

DRAFT QxQ Instructions for the HCHS/SOL Biospecimen Collection form

I. General Instructions

The BIOSPECIMEN COLLECTION FORM is completed during the participant's clinic visit to record information on the collection and processing of blood and urine samples. Technicians performing venipuncture and processing blood and urine samples must be certified and should have a working knowledge of the relevant Manuals of Operations.

Place a bar code participant ID and Lab ID# labels in the appropriate spots at the top of the form.

A. Safety Questions

1. If the participant has had a radical mastectomy or other surgery where lymph nodes were removed from their armpits, specify in Q15 and do not perform venipuncture on that arm. If lymph nodes were removed from both armpits, venipuncture cannot be performed on this participant.
2. If participant has a bleeding disorder, specify in Q15 and consult with the field center physician, physician assistant or nurse practitioner before proceeding with the venipuncture. If the participant does not know whether he/she has a bleeding disorder, offer the explanation, "If you have a bleeding disorder you would have symptoms like excessive nose bleeds, or very easy bruising, or problems with bleeding after tooth extractions, or any type of surgery." If the participant is still unsure, consult with field center medical personnel before going on.
3. If a participant has a graft or shunt for kidney dialysis, specify in Q15 and do not perform venipuncture from the arm with the graft or shunt. If the participant has a graft or shunt in both arms, venipuncture cannot be performed on this participant. If the participant is on kidney dialysis, exclude them from the OGTT. Tell them "Because you are on kidney dialysis, it may not be useful or safe for you to participate in this part of the study."
4. If participant has diabetes, exclude them from the OGTT. Tell them "Because you are already diagnosed with diabetes, it may not be useful or safe for you to participate in this part of the study."
5. If participant has part of their stomach or intestines removed, exclude them from the OGTT. Tell them "Because you have had part of your stomach or intestines removed, it may not be useful or safe for you to participate in this part of the study."
6. Enter glucose screening result. If the result is above 150 mg/dL, exclude from OGTT. Tell them "Because your glucose level is elevated, it may not be safe for you to participate in this part of the study."
 - 6a. If the glucose screen result is 200-399 mg/dL and the participant has hyperglycemic symptoms, mark the appropriate box and contact the clinic manager to refer participant to the emergency room. Symptoms of hyperglycemia include thirst, frequent urination, dizziness, active infection, or blurred vision.
 - 6b. If the glucose is above 200-399 mg/dL and the urine dipstick is positive for ketones, mark the appropriate box and contact the clinic manager to refer participant to the emergency room. If the urine dipstick is negative for ketones, make a note on the Clinic Check off Sheet so that during the exit interview the participant can be referred to a health care provider or a referral physician to be evaluated within one week.

If the glucose is above 400 mg/dL, STOP the examination and contact the clinic manager to refer the participant to the emergency room (regardless of the presence of symptoms).

B. Fasting Blood Collection Information

7. Check the box for the last day the participant ate or drank anything (other than water).
8. Enter the time that the participant ate or drank anything (other than water). If the participant has not fasted for at least 8 hours, exclude them from the OGTT. Tell them “ Because you are have not fasted for 8 hours, it is not useful for you to participate in this part of the study.”

C. Blood Collection

9. Enter the date of the blood collection.
10. Enter the time of the blood collection.
11. Confirm the fasting blood was collected before glucola or a snack was given. (Do not give a snack after collecting blood if OGTT is to be performed.)
12. Enter the number of venipuncture attempts. Include all venipuncture attempts by all phlebotomists. The same technician should not attempt a venipuncture more than twice.
13. Indicate if there were any problems with the blood collection.
14. Note any blood drawing incidents or problems, and document in the table provided. Place an “X” in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If an incident or problem is not listed below, document it on Item 15. If no incidents or problems, skip to Item 16.
15. Enter any blood drawing problems that were not listed in Item 14.
16. Enter the ID code for the technician who collected the blood. If more than one technician attempts to draw the blood, enter the code of the first technician.

D. Blood Processing

17. Record the time at which the centrifuge containing tubes 4, 5, 6, and 7 began to spin.
18. Record the time at which the centrifuge containing tubes 1 and 2 began to spin.
19. Record the time at which samples from tubes 1, 2, 4, 5, 6, and 7 were placed in the freezer.
20. Enter the code number of the technician who began processing blood tubes.
21. Indicate if there were any problems with the blood processing.
22. Note any blood processing incidents or problems, and document in the table provided. Place an “X” in box(es) corresponding to the tubes in which the blood processing problem(s) occurred. If an incident or problem is not listed below, document it on Item 23. If no incidents or problems, skip to Item 24.
23. Enter any blood processing problems that were not listed in Item 22. Also, enter any problems with the urine collection or processing and the OGTT. For example, if there is blood in the urine or not enough

urine was collected to complete all the aliquots. Example OGTT problems are if the participant becomes hyperglycemic and the test is stopped or intervention with food or beverage is required.

24. Indicate if a post-gluca sample is collected.

25. Record the time that the participant begins to drink the glucola.

26. Record the time the post-gluca blood sample was collected.

27. Enter the code number of the technician who processed the post-glucose load sample.

E. Urine Sample

28. Indicate if a urine sample was collected.

29. Record the date the urine sample was collected.

30. Record the time the urine sample was collected.

31. Record the time the urine sample was processed.

32. Enter the code number of the technician who processed the urine sample.