

**PREMIER Clinical Manual of Procedures**

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**Summary of Edits**

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### 27. Offsite Data Collection Visits

If randomized participants are unable or refuse to come to the clinical center, data collection can be performed at locations convenient for the participant. It is essential that staff try to have the data collection conducted in a quiet, private or semi-private room, where the required relaxed waiting time can occur before a random zero blood pressure measurement is taken, and where there is an interview setting that permits privacy.

In order to preserve blinding of the staff person measuring blood pressure, when the PAR is to be administered at an off-site data collection visit, two staff persons (one blinded and one unblinded) conduct the visit. If the PAR is conducted at this visit, the blinded staff person should not be present in the room.

The room should have a comfortable chair, and a table or desk so that the participant's arm can be at heart level. Check in advance that a table and chair are available, and that there is an uncarpeted area where the scale can be placed to measure weight. If necessary, staff may need to bring a card table and chair for the blood pressure measurement, and a sheet of hard plastic or wood to place under the scale. If blood samples are collected, they must be transported in a closed container with at least 2 latches, such as a tackle box or toolbox. Blood samples in vacutainers must be put into 2 plastic zip lock bags and transported inside the closed container.

#### *Materials*

- RZ or standard sphygmomanometer (see below)
- UC-300 portable scale
- Forms and questionnaires as needed for the visit
- Tape measure (if 6 or 18-month visit)

#### *if needed*

- Table
- Chair
- Sheet of hard plastic or wood to place under portable scale
- Lab supplies for fasting blood draw and 24-hr urine sample
  1. Transport container with at least 2 latches
  2. Ice packs to cool samples
  3. A biohazard sign must be placed on the outside of the container.
  4. In addition to supplies for the blood draw listed in Chapter 21, the container must include:
    - ◆ Plastic zip lock bags
    - ◆ A spill kit including 10% bleach solution

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- ◆ Plastic-backed “diapers” or barrier material to place under participant’s arm during blood draw
- ◆ Biohazard bags for all potentially infectious materials
- ◆ Sharps containers for needle disposal

### ***Conducting the visit***

In general, blood pressure should be done before the other procedures.

1. Measure blood pressure
2. Measure weight

*if 6 or 18-month visit, add:*

3. Measure waist circumference
4. Complete visit questionnaires, including 7-day Physical Activity Recall (see below)
5. Review instructions for the 24-hour food recall
6. Draw blood
7. Give participant supplies and instructions for 24-hour urine

### ***Measure blood pressure***

Take the participant’s blood pressure with the random zero sphygmomanometer using the procedures described in MOP Chapter 17 (Blood Pressure Assessment). If your institution or the participant’s workplace prohibits the use of random-zero devices, a standard manometer can be used. If no device containing mercury can be used, you may use a standard aneroid sphygmomanometer. When using a standard manometer, add 30 to the pulse obliteration point (POP) in order to determine the maximum inflation level (MIL).

### ***Measure weight***

Measure the participant’s weight using the off-site visit protocol in Clinical MOP Chapter 20, Other Clinical Measurements.

### ***Measure waist circumference***

Measure the participant’s waist circumference using the off-site visit protocol in Clinical MOP Chapter 20, Other Clinical Measurements.

### ***Complete questionnaires***

Encourage the participant to complete as many forms as possible. Unblinded staff certified in PAR techniques must administer the PAR.

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### ***Draw blood***

Draw fasting blood sample using procedure in Clinical MOP Chapter 21, Central Laboratory Procedures. Place sample on ice in container and return to clinic for processing within 1 hour of collection of the sample.

### ***Review instructions for 24-hour recall***

Review instructions for the 24-hour food recall with the participant.

### ***Review instructions for 24-hour urine***

Review instructions for collection of the 24-hour urine sample with the participant. Make arrangements for delivery or pick up of the sample once collection is complete.

### ***Review forms and conclude visit***

Clinic staff review all forms before leaving the site.