WOMEN'S INTERAGENCY HIV STUDY
QUESTION-BY-QUESTION SPECIFICATIONS
SCR: NEW RECRUITS SCREENING FORM

General Instructions:

1. The form is designed to capture screening data to help determine eligibility into the new cohort. Sites have the option of administering *the Screening Form (SCR)* through an interview or collecting all of the information contained on *SCR* through their medical records and a brief discussion with the candidate. If sites choose not to administer the form in an interview fashion, they must be sure to collect proper consent from the candidate as well as asking about and documenting the candidate's language preference (English or Spanish).

2. 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

If the participant cannot recall the exact date of the month, record the date as "15" per the Manual of Operations. Interviewers should have available an appropriate calendar to aid the participant in determining dates.

SECTION A: General Information

Question A1: All woman should be assigned a screening ID. Sites are responsible for assigning the screening IDs.

Question A2: If the participant is enrolled into WIHS, enter the participant's WIHSID (from the *Eligibility Form*) into this field.

Question A5: Record the date that the potential participant was screened. If the screening procedure is separated into different visits or time points, the first date that the woman visits the clinic for WIHS screening should be recorded in this field.

Question A7: The purpose of this step is to determine in which language, English or Spanish, the participant prefers to be interviewed. If the participant does not speak Spanish, read the introduction in English and proceed with the English version of *SCR*. If the participant prefers to be interviewed in Spanish, obtain a Spanish version of *SCR*. Complete **Questions A1** through **A7** on that form, read the introduction in Spanish, and proceed to conduct the screening procedures with a Spanish speaking interviewer.

NOTE: QUESTIONS A1 AND A7 THROUGH A15 WILL NOT BE DATA ENTERED.

READ INTRODUCTION TO PARTICIPANT: When reading the introduction that describes the study, the interviewer should answer all of the participant's questions. The participant should completely understand the nature of this study and what will be required of her.

Question A8: This question documents whether site-specific procedures require consent before proceeding with screening. Consent might be required for screening only, or for both screening and enrollment before screening may proceed.

If consent of any kind is required at your site before screening may begin, code **Question A8** as "YES" and circle "1." Read the introduction below **Question A8**. Acquire consent needed, and proceed to **Question A9**.

If no consent is needed at this point, skip to **Question A9**.

Question A9: For protocol monitoring purposes, *SCR* requires that all required consents be documented by recording the date that consent forms were signed. If "YES" was coded at **Question A8**, you must document that consent was obtained. **Question A9** provides a space to document the required consent. Ask the participant if she is willing to continue. If her response is "YES," circle "1," have her sign two copies of the consent form(s). Retain one copy for the site records and give the other copy to the participant. Then proceed to **Question A9a** and record today's date. If the participant declines to continue or does not sign all consent forms required by site protocol, code as "NO," circle "2" and **END** the form.

Question A10: If a woman does not consent to have her specimens stored in the WIHS national repository, she is ineligible for entry into the study. If a woman agrees to this, sites must document that the woman has agreed to have specimens stored in the national repository, and record the date this consent was obtained.

Question A11: Sites must verify DOB through a valid identification source such as a driver's license, a passport, a birth certificate, or another valid ID card. Without DOB verification, the participant is ineligible for enrollment into the WIHS.

Question A12: Ask the participant if she plans to move out of the area, i.e., to a location where she would be unable to travel to the WIHS clinic for follow-up visits, within the next 12 months. If she responds "yes," then she is not eligible for enrollment into the WIHS, and you should end the form.

Question A13: Read the question and indicate whether or not the participant considers herself to be of Hispanic or Latina origin.

Question A14: Read the question and code the race that the participant considers *herself* to be. Respondents whose parents are not from the same race/ethnicity will have the most difficulty with this question. For example, if the participant has one African-American parent and one Asian parent, ask the participant what race she considers herself to be, without suggesting that she is either African American or Asian. If she considers herself to be "both" or "bi/multiracial" enter response verbatim in "other."

Question A15: This question is used to track and assess the success/failure of various recruitment techniques. It also serves as a benign lead-in question before asking more personal questions. Probe by asking ***"Any other way?"*** to obtain all of the ways the participant found out about the study. Circle "2" for any sources not mentioned and proceed with **Question B1**.

If the participant does not know how she found out about the study, after probing, code **Question A15** as "6" and proceed to **Section B**.

SECTION B: HIV Status and Medical Conditions

Section B will be data entered for all women who enroll in WIHS.

QB1 & B2: All woman who report that they are seronegative are required to have blood drawn for a HIV test at either screening or baseline. HIV positive women are not required to be retested for HIV if the sites can find hardcopy documentation of a positive ELISA test with a confirmatory Western Blot. If sites are unable to provide this documentation, HIV positive women must be retested.

Question B3: Indicate if the participant has ever tested negative for HIV. In **Question B3a**, enter the date of the participant's most recent negative HIV test.

Question B4: Indicate if the participant is HIV-positive or HIV-negative. If she is HIV-negative, skip to Section C.

QB5 – B26: In this section, **Questions B5** through **B26** ask questions to try to discern if the woman has ever been diagnosed with an AIDS-defining illness. There are a few conditions that a woman may say "YES" to that are, in fact, not AIDS-defining illnesses. Conditions that might be erroneously reported include oral vs. candida esophagitis; candida in the lungs/airways; herpes simplex virus or HSV (cutaneous for 30 days, lungs or esophagus; the AIDS-defining herpes is the chronic presence, without remission of a single ulceration); wasting; non-PCP pneumonia; the diarrheas; TB; and salmonella.

