

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM 29: BLOOD SPECIMEN COLLECTION FORM

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 during the first draw, she should complete **Section A**, then proceed to **Section C**. If a second draw is necessary, complete **Section B** in addition to **Section A**. This form should be completed by **clinic staff, not laboratory staff**.

SECTION A. FIRST BLOOD DRAW

- 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. Record the phlebotomist's initials for the first blood draw.
- A4. 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.
- A5. 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. It is very important that clinic staff accurately assess the participant's fasting status. Circle 1 if she was fasting at the time of the draw, and 2 if she was not fasting.
- A6. 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 **A7**. If "NO," skip to **A8**. 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 A6 is coded "YES" only if the CPT tubes are centrifuged in the clinic where the blood is drawn.**
- A7. 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 **A7** 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).
- A8. 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 **A9**. If "NO," skip to **A10**. 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 A8 is coded "YES" only if the SST tube for metabolic panel is centrifuged in the clinic where the blood is drawn.**
- A9. 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 **A9** 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).

- A10. Indicate whether or not blood was drawn on a second date for this visit. If “YES,” complete **SECTION B**. If “NO,” skip to **SECTION C**.

SECTION B. SECOND BLOOD DRAW

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

- B1. Record the date of the second blood draw in MM/DD/YY format.
- B2. 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.
- B3. Record the initials of the phlebotomist who obtained the second blood draw.
- B4. 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.
- Record the date that the participant last ate or drank anything besides water.
 - Record the time that the participant last ate or drank anything besides water.
- B5. 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.
- B6. 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 **B7**. If “NO” or not applicable, skip to **B8**. 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 B6 is coded “YES” only if the CPT tubes are centrifuged in the clinic where the blood is drawn.**
- B7. 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 **B7** 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).
- B8. 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 **B9**. 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 B8 is coded “YES” only if the SST tube for metabolic panel is centrifuged in the clinic where the blood is drawn.**
- B9. 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 **B9** 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 **ai** 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**.

- c. If the required volume was not obtained, estimate, in milliliters, the volume collected.

NOTES REGARDING COLLECTION SCHEDULE:

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** (TC, HDL-C, TRIG, LDL-C, Insulin) should be collected on **all WIHS participants at odd visits only**, regardless of whether or not the participant has fasted prior to her visit. If a participant misses an odd visit, collect this tube at her next even visit, plus her next odd visit to get the participant back on an odd-visit schedule. If the participant is not fasting, then Triglycerides and Insulin will be omitted from the testing panel. Circle code “3” (N/A) if tube does not need to be collected at the current visit.
4. **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 at even visits. At odd visits, circle code “3” indicating not applicable.
5. **C13** (Glucose) should be collected, **at odd visits only**, on **WIHS participants only if they have fasted for at least eight hours** prior to the blood draw. If a participant misses an odd visit, collect this tube at her next even visit, plus her next odd visit to get the participant back on an odd-visit schedule. Circle code “3” (N/A) if the tube does not need to be collected at the current visit. Circle code “2” (NO) if the tube cannot be collected at the current visit because the participant is not fasting. In this case, enter “not fasting” into the specify field in **C13ai**.

FOR WOMEN ENROLLED IN THE CARDIOVASCULAR SUBSTUDY:

If a participant is enrolled in the CVD substudy and is non-fasting at her core visit at which lipid/glucose specimens are to be collected, please request that she return for a separate fasting visit so that lipid and glucose specimens can be collected. Complete form CV29 to record information about specimens collected at a separate fasting visit. Non-fasting women who are not enrolled in the CVD substudy do not need to return for a separate fasting visit for lipid/glucose collection.

EXAMPLES:

- Participant missed visit 23. Collect **C4** (TC, HDL-C, TRIG, LDL-C, Insulin) and **C13** (glucose) specimens at visit 24 and again at visit 25. Record collection on F29.
- Participant attended visit 23. Collect **C4** (TC, HDL-C, TRIG, LDL-C, Insulin) and **C13** (glucose) specimens at visit 25. Record collection on F29.
- Participant is not fasting at visit 25 core visit and *is not* enrolled in CVD substudy. Collect **C4** (TC, HDL-C, LDL-C) at visit 25 core visit. Do not collect **C13** (glucose). Record collection on F29. Do not schedule separate fasting visit.
- Participant is not fasting at visit 25 core visit and *is* enrolled in CVD substudy. Collect **C4** (TC, HDL-C, LDL-C) at visit 25 core visit. Do not collect **C13** (glucose) at visit 25 core visit. Record core visit collection on F29. Schedule separate fasting visit for collection of lipid (TC, HDL-C, TRIG, LDL-C, Insulin) and glucose specimens. Record separate fasting visit collection on CV29.