



Quality Control (QC) Appendix

Visit 12

Version 1.2 – 05/11/2026

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A. GENERAL SUMMARY AND TIMELINE DOCUMENTS



APPENDIX QC1. SUMMARY OF OBSERVATION AND EQUIPMENT CHECKLISTS

Instructions: This form should be completed quarterly and sent to the Coordinating Center (CC) within two weeks of the end of the quarter.

FIELD CENTER

DATE: / /
Month Day Year

Quarterly reporting period | Jan-Mar 20 Apr-Jun 20 Jul-Sept 20 Oct-Dec 20

A. Observation Checklist

| | | Technician ID | Supervisor ID | Date (mm/dd/yy) |
|------------------------------|--|---------------|---------------|-----------------|
| General interview techniques | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Anthropometry | | | | |
| | | | | |
| | | | | |
| Sitting blood pressure | | | | |
| | | | | |
| | | | | |
| Biospecimen collection | | | | |
| | | | | |
| | | | | |
| Physical Function | | | | |
| | | | | |
| | | | | |

B. Equipment Checklist

| | Frequency | No. times assessed | No. times within calibration |
|--|-------------|--------------------|------------------------------|
| Anthropometry | | | |
| 1) Scale read zero | Daily | | |
| 2) Weight scales* | Weekly | | |
| Blood Pressure | | | |
| 1) Checks for the OMRON BP machine <i>(Provide for each machine being used)</i> | Quarterly | | |
| Physical Function | | | |
| 1) Grip strength dynamometer | Bi-Annually | | |
| Biospecimen collection | | | |
| 1) Refrigerators, freezers, room temp | Daily | | |
| 2) Speed of centrifuge | Annually | | |
| CGM | | | |
| 1) Reader Time Checks | Monthly | | N/A |

Comments: _____

*Home visit scales should also be calibrated



APPENDIX QC2. TIMELINE FOR OBSERVATION AND EQUIPMENT CHECKS

| | |
|-------------|---|
| Daily | Anthropometry scales balanced to read zero (Appendix QC8) Temperature check in refrigerators, freezers, etc. (Manual 7) |
| Weekly | Anthropometry scales calibrated or when scales moved. Home visit scales should also be calibrated weekly (Appendix QC5) <i>Optional:</i> Interacoustic Equinox 2.0 audiometer and HearX audiometer should be checked using the Bioacoustics Simulator and/or undergo a biologic check for accuracy (Manual 22) |
| Monthly | Log time displayed on CGM reader and time displayed on Computer for each reader (Manual 39) |
| Quarterly | Summary of anthropometry technicians recorded (Appendix QC1) Summary of anthropometry equipment checks (Appendix QC1) Blood pressure technicians observed (Appendix QC6), recorded (Appendix QC1) OMRON BP equipment checks and calibration (Appendix QC9), summarized on (Appendix QC1) Biospecimen collection, processing observed (Manual 7), recorded (Appendix QC1) Biospecimen equipment checks summarized, info sent to CC (Appendix QC1) Physical function technicians observed (Appendix QC7), recorded (Appendix QC1) |
| Bi-Annually | Anthropometry technicians observed study coordinator twice monthly for the first month following certification and then twice per year observed (Appendix QC5) Grip strength dynamometer calibrated (Manual 32) |
| Annually | Checking of the actual speed of the centrifuge (Appendix QC1) Calibration and professional cleaning of pipettes (Appendix QC1) |



APPENDIX QC3. MINIMUM FREQUENCY OF PROCEDURES AND INTERVIEWS TO MAINTAIN DATA QUALITY

| Procedure (and associated forms) | Min. # / Month | Min. # / Month |
|--|--------------------------------|-------------------------------------|
| | Primary Technicians | Designated Back-up Techs |
| Anthropometry (ANT) | 6 | 2 |
| Blood collection & processing (BIO) | 4 | 4 |
| Seated BP (SBP) | 4 | 2 |
| Physical Function and Activity (PAC, PFX, TME, TMW, ZGM) | 4 | 2 |
| Medication Survey (MSR) | 4 | 2 |
| CES Depression (CES) | 2 | 1 |

B. OBSERVATION CHECKLISTS



APPENDIX QC4. CHECKLIST FOR OBSERVATION OF INTERVIEWING TECHNIQUE

ADMINISTRATIVE INFORMATION

0a. Completion Date: []/[]/[] 0b. Supervisor ID: []

0c. Interviewer ID: []

Table with 4 columns: Proficiency in Interview technique, Yes, No, Comments. Rows 1-14 list various interviewing skills with checkboxes for Yes/No and a line for comments.

