



To: Melissa Minotti, Catrina McDaniel, Stacey Naylor, Nancy McCreary

CC: Field Center PIs, Stephen Juraschek, Kim Ring, ARIChelp

From: Julia Wood, Micah McCumber

Date: November 5, 2021

RE: Visit 10 Blood Pressure Ancillary Studies Pre-Pilot

For this pre-pilot, it is our goal that each field center has a minimum of one (1) staff member run through the protocol for each component of the Blood Pressure ancillary study protocols, including Orthostatic Hypotension (OH), Ambulatory Blood Pressure Monitor (ABPM), and Home Blood Pressure Monitor (HBPM). If possible, we encourage field centers to ask more than one staff member to run through the protocols to ensure we receive thorough feedback.

To prepare for data collection of OH, ABPM, and HBPM, the necessary forms and other study documents have been uploaded to the ARIC website in a zipped folder for sites to access and download.

This is a chance for you to provide feedback on the MOPs and scripts, and for you to use and provide feedback on the data collection forms and certification checklists (*Note: we will be using paper copies for all pre-pilot activities*). This pre-pilot activity is separate from the Visit 10 pilot, which includes OH, ABPM, and HBPM, expected to occur February 21-25, 2022.

Recruiting volunteers for this pre-pilot is not necessary as the primary goal for this activity is for staff members to provide feedback on the OH, ABPM, and HBPM data collection processes and forms—not to practice the entire Blood Pressure monitoring protocol.

After each staff member has reviewed and entered mock data into each of the paper forms, they will contribute to the “Blood Pressure Ancillary Pre-Pilot Activity Evaluation Form,” a feedback form that should be sent to the Coordinating Center summarizing impressions of the pre-pilot. The goal of this pre-pilot is to work out any foreseeable data collection issues before the pilot and study startup.

Staff members will use Manual 37 for OH and Manual 38 for ABPM and HBPM, as well as the forms to complete the pre-pilot activities. Drafts of all materials have been posted to the website. This pre-pilot will consist of paper copies only. Please complete this pre-pilot activity as soon as possible, preferably before November 19, 2021.

Field centers are asked to please notify ARIChelp@unc.edu with their planned pre-pilot start and completion date.

PRE-PILOT ACTIVITIES

- ☐ Review the ARIC OH-ABPM-HBPM Introduction Handout that will be given to participants

Orthostatic Hypotension (OH)

- ☐ Review the OH Manual of Operations (Manual 37) to become familiar with the protocol
- ☐ Review the OH Protocol Instruction Script
- ☐ Review the OH Certification Checklist
- ☐ Review the following data collection forms (which will be in CDART for the official pilot)
 - ☐ OBP (Orthostatic Hypotension Blood Pressure)
 - ☐ OSQ (Orthostatic Hypotension Symptom Questionnaire)
- ☐ Enter mock data (written on paper copies) to practice using these data collection forms (following order from the MOP). Mock data can be collected by interviewing other staff members.

Ambulatory Blood Pressure Monitor (ABPM)

- ☐ Review the ABPM Manual of Operations (Manual 38) to become familiar with the protocols. (*Note: Before engaging in pre-pilot, make sure the Sentinel software is installed on at least 1 computer*)
- ☐ Review the ABPM Instruction Script
- ☐ Review the ABPM Certification Checklist
- ☐ Review the following data collection forms (which will be in CDART for the official pilot)
 - ☐ ABP (Ambulatory Blood Pressure Monitor [ABPM] Form)
 - ☐ ABPR (Ambulatory Blood Pressure [ABPM] Return Form)
- ☐ Review the Participant handouts and provide feedback ("Is this helpful?" or "What could make it more helpful?") (Note: These are attached below for convenience)
 - ☐ ABPM Participant Checklist
 - ☐ ABPM Cuff Placement Instructions
- ☐ Review and complete the ABPM Participant Activity Log and the ABPM Participant Experience Form (using mock data from another staff member)
- ☐ Enter mock data (written on paper copies) to practice using these forms (following order from the MOP). Mock data can be collected by interviewing other staff members
- ☐ Record mock data in the data collection forms using the device download process (refer to Manual 38). Note: we are asking staff to go through the whole process of wearing the monitor and then downloading the data
- ☐ Review the device return options and confirm what method will work best for your field center. (For FedEx, ensure you have an account set-up)

