



# INSTRUCTIONS FOR BHFU BIOSPECIMEN COLLECTION FORM (BIAX)

## I. General Instructions

The BHFU BIOSPECIMEN COLLECTION FORM is completed during the visits in which the blood draws take place but recorded in the ANX Lab form group in CDART. This form records information on the collection and processing of blood samples. The form has multiple occurrences so each attempt to draw blood may be documented. Note: the ACHIEVE BIA form did not allow for recording multiple blood draw attempts.

The BIA should be completed at least twice for de novo participants only. Blood is collected at two time points: on or near their first BHFU visit and on or near their last BHFU visit. Complete the BIA even if participant refuses the blood draw. The form should not be completed for ARIC participants.

Technicians performing venipuncture and processing blood samples must be certified and should have a working knowledge of ACHIEVE ANX MOP Appendix F Blood Draw 1.0.

If the tube was collected, but later lost or destroyed, and the participant is willing to return to collect the sample again, you should use the labels previously provided for that participant-visit if you still have them. Mark all re-draw tubes with the capital letter "R" using a black permanent marker that will not bleed, and then highlight. If you previously used the labels for that participant-visit and do not have enough extra labels, contact Kelly Weicht, well in advance of the scheduled replacement blood draw, at the ACHIEVE Study Central Repository at Johns Hopkins University ([kweicht1@jhu.edu](mailto:kweicht1@jhu.edu)) to request an additional set of labels.

Enter another occurrence of the BIA 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 ARICHELP: [ARICHELP@unc.edu](mailto:ARICHELP@unc.edu)).

## II. Detailed instructions for each item

Enter form information for Participant ID Number.

- 0a. Enter the date the biospecimen sample was collected (or the date the participant refused the blood draw).
- 0b. Enter the technician code of the phlebotomist.
- 0c. Indicate which biospecimen sample was collected or refused. If a participant is providing a sample for the BHFU Baseline visit, "ANX 6M" should be marked. Note: The BHFU Baseline collection may occur during ANX 6M, ANX Y1, or ANX 18M

visits. See provided chart at the end of this QxQ for further information. If the participant refuses the BHFU Baseline (ANX 6M) or ANX Y3 blood draw, the appropriate “refused” option should be marked on the BIAx 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 1a. 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 has 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). Time should be recorded and entered in 24-hour format (e.g., 13:30), and the input field will automatically convert to 12-hour format (e.g., 1:30 PM).
- 3-3a. Record the time of venipuncture. This is the time (HH:MM, using 24-hour clock) 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 that day. If unable to draw participant’s blood that day and blood collection is rescheduled for a later date, a separate occurrence of the BIAx should be entered.
- 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

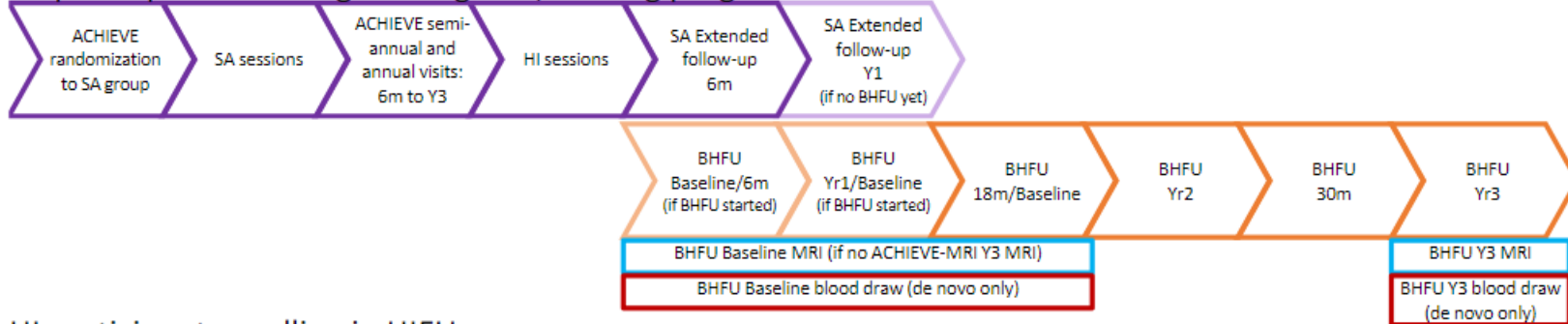
- d. Fist clenching
  - e. Needle movement
  - f. Participant reclining
7. Document any other blood drawing problems not listed in Item 6.
  8. Record whether this blood sample is able to be processed.
    - If 'YES': Proceed to section B. Blood Processing
    - If 'NO': Close form; use next occurrence for future sample. The future attempt to collect the sample should be documented on a new occurrence of the BIAx.