PROMPT: IF AN ENROLLED PARTICIPANT RESPONDS "YES" TO EITHER B26a or B26b, COMPLETE AN ATC FOR EACH ILLNESS.

SECTION C: Antiretroviral Medication History

Section C will be data entered for all women who enroll in WIHS.

Question C1: HAND THE PARTICIPANT THE ANTIVIRAL PHOTO MEDICATION CARD BEFORE READING THIS QUESTION. Read the participant the question, and then walk through the photo med cards with the participant, saying each of the drug names aloud and asking whether she has ever taken this drug.

If **Question C1** is "YES", skip to **Question C3**, otherwise proceed to **Question C2.**

If the participant does not know if she has been taking any antiretroviral medications, proceed to **Question C3**. If she reports taking any of the medications listed in **Questions C3** through **C7**, go back and re-code **Question C1** as "YES." If she reports that she has not taken any of the medications listed on the photo medication cards, re-code **Question C1** as "NO," and ask **Question C2.** Finally, if she reports "Don't know" to the medications in each drug class, keep **Question C1** coded as "DON'T KNOW."

Question C2: If the participant is not taking any antiretroviral treatments or medications, record the main reason why not in **Question C2**. After answering **Question C2**, skip to **Section D.**

QC3 – C7: The drugs listed in **Questions C3** through **C7** are drugs that indicate that a woman might have been on highly active antiretroviral therapy, or HAART. If a woman does not report any of the specific drugs listed in **Questions C3** through **C7**, and the woman reports that she has never been on HAART (**Question C8 = 2**), sites can then assume that this woman is reporting that she has never been on HAART.

If any of the boxes are checked in **Questions C3** through **C7** OR if **Question C8** = 1, obtain medical records release and fill out the box on the front page of a *RAB Form* to indicate to the abstractionist that these records need to be found and abstracted.

If the woman reports "Don't know," interviewers should try to probe for more information before checking the "Don't know" boxes in these questions. One suggestions is to ask ***"Do you have pill bottles with you today of any pills that you are currently taking?"*** If the participant has her current pills on her, interviewers can look at the label to identify dates of the medications and to see where the woman gets her prescriptions filled. Interviewers can also probe to ask the woman where she gets her care – this information can be noted in the margins to help abstractors try to locate the medical records of this woman. Sites should feel free to develop creative ways to try to get the participant to remember the approximate date of the meds she took, as well as the place she received care or got her prescriptions filled.

If, after probing, the woman still is unsure of whether or not she ever took antiviral medications, does not have pill bottles with her, and cannot provide any details about her care giver, care site, or place she fills prescriptions, the woman is inegligible for enrollment.

Question C3: Ask the participant the question, and read through each of the specific PIs listed on the form. If the participant reports any PIs listed in this sections, check the box next to the drug(s) the participant reported. Probe to see if the woman has taken any other PI(s) not listed. If so, record the name of the drug(s) in the space provided. If, overall, only one PI is reported, list that PI in **Question C3a** as the first PI the woman took. If more than one PI is reported, ask the woman which PI(s) the woman took first. It is possible that the woman started taking multiple PIs at the same time. If this is the case, list all PIs that the women reports as taking first in the spaces provided, and record the date she first began using these PI(s) in **Question C3b**.

Question C4: Follow above instructions for **Question C3**, asking about all the non-nucleoside reverse transcriptase inhibitors (NNRTIs) that the participant has ever taken.

Question C5: Follow above instructions for **Question C3**, asking about all the nucleoside reverse transcriptase inhibitors (NRTIs) that the participant has ever taken.

Question C6: Follow the above instructions for **Question C3**, asking about all the combination medications that the participant has ever taken.

Question C7: Follow the above instructions for **Question C3**, asking about all the other medications that the participant has ever taken.

Question C8: Indicate if the participant has ever been on a combination of HIV medications referred to as highly active antiretroviral therapy, or HAART.

PROMPT:	**IF PARTICIPANT REPORTED USE OF ANY OF THE MEDICATIONS IN QUESTIONS C3 THROUGH C7, OR HAART IN QUESTION C8, OBTAIN MEDICAL RECORD RELEASE AND FILL OUT BOX ON FRONT PAGE OF RAB FORM.**

SECTION D: Behavioral Information

NOTE: SECTION D WILL NOT BE DATA ENTERED.

Question D3: Try to ensure that the participant's answers throughout this section are consistent and do not conflict with one another. If there are conflicts, go back and try to resolve the conflicts with the participant. If necessary, make changes to the participant's responses as you probe for more information. For example, if the participant reports in **Question D3c** that she had unprotected sex in the past five years with three men, and reports in **Question D3a** that she had sex with zero men in the past five years, this is a conflict and should be resolved on the spot.

Question D3a: This question tries to get the participant to estimate how many men she has had sex with in the past five years. Emphasize "in the past five years." If the participant cannot remember or does not know, try to get her to estimate as best she can. If she reports a range, such as "between 5 to 10," record the lower end of the range (i.e., record as if the participant had responded "5," therefore **Question D3a** would be coded with the answer "1-5").

Question D3c: Apply same directions for **Question D3a** to **Question D3c**.

Questions D4 – D6d: These questions try to capture information on the risk of the participant's sex partner in the past five years. The participant's sex partner can either be a male or a female.

Question D6a: This question tries to get the participant to estimate how many women and men her sex partner has had sex with in the past five years. Emphasize "in the past five years." If the participant cannot remember or does not know, try to get her to estimate as best she can. If she reports a range, such as "between 5 to 10," record the lower end of the range (i.e., record as if the participant had responded "5," therefore **Question D6a** would be coded with the answer "1-5").

Question D6c: Apply same directions for **Question D6a** to **Question D6c**.