BLOOD PRESSURE AND PULSE

1. Background and Rationale

We are collecting a resting blood pressure and pulse measurement on all participants who return for Visit 4. We will also be collecting a pulse measurement. We will be collecting blood pressure and pulse when the participant is sitting down.

2. Equipment and Supplies

- BP Tru automated blood pressure monitor (model BMP-300)
- blood pressure cuffs (small, regular, large and thigh cuffs).
- tape measure
- eyebrow pencil
- chair with back support

3. Maintenance of Blood Pressure Equipment

Follow the manufacture's recommendations for the maintenance of the Bp Tru monitor.

In general, the following are other maintenance points.
With Each Use:
1) Device should be turned off at the completion of each participant's examination.
2) Squeeze all air from cuff.
3) Confirm that the connection of the cuff to the tubing is secure and tubing is not kinked.

Monthly:
1) Wipe the exterior of the monitor with a clean cloth.
2) Check the blood pressure cuffs to assure that all sizes are available and none have been misplaced.

4. Participant and Exam Room Preparation

Caffeine (from coffee, tea, or soda), eating, heavy physical activity, smoking and alcohol should be proscribed for 30 minutes prior to recording the blood pressure.

Arm circumference
If possible, use the right arm. If the participant's right arm is injured or missing use the left arm for the arm circumference and blood pressure measurement. Measure the participant's arm to determine the appropriate cuff size before allowing the participant to rest.

Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder.
- Request the participant to stand, bend the elbow, and put the forearm straight across the chest. The upper arm should be at a 90 degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax their arm along the side of the body.
- Draw the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin.
- Use the measurement to determine the correct cuff size.

Do not use the markings on the blood pressure cuff for reference. Instead, use the following criteria for determining the appropriate cuff size for the participant:

Arm circumference (cm/in.)	**Cuff's Bladder Size (cm)**
13.0 – 18.0 cm	Child cuff (6.5 x 12.5 cm)
18.1 – 26.0 cm	Small cuff (8.9 x 17.1 cm)
26.1 - 32.0 cm	Regular cuff (12 x 22.9 cm)
32.1 – 41.0 cm	Large cuff (15.2 x 33 cm)
41.1 – 52.0 cm	Extra-Large cuff (17.8 x 35.6 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

If the above listed cuff sizes do not appear to fit a participant, you may use the smaller size cuff as long as the arm circumference falls within the reference values printed directly on the cuff. Please mark the cuff size used on the TELEform.

5. Detailed Measurement Procedures

Before the first blood pressure measurement the participant should rest for approximately five minutes, sitting upright with feet flat on floor. During the measurement their feet should be flat on the floor and legs and ankles uncrossed.

5.1 Application of the Cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor. It is also acceptable to apply the cuff with the participant standing if this works better for staff and participants.

- Palpate the brachial artery.

- Mark the brachial artery with an eyebrow pencil.

- Place the appropriate-sized cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.

- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area that it overlaps the cuff. You should be able to insert two fingers under the cuff.

- If it is not feasible to measure blood pressure using the right arm, the left arm may be used.

5.2 Rest Period

Ask the participant to sit with both feet flat on the floor and to rest without talking for five minutes before measuring their first blood pressure. Instruct the participant on the correct posture with the back supported and both feet flat on the floor. The work station should be free of excessive noise and the participant should not be interviewed nor asked to read anything at this time.

5.3 Determining the Maximal Inflation Level

The Bp Tru will automatically determine the maximal inflation level.

6. Performing the Blood Pressure Measurement

1) Use the BP Tru monitor to obtain sitting blood pressure #1.
2) Record the systolic and diastolic values as they appear on the digital display on the Blood Pressure and Pulse TELEform under measurement 1. Also record the participant's pulse.
3) Allow for 1 minute rest.
4) Use the Bp Tru monitor to obtain a second sitting blood pressure.
5) Record the systolic and diastolic values as they appear on the digital display on the Blood Pressure and Pulse TELEform under measurement 2. Also record the participant's pulse.

If the average pulse (beats per minute) is a decimal, round to the nearest whole number. For example, if the average pulse is "65.5", record "66" on the TELEform.

If the automated device continues to pump the cuff during a blood pressure measurement and potentially misses the maximum inflation level or it is obvious that the participant is experiencing much discomfort, please manually stop the measurement. Let the participant rest for at least 1 minute and repeat the attempt. If after 2 attempts, the reading is still not obtainable, please mark that the blood pressure measurement was not obtained on the data collection form. If there were two failed attempts at measurement 1, do not attempt measurement 2.

