she is taking a particular class of alternative therapies but does not know the exact therapies, record her response in one of the specify fields at the end of the table. If the therapy is listed on **Drug List 3**, record the appropriate three-digit drug code in the corresponding boxes. If the therapy is not listed on **Drug List 3**, record the drug code as 699 (other alternative/complementary medication).

**NOTE:** Beginning with visit 20, codes 503 (other nutritional supplements, unspecified) and 539 (other herbs, unspecified) have been deleted from question **F1b** and **Drug List 3**. Henceforth, all alternative/complementary therapies that can not be classified using one of the specific codes on **Drug List 3** should be listed in one of the specify boxes with drug code 699 (other alternative/complementary medication). WDMAC will periodically review all therapies listed with code 699 to determine whether a new drug code is warranted.

F2. Mark only one response. If the participant's primary care provider is guiding the alternative therapy, go to **question F5.** 

If the participant responds that both she and her primary care provider are guiding treatment, mark this response as primary care provider guiding treatment (response 1).

- F3. If the participant has discussed her alternative medication usage with the primary care provider or if she does not have a primary care provider, go to **question F5.**
- F4. Hand the participant **Response Card D7.** Mark only one response.
- F5. Ask the participant if she has eaten powdered cornstarch for her health within the past six months. If "no," skip to **Section G.** 
  - a. Ask the participant how often she eats cornstarch for her health.
  - b. Ask the participant how much cornstarch she consumes when she eats it.

#### SECTION G. SYMPTOMS

G1. Hand the participant **Response Card D8.** These questions should be asked of ALL participants, regardless of their HIV status and regardless of whether or not they are taking any prescribed medications or alternative therapies. Read the symptoms listed in **G1a–G1r** one at a time to the participant. If the participant indicates that she has not experienced that symptom since her (MONTH) study visit, mark "not at all" and move on to the next symptom on the list. If she indicates that she has experienced that symptom since her (MONTH) study visit, ask her the severity of that symptom and record appropriately. Once you have recorded the severity, move on to subquestions **i** and **ii** asking if she felt that the particular symptom was a side effect of either her prescribed medications (**i**) or her alternative therapies (**ii**). If the participant has reported that she is on no prescribed medications at all, do not ask subquestion **i**, but rather record "N/A." Similarly, if the participant has reported that she is taking no alternative therapies, do not ask subquestion **ii**, but record "N/A."

- G2a–i: Hand the participant **Response Card 12** before asking her questions G2a–G2i. These questions ask about the participant's attitudes towards transmission of HIV in general. For each question, record whether she strongly agrees, agrees, is uncertain, disagrees or strongly disagrees. If the participant is hesitant to answer, **PROBE** for a response by saying, "We are interested how you feel on this question," or, "Which choice do you think is closest to how you feel?" If the participant has difficulty choosing a category, the interviewer should re-focus the participant by re-asking the question. If the participant has questions about the question you are asking, respond with, "Whatever you think the question means," or, "However you understand it." If the participant remains hesitant, **PROBE** further by saying, "Remember, there are no right or wrong answers. We are interested in your feelings on this." These questions will be asked of all women in the WIHS.
- G3. Record the time module ended. Circle the code for AM (code 1) or PM (code 2).