

WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS

DRUG FORM 1: ANTIRETROVIRAL MEDICATIONS

Complete a **Drug Form 1** for each medication a participant indicates she has taken in the past three days on the **Antiretroviral Dosage Form**. For example, if a participant has taken three antiviral medications in the past three days, 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 interviewer should also record the manner in which use of the medication is captured, e.g., self-report, participant brought bottle to visit, etc.

Do not complete a Drug Form 1 for antiretroviral medications the participant has taken since her last study visit but has not taken in the past three days at the time of her core visit.

The list of antiviral medications on **Drug Form 1** is not complete, but contains FDA-approved medications to the best of our knowledge. 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.

When reading the questions, insert the actual drug name as stated by the participant where it says (DRUG). Insert the date of the participant's **last completed core visit** where it says (MONTH).

PROMPT: INTERVIEWER READ TO PARTICIPANT IF NECESSARY: "A medication you have taken "in the past 3 days" includes one you have taken at least one time today, yesterday, or the day before yesterday."

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.

2. This question asks about how the participant has access to her antiretroviral medication. 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 that 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 not being taken as part of a research study, skip **Question 2b**. If the medication is part of a blinded research study, stop after **Question 2b**. 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**.

Do not answer Questions 3–11 if the participant is taking this drug as part of a blinded research study in which the participant does not know whether she is taking the actual drug.

Note: For data coding consistency, in **Question 1c**, response numbers 6 through 9 **precede** response number 5 (other reason) on the form.

3. **HAND PARTICIPANT RESPONSE CARD E1.** Mark only one response.

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 7**. 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 7**. This is to prevent the participant from having to listen to the long adherence introduction multiple times if she is taking multiple antiviral medications.

7. **HAND PARTICIPANT RESPONSE CARD E4.** Question 7 captures how much of her DRUG the participant has taken **in the past 3 days**. The participant should show her 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.**
8. **HAND PARTICIPANT RESPONSE CARD E4.** Question 8 captures how much of her DRUG the participant has taken **in the past 2 weeks**. The participant should show her 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.**
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 her 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.**
10. **HAND PARTICIPANT RESPONSE CARD E5.** Mark only one response.
11. **HAND PARTICIPANT RESPONSE CARD E6.** Question 11 captures how often the participant took her DRUG within two hours of her “normal time” **in the past month**. Instructions are given on the form so that the interviewer can help the participant to determine whether or not she has taken her medication within two hours of her “normal time.” 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 a **Drug Form 1** has been completed for each antiretroviral medication the participant reports she has taken in the past three days, go back and complete the remainder of **F22MED**.