Home Blood Pressure Monitor (HBPM)

- ☐ Review the HBPM Manual of Operations (Manual 38) to become familiar with the protocols.
- ☐ Review the HBPM Instruction Script
- ☐ Review the HBPM Certification Checklist
- ☐ Review the following data collection forms (which will be in CDART for the official pilot)

- ☐ HBP (Home Blood Pressure Monitoring Initialization Form)
- ☐ BPMC (Blood Pressure Monitoring Check-in Call Form)
- ☐ HBPR (Home Blood Pressure Monitor Return Form)
- ☐ VAS (Virtual Access Survey)
- ☐ Review the HBPM Participant Checklist (attached below). Provide any comments or feedback you might have
- ☐ Review and complete the HBPM Participant Experience Form (using mock data from another staff member)
- ☐ Enter mock data (written on paper copies) to practice using these forms (following order from the MOP). Mock data can be collected by interviewing other staff members
- ☐ Record mock data in the data collection forms using the device download process (refer to Manual 38). Note: we are asking staff to go through the whole process of wearing the monitor and then downloading the data
- ☐ Review the device return options and confirm what method will work best for your field center. (For FedEx, ensure you have an account set up)

Although staff are requested to review certification checklists, pre-pilot activities are *not* meant to impact certification on the OH, ABPM, and HBPM protocols. This pre-pilot activity serves to allow staff to become more comfortable with the forms and offer feedback to the Coordinating Center.

- ☐ Complete a “Blood Pressure Ancillary Pre-Pilot Activity Evaluation Form” (attached to the end of this memo) noting any impressions of the Forms, Manuals, or other study materials. Each site should send one (1) form to ARIChelp@unc.edu at the completion of the pre-pilot activities. If any parts of this pre-pilot are especially unclear, please be sure to provide feedback so that we can be sure to address this during the training.

COORDINATING CENTER

CDART Access

We will *not* use CDART for the pre-pilot activities. All data collection will be completed via paper forms.

Forms, Manuals, and Additional Resources

All manuals (Manual 37-OH and Manual 38-BPM), data collection forms, instructions, and scripts are available for download on the ARIC website (see ABPM_HBPM_OH_Pre-Pilot_11.03.2021.zip in <https://sites.csc.unc.edu/aric/ancillary-docs>).

Reports

The Blood Pressure Ancillary Studies will not have results reports for the pre-pilot.

Evaluation

Evaluation for this pre-pilot activity will be based on feedback from the “Blood Pressure Ancillary Pre-Pilot Activity Evaluation Form.” The Coordinating Center (CC) will summarize all feedback received from that form and work with the Blood Pressure Ancillary Study PI and the ARIC Steering Committee to evaluate and implement changes as necessary.

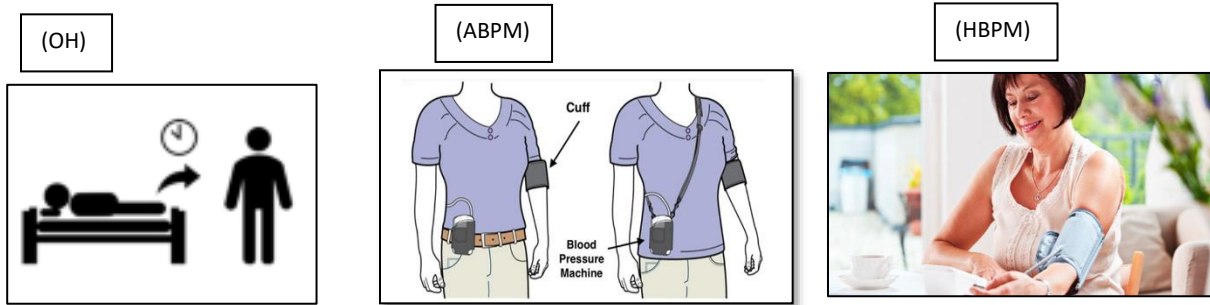
If there are any questions about this pre-pilot memo, please contact ARIChelp@unc.edu.



When: ARIC Visit 10

What: We want to check your blood pressure!

How: Through assessments including orthostatic hypotension (OH), ambulatory blood pressure monitoring (ABPM), and home blood pressure monitoring (HBPM).



Why is it so important for us to measure your blood pressure these ways?

