

# WOMEN'S INTERAGENCY HIV STUDY

## QUESTION-BY-QUESTION SPECIFICATIONS

### EL: ELIGIBILITY FORM

#### SECTION A: General Information

- Question A1: All woman should be assigned a screening ID. Sites are responsible for assigning the screening IDs.
- Question A3: 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 A5: Enter the participant's preferred interview language from **Question A7** on the *Screening Form (SCR)*.
- Question A6: Enter the participant's HIV (**Question B4**) and therapy use status (**Question C8**) from the *Screening Form (SCR)*. Seronegatives must have blood drawn for an HIV test at either the screening or the enrollment visit (or at the combined screening/enrollment visit). Seropositives for whom there is not hardcopy documentation of a positive HIV test result must also have blood drawn for an HIV test. Seropositives who have documentation of a positive HIV test do not need to be retested.
- Question A7: Enter the participant's date of birth from **Question A11** on the *Screening Form (SCR)*.
- Question A8: Enter the participant's ethnicity from **Question A13** on the *Screening Form (SCR)*.
- Question A9: Enter the participant's race from **Question A14** on the *Screening Form (SCR)*.

#### SECTION B: Eligibility

- Question B1a: If the participant is not between 25 and 60 years old at the time of enrollment, she is ineligible for enrollment. See "date of birth" in **Question A7** to determine participant's age at time of enrollment visit.
- Question B1b: If participant has used antiretroviral therapy (ART), but not HAART, the participant is ineligible for enrollment. See **Question B0** on the *Retroactive Abstraction (RAB) Form* to determine if the participant has ever used any type of ART.
- Question B1c: If participant is a HAART user:
- (1) date of first HAART use/prescription must be verified via MRA,
  - (2) date of first HAART cannot be before January 1, 2005, unless the participant used HAART only during pregnancy or for PEP/PrEP,
  - (3) HIV RNA and CD4 cell count must be known within the six months prior to first HAART use, and
  - (4) the participant must not have ever used ddI (Videx, didanosine), ddC (Hivid, zalcitabine) or d4T (Zerit, stavudine), unless if use was only during pregnancy or for PEP/PrEP.
- If any of these conditions is not met, participant is ineligible for enrollment.

- Question B1d: If participant has plans to move out of the WIHS clinic area within the next 12 months, she is not eligible for enrollment. See **Question A12** on the *Screening Form (SCR)*.
- Question B1e: Participant must give consent to participate in WIHS. See **Question A9** on the *Screening Form (SCR)*.
- Question B1f: Participant must give consent for her specimens to be stored in the WIHS National Repository. See **Question A10** on the *Screening Form (SCR)*.
- Question B2: Indicate how the participant found out about the WIHS. See **Question A15** on the *Screening Form (SCR)*.
- Question B3a: Indicate if the participant has reported injection drug use or use of crack, cocaine, heroin or methamphetamine in the past five years prior to enrollment. This information is available in **Question D1a** of the *Screening Form (SCR)*.
- Question B3b: Indicate if the participant has been told by a health care provider that she had an STD in the past five years prior to enrollment. This information is available in **Question D2** of the *Screening Form (SCR)*.
- Question B3c: Indicate if the participant had sex with a known HIV-positive man in the past five years prior to enrollment. This information is available in **Question D3b** of the *Screening Form (SCR)*.
- Question B3d: Indicate if the participant has had unprotected sex with three or more men in the past five years prior to enrollment. This information is available in **Question D3c** of the *Screening Form (SCR)*.
- Question B3e: Indicate if the participant has had sex for drugs, money or shelter in the past five years prior to enrollment. This information is available in **Question D3d** of the *Screening Form (SCR)*.
- Question B3f: Indicate if the participant has had sex with six or more men in the past five years prior to enrollment. This information is available in **Question D3a** of the *Screening Form (SCR)*.
- Question B3g: Indicate if the participant's sex partner has reported injection drug use or use of crack, cocaine, heroin or methamphetamine in the past five years prior to enrollment. This information is available in **Question D4** of the *Screen Form (SCR)*.
- Question B3h: Indicate if the participant's sex partner has been told by a health care provider that he/she had an STD in the past five years prior to enrollment. This information is available in **Question D5** of the *Screen Form (SCR)*.
- Question B3i: Indicate if the participant's sex partner had sex with a known HIV-positive woman or man in the past five years prior to enrollment. This information is available in **Question D6b** of the *Screen Form (SCR)*.
- Question B3j: Indicate if the participant's sex partner has had unprotected sex with three or more women or men in the past five years prior to enrollment. This information is available in **Question D6c** of the *Screen Form (SCR)*.

Question B3k: Indicate if the participant's sex partner has had sex for drugs, money or shelter in the past five years prior to enrollment. This information is available in **Question D6d** of the *Screening Form (SCR)*.

Question B3l: Indicate if the participant's sex partner has had sex with six or more women or men in the past five years prior to enrollment. This information is available in **Question D6a** of the *Screening Form (SCR)*.

**PROMPT: HIV-NEGATIVE ENROLLEES MUST MEET AT LEAST ONE OF THE CRITERIA IN QUESTION B3 IN ORDER TO BE ELIGIBLE FOR ENROLLMENT.**

Question B4: Indicate if the participant is eligible and/or enrolled for the WIHS.

Question B5: After generating a new WIHSID for the participant, record the WIHSID in **Question B5**.

Question B6: If the participant declined to participate in WIHS, enter the reason why in **Question B6**.