WOMEN'S INTERAGENCY HIV STUDY
QUESTION-BY-QUESTION SPECIFICATIONS
RAB: RETROSPECTIVE MEDICAL RECORD ABSTRACTION FORM

General Instructions:

1. The *RAB Form* WILL NOT be filled out for HIV-negative enrollees, unless they took ART/HAART as PEP (pre-exposure prophylaxis) or PrEP (pre-exposure prophylaxis). THIS FORM SHOULD BE DATA ENTERED ONLY FOR WOMEN WHO ARE ENROLLED IN THE WIHS. *RAB Forms* from women who were screened but not eligible should NOT be data entered into Apollo.
2. The front page tearsheet should be torn off and destroyed once abstraction has been completed. The front page should not be data entered or stored in the participant file with the *RAB Form*. The function of the front page is to facilitate abstraction by providing participant information so abstractionists can more easily identify pertinent participant files.
3. The date that the participant self-reported first taking a HAART regimen ("self-reported HAART date") should be recorded on the front page tearsheet. Abstractionists should begin searching medical records six-months prior to this self-reported date to ensure that the form captures the first time the participant began taking HAART. If the abstractionist finds that the woman was already taking HAART in the records dated six-months prior to this self-reported start date, the abstractionist should request records one year prior to the participant's self-reported date. Abstractionists should keep going back until they find the most likely HAART start date in the medical records.
4. There are two sections to this form; a section that is required to be complete for a participant to be eligible for enrollment into the WIHS (**Section B**), and an abstraction section that is not required for enrollment, but is supplemental information that is desired (**Section C**). For a participant to be eligible for enrollment into the WIHS, **Section B** must be complete.
5. It is recommended that sites designate a point person at each site that has HIV clinical experience. Once the *RAB Form* has been completed by the abstractionist, the abstractionist should then confer with the designated point person to deem whether or not the woman being screened is eligible for enrollment, and if so, into which of the three groups the woman should be put (HIV-, HIV+/HAART (started in 2008 or later), HIV+/ART naïve). At some sites the abstractionist will be designated as the point person; whereas at other sites a different person will be designated.
6. Throughout this form, a "regimen" refers to medications that a participant took simultaneously.
7. Follow the skip patterns as they appear on the form.

SECTION A: General Information

Question A1: The Screening ID should be entered for every *RAB Form*.

Question A2: Abstractionists should not fill out the WIHSID during abstraction. The WIHSID will be filled in only for women who are deemed eligible for enrollment into the WIHS at the end of the entire screening process. This field will remain blank for all women who complete the screening process but are not eligible for enrollment. Forms for women who are not eligible (i.e., do not have the WIHSID filled out) should not be data entered.

SECTION B: Required Abstraction

As indicated in the general instructions, this entire section MUST be complete for a participant to be eligible for enrollment into the WIHS. If any of the required information is unavailable or cannot be located in the medical records, the woman is ineligible for enrollment. There are two exceptions to this: (1) In **Questions B2, B3 and B4**, the prescribed dosage is not required for a participant to be eligible, and (2) While **Question B6Bii** asks for CD4, CD8, and CD3 counts and percentages, only the CD4 numbers are required.

Question B1: To determine whether the medical records indicate if a person has ever used antiretroviral therapy (ART), abstractionists should use ***Drug List 1/Appendix B*** of the *RAB Form*.

If the woman **has never used any ART**, then she is eligible for enrollment as an ART-naïve participant. **SKIP TO THE END** of the *RAB Form*.

If the participant **has** previously used ART, proceed to **Question B2**.

Question B2: To decide whether the medical records indicate if a person has ever used HAART, abstractionists should use the tools provided in ***Appendix A*** of the *RAB Form*. These tools outline the different possible combinations that define a HAART regimen, as well as provide a checklist with which to determine the number of medications from each class of antiviral drugs for any given regimen. The checklist is regimen specific in that it was created to be used to categorize a specific regimen that a woman may have taken in her past as "HAART" or "not HAART." A separate, blank checklist should be completed for each regimen that can be found in the medical records. Abstractionists should not fill in one checklist for all drugs in the participant's history, but rather should fill out multiple checklists, one for each regimen that can be defined through the participant's medical records. Abstractionists should be very careful to make sure that the drugs indicated on any given checklist were all taken by the participant at the same time.

HAART is defined as one of the specific regimen types outlined in ***Appendix A: Definition of HAART***. Abstractionists should consult with their site's designated point person if they have any questions at all about whether or not a regimen can be categorized as a HAART regimen. If sites come across a regimen that does not fit the outlined HAART definitions, but they think is a HAART regimen, contact Christine Alden (calden@jhsph.edu) at WDMAC.

