

WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS

DRUG FORM 1: ANTIRETROVIRAL MEDICATIONS

Guidelines for completing Drug Form 1, “Antiretroviral Medications.”

General Instructions:

1. A **Drug Form 1** should be completed for each medication a participant lists in **question B2A on Form 22MED**. Therefore, if a participant is or has been (since last visit) on three antiviral medications, the interviewer should fill out three **Drug Form 1**'s for that participant. To indicate to which specific drug a particular **Drug Form 1** refers, the interviewer should check off only ONE of the boxes listed on page 1 of the form.

The listing of antiviral medications on **Drug Form 1** is not complete. However, it does contain currently used medications to the best of our knowledge and each drug retains a unique code assigned by WDMAC. For any other antiviral medication used by the participant against HIV-1 that is not listed on **Drug Form 1**, mark the box denoted “*Other antiviral*” and print the name of the drug in the specify box. Refer to the current **Drug List 1** to obtain codes for drugs not listed on **Drug Form 1** and enter the code from **Drug List 1**. If the drug is not on **Drug List 1**, record code “998” for “other antiviral.” Bring this to the attention of the clinic coordinator/director. Notify WDMAC of any frequently used medications that do not have unique codes.

If a participant indicates that she is taking an antiviral medication, but does not know or cannot remember the name of the medication, mark the box denoted “*Other antiviral(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.

Interviewers should ignore the numbers in italics listed next to the check boxes at the beginning of the form. These numbers are for data entry purposes only.

2. Use the form version dated 04/01/04.
3. 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. Starting visit 20, interviewers are prompted to record the manner in which medications are reported.
5. When reading the questions, insert the actual drug name as stated by the participant where it says (DRUG). For both WIHS core visits and 3-month VRS visits, insert the date of the participant's **last completed core visit** where it says (MONTH), regardless of whether she has attended an interim VRS visit.
6. If a participant had been (since last visit) taking a medication as part of a research study but then continued that medication after the trial ended during the same visit period, complete two drug

forms. One form will correspond to the portion of the visit when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit continuing the medication usage but not as part of the trial.

7. If a participant is taking a medication as part of a research study but is not blinded to the treatment, complete the entire **Drug Form 1**, do not stop after question **2B**.
8. All questions refer to the period since the participant's last core study visit.
9. Questions **5–11** refer to antiretroviral medication adherence. They should only be answered for participants that are **currently** taking the specific anti-HIV medication referred to on the form. These questions should also be answered for medications taken as part of a research trial as long as the participant is not blinded to the treatment.

Follow the skip patterns as they appear on the form.

Question 1: This question refers to whether or not the participant started the medication since her last study visit. We want to know if this is a new medication **OR** a previous medication that the participant has started re-using since their last visit. If the participant has been on a medication break and then started using the same drug again, she should respond “YES” to this question. If the medication is not a new medication that the participant has begun taking since her last visit, skip questions **1B and 1C**.

If the medication is a previous one that the participant is re-using since their last visit, be sure to record the most recent date that she began re-taking that medication.

If the participant cannot remember the exact month she began taking the medication, probe for the season and assign 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.

Question 2: This question asks about how the participant has access to her antiretroviral medications. One of the responses for this question is a “Compassionate Use Program.” This type of program, also commonly referred to as an Expanded Access Program, is a program which makes investigational drugs available to patients prior to FDA approval. These types of programs are primarily used for very sick patients whose well being may depend upon early access to a particular drug.

If the medication is/was not being taken as part of a research study, skip question **2B**. If the medication is/was part of a blinded research study, stop after question **2B**.

Do not answer questions 3–11 if the participant is/was taking this drug as part of a blinded reasearch study in which the participant does not/did not know whether she is/was taking the actual drug.

Note: For data coding consistency, in question **1C**, response #6 (my CD4 level went down) **precedes** response #5 (other reason) on the form.

Question 3: **Hand participant RESPONSE CARD E1.** Mark only one response.

Question 4: If the participant is currently taking the medication, skip questions **4B** and **4C** and go to question **5**.

Question 4B: If the participant cannot remember the exact month during which she most recently took the medication, probe for the season and assign month as described under Question 1 above.

