SH07: Baseline Visit 2 Form

Purpose

The *Baseline Visit 2 Form* (SH07) was completed at the second of two baseline evaluation visits attended by potential participants. Determination of eligibility for the trial was completed at this visit. Eligibility was based on study inclusion and exclusion criteria given in **Section 2.4** of the *SHEP MOO*. The *SHEP Orientation Booklet* was reviewed with the eligible participant prior to obtaining his or her final informed consent to participate. Randomization was carried out by telephone contact with the Coordinating Center during this visit (see **MOO Section2.4.5**). Form SH07 is described in detail in **Section 2.4.6** of the *MOO*.

30-32 (1) FORM NUMBER

40 (518) SEQUENCE

33 (2) VERSION

BASELINE VISIT 2

Name: (4) _____

1. SHEP ID: (3) 22-23 - 24-27 - 38-29 (5) 2. Acrostic: 41-46 (6)

3. Today's Date: 36 37 (Month) 38 39 (Day) 34 35 (Year) (7)

4. a. Is this a repeat Baseline Visit 2? 47 (8) Yes ☐ 1 No ☐ 2 → SKIP to 5

Previous BV2 blood pressures (average of corrected readings):

b. SBP: (9) 48-50 mm Hg c. DBP: (10) 51-53 mm Hg

REVIEW THIS SECTION AT COMPLETION OF VISIT BEFORE PARTICIPANT LEAVES.

☐ Consent obtained for Baseline Visit 2, if not previously collected.
☐ SHEP ID and Acrostic are correct.
☐ Every item on each page is complete and legible.

A. Result of this visit:

54 (11) (1)
- ☐ 1 Participant is eligible and has been randomized.
- ☐ 2 Participant is eligible, but refuses to be randomized.
- ☐ 3 Participant is not eligible due to:

55 (12) (2)
- ☐ 1 Blood pressure
- ☐ 2 Creatinine
- ☐ 3 Dementia
- ☐ 4 Other → Specify: _____

B. Randomized participants only:

☐ Participant orientation completed.
☐ Consent form for SHEP participation signed.
☐ Goal SBP: (13) 56-58 mm Hg
☐ Bottle number of Step 1, Dose 1 drug: 59-61 (14)
☐ Fasting blood sample drawn.
☐ Non-fasting blood sample drawn.
☐ Blood sample refused.
☐ Behavioral evaluation completed.

C. **DISPENSING OF MEDICATIONS, APPOINTMENT FOR ONE-MONTH VISIT**

1. Give participant Step 1, Dose 1 medications. Make sure that the participant understands when and how to take the medications.

2. Make a clinic appointment for the one month visit (three to five weeks from today's visit):

62 (15)
- ☐ 1 Appointment made on (16) 65 66 (Month) 67 68 (Day) 63 64 (Year) at ☐☐:☐☐ (Hour: Min.) 69-72 (17) ☐ a.m. ☐ p.m. (18) 73
- ☐ 2 Appointment not made; reason: _____

SH07/1

5. a. Pulse: Beats in 30 seconds _____ x 2 = (19) 74-76 beats per minute.

b. Blood pressure:

Cuff Size:

77 (20)
- 1 ☐ Regular
- 2 ☐ Large arm
- 3 ☐ Thigh
- 4 ☐ Pediatric

Pulse Obliteration Pressure:

Observed Value: ☐

Subtract Zero Level: - ☐

Corrected Value: ☐

Add Maximum Zero Level Plus 10: + ☐

Peak Inflation Level: ☐

Seated Readings:

	Systolic	Diastolic
First	(21) 78-80	(22) 81-83
Zero level	(23) 84-85	(24) 86-87
Corrected	(25) 88-90	(26) 91-93
+ Second	(27) 94-96	(28) 97-99
+ Zero level	(29) 100-101	(30) 102-103
+ Corrected	(31) 104-106	(32) 107-109
Sum of two corrected readings	(33) 110-112	(34) 113-115
Average of two corrected readings	(35) 116-118	(36) 119-121

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

(37) x 4 = 122-124 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(38) 125-127	(39) 128-130
Zero	(40) 131-132	(41) 133-134
Corrected	(42) 135-137	(43) 138-140

Three minutes

Pulse: Beats in 15 seconds _____

(44) x 4 = 141-143 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(45) 144-146	(46) 147-149
Zero	(47) 150-151	(48) 152-153
Corrected	(49) 154-156	(50) 157-159

c. Did the participant volunteer any symptoms on standing? 160 (51) Yes ☐ 1 No ☐ 2 → SKIP to 5d.

(1) Dizziness? Yes ☐ 1 161 (52) No ☐ 2

(2) Other (specify)? Yes ☐ 1 162 (53) No ☐ 2

_____

d. Eligibility check (use average of two corrected readings):

(1) Blood Pressure at this visit:

163 (54)

- ☐ 1 SBP <150 or ≧220 mm Hg, or DBP ≧95 mm Hg → Ineligible

  Note: Participants with SBP ≧220 mm Hg and DBP < 95 mm Hg may return in one week for a repeat blood pressure measurement

- ☐ 2 SBP 150-219 mm Hg, and DBP <95 mm Hg → Continue

	Systolic	Diastolic
Baseline Visit 1 Average R-Z Blood Pressure	(55) 164-166	(56) 167-169
Average R-Z Blood Pressure from Section 5b:	(57) + 170-172	(58) + 173-175
Sum	(59) 176-178	(60) 179-181
Baseline = Sum ÷ 2 (61)	182-184	185-187 (62)

(2) Baseline Blood Pressure (Average of BL1 and BL2):

188 (63)

- ☐ 1 BL SBP <160 or ≧220 mm Hg, or BL DBP ≧90 mm Hg → Ineligible
- ☐ 2 BL SBP 160-219 mm Hg, and BL DBP <90 mm Hg → Continue

(3) Creatinine:

189 (64)

- ☐ 1 Creatinine >2.0 mg/dl → Ineligible
- ☐ 2 Creatinine ≦2.0 mg/dl → Eligible
- ☐ 3 Not applicable → Eligible

Ineligible participants should proceed to scheduling area for termination of their participation in the SHEP screening process. Only eligible participants should proceed with the remaining items in Baseline Visit 2.

e. Observer's signature: _____ (65) 190-191 Code

The SHORTCARE/CES-D section of the behavioral evaluation should be administered at this time.

6. Result of SHORTCARE evaluation, dementia component:

192 (66)

- ☐ 1 Participant did not reach criterion score for dementia → Eligible

Participant reached criterion score for dementia, and:

- ☐ 2 Remains eligible, in the judgment of the SHEP clinician → Eligible
- ☐ 3 Should be excluded, in the judgment of the SHEP clinician → Ineligible

Ineligible participants should proceed to scheduling area for termination of their participation in the SHEP screening process. Only eligible participants should proceed with the remaining items in Baseline Visit 2.

7. SIDE EFFECTS HISTORY

A. Questions in this section are to be asked at every visit. Use phraseology that you are comfortable with.

(1) Have you felt unwell in any way since your last clinic visit; has anything been bothering you? (Specify): _____ 193 (67) 1 ☐ Yes 2 ☐ No → Go to (3)

(2) Are any of these problems different from the way things were at your last clinic visit? 194 (68) 1 ☐ Yes 2 ☐ No

(3) Since your last visit, have you seen a doctor for any reason? (Specify): _____ 195 (69) 1 ☐ Yes 2 ☐ No

(4) Since your last visit, have you been in the hospital for any reason? 196 (70) 1 ☐ Yes 2 ☐ No → Go to B
How many times? (71) 197-198
When? (Start with the first one after your last visit.)

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	(72) 199-204	(74) 207-212	(76) 215-220
Date of admission	Month Day Year	Month Day Year	Month Day Year
Number of days	(73)	(75)	(77)
Reason	205-206	213-214	221-222

B. Specific queries: Elicit symptoms by asking about each of the items listed on the next pages using the specified phraseology. Record characteristics of positive responses.

