



HOME BLOOD PRESSURE FORM 12 INSTRUCTIONS

Form # 12A

This form is to be used to record and report all home blood pressure measurements. It is to be completed by the participant whenever home BP is measured, and by study personnel whenever home BP is reported by telephone (form may be used as source documentation if allowed by the local IRB.). Record the date and time each BP sitting (at least 3 readings) was completed. If participants require more than one copy of this form, generate or photocopy as many pages as necessary.

Do not smoke or consume caffeine within 30 minutes of taking BP measurements. Rest while seated with arm supported at heart level for at least five minutes, then take three readings, at least 30 seconds apart. Twice-daily readings (#5 below) are to be taken before breakfast (but at least 30 minutes after waking) and before the evening meal.

Note: If there is a difference of more than 10 mm Hg (systolic or diastolic) between the 2nd and 3rd readings in one sitting, record a 4th and 5th reading for that sitting in the column on the right.

There are five distinct categories for Home BP, three of which are entered in WDES:

1. Routine BP taken during washout (before the start of ACE+ARB therapy at the B2 visit):

Participants are to record at least one sitting at least every other day during washout. Study personnel are to transcribe BP readings reported over the phone. Participants are to bring the completed form to the B1 visit. The form is to be data-entered within 2 weeks and stored in the participant's research chart. If additional readings are collected after the B1 visit but before B2, the form is to be edited as necessary. WDES does not calculate average BP for the washout period.

2. Routine BP taken during titration (after the start ACE+ARB therapy but before stabilization):

Participants are to record at least one sitting at least every four days until BP is stabilized and ACE+ARB therapy is maximized. After stabilization (expected at the F4 visit) participants are to record at least one sitting per month. Study personnel are to transcribe BP readings reported by phone (at visits F1-F4). Participants are to bring the completed form to the F5 visit. This form completed during titration is to be stored in the research chart, but does not require data entry.

3. Routine BP reported at F7 and F10: Participants are to record at least one sitting at least every month after stabilization, which is expected at the F4. Study personnel are to transcribe all BP readings reported by phone at visits F7 and F10 and the form is to be data-entered within 2 weeks. WDES will calculate average monthly BP. Participants are to bring the completed form to the subsequent clinic visit and the form is to be stored in the participant's research chart.

4. Routine BP taken after F12: Participants are to record at least one sitting at least every month after stabilization. Study personnel are to transcribe BP readings reported by phone (at visits F15, F21, etc.) but the form is not data-entered. Participants are to bring the completed form to the subsequent clinic visit and the form is to be stored in the participant's research chart.

5. BP taken over 7 consecutive days within the month before the PCC visit (F5 and after): BP is to be measured twice daily (morning and evening) over seven consecutive days within the month prior to each clinic visit, F5 and after. *This form is to be entered via WDES at or before the clinic visit. Dosing should be based on the Official BP calculated by WDES.* If an insufficient number of complete sittings is reported prior to the visit, the participant should repeat BP readings over seven consecutive days within the month after the clinic visit (indicate "initial" or "repeat" at the time of data entry).