15. Comments: _____



APPENDIX QC5. CHECKLIST FOR OBSERVATION OF ANTHROPOMETRY MEASUREMENT

Instructions: This checklist documents observation of anthropometry technicians by supervisors. Quarterly checklists and logs are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 1).

TECH ID NUMBER: SUPERVISOR ID NUMBER: DATE: / /
Month Day Year

| | Yes | No | Comments |
|--|------------|-----------|-----------------|
| 1. Anthropometry is done BEFORE the snack. | _____ | _____ | _____ |
| 2. If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose. | _____ | _____ | _____ |
| 3. Participant is wearing light-weight, non-constricting underwear. | _____ | _____ | _____ |
| 4. Participant is wearing a light clothes or scrub suit. | _____ | _____ | _____ |
| 5. Participant has removed shoes. | _____ | _____ | _____ |
| 6. Participant has emptied bladder. | _____ | _____ | _____ |

Weight Measurement **Yes** **No** **Comments**

A. Equipment

| | | | |
|--|-------|-------|-------|
| 1. Scale firm on floor. | _____ | _____ | _____ |
| 2. 10 kg standard weight available. | _____ | _____ | _____ |
| 3. Anthropometry Equipment Calibration log up-to-date. | _____ | _____ | _____ |

B. Procedure

| | | | |
|--|-------|-------|-------|
| 1. Participant prepared and procedure explained. | _____ | _____ | _____ |
| 2. Participant is bare-foot. | _____ | _____ | _____ |
| 3. Position of participant on center of scale. | _____ | _____ | _____ |
| 4. Balance achieved. | _____ | _____ | _____ |
| 5. Recordings completed. | _____ | _____ | _____ |

Technician's measurement of participant weight: _____ kg

Supervisor's measurement of participant weight: _____ kg

| Waist Measurement | Yes | No | Comments |
|--|-------|-------|----------|
| 1. Procedure is explained to participant. | _____ | _____ | _____ |
| 2. Subject stands erect, yet relaxed, with weight equally distributed on both feet, and feet together. | _____ | _____ | _____ |
| 3. Place the tape horizontally at the level of the umbilicus (navel). | _____ | _____ | _____ |
| 4. Subject takes a normal breath and <u>gently</u> exhales, holding breath in a <u>relaxed</u> manner at the end of exhalation. | _____ | _____ | _____ |
| 5. Tape is horizontal and snug, but not tight enough to compress tissue. [Invert tape, <u>if needed</u> , to insure reading edge of tape is snug to skin for measurement.] | _____ | _____ | _____ |
| 6. Reading is recorded to the nearest centimeter, rounding down. | _____ | _____ | _____ |
| Technician's measurement of participant waist: | _____ | cm | |
| Supervisor's measurement of participant waist: | _____ | cm | |

Comments: _____



APPENDIX QC6. CHECKLIST FOR OBSERVATION OF BLOOD PRESSURE MEASUREMENTS

Instructions: This checklist documents observation of technicians certified to perform blood pressure by supervisors. Quarterly checklists and logs are summarized onto the Summary of Observation and Equipment Checklists (Appendix 1).

TECH ID NUMBER: SUPERVISOR ID NUMBER: DATE: / /

Month Day Year

| Blood Pressure Measurement | Yes | No | Comments |
|---|-------|-------|----------|
| 1. Checks function settings on OMRON unit (ENTER, 3 inflations, 30) | _____ | _____ | _____ |
| 2. Checks Mode and P-setting on OMRON unit | _____ | _____ | _____ |
| 3. Makes sure AC adapter for OMRON unit is securely connected (tends disconnect from unit) | _____ | _____ | _____ |
| 4. Checks AC adapter cord and tubing for cracks | _____ | _____ | _____ |
| 5. Cleans all the equipment | _____ | _____ | _____ |
| 6. Allows subject to rest for five full minutes | _____ | _____ | _____ |
| 7. Performs arm measurement and cuff selection properly | _____ | _____ | _____ |
| 8. Identified brachial pulse location properly | _____ | _____ | _____ |
| 9. Proper cuff placement | _____ | _____ | _____ |
| 10. Attaches cuff to monitor | _____ | _____ | _____ |
| 11. Uses proper settings on OMRON unit | _____ | _____ | _____ |
| 12. Turns monitor on with ON/OFF button | _____ | _____ | _____ |
| 13. Sets MODE selector to AVG | _____ | _____ | _____ |
| 14. Sets P-SET knob to AUTO | _____ | _____ | _____ |
| 15. Pushes START button | _____ | _____ | _____ |
| 16. Records 1 st , 2 nd , 3 rd systolic and diastolic BP readings and average heart rate | _____ | _____ | _____ |
| 17. Instructions to participant are clear | _____ | _____ | _____ |
| 18. Holds arm vertically for 5 seconds between readings | _____ | _____ | _____ |
| 19. Informs participant of average readings | _____ | _____ | _____ |

Comments: _____



APPENDIX QC7. CHECKLIST FOR OBSERVATION OF PHYSICAL FUNCTION

Instructions: This checklist documents observation of technicians responsible for physical function by the lead supervisor. Quarterly checklists and logs are summarized onto the Summary of Observation and Equipment Checklists (Appendix 1). Copies of this log may be requested by the CC.

TECH ID NUMBER: SUPERVISOR ID NUMBER: DATE: / /
Month Day Year

| Chair Stands | Satisfactory/ Unsatisfactory | Comments |
|--|---|-----------------|
| 1. Back of chair against a wall | _____ | _____ |
| 2. Script correctly and clearly delivered | _____ | _____ |
| 3. Correctly demonstrates single stand, emphasizing keeping arms tight across chest | _____ | _____ |
| 4. Correctly demonstrates two stands, emphasizing full stand and return to complete sit | _____ | _____ |
| 5. Says "ready? Go" for each test | _____ | _____ |
| 6. Counts each chair stand and record final time when participant comes to a full standing position on the fifth stand | _____ | _____ |
| 7. Records and explains unusual values | _____ | _____ |
| 8. If task was not performed, codes and explains reasons | _____ | _____ |
| Standing Balance/Side-by-side Stand | | |
| 1. Script correctly and clearly delivered | _____ | _____ |
| 2. Correctly demonstrates position | _____ | _____ |
| 3. Timing started coincident with participant release and stopped when participant takes a step or holds on | _____ | _____ |
| 4. If task was not performed, codes and explains reasons | _____ | _____ |
| Semi-tandem Stand | | |
| 1. Script correctly and clearly delivered | _____ | _____ |
| 2. Correctly demonstrates position | _____ | _____ |
| 3. Timing started coincident with participant release and stopped when participant takes a step or holds on | _____ | _____ |

4. If task was not performed, codes and explains reasons _____

Tandem Stand

1. Script correctly and clearly delivered _____

2. Correctly demonstrates position _____

3. Timing started coincident with participant release and stopped when participant takes a step or holds on _____

4. If task was not performed, codes and explains reasons _____

5. Repeats second trial, if necessary _____

Short Walks, Usual Pace

1. Script correctly and clearly delivered _____

2. Correctly demonstrates _____

3. Toes touching start line _____

4. Clicker started on "Go" _____

5. Time stopped when the first foot crosses imaginary plane extending vertically up from the ending line/tape _____

6. Repeats second trial _____

Grip Strength

1. Asked pt about recent surgery on hands _____

2. Asked pt about pain and arthritis in hands _____

3. Recording dial reset to zero after sub maximal practice _____

4. Appropriate hand placement and grip adjustment if needed _____

5. Forearm resting on table, elbow bent to approximate right angle _____

6. Standard encouragement (motivation and feedback) offered to participant _____

7. Recording dial (peak hold needle) reset to zero after first trial _____

Comments: _____

C. CALIBRATION AND MAINTENANCE LOGS



APPENDIX QC8. ANTHROPOMETRY EQUIPMENT CALIBRATION LOG

Instructions: This checklist documents the daily, weekly and monthly calibration of anthropometry measurement equipment. Quarterly checklists and logs are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 1). Copies of this log may be requested by the CC. There should be one such log done each week though the monthly portion will be filled out only in the weeks that it is needed. If there is more than one piece of equipment used for a particular function indicate the checks for each piece on the same log. Home visit scales should also be checked/calibrated weekly.