## **B. Blood processing**

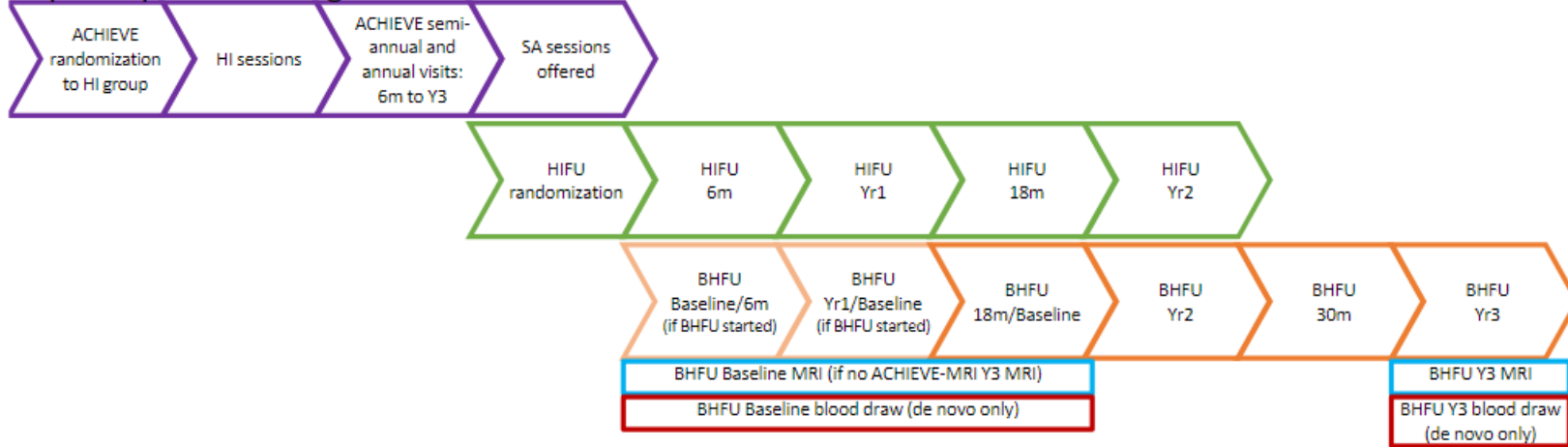
9. Record the time at which the centrifuge containing the tube began to spin (HH:MM, 24-hour clock).
10. Record the time at which samples from the tube were placed in the freezer (HH:MM, 24-hour clock).
- 11-11e. Note any blood processing incidents or problems listed below. If no incidents or problems occurred while processing, skip to Item 13a.
  - 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.
- 13a-c. Enter the code number of the technicians who participated in processing the blood tube. Typically this will only be 1 technician and 13b, 13c will be blank.
14. Record whether the blood sample is able to be shipped for storage. If 'NO': Collect another sample in future. Save and close the form. Record the information on the repeated blood collection on the next occurrence of the BIAx form. This process is different from ACHIEVE where the BIA form from the first blood collection would have been overwritten in CDART.

0c Supplemental image

SA participant receiving hearing aids/hearing program:



HI participant enrolling in HIFU:



Participant not enrolling in HIFU or SA extended follow-up:

