SH06: Baseline Visit 1 Form

Purpose

The *Baseline Visit 1 Form* (SH06) was completed at the first of two baseline evaluation visits attended by potential participants. Eligibility for the trial was based on study inclusion and exclusion criteria given in **Section 2.3** of the *SHEP MOO*. The SH02, SH03, and SH04 forms were reviewed at this visit to aid in determining eligibility. Form SH06 is described in detail in **Section 2.3.5** of the *MOO*.

30-32 (1) FORM NUMBER

33 (2) VERSION

(518) SEQUENCE 40

BASELINE VISIT 1

Name: (3) 22-23 (4) 24-27

1. SHEP ID: ☐☐ - ☐☐☐☐ - ☐☐ (5) 28-29 2. Acrostic: ☐☐☐☐☐☐ (6) 41-46

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

4. Copy from Initial Contact Form SH01, Participant Information Sheet SH02 and, if applicable, Drug Evaluation Visit Summary SH05:

a. Date of birth: ☐☐ Month (8) 47-49 ☐☐ Day ☐☐☐☐ Year (9) 51-54

b. Was participant on antihypertensive medications at Initial Contact?

55 (10) Yes ☐ 1 No ☐ 2 Don't know ☐ 3

c. Three blood pressure readings, from Initial Contact for those not on meds at Initial Contact, or from last Drug Evaluation Visit for those taken off of meds:

	Systolic	Diastolic	d. Date of blood pressures in 4c.
Reading 1:	(11) 56-58 ☐☐☐	☐☐☐ (12) 59-61	76 77 Month, 78 79 Day, 74 75 Year (17)
Reading 2:	(13) 62-64 ☐☐☐	☐☐☐ (14) 65-67	e. Social Security Number: (18) 80-88
Reading 3:	(15) 68-70 ☐☐☐	☐☐☐ (16) 71-73	☐☐☐ - ☐☐ - ☐☐☐☐

f. Medicare Number: ☐☐☐ - ☐☐ - ☐☐☐☐ - ☐☐ (20) 98-99

5. Collect, review and complete the following items: (19) 89-97

- ☐ Consent for Baseline Visit 1 (and Baseline Visit 2, if allowed)
- ☐ Participant Information Sheet, SH02
- ☐ Demographic Information and Medication History, SH03
- ☐ Baseline Medical History, SH04

COMPLETE SECTION BELOW AT TERMINATION OF VISIT BEFORE PARTICIPANT LEAVES.

- ☐ SHEP ID and Acrostic correct.
- ☐ All required items are complete and legible.

100 (21) a. Procedures completed: ☐ 1 None, participant not BP eligible.

		Yes	No	Reason
101 (22)	(1) ECG	☐ 1	☐ 2 →	
102 (23)	(2) Physical exam	☐ 1	☐ 2 →	
103 (24)	(3) Dipstick urinalysis	☐ 1	☐ 2 →	
104 (25)	(4) Blood sample drawn for local determination of serum creatinine:	☐ 1	☐ 2	

b. Result of this visit:

105 (26)
- ☐ 1 Participant is not eligible for Baseline Visit 2.
- ☐ 2 Participant is eligible but currently refuses Baseline Visit 2.
- ☐ 3 Participant is eligible and Baseline Visit 2 scheduled:

c. (27) ☐☐ Month ☐☐ Day ☐☐ Year at ☐☐ Hour : ☐☐ Minute (28) ☐ a.m. ☐ p.m. (29) 116

106-111 112-115

6. a. Pulse: Beats in 30 seconds _____ x 2 = [ ][ ][ ] (30) 117-119 beats per minute.

b. Blood pressure:

Cuff Size:

120 (31)
- 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	(32) 121-123 [ ][ ][ ]	(33) 124-126 [ ][ ][ ]
Zero level	(34) 127-128 [ ][ ]	(35) 129-130 [ ][ ]
+ Corrected	(36) 131-133 [ ][ ][ ]	(37) 134-136 [ ][ ][ ]
+ Second	(38) 137-139 [ ][ ][ ]	(39) 140-142 [ ][ ][ ]
+ Zero level	(40) 143-144 [ ][ ]	(41) 145-146 [ ][ ]
+ Corrected	(42) [ ][ ][ ]	(43) [ ][ ][ ]
	147-149	150-152
Sum of two corrected readings	(44) [ ][ ][ ]	(45) [ ][ ][ ]
	153-155	156-158
Average of two corrected readings	(46) [ ][ ][ ]	(47) [ ][ ][ ]
	159-161	162-164