Week of: _____ Field Center: _____ Tech ID: _____
[Monday's Date]

Daily Checks:

Scales read zero _____ _____ _____ _____ _____ _____ _____
 M T W Th F Sa Su

Weekly Checks

A. Reading of scale with 10 kg weight (if reading outside 9.5 to 10.5 range, scale should be serviced).

Date: ___/___/___ Reading: _____

Date service REQUESTED, ___/___/___

Date RECALIBRATED by service technician. ___/___/___

B. Repeat calibration because of moving scales

Date: ___/___/___ Reading: _____

Date: ___/___/___ Reading: _____



APPENDIX QC9. OMRON BP MONITOR MAINTENANCE AND CALIBRATION LOG

Instructions: This checklist documents the quarterly checks for the OMRON BP machine. There should be one such log done every quarter. If there is more than one BP monitor used indicate the checks with a separate log for each monitor. Quarterly checklists are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 1).

TECH ID NUMBER: FIELD CENTER:

DATE: / /

Month Day Year

Blood Pressure Measurement

OMRON unit #: _____

| | Y/N | If YES, action |
|--|--|---|
| Cracking | | |
| Holes | | |
| Worn outer cloth of Velcro | | |
| Leakage of cuff bladder | | |
| Calibration Check with Pressure-Vacuum Meter | | |
| Smooth descent of OMRON LED mm Hg from 280 to 20 mm Hg | | |
| Observed pressure values 250 to 20 mmHg, in approximant decrements of 20 mmHg | OMRON (mmHg) | Pressure-Vacuum Meter (mmHg) |
| Measurement Number 1 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 2 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 3 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 4 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 5 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 6 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 7 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 8 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 9 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 10 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 11 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |
| Measurement Number 12 | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mmHg |



APPENDIX QC10. SAMPLE OF ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Sample of Adverse Events and Unanticipated Problems for Use in Calibration

XXXXXX on --/--/-- During the regular echocardiography scan the sonographer identified a "mobile vegetation". The ppt is asymptomatic. The study physician was contacted and the reading center was asked for an expedited report. The study physician recommended immediate follow up with the participant's cardiologist or PCP. The ppt remained asymptomatic and was sent to the physician's office via taxi. -- Follow-up (added the following day): Ppt was seen by a cardiologist, echocardiogram was repeated, not admitted. Spoke with ppt the next day, who reports doing well.

Circle One

Action needed re. procedures or training?

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX < Date > The echo tech reported the participant asleep but unresponsive after completing the study echo. Breathing and heart rate were normal; skin was warm. The ppt. remained unresponsive for 2-3 minutes. The study MD was contacted and a 911 call was initiated. The EMS crew elicited a response, obtained a med hx and vital signs. The ppt. refused to be taken to the ER. AMA form signed. Ppt was escorted home in a cab by a member of the study staff. Study RN will follow up on < Date >

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX < Date > Participant called the field center to report experiencing severe nausea and feeling extremely hot after leaving the clinic the previous day. She initially thought this was due to a gastric problem and made an appointment to see her doctor. No significant findings were identified at the doctor's office. The participant then felt that her symptoms are associated with participation in the ARIC exam visit. The case was reported to the PI and a ___ form was entered in CDART. Since the participant is now feeling well and had obtained medical evaluation the event is considered resolved. No further action was taken.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX < Date > Immediately following removal of the electrode placed on the interior of the L arm for the echo procedure, the participant complained of pain. Skin irritation with blisters was observed at the site. An ice pack was applied to the area for 20 min; blisters had resorbed but the participant was left with reddened skin area of 1cm x 3.5 cm, and a burning sensation at this site.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > After the snack the participant was taken for the first set of neurocog. interviews. He started trembling, felt cold and anxious, no sweating, no nausea, no blurry vision. Vital signs were in the normal range and stable. The participant was placed lying down with legs elevated, covered with a blanket. His vital signs were monitored for 15 minutes until the trembling subsided and he felt calm and warm.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > 76 y/o male participant who is wheelchair bound following CVA one year ago. Ppt went to use toilet after snack, accompanied by home health aide. Ppt became unresponsive while sitting on toilet. Health aide called nursing staff for assistance. Ppt was transferred from toilet to wheelchair by staff and 911 was called. Ppt slowly became aware. The entire episode of unresponsiveness lasted about 2 mins.

