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

SECTION A

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 A1–A6 then proceed to Section B. If a second draw is necessary, complete A7–A11 in addition to A1–A6. This form should be completed by **clinic staff**, <u>not</u> **laboratory staff**.

- 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.
- A4. 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 A5. If "NO," skip to A6. 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 A4 is coded "YES" only if the CPT tubes are centrifuged in the clinic where the blood is drawn.
- A5. 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 A5 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).
- A6. Indicate whether or not blood was drawn on a second date for this visit. If "YES," go A7. If "NO," skip to B1.
- A7. Record the date of the second blood draw in MM/DD/YY format.
- A8. 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.
- A9. Record the initials of the phlebotomist who obtained the second blood draw.
- A10. 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 A11. If "NO" or not applicable, skip to B1. 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 A10 is coded "YES" only if the CPT tubes are centrifuged in the clinic where the blood is drawn.
- A11. 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 A11 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 B. BLOOD DRAW

- B1-B13 Listed in order of priority, are the test type and tubes required for the WIHS follow-up visit.
 - 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.

NOTE: B1 (HIVAb), should **not** be collected on HIV positive participants after baseline. This should be indicated by circling code "3" (N/A) during follow-up.

NOTE: B2 (CBC/Diff) and **B3** (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.

NOTE: Beginning with visit 14, B9 (Liver/Renal Function) will be collected at every visit.

NOTE: B10–B12 (Insulin/Lipids Repository, Hemoglobin A1c Repository, Glucose) should be collected from visit 13 through visit 16 on **all WIHS participants**, regardless of whether or not the participant has fasted prior to her visit.