Question 4C: The interviewer should show the participant **RESPONSE CARD E2**. The interviewer should circle only ONE response. If none of the available responses matches the participant's answer, the interviewer should circle "*Any other reason*" and record the specific reason in the corresponding specify field. We are interested only in the participant's MAIN reason for stopping the medication. Though she may have multiple reasons, probe for the most important one and **CIRCLE ONLY ONE RESPONSE**.

Participants are asked question **4C** only if they are not currently taking the medication (i.e., 4A = No). **Regardless** of how question **4C** is answered, the interviewer should **STOP** at this point and not ask the participant any further questions on **Drug Form 1**.

Question 5: For the first drug form administered at each visit, the interviewer should read **Introduction 1** to the participant, skip **Introduction 2**, and then proceed with question **5A**. If the interviewer has already administered at least one **Drug Form 1** to the participant during the same visit, the interviewer should skip over **Introduction 1**, read **Introduction 2**, and then proceed with question **5A**. This is to prevent the participant from having to listen to the long adherence introduction multiple times if she is taking or has taken multiple antiviral medications.

Mark only one response for both questions **5A** and **5B**.

Based on the participant's response to question **5B**, the interviewer should insert only the appropriate dosage form (i.e., pills, packs, teaspoons/drops OR injections/IV) when asking question **5C**.

Question 6: This question refers to medication usage **in the last three days**. Question **6A** asks the participant how many times a day she actually took the medication and question **6B** asks for the TOTAL number of pills/packs/teaspoons/injections she took throughout the whole day. If a participant took only a portion of a dose (i.e., not the full dose prescribed by the physician), this dose should be reported as being **missed** in question **6A**.

For example, suppose the prescribed dosage is 5 pills, 3 times per day.

- If a women was fully adherent (i.e., took 5, 5, and 5 pills) then she would report "3 times" in question **6A** and "15 pills" in question **6B**.
- If she missed 1 pill in the morning dose (i.e., took 4, 5, and 5 pills) then she would report "2 times" and "14 pills."
- If she missed her entire morning dose and 1 pill from her evening dose (i.e., took 0, 5, and 4 pills) then she should report "1 time" and "9 pills."

When referring to two days ago and three days ago, mention the actual day of the week to which you are alluding (DAY). For example, if the interview is on Friday and you are asking about three days ago, prompt the participant by saying "that would be on

Tuesday.” Based on the participant’s response to question **5B**, the interviewer should insert only the appropriate dosage form (i.e., pills, packs, teaspoons/drops OR injections/IV) when asking question **6B**.

Question 7: This item asks if the pattern of use described in the previous three-day period is more than, less than, or about the same as the participant's general pattern of use. If the participant is confused by the different time periods, explain as best as possible that we are interested in comparing her use over the past three days to how she usually takes the medication. If the participant responds that she “never misses a dose,” this should be reflected in questions **6A** and **6B**, and her response for question **7** should be coded as 3, “*About the same.*”

Question 8: **Hand participant RESPONSE CARD E3.** Mark only one response.

Question 9: **Hand participant RESPONSE CARD E4.** Question 9 captures how much of her DRUG the participant has taken **in the past month**. The participant should show their best guess by pointing to the scale on response card E4. The interviewer should translate the approximate location where the participant pointed into one of the 20 categories listed on **Drug Form 1**. (0%-5%, 6%-10%, ..., 91%-95%, 96%-100%). **PROMPT: 0 = none of DRUG, 50 = half of DRUG, 75 = three-quarters of DRUG, 100 = all of DRUG.**

Question 10: **Hand participant RESPONSE CARD E5.** Mark only one response.

Question 11: Read the introduction. Based on the response the participant gave for question **5a** (number of times a day she is supposed to take DRUG), the interviewer should be able to choose the correct timing for each dose.

Once per day = every 24 hours

Twice per day = every 12 hours

Three times per day = every 8 hours

Four times per day = every 6 hours

This question captures how often the participant took her DRUG within two hours of the correct time **in the past month**. **Hand participant RESPONSE CARD E6.** The participant should show her best guess by pointing to the scale on response card E6. The interviewer should translate the approximate location where the participant pointed into one of the 20 categories listed on **Drug Form 1**. (0%-5%, 6%-10%, ..., 91%-95%, 96%-100%). **PROMPT: 0 = none of the time, 50 = half of the time, 75 = three-quarters of the time, 100 = all of the time.**

After **Drug Form 1**'s have been completed for each antiretroviral reported in **F22Med** question B2a, go back and complete the remainder of **F22Med**.