

**WIHS VIROLOGIC REBOUND AND RESISTANCE STUDY
QUESTION BY QUESTION SPECIFICATIONS
VRS 5: SCREENING TO DETERMINE CHANGES IN HAART REGIMEN**

Guidelines for completing VRS 5, "Screening to Determine Changes in HAART Regimen"

General Instructions:

The VRS protocol for visits 19 and up calls for contacting a participant's physician to complete VRS 6, if she reported any changes in HAART. 2 hour PK sampling is discontinued as of Visit 19. Random PK samples should be collected from all participants reporting current use of a PI or an NNRTI.

A change in HAART regimen is defined as either adding or dropping one or more medications. This form is mainly a tool to determine whether there have been changes in HAART.

For core visits, this form should be completed after the core interview and at the beginning of the VRS interview.

For 3 month VRS visits, this form should be completed either over the phone when scheduling a patient, or at the very beginning of a visit.

IMPORTANT: Question A7 needs to be completed before the interview.

- A1. Affix WIHS ID label in the space provided or record participant's ID number.
- A2. Use the form version dated 10/01/03.
- A3. Date should be recorded in MM/DD/YY format.
- A4. Enter initials of person completing the form.
- A5. For a core visit, enter the number of the core visit. For a three month visit, enter the number of the core visit preceding the 3 month visit.
- A6. If this form is administered at a Core Visit, circle '1'. If this form is administered at a 3 month VRS visit, circle '2'.
- A7. This question needs to be completed before the interview. Information should come from all VRS 4 forms completed at participant's last interview. In column A7, please circle the codes of all medications for which a VRS 4 was completed at participant's last interview.

- A8. The purpose of this question is to determine whether the participant is still taking the same medications she reported at the last visit, or whether her medications have changed.
- A8a. If this is a core visit, review all Drug Forms 1 completed at this visit, and, in column A8, circle the codes for all medications which participant reported to be currently taking (i.e. question 4A is answered "yes").
- A8b. If this is a 3 month VRS visit, ask the participant for each drug: "Are you currently taking (DRUG)?"
If the form is administered over the phone, it is recommended to ask the participant to get her HIV medications, so she can confirm the names of the medications. If the form is administered in person, the participant should have her medications with her. Ask her to show them to you and confirm her answers. For each medication that respondent reports she is currently taking, circle the code in column A8.
- A11. If the participant is currently not taking any PIs or NNRTIs, PK sampling does not need to be done.
- A12. Compare the medication checked in column A7 and column A8. If at least one medication is different between the two columns, circle '1' for yes. If all medications are the same, circle '2' for no.