Since your last visit, have you had:	(a)	New since last visit? (b) 1=Yes 2=No	Frequency: (c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	Severity: (d) 1=Not troublesome 2=Troublesome 3=Intolerable	
(1) Unusual coldness or numbness of the hands or feet?	223 (78) Yes ☐ 1 → No ☐ 2	(79) ☐ 224	(80) ☐ 225	(81) ☐ 226	
(2) Unusual skin rash or bruising?	227 (82) Yes ☐ 1 → No ☐ 2	(83) ☐ 228	(84) ☐ 229	(85) ☐ 230 →	(e) Is an acute skin rash present on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 (86) 231
(3) Any feelings of unsteadiness or imbalance?	232 (87) Yes ☐ 1 → No ☐ 2	(88) ☐ 233	(89) ☐ 234	(90) ☐ 235	
(4) Faintness or light headedness when you stand up quickly?	236 (91) Yes ☐ 1 → No ☐ 2	(92) ☐ 237	(93) ☐ 238	(94) ☐ 239	→ (e) Is there an observabl postural drop in blooc pressure? Yes ☐ 1 No ☐ 2 (99) 244
(5) Loss of consciousness or passing out	240 (95) Yes ☐ 1 → No ☐ 2	(96) ☐ 241	(97) ☐ 242	(98) ☐ 243	
(6) Falls?	245 (100) Yes ☐ 1 → No ☐ 2	(101) ☐ 246	(102) ☐ 247	(103) ☐ 248	
(7) Fractures?	249 (104) Yes ☐ 1 → No ☐ ~~1~~ 2	(105) ☐ 250	(106) ☐ 251	(107) ☐ 252 →	(e) Hip? 253 Yes ☐ 1 No ☐ 2 (108) (f) Spine? 254 Yes ☐ 1 No ☐ 2 (109) (g) Forearm? 255 Yes ☐ 1 No ☐ 2 (110)

Continued

Since your last visit, have you had: (a)		New since last visit? (b) 1=Yes 2=No	Frequency: (c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	Severity: (d) 1=Not troublesome 2=Troublesome 3=Intolerable
(8) Unusual pain in any joint?	256 (111) Yes ☐ 1 → No ☐ 2	(112) ☐ 257	(113) ☐ 258	(114) ☐ 259 → (e) Are there physical signs of acute arthritis? Yes ☐ 1, Possibly ☐ 2, No ☐ 3 (115) 260
(9) Muscle weakness or cramping?	261 (116) Yes ☐ 1 → No ☐ 2	(117) ☐ 262	(118) ☐ 263	(119) ☐ 264
(10) Excessive thirst?	265 (120) Yes ☐ 1 → No ☐ 2	(121) ☐ 266	(122) ☐ 267	(123) ☐ 268
(11) Loss of appetite?	269 (124) Yes ☐ 1 → No ☐ 2	(125) ☐ 270	(126) ☐ 271	(127) ☐ 272
(12) Nausea or vomiting?	273 (128) Yes ☐ 1 → No ☐ 2	(129) ☐ 274	(130) ☐ 275	(131) ☐ 276
(13) Unusual indigestion?	277 (132) Yes ☐ 1 → No ☐ 2	(133) ☐ 278	(134) ☐ 279	(135) ☐ 280
(14) Change in bowel habits?	281 (136) Yes ☐ 1 → No ☐ 2	(137) ☐ 282	(138) ☐ 283	(139) ☐ 284
(15) Tarry black stools or red blood in the stools?	285 (140) Yes ☐ 1 → No ☐ 2 →	(141) ☐ 286	(142) ☐ 287	(143) ☐ 288
(16) Heart beating unusually fast or skipping beats?	289 (144) Yes ☐ 1 → No ☐ 2	(145) ☐ 290	(146) ☐ 291	(147) ☐ 292 → (e) Is an arrhythmia present on physical exam? Yes ☐ 1, Possibly ☐ 2, No ☐ 3 (156) 301
(17) Heart beating unusually slow?	293 (148) Yes ☐ 1 → No ☐ 2	(149) ☐ 294	(150) ☐ 295	(151) ☐ 296
(18) Episodes of chest pain or heaviness in the chest?	297 (152) Yes ☐ 1 → No ☐ 2	(153) ☐ 298	(154) ☐ 299	(155) ☐ 300

Continued

Since your last visit, have you had:	(a)	New since last visit? (b) 1=Yes 2=No	Frequency: (c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	Severity: (d) 1=Not troublesome 2=Troublesome 3=Intolerable	
(19) Headaches so bad you had to stop what you were doing?	302 (157) Yes ☐ 1 → No ☐ 2	(158) ☐ 303	(159) ☐ 304	(160) ☐ 305	
(20) Stuffy nose?	306 (161) Yes ☐ 1 → No ☐ 2	(162) ☐ 307	(163) ☐ 308	(164) ☐ 309	
(21) Unusual shortness of breath or wheezing?	310 (165) Yes ☐ 1 → No ☐ 2	(166) ☐ 311	(167) ☐ 312	(168) ☐ 313	→ (e) Is there evidence for bronchospasm on auscultation of the chest? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 314 (169)
(22) Unusual tiredness or loss of pep?	315 (170) Yes ☐ 1 → No ☐ 2	(171) ☐ 316	(172) ☐ 317	(173) ☐ 318	→ (e) Is there evidence of CHF on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 (178) 323
(23) Swelling of the ankles?	319 (174) Yes ☐ 1 → No ☐ 2	(175) ☐ 320	(176) ☐ 321	(177) ☐ 322	
(24) Feeling so depressed (sad or blue) that it interfered with your work, recreation or sleep?	324 (179) Yes ☐ 1 → No ☐ 2	(180) ☐ 325	(181) ☐ 326	(182) ☐ 327	
(25) Any trouble with your memory or concentration?	328 (183) Yes ☐ 1 → No ☐ 2	(184) ☐ 329	(185) ☐ 330	(186) ☐ 331	
(26) Nightmares?	332 (187) Yes ☐ 1 → No ☐ 2	(188) ☐ 333	(189) ☐ 334	(190) ☐ 335	

