

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 Section 2.4.5**). Form SH07 is described in detail in **Section 2.4.6** of the *MOO*.

BASELINE VISIT 2

33 (2) VERSION

Name:

(4)

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

3. Today's Date: 36 37 38 39 34 35 (7) (6)
Month Day Year

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:

- (1) 1 Participant is eligible and has been randomized.
(11) 2 Participant is eligible, but refuses to be randomized.
 3 Participant is not eligible due to:
(2) 1 Blood pressure
(12) 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):

(16) 1 Appointment made on (15) 65 66 67 68 63 64 at 69-72 (17) : Min. (18) 73
 2 Appointment not made; reason: _____

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

b. Blood pressure:

Cuff Size:

Pulse Obliteration Pressure:

77	}	(20)	1 <input type="checkbox"/> Regular	Observed Value:	<input type="text"/>
			2 <input type="checkbox"/> Large arm	Subtract Zero Level:	- <input type="text"/>
			3 <input type="checkbox"/> Thigh	Corrected Value:	<input type="text"/>
			4 <input type="checkbox"/> Pediatric	Add Maximum Zero Level Plus 10:	+ <input type="text"/>
			Peak Inflation Level:	<input type="text"/>	

Seated Readings:

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

Standing Readings:

<u>One minute</u>	
Pulse: Beats in 15 seconds _____	(39) x 4 = <input type="text" value="122-124"/> beats per minute.
Blood Pressure: <u>Systolic</u>	<u>Diastolic</u>
Reading	(38) <input type="text" value="125-127"/> (39) <input type="text" value="128-130"/>
Zero	(40) <input type="text" value="131-132"/> (41) <input type="text" value="133-134"/>
Corrected	(42) <input type="text" value="135-137"/> (43) <input type="text" value="138-140"/>
<u>Three minutes</u>	
Pulse: Beats in 15 seconds _____	(44) x 4 = <input type="text" value="141-143"/> beats per minute.
Blood Pressure: <u>Systolic</u>	<u>Diastolic</u>
Reading	(45) <input type="text" value="144-146"/> (46) <input type="text" value="147-149"/>
Zero	(47) <input type="text" value="150-151"/> (48) <input type="text" value="152-153"/>
Corrected	(49) <input type="text" value="154-156"/> (50) <input type="text" value="157-159"/>

c. Did the participant volunteer any symptoms on standing? 160 (51) Yes 1 No 2

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

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

162 (53)

SKIP to 5d.

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

	<u>Systolic</u>	<u>Diastolic</u>
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 \div 2	(61) 182-184	(62) 185-187

(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? 193 (67) 1 Yes 2 No
(Specify): _____

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? 195 (69) 1 Yes 2 No
(Specify): _____

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

Go to B

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	(72) 199-204	(74) 207-212	(76) 215-220
Date of admission	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
Number of days	(73) <input type="text"/> <input type="text"/>	(75) <input type="text"/> <input type="text"/>	(77) <input type="text"/> <input type="text"/>
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?	Frequency:	Severity:
		(b) 1=Yes 2=No	(c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	(d) 1=Not troublesome 2=Troublesome 3=Intolerable
(1) Unusual coldness or numbness of the hands or feet?	223 <input checked="" type="radio"/> 78 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 79 <input type="checkbox"/> 224	<input checked="" type="radio"/> 80 <input type="checkbox"/> 225	<input checked="" type="radio"/> 81 <input type="checkbox"/> 226
(2) Unusual skin rash or bruising?	227 <input checked="" type="radio"/> 82 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 83 <input type="checkbox"/> 228	<input checked="" type="radio"/> 84 <input type="checkbox"/> 229	<input checked="" type="radio"/> 85 <input type="checkbox"/> 230 → (e) Is an acute skin rash present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 <input checked="" type="radio"/> 86 No <input type="checkbox"/> 3 <input type="checkbox"/> 231
(3) Any feelings of unsteadiness or imbalance?	232 <input checked="" type="radio"/> 87 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 88 <input type="checkbox"/> 233	<input checked="" type="radio"/> 89 <input type="checkbox"/> 234	<input checked="" type="radio"/> 90 <input type="checkbox"/> 235 <input checked="" type="radio"/> 94 <input type="checkbox"/> 239 <input checked="" type="radio"/> 98 <input type="checkbox"/> 243 → (e) Is there an observable postural drop in blood pressure? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 <input checked="" type="radio"/> 99 244
(4) Faintness or light headedness when you stand up quickly?	236 <input checked="" type="radio"/> 91 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 92 <input type="checkbox"/> 237	<input checked="" type="radio"/> 93 <input type="checkbox"/> 238	
(5) Loss of consciousness or passing out	240 <input checked="" type="radio"/> 95 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 96 <input type="checkbox"/> 241	<input checked="" type="radio"/> 97 <input type="checkbox"/> 242	
(6) Falls?	245 <input checked="" type="radio"/> 100 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 101 <input type="checkbox"/> 246	<input checked="" type="radio"/> 102 <input type="checkbox"/> 247	<input checked="" type="radio"/> 103 <input type="checkbox"/> 248
(7) Fractures?	249 <input checked="" type="radio"/> 104 Yes <input type="checkbox"/> 1 → <input type="checkbox"/> 2	<input checked="" type="radio"/> 105 <input type="checkbox"/> 250	<input checked="" type="radio"/> 106 <input type="checkbox"/> 251	<input checked="" type="radio"/> 107 <input type="checkbox"/> 252 → (e) Hip? 253 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 <input checked="" type="radio"/> 108 (f) Spine? 254 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 <input checked="" type="radio"/> 109 (g) Forearm? 255 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 <input checked="" type="radio"/> 110

