

WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
CV29: CARDIOVASCULAR SUBSTUDY FASTING
BLOOD SPECIMEN COLLECTION FORM

Women enrolled in the Cardiovascular (CVD) Substudy are required to provide fasting specimens for lipid and glucose assays at least once per year (to be collected at odd visits).

If a participant attends her core visit fasting, collect the lipid and glucose specimens during the core visit and record information about their collection on form F29 (questions C4 and C13). Do not complete CV29 for specimens collected at the core visit.

If the participant 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 CV29 to record information only about these specimens collected at a separate fasting visit.

SECTION A. PARTICIPANT'S FASTING STATUS

- 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. It is very important that clinic staff accurately assesses the participant's fasting status.
 - 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. If participant is not fasting, end form and attempt to reschedule participant for a new fasting visit. Do not complete blood draw if participant is not fasting.

SECTION B. CENTRIFUGE INFORMATION

This form is designed to collect information from the separate fasting visit for participants enrolled in the Cardiovascular Substudy.

- B2. Record the initials of the phlebotomist who obtained the fasting blood draw.
- B3. Indicate whether or not the gold or tiger-top SST tubes were centrifuged in the clinic, **before the tubes were sent to the lab for processing**. If "YES," go to B4. If "NO," skip to Section C. **Be sure that question B3 is coded "YES" only if the gold or tiger-top SST tubes are centrifuged in the clinic where the blood is drawn.**
- B4. Record the time the gold or tiger-top SST 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 B4 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 & C4 Listed in order of priority, are the test type and tubes required for the Cardiovascular Substudy fasting blood draw. Women enrolled into this substudy will need to provide the tubes listed on this form with a fasting status (no food or drink except water for 8 or more hours) at least once per year.
- 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.

EXAMPLES:

- Participant is not fasting at her core visit and *is not* enrolled in CVD substudy. Collect **C4** (TC, HDL-C, LDL-C) at core visit. Do not collect **C13** (glucose). Record collection on F29. Do not schedule separate fasting visit.
- Participant is not fasting at core visit and *is* enrolled in CVD substudy. Collect **C4** (TC, HDL-C, LDL-C) at core visit. Do not collect **C13** (glucose) at 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.