

SH01: Randomization Form

Purpose

The *Randomization Form* was used to document the telephone randomization of an eligible SHEP participant. (See **Section 2.4.5** of the *SHEP Manual of Operations* for details.) Randomization took place during Baseline Visit 2.

Information on the SH01 was largely taken from the SH06 form, which was completed at Baseline Visit 1. All 4,736 randomized participants have an SH01 form. In addition to the 4736 randomized SHEP trial participants, the SHEP Masterfile contains some information on another 7,260 patients screened for the trial but either declined to participate in the trial or were ineligible for it. These individuals have one or more of the forms on the Masterfile but do not have an SH01 form. Randomized participants have a complete set of forms SH01, SH03, SH04, SH06, SH07. Persons who were not randomized may have one or more of the SH03, SH04, SH06, and SH07 forms, but, generally, not a full set.

The total number of individuals with forms on the Masterfile is 11, 996. Of these, 6,928 have an SH03 form, 3,988 have an SH04 form (15 of whom do not have an SH03), 7,228 have an SH06 form (302 of whom do have neither an SH03 nor SH04), and 2,225 have an SH07 form.

The SHEP blood pressure eligibility criteria are given in Table 3, below. See **Chapter 2** of the *SHEP MOO* for details about screening procedures, visits, and eligibility criteria.

SH02: Participant Information Sheet

The SH02 form (*Participant Information Sheet*) was not collected by the SHEP Coordinating Center. It was retained by the respective Clinical Centers. (See **Section 2.3.4** of the *SHEP MOO*.)

Table 3. SHEP Blood Pressure Eligibility Criteria for Persons Not On Antihypertensive Medications and for Persons On Antihypertensive Medications at Initial Contact

Visit	Persons Not on Antihypertensive Medication	Persons on Antihypertensive Medication
Initial Contact	SBP 160 - 219 mm Hg DBP < 100 mm Hg	SBP 130 - 219 mm Hg DBP < 85 mm Hg
Drug Evaluation Visit 1		SBP 130 - 219 mm Hg DBP 85 mm Hg
Drug Evaluation Visit 2 **		SBP 160 - 219 mm Hg DBP < 100 mm Hg
Baseline Visit 1 (SH06)	SBP 150 - 219 mm Hg DBP < 95 mm Hg	
Baseline Visit 2 (SH07) ***	SBP 150 - 219 mm Hg DBP < 95mmHg and average of BL1 and BL2: SBP 160 - 219 mm Hg DBP < 90 mm Hg	

* Mean of second and third readings of DBP and SBP values at Initial Contact and all Drug Evaluation Visits; mean of two determinations at Baseline Visits 1 and 2.

** Or subsequent visit in evaluation period, up to 8 weeks after withdrawal of antihypertensive medications; participants with SBP less than 160 mm Hg should continue to be followed until SBP is in eligible range, SBP or DBP rise above eligible levels, or the 8-week evaluation period ends.

*** Allow one more visit to qualify if SBP \geq 220.