Continued

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

Continued

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

(e) Is there evidence for bronchospasm on auscultation of the chest? **314**
 Yes 1
 Possibly 2 168
 No 3

(e) Is there evidence of CHF on physical exam?
 Yes 1
 Possibly 2 178
 No 3 **323**

Continued

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

340-343

Continued

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

1 Yes 2 No →
366

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?

Yes 1 No 2
367

2. Comments:

2/23 P O/I
368

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 } SBP: _____
If not on meds at SH01, BP at SH01 } 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:

- 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) <input type="checkbox"/> 1	375 <input type="checkbox"/> 2
b. Do nothing and take usual dose next time	<input type="checkbox"/> 1 (228)	<input type="checkbox"/> 2
c. Report missed dose(s) at next clinic visit	(229) <input type="checkbox"/> 1	377 <input type="checkbox"/> 2
d. Call SHEP clinic	376 (230) <input type="checkbox"/> 1	<input type="checkbox"/> 2
e. Record missed dose(s)	378 (231) <input type="checkbox"/> 1	379 <input type="checkbox"/> 2
f. Take it later	<input type="checkbox"/> 1 (232)	<input type="checkbox"/> 2
g. Nothing	380 (233) <input type="checkbox"/> 1	<input type="checkbox"/> 2
h. Other (Specify _____)	<input type="checkbox"/> 1 (234)	381 <input type="checkbox"/> 2

2. How many times per day should you take your pills that you were given today? 382 1
Other (specify): 2 (235)

3. How many pills should you take each time? 383 1
Two 2
Other (specify): (236) 3

4. When should you take these pills? 384
Morning when getting up 1
Other (specify): (237) 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? Friend 1
 Relative **387** 2
 Neighbor **240** 3
 Other (Specify): 4

c. Does this person live with you? **388** 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 <input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
b. Free medical care	<input type="checkbox"/> 1 243 390	<input type="checkbox"/> 2	<input type="checkbox"/> 3
c. Contribute to science 391	244 <input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
d. Improve health of others	<input type="checkbox"/> 1 245 392	<input type="checkbox"/> 2	<input type="checkbox"/> 3
e. Some place to go 393	246 <input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
f. Someone to talk with	<input type="checkbox"/> 1 247 394	<input type="checkbox"/> 2	<input type="checkbox"/> 3
g. Other Reasons (Please list)	<input type="checkbox"/> 1 248 395	<input type="checkbox"/> 2	<input type="checkbox"/> 3

11. BLOOD SAMPLE

396 **249** { 1 Fasting blood sample drawn } Date drawn: **250** 397-402
 2 Non-fasting blood sample drawn } Month Day Year
 3 Blood sample refused

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 **251** Cross form edit
- 3-8 **514** BATCH DATE
- 11-16 **515** DATE MODIFIED
- 17-20 **516** TIME MODIFIED SH07/11
- 21 **517** EDIT STATUS