Continued

Since your last visit, have you had: (a)	New since last visit? (b) 1=Yes 2=No	Frequency: (c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	Severity: (d) =Not troublesome 2=Troublesome 3=Intolerable	
(27) Any changes in your sexual activity? 336 (191) Yes ☐ 1 No ☐ 2 →	(192) ☐ 337	(193) ☐ 338	(194) ☐ 339 →	(e) Loss of interest? Yes ☐ 1 No ☐ 2 (195) (f) Decline in frequency? Yes ☐ 1 No ☐ 2 (196) (g) Loss of enjoyment? Yes ☐ 1 No ☐ 2 (197) (h) Functional impairment Yes ☐ 1 No ☐ 2 (198) 340-343
(28) Trouble going to sleep, or waking early and having trouble getting back to sleep? 344 (199) Yes ☐ 1 No ☐ 2 →	(200) ☐ 345	(201) ☐ 346	(202) ☐ 347	
(29) Waking up in the night more frequently to urinate? 348 (203) Yes ☐ 1 No ☐ 2 →	(204) ☐ 349	(205) ☐ 350	(206) ☐ 351	
(30) More worry or anxiety than usual? 352 (207) Yes ☐ 1 No ☐ 2 →	(208) ☐ 353	(209) ☐ 354	(210) ☐ 355	
(31) Weakness or numbness on one side, or unexpected difficulties talking or thinking? (211) Yes ☐ 1 No ☐ 2 356 →	(212) ☐ 357	(213) ☐ 358	(214) ☐ 359 →	(e) Is there evidence of a stroke on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 (215) 360
(32) Other relevant symptoms: Specify: _____ 362 (216) Yes ☐ 1 No ☐ 2 →	(217) ☐ 362	(218) ☐ 363	(219) ☐ 364 →	(e) Are there other relevant signs on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 (220) 365 Specify: _____

Continued

(33) Are there any positive responses in Section 7A or 7B?

☐ 1 Yes (221) 366 ☐ 2 No → GO TO SECTION 8 - ORIENTATION AND INFORMED CONSENT.

C. 1. In the clinician's judgment, should the participant be excluded from the SHEP due to any of these conditions? (222) 367 Yes ☐ 1 No ☐ 2

2. Comments: (223) 368 ✓ 0/1

Participants to be excluded should proceed to the scheduling area for termination of their participation in the SHEP. Only eligible participants should proceed with the remaining items in Baseline Visit 2.

8. ORIENTATION AND INFORMED CONSENT CHECKLIST: Do not proceed until all of these have been completed.

☐ Participant orientation completed.
☐ Consent form signed for randomization and participation in the trial.

9. RANDOMIZATION.

A. The following items of data should be available prior to calling the Coordinating Center:

(1) SHEP ID _____ and Acrostic _____

(2) Birthdate: _____

(3) On BP meds at Initial Contact? ☐ Yes ☐ No

(4) If on meds at SH01, BP at last DEV
If not on meds at SH01, BP at SH01 } SBP: _____ DBP: _____

(5) Baseline Visit 1 BP readings (average of two corrected readings): SBP:_____ DBP:_____

(6) Judged to be eligible by SHEP clinician at Baseline Visit 1 review, according to SHEP criteria (SH06, Item 9z)? ☐ Yes ☐ No

(7) Is a serum creatinine measurement available? ☐ Yes ☐ No

(8) If (7) = Yes, serum creatinine = _____ mg/dl

(9) Baseline Visit 2 BP (average of two corrected readings): SBP:_____ DBP:_____

(10) Baseline BP (average of BV1 and BV2): SBP:_____ DBP:_____

(11) Other exclusions (Items 6 and 7C1 this form)? ☐ Yes ☐ No

(12) Has the informed consent for randomization been signed? ☐ Yes ☐ No

(13) Your Clinical Center personnel code: _____

B. Use information in A(1)-A(13) to verify eligibility and baseline blood pressure, as queried by Coordinating Center personnel.