If a participant was ever on a HAART regimen (even if only for a day or two), she should be categorized as having been on HAART. For example, if a participant started a HAART regimen on 06/01/08 but could only tolerate it for one week, stopped and did not start on HAART again until 03/15/09 (when she began taking HAART regularly), then she should be put in the HAART category, and her start date should be recorded as "06/01/08."

If a woman is involved in a clinical trial or research study, she should only be classified as using HAART if the drugs in that study can be documented in a way that verifies the woman was on HAART. For example, if the woman is receiveing AZT, 3TC, and an unknown PI (blinded to the PI), the abstractor should list AZT and 3TC as usual, and then list "Unknown PI" and use the 3-sigit code "999."

For Question B2, circle only one response that best describes the participant's ART/HAART use history:

1) The participant has taken no ART prior to HAART, and HAART was started after December 31, 2007. PARTICIPANT IS ELIGIBLE FOR ENROLLMENT. COMPLETE QUETSIONS B5 AND B6, THEN PROCEED TO SECTION C.

2) The only ART/HAART use by the participant was during pregnancy and occurred prior to January 1, 2008. PARTICIPANT IS ELIGIBLE FOR ENROLLMENT. COMPLETE QUESTION B3 AND B6, THEN SKIP TO SECTION C.

3) The only ART/HAART use by the participant was for PEP (post-exposure prophylaxis) or PrEP (pre-exposure prophylaxis) and occurred prior to January 1, 2008. PARTICIPANT IS ELIGIBLE FOR ENROLLMENT. COMPLETE QUESTION B4 AND B6, THEN SKIP TO SECTION C.

4) The participant has taken ART/HAART prior to January 1, 2008, for pregnancy, and has additionally started HAART after December 31, 2007. PARTICIPANT IS ELIGIBLE FOR ENROLLMENT. COMPLETE QUESTIONS B3, B5 AND B6, THEN PROCEED TO SECTION C.

5) The participant has taken ART/HAART prior to January 1, 2008, for PEP or PrEP, and has additionally started HAART after December 31, 2007. PARTICIPANT IS ELIGIBLE FOR ENROLLMENT. COMPLETE QUESTIONS B4, B5 AND B6, THEN PROCEED TO SECTION C.

6) The participant has taken ART or HAART prior to January 1, 2008, that was not for pregnancy or PEP/PrEP. PARTICIPANT IS NOT ELIGIBLE FOR ENROLLMENT. END FORM.

7) The participant has taken any non-HAART ART that was not for pregnancy or PEP/PrEP. PARTICIPANT IS NOT ELIGIBLE FOR ENROLLMENT. END FORM.

Question B3: Abstractionists should list only those medications which comprised the participant's ART/HAART regimen taken during pregnancy, as well as the corresponding drug code, the start date, and the prescribed dosage.

All medications for that particular regimen should be listed. Drug codes can be found in ***Appendix B: Drug List 1***. If a drug is reported that is not listed in Drug List 1, sites should contact Christine Alden (calden@jhsph.edu) at WDMAC to get a three-digit drug code assigned to the drug. If additional spaces are needed (i.e., a participant has more than five medications comprising her ART/HAART regimen during pregnancy), Xerox the chart in **Question B3**, fill in additional medications, and attach to the *RAB Form*.

For the start date, abstractionists should try to locate the date in the medical record that represents the date the participant actually began taking the medication. **NOTE** that this date may be different from the date that the regimen was first prescribed. Sometimes there is a lag in actually obtaining the medications, and in some instances, the participant may never begin taking the medications. Abstractors may need to look at records for the next visit after the regimen was prescribed to confirm that the participant began taking her HAART regimen. If only the month and year can be found, abstractionists should code the day as "15." If start date cannot be found in the medical records (i.e., can only find date medication was first prescribed), write "Not located" in the box for start date. Data entry should code this as "-9" in Apollo.

While prescribed dosage is not required information for a participant to be eligible, abstractionists should try to find and abstract this information from the medical records.

Under prescribed dosage, abstractionists should record the target (full) dose in milligrams (mg) (e.g., if the starting dose of ritonavir is 300mg, but it is increased to a full dose of 600mg bid over 14 days – record the full dose). Abstractors should use the following notation to denote frequency of dosing:

qod = every 48 hours, or every other day

qd = every 24 hours, or every day

bid = every 12 hours, or 2 times/day

tid = every 8 hours, or 3 times/day

qid = every 6 hours, or 4 times/day.