When you consent to being a part of this ancillary study, it means that you are allowing us to measure your blood pressure lying down and standing up, every 20-30 minutes over the course of 1 day, and twice a day (once in the morning and once in the evening) over the course of 8 days.

This might seem like a lot, but ultimately, gathering all of your blood pressure results through these assessments will provide you a unique understanding of what your blood pressure is actually like in your real life.

High blood pressure affects many older adults and is one of the most important causes of cardiovascular disease (CVD) and dementia.

Sometimes your blood pressure in a medical setting does not reflect what your blood pressure is at home. It can be difficult to measure your blood pressure throughout the day and this can result in over-or-under treatment.

The U.S. Preventive Services Task Forces gives blood pressure measurement outside of clinic its top recommendation (grade A), yet virtually no one has access to ambulatory blood pressure monitoring. There are only 15 American Heart Association Certified centers in the country that do this type of assessment regularly. We are delighted to offer this to all of you in the ARIC study.

This is an unprecedented and unique research project. By utilizing these assessments, we will gather blood pressure readings that are unique to you, throughout every aspect of your life, and be able to report your true blood pressure. We will be able to know how your blood pressure reacts to you lying down or standing up. We will know how your blood pressure fluctuates over 24 hours, as you go about your ordinary, day-to-day activities, and what might impact it, such as physical activity, medications, or stress. Additionally, we will learn about your blood pressure at home in a quiet, comfortable environment without the stress of a doctor's office.

With your willingness to participate in this blood pressure study, you will receive a comprehensive report of your BP in all its stages to inform your health care provider. This has the potential to improve your current blood pressure treatment.

Thank you for your participation and support!



Ambulatory Blood Pressure Monitor (ABPM) Participant Checklist

- ☐ Please try to wear the cuff for the full 26-hour period. However, please remove the cuff when driving or taking a bath or shower. Please do not submerge the cuff under water.
- ☐ Observe how the cuff is positioned on your arm in case you need to remove during the 26-hour period. When you put it back on, please try to return it to the same position.
- ☐ When sleeping, it may be helpful to put the device under your pillow.
- ☐ Write down your sleep and wake time on your log.
- ☐ At the end of the monitoring period (before taking the batteries out), press the action button on the monitor to obtain 1 last measurement.
- ☐ Complete the questionnaire on the log related to the measurement period.
- ☐ Remove batteries before placing monitor in the return package.
- ☐ For mailing, please include the monitor, cuff, "Participant ABPM Experience Form", and "ABPM Activity Log" in the return package.



Ambulatory Blood Pressure Monitor (ABPM) Cuff Placement Instructions

Should you need to take your cuff off at any time, or should the cuff become loose, this sheet describes how to correctly position the cuff back on your arm.

- Place the cuff on your bare upper arm (same arm you used for your other ARIC blood pressure measurements).
- Position the cuff slightly above your elbow (about ½" above where your elbow bends).
- Wrap the cuff tight enough to be able to fit two of your fingertips side-by-side under the cuff (this will ensure it is tight enough to correctly measure your blood pressure, but not too tight that it is uncomfortable).

*You should be able to fit
2 fingers between your arm
and the cuff.*



- Place the cuff so the tubing is going up your arm and down around your shoulder towards your back.

- You can slide the tubing underneath your shirt if you want to make sure it is completely out of the way or unnoticed.
- The tubing will stay connected to the device via an air-pressure connector, so you don't have to worry about it disconnecting while you go about your typical routine.
- You can hook the device on the hip opposite of your arm with the cuff while you are standing or walking, or you can place the device on the table or sofa next to you while you are seated.
- If your cuff loosens and slips down your arm beneath your elbow, slide it back up to your upper arm, and wrap it tight enough so that you can fit your 2 fingers underneath.



More Information on the Ambulatory Blood Pressure Monitor

(This information can also be found on the instruction script)

What You Need to Know

An ambulatory blood pressure monitoring (ABPM) device has been placed on the bare skin of upper arm. The ABPM will inflate every 20 minutes during the day and every 30 minutes while you sleep (between the hours of midnight – 5 am) for a 24-hour period. After you've worn the ABPM for 26-hours, we need you to remove the cuff from your arm and place it, along with device, ABPM Participant Activity log, and ABPM Participant Experience Form into a FedEx box with the pre-paid shipping label, to be returned to the ARIC clinic.

