INSTRUCTIONS FOR THE ORTHOSTATIC HYPOTENSION BLOOD PRESSURE (OBP) FORM

I. General Instructions

This form is completed for all participants who agree to take part in the Orthostatic Hypotension (OH) ancillary study.

The blood pressure measurements can be recorded from the OMRON device onto the paper form or directly into the CDART form. Sitting Blood Pressure should be completed prior to completing the Orthostatic Hypotension Blood Pressure protocol.

It is highly suggested that two staff are present for the OH assessment. Ideally, one staff would be focused on participant safety, and one staff would be responsible for capturing the blood pressure measurements. Additionally, two staff would be helpful for timing this protocol appropriately. It is suggested that one team member use a stopwatch to observe the time it takes to go from supine to standing, and one team member use a stopwatch to follow the time for all 6 standing measurements.

During the course of the OH protocol, it is possible to encounter clinically concerning blood pressure measurements. All extremely low or high blood pressure values should be verified in the seated position 5 minutes after the protocol is complete. If the extreme blood pressure values continue, follow the ARIC safety algorithm for seated blood pressure.

The OH protocol will take place **after** the ARIC Seated Blood Pressure. Following standard ARIC safety protocols, if a participant has an **average Systolic Blood Pressure >= 200 or Diastolic Blood Pressure >= 120 mmHg**, the exam will be stopped for the participant to receive urgent care. The participant will be ineligible for the OH protocol.

II. Detailed Instructions for Each Item

0a. Enter the date on which the participant was seen in the clinic.

0b. Enter the staff ID for the person who completed the OH protocol.

0c. Record whether the participant is interested in participating in the OH ancillary study. If the participant is not interested in the OH study, select No and do not open or complete the OSQ form. It is not necessary to mark the OSQ form as Permanently Missing. Continue with item 0c1. If they are interested in participating, select Yes and skip to item 1.

0c1. If the participant indicates that they are not interested in participating in the OH ancillary study, record the reason why not.

A. Visit Details

1. Record the arm used for the blood pressure measurements. This should be the same arm used for the Sitting Blood Pressure (SBP form) measurement.

2. Record the participant's dominant arm as recorded on the SBP form.

3. Record the cuff size used for the Orthostatic Hypotension Blood Pressure (OBP) measurements. You may refer to the SBP form and use the same cuff size.

Arm Circumference	Cuff Size
17.0-22.0 cm	CS19, Small
22.0-32.0 cm	CR19, Adult
32.0-42.0 cm	CL19, Large
42.0-50.0 cm	CX19, X Large

4. Record the time of the assessment. This is the time that staff press the START button on the Omron device, starting the 5 minutes of rest before the first supine blood pressure measurement.

5. Record if the participant has taken any blood pressure medication today. If Yes, record the time the participant took their blood pressure medication in 5a. If No, skip to item 6. The answer "No" can be used to indicate that the participant did not take medications yet today for blood pressure, or that the participant does not take blood pressure medications.

6. Record if the participant has eaten food today. There must be at least 30 minutes between food consumption and this protocol. In the rare event that a participant has eaten food within the last 30 minutes, perform other measurements or surveys to pass some time before returning to complete this protocol. If the participant has eaten food today, record the time the participant ate in 6a. If they have not eaten today, skip to item 7.

B. Supine position (after 5 minutes of rest; use "avg" mode on OMRON):

**** Make sure the Omron is in the 'AVG' mode before starting to take the supine measurements. ****

7-9. Measure and record systolic blood pressure, diastolic blood pressure, and heart rate as described in the Manual of Procedures in the Supine position. There will be three measurements in total.

10. The reported averages for SBP, DBP, and HR are calculated automatically by the OMRON system. Record these values from the OMRON device. Calculate a manual average and compare with the reported average to avoid transcription errors.

11. Proceed with the OH protocol and record the time required to go from supine to standing position in minutes and seconds. Watch for shifting of the OMRON cuff and reposition the cuff to the best of your ability, if needed. Try to avoid prolonged time to standing, as this can affect the measures.

C. Standing Position ("single" mode) – Six Measurements (6):

**** Make sure to change the OMRON from 'AVG' to 'SINGLE' mode. ****

SAFETY NOTE: during the transition from Supine to Standing, there is a fall risk; resist any pressure to rush the participant, as safety is the priority. Assistance may be provided to the participant to help them get up. These measurements can be performed in the seated position, although standing is preferred. If the participant feels dizzy or uncomfortable, instruct them to rest against the bed or lean on the table while standing. Staff should use their clinical judgment to ensure the safety of the participant – if there are concerns about the participant's ability to safely stand and remain standing, the protocol may be completed in a seated position. In the rare event of a seated position, this should be documented in 12d-17d.

12-17. Measure and record systolic blood pressure, diastolic blood pressure, and heart rate as described in the Manual of Procedures with the participant in the standing position (0 minutes [immediately after standing], 1 minute, 2 minutes, 3 minutes, 4 minutes, and 5 minutes after standing).