Please note that if an error message is displayed for either the diastolic or systolic reading after one of the measures, it should be repeated. Allow for 1 minute rest before starting another measurement. If an error message is displayed after the second attempt, please mark on the TELEform that the blood pressure reading was obtained but that there was an error message for the particular value. If both the systolic and diastolic values are errors, mark that both are errors. If there was a reading for the systolic measure and an error for the diastolic, you should record the systolic value and mark the 'diastolic error' bubble (or visa versa). If there were error messages for measures on both attempts for measurement 1, do not attempt measurement 2.

If a blood pressure measurement is not obtainable using the automated device, it is fine to perform a manual blood pressure measurement to give the participant result information. However, only data obtained from the automatic blood pressure device should be recorded on the TELEform.

7. Blood Pressure & Pulse Alert Levels

There are two levels of alert values for the blood pressure and measurements: immediate referrals and alerts. The values for both types of alerts are provided below along with suggested guidelines for handling both types of alerts. However, protocols for immediate referrals and alerts will be determined locally at each clinical site.

Immediate referrals are potential emergencies which may require immediate notification of the participant (and if so requested by the participant) his primary physician or other available health care provider. Depending on the specific protocol are your site, the site staff may contact the MrOS study investigator for a clinical diagnostic assessment, determine whether immediate referral is indicated or may send the participant directly to their physician or to an emergency room. With the participant's consent (obtained verbally at the time of the alert), the study physician and/or investigator could contact the participants physician directly.

Notification of the participant should occur prior to the participant leaving the clinic.

Findings requiring immediate referral at the time of the clinic visit are as follows:

- Blood pressure (awake, seated) (on EITHER reading)
  Systolic blood pressure $\geq$ 210 mmHg

OR
Diastolic blood pressure ≥ 120 mmHg

- Pulse (on EITHER reading)
  Heart Rate ≥ 140 OR ≤ 40 beats/minute

Urgent Alerts are related to abnormalities detected at the time of the clinic visit which require medical attention but generally not on an emergency basis. In most cases, notification of the participant should be sent by mail within 10 days. However, certain alerts may require more immediate attention at the discretion (and responsibility) of the study physician. Therefore, all alerts should be reviewed by the study physician no later than the next business day following the observation of the alert condition. If the study physican judges the condition to require more immediate attention, the study investigator or their designate has the responsibility of contacting the participant directly by phone to discuess the need for medical follow-up and to seek consent to notify the participant's referring physician about the condition. If the participant refuses, then the study physician should minimally refer the participant to the ER and/or provide a listing of specialist (e.g. cardiologists) or medical care facilities the participant could contact for medical care.

Clinic visit findings requiring an alert are as follows:

- Blood pressure (awake, seated) (on EITHER reading)
  Systolic blood pressure ≥ 180 mmHg
  OR
  Diastolic blood pressure ≥ 110 mmHg
- Heart Rate (on EITHER reading)
  Heart Rate ≥ 120 beats/minute

Any alert observed during the blood pressure or pulse measurement, whether immediate or urgent, should be reported on the Medical Alerts TELEform and sent to the MrOS data system.

8. Quality Assurance

Training Requirements

Clinical experience with blood pressure measurement is required. In addition, training should include:

- Read and study manual
- Observe administration by experienced examiner.
- Practice on volunteers
- Discuss problems and questions with local expert

CERTIFICATION REQUIREMENTS

- Complete training requirements
- Conduct exam on two volunteers while being observed by QC

- Performs exam according to protocol as demonstrated on completed QC checklist

9. QA Checklist

Blood Pressure

- ❑ Explains procedure
- ❑ Measures for cuff size
- ❑ Palpates brachial artery
- ❑ Wraps cuff snugly, centering bladder over brachial artery
- ❑ Five minute rest period before first measurement and 1 minute between subsequent measurements
- ❑ Uses Bp Tru monitor to obtain measurement #1.
- ❑ Records systolic and diastolic blood pressure values and pulse on the TELEform.
- ❑ Allows for 1 minute rest
- ❑ Uses Bp Tru monitor to obtain measurement #2.
- ❑ Records systolic and diastolic blood pressure values and pulse on the TELEform.
- ❑ Reviews forms for completeness
- ❑ Tells participant BP and pulse readings.
- ❑ Knows alert levels and appropriate follow-up procedures for alerts

10. Acknowledgments

Women's Health Initiative Operations Manual. Volume 2, Section 9.2: Blood Pressure. 8/30/95.

WHAS Operations Manual. Section 3.5 Blood Pressure Measurements. 6/18/93.