

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM 29: 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 assess 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. PROCESSING INFORMATION

This form is designed to collect information about the blood draw. Blood can be drawn on two different dates and the information from both draws should be recorded on this form. If the phlebotomist successfully obtains the required volume in the first draw, s/he should complete B1–B6 then proceed to Section C. If a second draw is necessary, complete B7–B13 in addition to B1–B6. This form should be completed by **clinic staff, not laboratory staff.**

- B1. Record the phlebotomist's initials for the first blood draw.
- B2. Indicate whether or not the CPT tubes were centrifuged in the clinic, **before the tubes were sent to the lab for processing.** If "YES," go to **B3.** If "NO," skip to **B4.** Please note: if tubes are centrifuged in the lab (not in the clinic where the blood is drawn) information about centrifugation is captured on Form 10 (Plasma and Cell Separation and Freezing Form). **Be sure that question B2 is coded "YES" only if the CPT tubes are centrifuged in the clinic where the blood is drawn.**
- B3. Record the time the CPT 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 B3 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).
- B4. Indicate whether or not the SST tube for metabolic panel was centrifuged in the clinic, **before the tube was sent to the lab for processing.** If "YES," go to **B5.** If "NO," skip to **B6.** Please note: if tube is centrifuged in the lab (not in the clinic where the blood is drawn) information about centrifugation is captured on Form 10 (Plasma and Cell Separation and Freezing Form). **Be sure that question B4 is**

coded “YES” only if the SST tube for metabolic panel is centrifuged in the clinic where the blood is drawn.

- B5. Record the time the SST tube for metabolic panel 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 B5 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).
- B6. Indicate whether or not blood was drawn on a second date for this visit. If “YES,” go **B7**. If “NO,” skip to **C1**.

PROMPT: IF SECOND BLOOD DRAW IS PERFORMED, COMPLETE A SECOND F29a FORM PRIOR TO BLOOD DRAW.

- B7. Record the date of the second blood draw in MM/DD/YY format.
- B8. Record the time of the second blood draw 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.
- B9. Record the initials of the phlebotomist who obtained the second blood draw.
- B10. Indicate whether or not the CPT tubes were centrifuged in the clinic, **before the tubes were sent to the lab for processing**. If “YES,” go to **B11**. If “NO” or not applicable, skip to **B12**. Please note: if tubes are centrifuged in the lab (not in the clinic where the blood is drawn) information about centrifugation is captured on Form 10 (Plasma and Cell Separation and Freezing Form). **Be sure that question B10 is coded “YES” only if the CPT tubes are centrifuged in the clinic where the blood is drawn.**
- B11. Record the time the CPT tubes were centrifuged 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 **B11** 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).
- B12. Indicate whether or not the SST tube for metabolic panel was centrifuged in the clinic, **before the tube was sent to the lab for processing**. If “YES,” go to **B13**. If “NO,” skip to **Section C**. Please note: if tube is centrifuged in the lab (not in the clinic where the blood is drawn) information about centrifugation is captured on Form 10 (Plasma and Cell Separation and Freezing Form). **Be sure that question B12 is coded “YES” only if the SST tube for metabolic panel is centrifuged in the clinic where the blood is drawn.**
- B13. Record the time the SST tube for metabolic panel 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 B13 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–C13 Listed in order of draw, are the test types and tubes required for the WIHS follow-up visit.
- 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.
 - 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**.
 - If the required volume was not obtained, estimate, in milliliters, the volume collected.

NOTES:

1. **C1** (HIVAb), should **not** be collected on HIV-positive participants after baseline. This should be indicated by circling code “3” (N/A) during follow-up.
2. Beginning with visit 14, **C2** (Liver/Renal Function) will be collected **at every visit**.
3. **C4 and C12** (TC, HDL-C, TRIG, dLDL-C, Insulin, Hemoglobin A1c) should be collected from visit 20 through visit 26 on **all WIHS participants**, regardless of whether or not the participant has fasted prior to her visit. If the participant is not fasting, then Triglycerides and Insulin will be omitted from the testing panel.
4. **C4d** (Novel CVD Assay) and **C12d** (NMR Lipoprotein) should be collected only for **women enrolled in the Cardiovascular Disease Substudy who have fasted for at least eight hours** prior to the blood draw. Prompts for collection of these tubes are included on the F29 form to ensure specimens are collected in the correct order; however, specifics about their collection will be recorded on form CV29.
5. **C10** (CBC/Diff) and **C11** (T-cell Subsets) should not be collected at odd-numbered visits for sero-negative WIHS participants. Beginning with visit 11, CBC/Diff and T-cell Subsets will be collected annually for sero-negative WIHS participants, only on even visits. On odd visits, circle code “3” indicating not applicable.
6. **C13** (Glucose) should be collected from visit 20 through visit 26 on **WIHS participants only if they have fasted for at least eight hours** prior to the blood draw.