

## WOMEN'S INTERAGENCY HIV STUDY

### QUESTION BY QUESTION SPECIFICATIONS

#### **F29a: DRUG USAGE ASSESSMENT FOR BLOOD DRAW**

Guidelines for completing F29a, “Drug Usage Assessment for Blood Draw.”

This form should be completed by the phlebotomist immediately before the participant’s blood draw. The information collected will allow us to look at drug levels in blood and urine and compare with standard pharmacokinetic data to assess absorption and/or adherence. Additionally, this form will be used to record the date and time of the participant’s last meal to indicate whether or not the blood drawn is a fasting sample, and to record the amount of alcohol consumed by the participant in the 48 hours prior to the blood draw.

If the participant receives more than one blood draw (due to clotting, mishandling of the first specimen, etc.), an additional F29a form should be completed by the phlebotomist immediately preceding each additional blood draw. The WDMS will allow entry of more than one F29a per ID/VISIT.

**Question 1A: HAND THE PARTICIPANT THE CURRENT ANTIRETROVIRAL PHOTO MEDICATION CARDS.**

Go through each card with the participant. For EACH medication, ask the participant “In the past three days, have you taken (DRUG NAME)?”. Mark each drug to which the participant responds with a “Yes” by placing an “X” on the corresponding line.

Ensure that, in addition to her prescribed antiviral medications, the participant includes all antiviral medications that she 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.

If the participant is HIV-negative, you do not need to read through the entire list of antiviral medications and can simply check the box at Question 1B and proceed to question #3.

The listing of antiviral medications on **F29a** 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 **F29a**, mark the line denoted “*Other anti-viral*” 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 **F29a** and enter the code from **Drug List 1**. If the drug is not on **Drug List 1**, check “*Other anti-viral*,” record the name of the drug in the specify box and enter “998” as the drug code. 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 line denoted “*Other anti-viral*” and print “unknown” in the specify box. Enter “999” in the space provided for the three-digit drug code. If the participant reports taking more than one unknown antiretroviral

medication in the three days prior to the blood draw, please list them in the specify boxes as “unknown1,” “unknown2,” etc., for tracking purposes.

- Question 1B: If the participant is not taking any antiviral medications, check the box at Question 1B and proceed to question #3.
- Question 2: For each medication the participant indicated she has taken in the past three days in Question 1A, ask the date and time she last took that medication and complete columns A, B, C and D.
- Question 2A: Enter the three-digit drug code from Question 1A, e.g., if participant is taking 3-TC, enter 204; if participant is taking ddI, enter 147.
- Question 2B: Enter the date the participant last took the medication. Phlebotomists should have available an appropriate calendar to aid the participant in determining dates.
- Question 2C: Enter the time the participant last took a dose of the medication.
- Question 2D: Circle 1 or 2 to indicate AM or PM.
- Question 3: Ask the participant when she last had anything to eat or drink other than water. Beverages such as black coffee, plain tea and diet soft-drinks contain ingredients that may affect some of the fasting blood measurements. Therefore, we need to know the last time the participant had anything to eat or drink other than plain, uncarbonated water.
- Question 3A: Enter the date the participant last ate or drank anything other than water.
- Question 3B: Enter the time the participant last ate or drank anything other than water. Circle 1 or 2 to indicate AM or PM.
- Question 4: Ask the participant how many drinks of alcohol she has had in the past 48 hours. One drink is the equivalent of one can or glass of beer, a glass of wine, a shot of liquor, a mixed drink with that amount of liquor, or any other kind of alcoholic beverage. If the participant has trouble answering this question, ask her to give her best estimate of the number of drinks she has had. Alcohol can affect the results of some tests and it is important for us to know how much alcohol she has consumed in the last 48 hours.

Proceed with the participant’s blood draw.