



Pre-randomization
ID: _____
Date: ____ / ____ / _____

4th Baseline Blood Pressure Form

1. PREPARATION FOR BLOOD PRESSURE MEASUREMENTS

a. Time of blood pressure measurements : _____
(Noon is 12 PM) AM 1
PM 2

b.

Cuff size from SV1 _____

 Cuff size used: Small adult (<24 cm) 1
Adult (24-32 cm) 2
Large adult (33-41 cm) 3
Thigh (42-52 cm) 4

c. Does cuff fit properly? Yes 1
No 2

WAIT 5 MINUTES SEATED

d. Resting 30-second pulse _____

e. Pulse obliteration pressure (POP)..... _____
+ 6 0

f. Random zero peak inflation level (PIL), minimum 180..... _____

g. Blood pressure device number..... _____

PIL

ID: _____

2. FIRST RANDOM ZERO BLOOD PRESSURE

SBP / DBP

- a. Uncorrected value..... /
- b. Zero value.....
- c. Corrected value (a-b)..... /

WAIT 30 SECONDS

3. SECOND RANDOM ZERO BLOOD PRESSURE

SBP / DBP

- a. Uncorrected value..... /
- b. Zero value.....
- c. Corrected value (a-b)..... /

4. COMPUTE SUM

- a. Sum of 2 SBPs and 2 DBPs (2c + 3c) /

5. DETERMINE BLOOD PRESSURE OUTCOME (check the first applicable box)

Ineligible: escape-level BP.....Sum of SBPs for this visit ≥ 359 1

Sum of DBPs for this visit ≥ 219 2

If box 1 or 2 is checked: complete form #32 (escape level 1), participant is ineligible

EligibleSum of SBPs ≤ 358 , Sum of DBPs ≤ 218 7

Collected by (staff ID):	_____
Reviewed by (staff ID):	_____
Entered by (staff ID):	_____

Overview

The 4th Baseline Blood Pressure Form is filled out by clinic staff and is used for blood pressure screening to determine eligibility of potential participants.

The 4th Baseline Blood Pressure must be done at some point between the SV3 blood pressure and the R/I visit. The 4th Baseline Blood Pressure may be done on the day of the R/I visit.

This is not an eligibility measure except that if the blood pressure reaches escape level 1, the participant will be excluded. There is no lower limit, and no exclusion for high blood pressures so long as they are below escape level 1.

If item 1c=No, all subsequent questions are left blank and the participant is ineligible. If item 1c=Yes, ALL fields should be complete. If a field is missing or outside the normal range, the data system will reject the form.

Administration Instructions

Use correct version of form. The correct version will always be on the site workstation computer.

Place ID labels on pages 1 and 2. Check for accuracy.

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions</u>
1	1	<p>Before the actual measurements are obtained, items a-g must be recorded. If there are any questions about preparing for or taking the measurements, refer to MOP Chapter 17.</p> <p>a. Record the time. The person should be seated. Remember that noon is 12:00 pm. Mark appropriate box to indicate am or pm.</p> <p>b. Measure the participant's arm circumference. Round all fractions up to the next whole number (i.e. 32.1 should be coded as 33). Record the rounded arm circumference. Based on the arm circumference obtained, mark an "X" on the corresponding line indicating proper <u>cuff size</u> for the measurement. Use the cuff size obtained at SV1 for all of the participant's blood pressure measurements during screening.</p> <p>c. Indicate here whether or not the cuff fits properly. If the brachial artery is occluded by the cuff, the participant is excluded from participating in PREMIER (see MOP Chapter 17). If this is so, check No, and check "ineligible" on the Randomization Checklist Visit Form (Form #60) for the 4th Baseline Blood Pressure Form outcome. If the cuff fits properly, check Yes.</p>

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions</u>
1		<p>WAIT 5 MINUTES SEATED</p> <p>1 d. Obtain and record the <u>resting 30-second</u> pulse (radial artery) by counting the number of beats in 30 seconds.</p> <p>e. Connect the cuff to a standard mercury sphygmomanometer to establish and record the pulse obliteration pressure (the pressure at which the radial pulse can no longer be felt).</p> <p>f. Add 60 to the pulse obliteration pressure to obtain the <u>random zero peak inflation level</u> (PIL) and record the result. If this value is less than 180, enter 180. Also, record the PIL on page 2 in the upper left hand corner.</p> <p>g. Record the device number for the blood pressure machine you will be using to take the blood pressure. This is a two digit field, use leading zeros as appropriate.</p>
2	2 a.	Obtain a sitting blood pressure measurement using the random-zero device and record the reading. If the meniscus is exactly between the lines, round up to the nearest even number. Use leading zeros if less than 100.
	b.	Record the zero value. If the meniscus is exactly between the lines, round up to the nearest even number. Use a leading zero if less than 10.
	c.	Do Items 3a and 3b first. Then follow instructions for Item #3c.
		Wait 30 seconds
	3 a.	Repeat item #2a.
	b.	Repeat item #2b.
	c.	AFTER MEASUREMENTS ARE OBTAINED FOR #2a and #3a, subtract the zero values from the corresponding blood pressure measurement readings with a hand calculator. Record the resulting corrected value for both the SBP and DBP values. If the DBP goes to 0mmHg during the 5th phase, repeat the measurement recording the 4th phase DBP. If you don't hear the 5th phase DBP on the repeat measurement, then use the 4th phase DBP. Use a leading zero if the value is less than 100.
	4	Add the values from lines 2c and 3c together and record the sum on line #4. The sum should be an even number. Use a leading zero if the value is less than 100.
	5	Using the sum value from item #4, check the first applicable box . If ineligible, check "ineligible" on the Randomization Checklist (#60) for the 4th Baseline Blood Pressure Form outcome. If eligible, check "eligible" on the Randomization Checklist (#60) for the 4th Baseline Blood Pressure Form outcome. If the BP escape levels are reached, the participant needs to be referred for medical counseling and the BP escape tracking form (#32) should be filled out. Refer to MOP Chapter 23 for details and complete form #32.

Coding Instructions

All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 4/30/99, incorrect ID).

When filling out the “Collected by”, “Reviewed by”, and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID # should not be written until the form is entered.

Review Instructions

Check for correct calculations in items 1f, 2c, 3c, and 4.

If the participant is ELIGIBLE (Q5= box #3 marked), check the following items:

- Page 1 should be dated.
- Pages 1-2 should have correct ID# labels.
- Page 1:
 - items 1a-b and 1d-g should be completed;
 - item 1c should be coded as Yes;
- Page 2:
 - items 2 and 3 should be completed;
 - item 4 should be within the range allowed for blood pressure shown in the last option for item 5, the eligible line;
 - item 5 should have box 3 marked.
- All pages: all corrections should be explained, initialed, and dated. Correction should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.

Additional Instructions

Use the cuff size obtained at SV1 to record all of a participant’s blood pressure measurements during screening.