Select Yes for **12d-17d** if the participant was seated for safety for that particular measurement.

If there is more than a 15-second delay between the time the measurement *should* be taken (e.g., 1 minute after standing) and when the measurement is actually taken, the measurement should be skipped in order to stay on the appropriate schedule of measurements. This measurement should be marked as Missing in CDART and the reason for the delay and needing to skip the measurement should be added as a notelog.

18a – 18c. These blood pressure and heart rate averages are calculated by CDART. Save the form and click the arrows [] to calculate each field.

Elevated Blood Pressure

If the average of the 3 **supine** or 6 **standing** measurements is Systolic Blood Pressure (SBP) ≥210 mm Hg or Diastolic Blood Pressure (DBP) ≥130 mm Hg, complete the procedure and then verify blood pressure in the **seated** position after 5 minutes of rest.

If the average of 3 **seated** measurements is SBP≥200 mm Hg or DBP≥120 mm Hg, stop the procedure and send the participant to the emergency room; notify the study clinician. Note: this is the same safety threshold that is used in standard ARIC blood pressure assessments.**Low Blood Pressure**

If the average of the 3 **supine** or 6 **standing** measurements is SBP≤80 mm Hg or DBP≤30 mm Hg, then complete the procedure and then verify the blood pressure in the **seated** position after 5 minutes of rest.

If the average of 3 **seated** measurements is SBP≤90 mm Hg or DBP ≤40 mm Hg and the participant demonstrates symptoms of low blood pressure (light-headedness, dizziness, pre-syncope, imbalance), then stop procedure and send the participant to the emergency room. May provide water or an electrolyte-enriched beverage (e.g., a sports drink) if symptoms

continue after being seated. Note: the standard ARIC blood pressure assessment manual does not have a safety threshold for low blood pressure.

D. Symptom Ratings During Standing Portion

19. Ask the participant whether they experienced feeling dizziness, lightheadedness, fainting, or like they might black out while in the process of standing up. Ask them to rank them on a scale of 1 to 5, with 1 being “no symptoms” and 5 being the “worst possible”. Use this same scale for all symptom ratings.

20. Ask the participant whether they experienced dizziness, lightheadedness, fainting, or like they might black out at any point while they were standing. Ask the participant to rank their symptoms on a scale of 1 to 5.

E. Staff Observations

21. Record whether any form of assistance was provided during the standing portion of the assessment. This includes help from another person or staff, wall, table, bed, cane, walker, etc. If no assistance was provided, skip to item 22. If assistance was provided, record whether assistance was provided because the participant felt dizziness, light-headedness, faint, or like they might black out in item 21a.

22. Record whether the participant leaned on support during the standing blood pressure assessments.

23. Record if the participant used a walker for any reason during the protocol.

24. Record if staff needed to reposition the blood pressure cuff because it slipped after the participant stood up.

25. Record if staff had to end the OH assessment early. If No, skip to item 27.

26. If the OH assessment was ended early, answer 26a-e to indicate the reason that the assessment was stopped early.

27. If staff previously indicated that a participant was seated for safety during the “standing” assessment (questions 12d-17d), staff will respond to items 27-27e with the reason why. Record the reason for a clinical decision to sit. Answer whether the risk of the participant falling, symptoms like dizziness, lightheadedness, feeling faint or like they might black out, balance concerns, or pain while standing influenced the decision to sit during the “standing” assessment. Complete all items by selecting "yes" if the symptom contributed to the reason to sit during the assessment and selecting "no" if the symptom did not apply to the reason to sit during the “standing” assessment. If there was a reason that caused staff to stop the assessment early that was not included in 27a-27d, select Yes in 27e and specify the Other reason in 27e1.

In the rare event that the participant’s average blood pressure (supine or standing) is >= 200 systolic or >=120 diastolic, stop the exam. This *may be* an urgent referral, but measurement should be confirmed in the seated position. Follow the ARIC safety algorithm for seated blood pressure. The ARIC safety algorithm for seated blood pressure is as follows:

"As a participant safety procedure, if the average [seated] blood pressure is equal to or greater than 200 mmHg systolic or equal to or greater than 120 mmHg diastolic, the technician tells the participant that the procedure will be repeated as part of the study protocol, removes the cuff and locates the brachial artery by palpation as shown in Figure 5 of this section [Manual 2], and repeats the [seated] blood pressure measurement steps. This second set of blood pressure values is recorded on the form and entered into the DMS instead of the first set. If the average blood [seated] pressure still is equal to or greater than 200 mmHg systolic or equal to or greater than 120 mmHg diastolic, the technician closes out the data entry screen per protocol, interrupts the field center examination, and notifies the supervisor of this immediate alert situation. With input from the supervisor or clinic manager, ARIC personnel then assist the participant in scheduling a visit to their provider of care during the same day, or arranges transportation to the nearest emergency room for a medical evaluation of the participant's blood pressure."