

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**.

- A0. Complete the checklist in Questions A0a through A0e to help in determination of which tubes should be collected from participant.
- a. If participant is an elite controller, collect tubes labeled for "VIPS," i.e., tubes C5 and C12 through C14. To be an elite controller, (1) participant must have had undetectable viral load at previous visit, and (2) participant must not have been on antiretroviral therapy at her previous visit.
 - b. If participant is formerly ART-naïve and is taking ART or HAART for the first time at the current visit, collect tubes labeled for "VIPS," i.e., tubes C5 and C12 through C14.
 - c. If participant is a seroconverter, collect tubes labeled for "VIPS," i.e., tubes C5 and C12 through C14. Participant must have been identified as a seroconverter at her previous visit.
 - d. If participant is in the HPV Substudy, collect tube labeled for "HPV Substudy," i.e., tube C18. Participants in the Oral HPV Study (POPS) should be targeted for enrollment into the HPV Substudy.
 - e. If participant is in the Musculoskeletal (MSK) Substudy, collect tubes labeled for "MSK Substudy," i.e., tubes C6 and C15 through C17.

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, tea 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 **Question A7**. If "NO," skip to **Question 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 **Question A9**. If “NO,” skip to **Question 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, tea 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 **Question B7**. If “NO” or not applicable, skip to **Question 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 **Question 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–C23 Listed, in order of draw, are the test types and tubes to be collected for the WIHS follow-up visit. Tubes shaded in gray are for substudies and will not be collected from all participants. See checklist in Question A0 and footnotes for details regarding which tubes should be collected from which participants.
- 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**.
 - If the required volume was not obtained, estimate, in milliliters, the volume collected.

NOTES REGARDING COLLECTION SCHEDULE:

Question C1 (HIV Ab), should **not** be collected on HIV-positive participants after baseline. At follow-up visits, circle code “3” (N/A) for this question for HIV-positive participants.

Beginning with visit 14, **Question C2** (Liver/Renal Function) will be collected **at every visit**.

Question C4 (TC, HDL-C, TRIG, LDL-C, Insulin) should be collected on **all WIHS participants once per year only, at odd-numbered visits**, 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. Circle code “3” (N/A) if tube does not need to be collected at the current visit, i.e., at an even-numbered visit.

Question C5 (serum repository for VIPs) should be collected only if the participant has been identified as a VIP participant based on prior visit data. If the participant has not been identified as “VIP,” then circle code “3” (N/A).

Question C6 (serum for MSK Substudy) should be collected only if the participant has been identified as a participant in the Musculoskeletal (MSK) Substudy. If the participant is not in the MSK Substudy, then circle code “3” (N/A).

Questions C12 through C14 (cell repository for VIPs) should be collected only if the participant has been identified as a VIP participant based on prior visit data. If the participant has not been identified as “VIP,” then circle code “3” (N/A).

Questions C15 through C17 (cells for MSK Substudy) should be collected only if the participant has been identified as a participant in the Musculoskeletal (MSK) Substudy. If the participant is not in the MSK Substudy, then circle code “3” (N/A).

Question C18 (fresh blood for HPV study) should be collected only if the participant has been identified as a participant in Howard Strickler’s HPV substudy. If the participant is not in the HPV substudy, then circle code “3” (N/A).

Question C19 (CBC/Diff) and **Question C20** (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.

Question C21 (Hemoglobin A1c) should be collected on **all WIHS participants once per year only at odd-numbered visits**, regardless of whether or not the participant has fasted prior to her visit. Circle code “3” (N/A) if tube does not need to be collected at the current visit.

Question C23 (Glucose) should be collected, **once per year only at odd-numbered visits**, on **WIHS participants only if they have fasted for at least eight hours** prior to the blood draw. 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 **Question C23ai**.