

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
CV29: CARDIOVASCULAR SUBSTUDY FASTING
BLOOD SPECIMEN COLLECTION FORM

SECTION A. PARTICIPANT'S FASTING STATUS

Prior to visit 20, WDMAC would calculate fasting status and request that only fasting specimens be sent for metabolic-related assays twice a year. Beginning with visit 20, however, the metabolic panel will be completed on a monthly basis and both fasting and non-fasting specimens will be sent directly from the sites for testing. The tests ordered will differ slightly for participants that have fasted for eight or more hours vs. participants that have not. Therefore, it is very important that clinic staff accurately assesses the participant's fasting status and relay that information to the local processing laboratory. This information will determine the type of tests ordered and the cost of the panel.

- A1. Record the date the blood was drawn in MM/DD/YY format.
- A2. Record the time the blood was drawn in HH:MM format. Use leading zeros. Do not use military time. Be sure to indicate AM or PM by circling the appropriate code, 1 = AM or 2 = PM.
- A3. Ask the participant when she last had anything to eat or drink except water. If the participant ate or drank anything (besides water), including gum or coffee, less than eight hours prior to the blood draw, then the participant is not fasting.
 - a. Record the date that the participant last ate or drank anything besides water.
 - b. Record the time that the participant last ate or drank anything besides water.
- A4. Keeping in mind the eight-hour fasting criteria, review the time and date of the blood draw and the participant's report of the last time she ate or drank anything besides water. Circle 1 if she was fasting at the time of the draw, and 2 if she was not fasting.

SECTION B. CENTRIFUGE INFORMATION

This form is designed to collect information about the fasting blood draw for participants enrolled in the Cardiovascular Substudy.

- B1. Record the type of visit during which this blood collection event will occur. Select each option according to the criteria listed.
 - 1. CORE, prior to Ultrasound visit: In addition to Form 29, if the participant is fasting at the core visit AND enrolls in the Cardiovascular Substudy.
 - 2. At Ultrasound visit: If the participant and site are able to coordinate a fasting blood draw at the Ultrasound visit.
 - 3. At Quality Control Ultrasound visit: If the participant and site are able to coordinate a fasting blood draw at the Quality Control Ultrasound visit.
 - 4. At special Cardiovascular Substudy blood collection visit: If the participant has been unable to provide fasting specimens at all other visits but comes in to the clinic for a special fasting blood draw specifically to meet the requirements of the Cardiovascular Substudy.
 - 5. CORE: In addition to Form 29, if the participant is fasting at the core visit AND is enrolled in the Cardiovascular Substudy.
- B2. Record the initials of the phlebotomist who obtained the fasting blood draw.

- B3. Indicate whether or not the gold or tiger-top SST tubes were centrifuged in the clinic, **before the tubes were sent to the lab for processing**. If “YES,” go to **B4**. If “NO,” skip to **B5**. **Be sure that question B3 is coded “YES” only if the gold or tiger-top SST tubes are centrifuged in the clinic where the blood is drawn.**
- B4. Record the time the gold or tiger-top SST tubes were centrifuged in the clinic in HH:MM format. Use leading zeros. Do not use military time. Be sure to indicate AM or PM by circling the appropriate code, 1 = AM or 2 = PM. Please note: question **B4** refers to centrifugation that occurs **in the clinic** where the blood is drawn. **Do not record information regarding centrifugation that occurs in the lab.** That information will be captured on Form 10 (Plasma and Cell Separation and Freezing Form).
- B5. Indicate whether or not the NMR lipoprotein lavender-top tube was centrifuged in the clinic, **before the tube was sent to the lab for processing**. If “YES,” go to **B6**. If “NO,” skip to **C1**. **Be sure that question B5 is coded “YES” only if the NMR lipoprotein lavender-top tube is centrifuged in the clinic where the blood is drawn.**
- B6. Record the time the NMR lavender-top tube was centrifuged in the clinic in HH:MM format. Use leading zeros. Do not use military time. Be sure to indicate AM or PM by circling the appropriate code, 1 = AM or 2 = PM. Please note: question **B6** refers to centrifugation that occurs **in the clinic** where the blood is drawn. **Do not record information regarding centrifugation that occurs in the lab.** That information will be captured on Form 10 (Plasma and Cell Separation and Freezing Form).

SECTION C. BLOOD DRAW

- C1–C4 Listed in order of priority, are the test type and tubes required for the Cardiovascular Substudy fasting blood draw. Women enrolled into this substudy will need to provide the tubes listed on this form with a fasting status (no food or drink except water for 8 or more hours) at least once per year.
- C1 & C4. If this tube was collected at a fasting Core visit then circle code “3” and only draw blood for tubes listed in C2 and C3.
- a. Indicate whether or not a tube was drawn/collected for each test. If “YES,” go to subquestion **b**. If “NO,” specify the reason why that tube was not drawn at subquestion **a.i.** and proceed to the next test type.
 - b. Indicate whether or not the required volume for each tube was collected. If “YES,” proceed to the next test type. If “NO,” go to subquestion **c**.
 - c. If the required volume was not obtained, estimate, in milliliters, the volume collected.