



INSTRUCTIONS FOR THE BIOSPECIMEN COLLECTION (BIO11) FORM 01/16/2024

General Instructions

The BIOSPECIMEN COLLECTION FORM is completed during the participant's clinic or home 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. ID Number of participant and Code Number of person completing this form should be completed prior to the arrival of the participant. A copy of this form should be included with other shipping paperwork in any shipment to the laboratories and the original form should be maintained at the field center until the end of the visit.

If not all the 5 blood sample tubes can be drawn at the initial visit and the participant is willing to return to collect the missing tubes, collect only those tubes not drawn at the initial visit. Use a notelog to indicate if a tube is collected at a different time from the original sample collection.

If a full set of tubes was lost or destroyed and the participant is willing to return to collect the samples again, call the data coordinating center at least 5 business days in advance of the re-draw visit to request another set of labels. Enter the information using the same BIO form as the initial visit and use a notelog to indicate details about the redraw.

When collecting the BIO form on paper, mark all re-draw tubes with the capital letter "R" and highlight. Use a black permanent marker that will not bleed.

Record all times using a 24-hour clock (e.g. 8:00AM is 8:00, 3:00PM is 15:00).

I. Detailed Instructions for Each Item

Administrative Information

- 0a. Enter the date the biospecimen samples were collected.
- 0b. Enter the technician code of the person completing this form.
- 0c. Selected for Additional Phantom Tube. This item is system generated in CDART. If the participant is randomly selected to donate an additional "phantom" tube then you will see a "Yes" in this item. If they were not selected, then you will see "NO". This information can also be found on the Participant Snapshot Report in the "General Appointment Information" section. If selected to provide a phantom sample, you will use the Phantom Tracking Sheet to determine which additional tube to collect.
- 0d. Enter whether the visit was completed at the clinic or in a home/ long term care facility location.

A. URINE SAMPLE

At the reception station (clinic visits) or upon arrival at the home visit the participant is told that a urine specimen will be collected when it is convenient for the participant. This is best done early during the clinic/home visit but can be done anytime during the examination sequence if the participant is not able to provide a specimen before blood drawing. In the latter case, it is useful to encourage the participant to drink one or two glasses during the visit and alert the technician

when he/she wishes to empty his/her bladder. If a urine specimen has not been obtained over the course of the examination visit, the technician asks the participant again to provide a specimen at the end of the examination.

1. Indicate whether a urine sample was collected. If NO, urine sample was not collected, go to Item#5; if YES, continue.
2. Record the time the urine was collected using a 24-hour clock.

B. URINE PROCESSING

3. Note if urine volume is adequate for processing. Choose either Y ≥ 10 mL (desired). B between 10 mL and 5 mL or N < 5 mL (discard and-collect at a different date, go to item #5).
- 4 – 4b. If the urine volume is adequate for processing (either ≥ 10 mL or between 10mL and 5mL), record the technician ID for the urine sample, the time of urine processing, and the time urine specimens were placed in the freezer.
- 4c. If the urine volume is between 10mL and 5mL, record the number of urine aliquots yielded after processing.

C. BLOOD DRAWING

- 5 – 5a. For the clinic and home visits: Ask if the participant has a bleeding disorder that is not related to the use of medications such as aspirin and Plavix. If the participant's answer is NO, check the box indicating the negative answer and proceed to item #6. If the answer is YES, ask that he/she specify the nature of the bleeding disorder and record in 5a. Proceed with caution by executing pressure at the venipuncture site for a prolonged period. You may have the participant assist by elevating the arm and holding the gauze firmly on the venipuncture site. You must check that clotting has occurred and bleeding stopped before applying a band aid and releasing the participant. 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*" and continue as described above for NO or YES responses.
6. Enter the last time the participant ate or drank anything using a 24-hour clock (other than water or coffee/tea without cream and sugar) using a 24-hour clock. If the participant is rescheduled for another day, a new BIO form under a new sequence number should be entered.
7. Record the time of venipuncture using a 24-hour clock. This is the time when the vein is punctured and blood is drawn for specimens.
- 7a. Select YES if the time of venipuncture recorded in Item#7 is at least 8 hours after the last time the participant ate or drank anything recorded in Item#6.
8. Enter the number of venipuncture attempts. If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm. The same technician should not attempt a venipuncture more than twice (once in each arm). If a third attempt is necessary, a different phlebotomist should attempt the venipuncture following the same guidelines. If a third attempt is unsuccessful the study participant is asked whether s/he would like to have staff make another attempt to obtain blood for the tests to be done by the study. If affirmative, at the conclusion of phlebotomy the participant is asked to sign a