C. Verify Baseline SBP _____ DBP _____

D. Goal SBP: _____ mm Hg
(For participants with baseline SBP 160-179 mm Hg, goal SBP is a 21 mm Hg drop; participants with a baseline SBP of 180 mm Hg or more will have a goal SBP of 159.)

E. Result:

224 369 ☐ 1 Randomization complete: Step 1, Dose 1 drug bottle number ☐☐☐

☐ 2 Randomization incomplete: (describe)

_____

_____

F. Create participant SHEP identification card

G. Signature of person completing this section: _____ 225 370-371 Code

H. Signature of clinic physician: _____ 226 372-373 Code

10. BASELINE COMPLIANCE

"We would like to make sure that you understand how to take your medicine that we will give you."

1. What have you been told you should do when you miss taking your SHEP medicine? (Don't provide the specific categories: if only one response given, ask, "anything else?")

		Mentioned	Not Mentioned
a.	Wait and double up the next dose	374 227 ☐ 1	375 228 ☐ 2
b.	Do nothing and take usual dose next time	☐ 1	☐ 2
c.	Report missed dose(s) at next clinic visit	229 ☐ 1	☐ 2
d.	Call SHEP clinic	376 ☐ 1	377 230 ☐ 2
e.	Record missed dose(s)	☐ 1	☐ 2
f.	Take it later	378 231 ☐ 1	379 232 ☐ 2
g.	Nothing	380 233 ☐ 1	☐ 2
h.	Other (Specify _____)	☐ 1	381 234 ☐ 2

2. How many times per day should you take your pills that you were given today?

382 235
One time per day ☐ 1
Other (specify): ☐ 2

_____

3. How many pills should you take each time?

383 236
One ☐ 1
Two ☐ 2
Other (specify): ☐ 3

_____

4. When should you take these pills?

384 237
Morning when getting up ☐ 1
Other (specify): ☐ 2

_____

5. a. Will you need to do anything to help you to remember to take the SHEP medicine(s)? 238 385 Yes ☐ 1 No ☐ 2 Maybe ☐ 3

↓ Skip to Question 6

b. What will you do? _____

_____

6. a. Will there be anyone who helps you to remember to take your SHEP medicine(s)? 239 386 Yes ☐ 1 No ☐ 2 Maybe ☐ 3

↓ Skip to Question 7

b. Who is that person?

387 240
- ☐ 1 Friend
- ☐ 2 Relative
- ☐ 3 Neighbor
- ☐ 4 Other (Specify): _____

~~b~~ c. Does this person live with you? 388 241 Yes ☐ 1 No ☐ 2

7. People have different reasons for taking part in a study like this. We'd like to find out why you joined the SHEP and how important these reasons are to you.

		Not Important	Important	Very Important
a.	Improve my health	389 242 ☐ 1	☐ 2	☐ 3
b.	Free medical care	☐ 1 243 390	☐ 2	☐ 3
c.	Contribute to science	391 244 ☐ 1	☐ 2	☐ 3
d.	Improve health of others	☐ 1 245 392	☐ 2	☐ 3
e.	Some place to go	393 246 ☐ 1	☐ 2	☐ 3
f.	Someone to talk with	☐ 1 247 394	☐ 2	☐ 3
g.	Other Reasons (Please list)	☐ 1	☐ 2	☐ 3

_____ 248 395

_____

11. BLOOD SAMPLE

396 249
- 1 ☐ Fasting blood sample drawn
- 2 ☐ Non-fasting blood sample drawn
- 3 ☐ Blood sample refused

→ Date drawn: 250 397-402 ☐☐ Month ☐☐ Day ☐☐ Year

NOTE: Field 251 appeared on SH07 versions 2 and 3, only.

PARTICIPANT MAY NOW BE SENT FOR THE REMAINDER OF THE BEHAVIORAL EVALUATION.

411 252 RECORD TYPE

412-417 253 DATE RECEIVED

418-420 254 UPDATE NUMBER

421-426 255 DATE LAST PROCESSED

427 256 PAPER COPY

428 257 **Cross form edit**

3-8 514 BATCH DATE

11-16 515 DATE MODIFIED

17-20 516 TIME MODIFIED SH07/11

21 517 EDIT STATUS