

**WOMEN'S INTERAGENCY HIV STUDY
CARDIOVASCULAR SUBSTUDY
FORM CVNOTI: PARTICIPATION NOTIFICATION
QUESTION-BY-QUESTION SPECIFICATIONS**

INSTRUCTIONS FOR COMPLETION OF CVNOTI FORM

Every WIHS participant who completes a core visit during the visit 20 window should be invited to enroll in the Cardiovascular Substudy. If the participant does not enroll at visit 20, attempt to enroll her at each subsequent visit through visit 23.

- **If the participant agrees to enroll into the substudy**, schedule her carotid ultrasound visit. The *CVNOTI* form should be completed at the ultrasound visit and entered at that time into Apollo. Fasting blood specimens should be collected at the participant's core visit (if she is fasting), at a special fasting visit, or at the ultrasound visit.
- **If the participant does not enroll into the substudy**, complete the *CVNOTI* form (through question A5a) at the participant's core visit and enter into Apollo.

- A1. Enter the participant's WIHSID number.
- A2. The form version will be pre-printed on the form.
- A3. Enter the initials of the person completing the form.
- A4. Enter the WIHS core visit number during which the participant was approached for enrollment into the substudy.
- A5. Indicate whether or not the participant will enroll into the substudy during the current visit window. If "YES," skip to question A6.
- a. Indicate the main reason the participant is not enrolling into the substudy during the current visit window. Circle only one response. If the participant does not enroll into the substudy during the current visit window, enrollment should be re-attempted at each subsequent core visit through visit 23.

**PROMPT: IF PARTICIPANT DOES NOT ENROLL INTO THE SUBSTUDY, END FORM HERE.
DATA ENTER *CVNOTI* AT CORE VISIT. BASED ON RESPONSE IN A5a ABOVE,
ATTEMPT ENROLLMENT AT A SUBSEQUENT VISIT IF APPLICABLE.**

- A6. Indicate whether the participant was HIV-positive or HIV-negative at the time of enrollment. This information will be used for tracking enrollment statistics only.
- A7. Indicate in whether or not the participant is currently taking each of the listed classes of antiretroviral medications (NRTI, NNRTI, PI, Entry Inhibitor). Information regarding the participant's antiretroviral medication use should be obtained from the Drug 1 forms completed at her most recent core WIHS visit. This information will be used for tracking enrollment statistics only.
- A8. If the participant agrees to enroll into the substudy, a date should be scheduled for the carotid ultrasound exam. Record this date in question A8.
- A9. The first 20 women who agree to have a second carotid ultrasound scan at each clinical site will be selected to receive a Quality Control (QC) ultrasound scan. Indicate here whether this participant has agreed to receive a QC ultrasound scan. If "NO," skip to question A10.
- a. Enter the date on which the participant's QC scan has been scheduled. The QC scan should be conducted within one month of the original scan.

WIHS ID#

- A10. Collection of a fasting blood specimen at least once per year is a criterion of participation in the Cardiovascular Substudy. Indicate when fasting blood for the substudy has been or will be collected. If the participant attended her core visit while fasting, the specimens should have been collected during the core visit and recorded on WIHS forms F29 and CV29. If the participant did not fast for her core visit, fasting specimens can be collected during the carotid ultrasound visit, or during a specially scheduled fasting visit.
- A11. Indicate whether or not fasting specimens have already been collected for the participant. If “NO,” skip to PROMPT and schedule a date for special CVD blood collection.
- a. Record the date on which fasting blood specimens were collected. End the form.

PROMPT: IF FASTING CVD BLOOD DRAW HAS NOT YET BEEN COMPLETED, SCHEDULE A SPECIAL CVD BLOOD COLLECTION VISIT NOW (PREFERABLY WITHIN TWO WEEKS) AND ENTER DATE OF SCHEDULED VISIT BELOW. REMIND PARTICIPANT THAT SHE MUST NOT EAT OR DRINK ANYTHING OTHER THAN WATER FOR EIGHT HOURS PRIOR TO HER SPECIAL CVD BLOOD COLLECTION VISIT.

- b. Record the date on which fasting blood specimens are scheduled to be collected.

PROMPT: ENTER *CVNOTI* INTO APOLLO. PERFORM CAROTID ULTRASOUND AND COMPLETE *CV01* (CAROTID ULTRASOUND TRACKING FORM).