brief form stating that additional venipuncture was authorized (to be filed with the participant's informed consent).

Note that It is acceptable to reapply the tourniquet if the blood flow slows. One method is, when first applying the tourniquet, place it in the "rabbit" (release ends upward) position. After releasing the knot, drape the tourniquet ends (criss-cross) on the arm allowing it to hang loosely rather than removing it. This may facilitate re-application timing. Multiple re-applications may be necessary.



- 8a. Indicate whether at least one tube is able to be drawn from the participant. If no tubes are able to be drawn, then items 10-17 do not need to be completed, however the code number of the phlebotomist should still be recorded in item 9-9a. Question 8a is intended to facilitate data entry and should not be used as an opt-out for a participant.
- 8b. If no blood is able to be drawn, indicate the reason why in item 8b. If "other" is selected, indicate the reason using the notelog function in CDART.
- 9 - 9a. Enter the code number of the technician who performed the venipuncture and the blood drawing assistant or second phlebotomist if necessary. If more than one technician attempts to draw the blood, enter the code of the first technician. The same technician should not attempt a venipuncture more than twice. If written consent has been given by the patient and a second phlebotomist is available a third attempt can be tried.
- 10a-f. 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/problem is not listed below, document it on Item#11. If no incidents or problems occurred while drawing, skip to Item#12.

Blood drawing incidents or problems:

- a. Sample not drawn
- b. Partial sample drawn
- c. Tourniquet reapplied
- d. Fist clenching
- e. Needle movement
- f. Participant reclining

If option a, "Sample not drawn" is indicated for all tubes, use item 8a instead of item 10 to record that no tubes were able to be drawn. All other problems during data collection should be recorded using item 10.

- 11. Document any other blood drawing problems not listed in Item#10.

D. BLOOD PROCESSING

- 12. Record the time using a 24-hour clock at which the centrifuge containing tubes 2, 3 and 4 began to spin.
- 13. Record the time using a 24-hour clock at which the centrifuge containing tube 1 began to spin.
- 14. Record the time using a 24-hour clock at which samples from tubes 1, 2, 3 and 4 were placed in the freezer.
- 15. Record if there were any specimen processing incidents or problems. If no incidents or problems occurred while processing, skip to Item#17a.

- 15a-e. Note any specimen processing incidents or problems listed below. Place an "X" in box(es) corresponding to the tubes in which the problem(s) occurred. If an incident/problem is not listed below, document it on Item#16.
- a. Broken tube
 - b. Clotted
 - c. Hemolyzed
 - d. Lipemic
 - e. Other
16. Record comments or other problems in blood processing such as centrifuge or freezer issues and shipping problems such as lost shipments or broken tubes. Attach a sheet if more space is needed for notations.
- 17a-c. Enter technician(s) ID for processing blood specimens. If there was only one technician then leave items 17b and 17c blank.
18. Record whether the blood specimens yielded a complete aliquot set after processing. A complete aliquot set is defined as 8 serum aliquots, 4 EDTA + BHT plasma aliquots, 12 EDTA plasma aliquots, 3 buffy coat aliquots, and 2 whole blood aliquots. If the blood specimens did yield a complete aliquot set after processing, continue to item 19.
- 18a-e. If the blood specimens did not yield a complete aliquot set after processing, record the number of aliquots yielded after processing for each specimen type (Serum, EDTA + BHT Plasma, EDTA Plasma, Buffy Coat, and Whole Blood).
19. Record whether one serum aliquot was labeled for C4R use.