EMS arrived about 15 mins later. Medical hx, ascertained from study visit given to EMS staff (hx significant for seizures, diabetes and asthma). EMS recommended transfer to xxxxxxxx medical center for further f/u. The ppt was transferred to the ER via ambulance, accompanied by home health aide. At the time of the transfer to the ER, ppt was alert and oriented, appeared cognitively intact and BP was 124/72.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > Sitting blood pressure recorded as 178/96. When rechecked during cardiac echo, BP was 216/106. Rechecked sitting blood pressure per protocol and found it to be 170/92 with a heart rate of 72. Participant took her medications with the snack, at the field center (benazepril 40 mg and amlodipine 5 mg). She has a follow up appointment with her PMD within the week; a report of her blood pressures was provided to her for review with the PCP. The participant was able to complete the exam visit without further incident

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > Staff reported that the participant became emotional during administration of questionnaires. When engaged by the interviewer the participant mentioned feeling lonely. The study nurse spoke with participant and options for counseling/mental health services were discussed. The participant approved of ARIC staff assisting her in making an appointment with her PCP to discuss her feelings of sadness and a possible referral. Appt. made for __/__/__

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - <Date > Assay results were transposed as a result of an incorrect transfer file format. The error was detected at the laboratory and the ARIC coordinating center was notified. By this time the study results had been mailed to this study participant. The assay result affected was the albumin-to-creatinine ratio. The assay values were in the normal range for both specimens, and the message provided to the study participant on account of these results did not differ between the new and old study results. A phone call was made to the study

participant, who was then sent an updated set of results. Corrective actions were implemented at the ARIC coordinating center; no further action required by the field center.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX – Date > On 1/30/17 the participant's husband called to notify staff (L.P.) that his wife's Ziopatch was removed early due to "hives". The study nurse (B.E.) called the participant on __/__/ to ask about the incident. The participant reported having itching within hours of the Ziopatch being placed, with a rash and hives developing as well. Due to this reaction, she removed the patch after wearing it for 7 days (as opposed to 14 days). She states that there was 1 hive underneath the patch and several around the patch. They had since "dried up" and scabbed over. The participant states that she has never had any reaction to any type of adhesive.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > Study participant stood up after completing the pulse wave velocity exam and sat in exam chair at 12:48. Peripheral neuropathy procedure was started at 12:50; approximately one minute later the study participant complained of dizziness. Peripheral neuropathy exam ceased and study nurse went to participant's side. The participant again stated that he felt hot and dizzy. At 12:54 the participant became unresponsive to verbal stimuli with a fixed gaze and was noted to be cool and clammy to the touch, and appeared lethargic. Vital signs were obtained and paramedics were summoned. At 13:00 participant stated that he felt better but was cool and clammy to the touch. 13:05 paramedics arrived and at 1320 participant was transported to local ER.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > While walking through the clinic to the lobby escorted by staff, the participant tripped over his cane and fell forward injuring the top of his right hand (skin tear), the underside of his left hand (skin tear) and his forehead above his right eye (scratch from his glasses). Participant denied any loss of consciousness, dizziness, or other illness (before or after fall), and said he believed that the fall was a result of him being clumsier than usual due to leg weakness - he insisted that he just tangled his legs up with his cane while walking.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > Ppt had a nice day with us and was not aware that anything was wrong until after she had gone home and woken up from an hour long nap and had pain in her left groin and front upper left leg. It hurts a great deal when she walks, but not when she sits or lies down. She waited a couple days then called to tell me. She wondered if it was from the ZioPatch or the ankle cuff, but the left groin is where the femoral ABI/PVW sensor is placed and where technicians probe with their fingers to locate the femoral pulse. She says the area is not red, or swollen, and there is no lump and at the time of the ABI test she was not aware of pressure on her groin area from the sensor. She appears to be familiar with the symptoms of a blood clot, but said several times that that was not the problem.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

XXXXXX - < Date > Ppt and spouse came in for Visit 7 today. The (average) sitting blood pressure measurement was 207/070. Rechecked after 15min: 208/069. The participant reported she is on BP meds but did not take them today and does not have them with her. The exam was interrupted. When questioned, the participant stated she does have some headache. The participant agreed to see her physician and an appointment was made for the same day. During a follow-up call to the study participant on the next day the participant reported that her physician had modified her blood pressure medication, a follow-up appointment had been made, and that she was feeling well.

Report as UP / SAE / MAE / Do not report

Follow-up needed?

Note: For definition of events and reporting procedures, see MOP 2 section for Participant Safety.