WOMEN'S INTERAGENCY HIV STUDY

QUESTION BY QUESTION SPECIFICATIONS

DRUG FORM 2: NON-ANTIVIRAL MEDICATIONS

Guidelines for completing Drug Form 2, "Non-Antiviral Medications."

General Instructions:

- 1. A **Drug Form 2** should be completed for each medication a participant lists in **questions C1a, C1b** and C1c on Form 22Med. Therefore, if a participant is or has been (since last visit) on two non-antiviral medications, the interviewer should fill out two **Drug Form 2's** for that participant. To indicate to which specific drug a particular **Drug Form 2** refers, the interviewer should check off ONE of the boxes listed on the front page for each form completed.
- 2. 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.
- 3. Starting visit 20, interviewers are prompted to record the manner in which medications are reported.
- 4. When reading the questions, insert the actual drug name 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.
- 5. 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.
- 6. If a participant was taking a medication as part of a research study but then continues taking that medication after the trial ends and this occurs during the same visit period, complete two drug forms. One form will correspond to the portion of the visit period when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit period when the participant was continuing the medication usage but not as part of the trial.
- 7. If a participant is or was taking a medication as part of a research study but is/was not blinded to the treatment, complete the entire **Drug Form 2**; do not stop after question **1B**.
- 8. All questions refer to the period since the participant's last visit.
- 9. No **Drug Form 2'**s should be filled out for antiretroviral medications (record in F22Med question B2a; complete Drug Form 1), for hepatitis medications (record in F22Med question D1a; complete Drug Form 3), for complementary/alternative therapies (record in F22Med question F1b), or for other prescribed medications (record in specify boxes in F22Med question E10).

Question 1:

If the medication is/was not being taken as part of a research study, skip question 1B.

Do not answer questions 2-5 if the participant is/was taking this drug as part of a <u>blinded</u> research study in which the participant does not/did not know whether she is/was taking the actual drug.

Question 2:

For each indication (a–e), circle the code for either "YES" or "NO." If participant reports use for an "other condition," circle "YES" for 2f, and record name of condition in specify field.

Question 3:

If the medication was taken more than 99 times, code as "99." RECORD MOST RECENT NUMBER OF TIMES PER [ONE OF THE FOLLOWING] DAY OR WEEK OR MONTH OR YEAR. If the participant is taking the medication on an "as needed" basis, record the estimated total number of times she has taken it since her last study visit [one of the following] per day, week, month or year.

Question 4:

Hand the participant RESPONSE CARD E1.

This question tries to capture the duration of medication use since the last visit to the best of the participant's recollection. If the participant says that she cannot remember, assure her that her answer does not have to be exact and you are just looking for her best guess as to the duration of her drug use since her last visit.

Question 5:

Mark only one response.