



# INSTRUCTIONS FOR BIOSPECIMEN COLLECTION FORM (BIA)

## I. General Instructions

The BIOSPECIMEN COLLECTION FORM is completed during the visit in which the blood draw takes place. Blood is collected for de novo participants only. For most de novo participants, this will be Visit 1 (baseline) but it may take place at a later visit if the required staff are not available during Visit 1, or there are other factors impacting blood collection at baseline. This form records information on the collection and processing of blood samples.

Technicians performing venipuncture and processing blood samples must be certified and should have a working knowledge of the relevant Manuals of Operations.

If the blood sample tube cannot be drawn at the initial visit and the participant is willing to return to collect the missing tube, collect the tube that was not drawn at the initial visit. Go back into the BIA form in CDART and update it with the information on the newly collected tube.

If the tube was collected, but later lost or destroyed and the participant is willing to return to collect the sample again, you will need to assign a new biospecimen ID. Choose the next available biospecimen ID from your package of labels. Enter another occurrence of the BIO form for this participant's re-draw (instructions on completing a second occurrence of a form is located on the ARIC website under 'Training', 'DMS', 'Occurrences Instructions'; or contact Sheila Burgard: sheila\_burgard@unc.edu).

Mark all re-draw tubes with the capital letter, "R" and highlight. Use a black permanent marker that will not bleed.

## II. Detailed instructions for each item

Enter form information for Participant ID Number.

- 0a. Enter the date the biospecimen sample was collected.
- 0b. Enter the technician code of the phlebotomist.
- 0c. The CDART system will populate a "Yes" or "No" response to this item, based on a random number assigned to the participant.

If the participant was selected for phantom blood collection, use a biospecimen ID from the end of your package of labels. Complete the PHA form.

## A. Blood drawing

- 1 – 1a. 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 #2. If the answer is YES, ask that he/she specify the nature of the bleeding disorder and record in 1 a. 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.
2. Enter the last time the participant ate or drank anything (other than water or coffee/tea without cream and sugar). If the participant is rescheduled for another day, a new BIA form should be entered.
- 3-3a. Record the time of venipuncture. This is the time (HH:MM) when the vein is punctured and blood is drawn for specimens. Check the box to indicate if the participant has or has not been fasting for at least 8 hours.
4. Enter the number of venipuncture attempts.
- 5 - 5a. Enter the code number of the technician who performed the venipuncture and the blood drawing assistant. 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.
- 6-6f. Note any blood drawing incidents or problems, and document in the table provided.

Place an "X" in box(es) corresponding to the problem(s) that occurred. If an incident/problem is not listed below, document it on Item 7. If no incidents or problems occurred while drawing, skip to Item 8.

### 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
7. Document any other blood drawing problems not listed in Item 6.

8. Record whether this blood sample is able to be processed.
  - If 'YES': Proceed to section B. Blood Processing
  - If 'NO': Close form; collect ather sample in future.

## **B. Blood processing**

9. Record the time at which the centrifuge containing the tube began to spin.
10. Record the time at which samples from the tube were placed in the freezer.
- 11-11e. Note any blood processing incidents or problems listed below.
  - a. Broken tube
  - b. Clotted
  - c. Hemolyzed
  - d. Lipemic
  - e. Other
12. Document any other blood processing problems not listed in Item 12. For example, centrifuge or freezer problems, lost shipments or broken tubes. Attach a sheet if more space is needed for notations.
- 13a-c. Enter the code number of the technician(s) who began processing the blood tube.
14. Record whether the blood sample is able to be shipped for analysis. If 'NO': Collect another sample in future. Save and close the form. The BIA will be updated at a future collection.
15. Each site received a shipment of ACHIEVE biospecimen ID labels. Those labels have IDs that start with "FD1" for Forsyth, JD2" for Jackson, "MD3" for Minnesota, and "WD4" for Washington County. There are 200 unique biospecimen IDs for each field center. Each de novo participant randomized to ACHIEVE is assigned a unique biospecimen ID. Start from the beginning of the labels and assign them to de novo participants as they are enrolled, have agreed to a blood draw, and completed the blood draw. The biospecimen ID is assigned the end of the blood draw procedure, at the end of the BIA form, to ensure that the blood was in fact drawn from the de novo participant. Biospecimen IDs are assigned only when blood is drawn. Place the paper barcoded label on the paper form and scan the ID into CDART. For ID entry into CDART, always try to scan the labels as opposed to typing in the ID to prevent data entry error.