

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. If necessary, blood can be drawn on two different dates. The information from each draw should be recorded on a separate F29 form, with the number of the blood draw (i.e., “first” or “second”) recorded in **Question A2a**.

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 “EVENT,” i.e., tubes C6 and C13 through C15. 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. If participant is HIV-negative, circle “3” for “N/A in Question A0a.”
 - b. If participant is formerly ART-naïve and is taking ART or HAART for the first time at the current visit, collect tubes labeled “EVENT,” i.e., tubes C6 and C13 through C15. If participant is HIV-negative, circle “3” for “N/A in Question A0bi and skip to Question A0c.”
 - c. If participant is a seroconverter, collect tubes labeled “EVENT,” i.e., tubes C6 and C13 through C15. Participant must have been identified as a seroconverter at her previous visit.
 - e. If participant is in the Musculoskeletal (MSK) Substudy, collect tubes labeled for “MSK Substudy,” i.e., tubes C7 and C16 through C18.
 - f. If, according to the Visit Control Sheet (VCS), the participant has completed treatment for Hepatitis C at her prior visit, then collect tube labeled “Serum HCV med tx completed,” i.e., tube C5.

SECTION A. 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.
- a. Indicate if this is the “first” or “second” blood draw at this visit for this participant.

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

- A3. Record the phlebotomist's initials for the 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: 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.
- 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 **Section C**.
PLEASE NOTE: 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.

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.
- 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 **ai** 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.

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 even-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 odd-numbered visit.

Question C5 (serum HCV med tx completed) should be collected only if the participant has been identified as an eligible participant based on prior visit data as indicated on the Visit Control Sheet (VCS). If the participant has not been identified as such, then circle code “3” (N/A).

Question C6 (serum repository EVENT) should be collected only if the participant has been identified as an eligible participant based on prior visit data. If the participant has not been identified as such, then circle code “3” (N/A).

Question C7 (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 C13 through C15 (cell repository EVENT) should be collected only if the participant has been identified as an eligible participant based on prior visit data. If the participant has not been identified as such, then circle code “3” (N/A).

Questions C16 through C18 (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 C19 (CBC/Diff) should not be collected at odd-numbered visits for sero-negative WIHS participants. Beginning with visit 11, CBC/Diff will be collected annually for sero-negative WIHS participants, only at even visits. At odd visits, circle code “3” indicating not applicable.

Question C20 (T-cell Subsets) should not be collected for sero-negative WIHS participants. Beginning with visit 36, T-cell Subsets will be collected only at baseline for sero-negative WIHS participants. At follow-up visits, circle code “3” indicating not applicable.

Question C21 (Hemoglobin A1c) should be collected on **all WIHS participants once per year only at even-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 even-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**.