Once the device is returned, we will download the data. If you have told us that you want to receive your results, we will email you a one-page summary of your results. This summary will tell you about how your blood pressure trended throughout the day and night during the time you wore the ABPM.

What You Need to Do

- Wear the cuff attached to the ABPM on your arm for 26-hours. When you feel the cuff start to inflate, relax your arm and hold it still. Do not change your body position.
- Feel free to loop the device to your belt, or use the ARIC travel bag, to hold the monitor on your waist.
- There's no need for you to interact with the device until the very end of your monitoring period. Just go about your daily routine. At the end of your monitoring, you should press the action button to do one manual measurement (as instructed by ARIC staff).

A Little Extra Care for Special Activities

- Use care to avoid accidentally loosening or removing it, especially when dressing or undressing.
- If the cuff slips down or you need to re-position it, wrap the cuff tight enough around your arm so that your pointer and middle finger can slide underneath the cuff (this is the "2-finger rule").
- Do not get the monitor wet, but if it does get wet, you are in no danger of being electrically shocked. Take off the cuff if you need to bathe or shower. Do not turn off the monitor.

Removing the ABPM

- You will receive a call from the ARIC Clinic the day after your in-person visit to remind you to remove the monitor and review the device return instructions.
- It is important to send the ABPM back no later than 1 day after you complete the monitoring. FedEx will come to your home and pick up the package. This home pick-up will be scheduled by the ARIC clinic.

If you have questions, please call the ARIC Clinic:

[PHONE]

Contact us if:

- You have irritation or discomfort
- You have any questions about your monitor



More Information on the Omron Blood Pressure Monitor

(This information can also be found on the instruction script)

What You Need to Know

You will use the Omron monitor to check your blood pressure in the morning and evening for 8 consecutive days. You will begin this home blood pressure monitoring the day after you finish the ABPM.

This device will be yours to keep! However, we will need to download your measurements from the monitor to obtain your results. We will send you a one-page summary that will provide you with the average of your blood pressure and your heart rate, over the 8-day period. This will help provide a more personalized blood pressure treatment. The results can be shared with your health care provider.

What You Need to Do

- Please take the morning reading between 7 am-9 am and the evening reading between 7 pm-9 pm. Repeat this schedule for 8 days.
- Choose a quiet place in your home where you will check your blood pressure every day. Before you take a reading, be sure that your bladder is empty, and you have not had caffeine, tobacco, or exercised 30 minutes before. Perform this assessment before taking antihypertensive medications.
- Please refer to the HBPM Participant Checklist for questions on how to correctly do the monitoring.

What You Need to Do

- You will receive a call from the ARIC Clinic the day after you start home monitoring with the Omron, to confirm that you did in fact start the monitoring in the morning.
- You will receive an additional call from the ARIC Clinic four days later (two days before you are due to end the home blood pressure monitoring). This call will confirm how the ARIC Clinic will obtain your measurements from the monitor.
 - An ARIC staff member can either (1) come to your home and pick up the monitor in person, (2) schedule FedEx to come and pick up your monitor (which will be returned to you once we have your results), or (3) you can drop off the monitor in person at the ARIC Clinic.
 - Be sure to complete the HBPM Participant Experience Form and give it to ARIC Staff or return it with your monitor.

If you have questions, please call the ARIC Clinic:

[PHONE]

Contact us if:

- You have irritation or discomfort
- You have any questions about your monitor



**Blood Pressure Ancillary Pre-Pilot
Activity Evaluation Form**

Staff code or initials:

--	--	--

Date completing this form:

____ / ____ / ____

1. General comments on data collection forms, participant forms/instructions, and manual

Topic	Comments & suggested changes
Any issues with forms? (if so, list the form code below and add rows as needed)	
Any issues with participant forms, logs, and instructions? (if so, list the form below and add rows as needed)	
Any issues with Manual 38 – Orthostatic Hypotension (OH)?	
Any issues with Manual 39 – Blood Pressure Monitoring (BPM) for Ambulatory BPM and Home BPM?	

2. General comments on data collection forms, participant materials, and listed manuals

Topic	Comments & suggested changes
Any additional concerns?	

All field center staff who participate in the pre-pilot should contribute input into this evaluation throughout the course of the pre-pilot. Submit one evaluation form per field center to Arichelp [arichelp@unc.edu] at the completion of the pre-pilot activity.