Any other variation not listed above should be written as every number of hours.

Example: If a prescription is written: "Norvir 100mg; take 6 caps bid," the abstractor should record this as 600mg bid. If the prescription reads "100mg; take 4 caps bid," then this should be recorded as 400mg bid.

Example: The oral solution for Norvir comes as 80mg/mL, so a full dose of 600mg = 7.5mL bid. While this will be seen infrequently in the medical records, the abstractor should convert the 7.5mL bid to milligrams (mg), and the dose should be recorded as 600mg bid.

Combination medications that contain multiple medications in one pill (such as Combivir and Trizivir), should be coded as the name and three-digit code for the combination pill. Therefore, if a participant reports Combivir, "Combivir" should be written in the space for the drug's name, and the three-digit code "227" should be written in for the drug code. For the combination medications, the dosage amount (e.g., mg) will not be able to be recorded. In this case, code the prescribed dosage without milligrams (e.g., "Trizivir, one pill bid"). The checklist in ***Appendix A: Antiviral Medication checklist*** accounts for the use of these combination-type pills and has instructions for how to define HAART if a participant is on one of these medications.

Question B4: Abstractionists should list only those medications which comprised the participant's ART/HAART regimen taken for PEP/PreP, as well as the corresponding drug code, the start date, and the prescribed dosage.

Follow other instructions as indicated for **Question B3.**

Question B5: Abstractionists should list only those medications which comprised the participant's first documented HAART regimen started after 12/31/2007, here, as well as the corresponding drug code, the start date, and the prescribed dosage.

Follow other instructions as indicated for **Question B3.**

Question B6: For this question, abstractionists should identify the blood draw at the time of HAART initiation subsequent to December 31, 2007 (i.e., blood drawn the same day that the regimen was prescribed). If a same-day blood draw is not available, the abstractionist should record results from the most recent blood draw prior to HAART initiation in **Question B6**. This draw will be referred to as the most recent draw before HAART initiation. In order for the participant to be eligible for enrollment, both blood draws listed in **Questions B6A** and **B6B** must be within six months of the date that post-2007 HAART was actually initiated.

If the HIV RNA and/or T-cell results are not at or within six months prior to post-2007 HAART initiation, the woman is ineligible for enrollment. END THE FORM.

If the participant has not taken any HAART subsequent to December 31, 2007, then circle "3" and skip to **Section C**.

B6A: If the results of the assay are below the limit of the assay's detection (also called an "undetectable" result), sites should circle "YES" to **Question B6Aii** and list the assay kit's lower limit of detection in **B6Aiii**.

B6B: For this question, only the CD4 information is required, although, if the CD8 and CD3 information is available, that should be recorded in the spaces provided as well.

SECTION C: Supplemental Abstraction

This section contains fields in which to record supplemental information that is abstracted but not required for enrollment. While no part of this section is required to be completed for a participant to be eligible for enrollment, abstractionists should record here any supplemental information they are able to obtain from the participant's medical records while they are reviewing them for the required information.

Question C2: This question should be completed only if the abstractionist can find information on additional ART/HAART regimens that a participant was on after her first HAART regimen. This would include both HAART and non-HAART regimens. **Question C2** should be completed based on antiretroviral regimens, or antiretroviral drugs that a participant took concurrently. Each regimen should be listed in a different section of **Question C2**.

If no additional regimen information is available after HAART initiation, or if person has never been on an additional regimen, check the pertinent box and skip to **Question C3**.

Question C3: **Question C3** should be used to document a second HIV RNA and/or T-cell result in addition to those results listed in **Question B6**. Any results listed here should be within six months prior to the date of HAART initiation. List the second most recent blood draw in **Question C3** (the most recent draw should be listed in **Question B6**).

If no additional prior results are available, check the pertinent box and skip to **Question C4**.

Question C4: **Question C4** should be used to document any HIV RNA and/or T-cell results that are available post HAART initiation (HIV RNA results in **Question B4A;** T-cell results in **Question B4B**). If multiple results are available, do not include results more frequently than quarterly (e.g., if participant initiated HAART on 1/1 and results are available from 2/5, 3/17, 5/20, 6/18, 9/10 and 12/22, only record the results dated 2/5, 5/20, 9/10 and 12/22). If additional spaces are needed, Xerox either part A or part B as needed.

If no post-HAART HIV RNA and/or T-cell results are available, check the pertinent box and skip to **Question C5**.

Question C5: In **Question C5**, abstractionists can write any additional comments they feel are important to document.