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

x 4 = [ ][ ][ ] beats per minute. (48) 165-167

Blood Pressure:	Systolic	Diastolic
Reading	(49) 168-170 [ ][ ][ ]	(50) 171-173 [ ][ ][ ]
Zero	(51) 174-175 [ ][ ]	(52) 176-177 [ ][ ]
Corrected	(53) [ ][ ][ ]	(54) [ ][ ][ ]
	178-180	181-183

Three minutes

Pulse: Beats in 15 seconds _____

(55) x 4 = [ ][ ][ ] beats per minute. 184-186

Blood Pressure:	Systolic	Diastolic
Reading	(56) 187-189 [ ][ ][ ]	(57) 190-192 [ ][ ][ ]
Zero	(58) 193-194 [ ][ ]	(59) 195-196 [ ][ ]
Corrected	(60) [ ][ ][ ]	(61) [ ][ ][ ]
	197-199	200-202

c. Did the participant volunteer any symptoms on standing? (62) Yes ☐ 1 No ☐ 2 → SKIP to 6d. 203

(1) Dizziness? Yes ☐ 1 (63) 204 No ☐ 2

(2) Other (specify)? Yes ☐ 1 (64) 205 No ☐ 2

_____

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

206 (65) ☐ 1 SBP 150-219 and DBP <95 mm Hg → Eligible

☐ 2 Other → Not eligible

e. Observer: _____ (66) 207-208 ☐☐ Code

Ineligible persons 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 1.

PARTICIPANT SHOULD NOW BE SENT FOR ECG AND URINE SAMPLE.

7. CLINICIAN REVIEW OF MEDICATION HISTORY (To be completed by clinician using information from the Baseline Demographic Information and Medication History Form, SH03.)

Is the participant taking any of the drugs listed below? Drugs marked with an * may be involved in various exclusion criteria.

			Current (last 2 weeks)	Not Current or Not Sure
* a.	Any medication for blood pressure, or drugs with antihypertensive action	209 (67)	☐ 1	☐ 2
b.	Digitalis	210 (68)	☐ 1	☐ 2
c.	Nitrates including nitroglycerine	211 (69)	☐ 1	☐ 2
* d.	Propranolol or other beta blockers for other than treatment of blood pressure	(70) 212	☐ 1	☐ 2
e.	Anti-arrhythmic drugs	213 (71)	☐ 1	☐ 2
f.	Lipid-lowering drugs, including clofibrate, cholestryramine, colestipol, nicotinic acid, etc.	214 (72)	☐ 1	☐ 2
g.	Agents for gout, including probenecid, allopurinol or colchicine	215 (73)	☐ 1	☐ 2
* h.	Insulin	216 (74)	☐ 1	☐ 2
i.	Oral hypoglycemic agents	217 (75)	☐ 1	☐ 2
* j.	Anticoagulants	218 (76)	☐ 1	☐ 2
k.	Antibiotics or anti-infection agents	219 (77)	☐ 1	☐ 2
l.	Cortisone or other gluco corticoids	220 (78)	☐ 1	☐ 2
m.	Amphetamines or other stimulant	221 (79)	☐ 1	☐ 2
n.	Flurazepam or other sedative	222 (80)	☐ 1	☐ 2
o.	Anti-depressants	223 (81)	☐ 1	☐ 2
p.	Librium, valium or other antianxiety agents	(82) 224	☐ 1	☐ 2

7. CLINICIAN REVIEW OF MEDICATION HISTORY (continued):

		Current (last 2 weeks)	Not Current or Not Sure
q.	Other psychotropic agents	225 (83) ☐ 1	☐ 2
r.	Potassium supplementation other than dietary recommendations	226 (84) ☐ 1	☐ 2
s.	Estrogen	227 (85) ☐ 1	☐ 2
t.	Anturane® (Sulfinpyrazone) at least 4 weeks	228 (86) ☐ 1	☐ 2
u.	Persantine® (Dipyridamole) at least 4 weeks	☐ 1 (87) 229	☐ 2
v.	Aspirin at least 4 weeks	230 (88) ☐ 1	☐ 2
w.	Non-steroidal anti-inflammatory drugs	☐ 1 (89) 231	☐ 2

8. PHYSICAL EXAMINATION

The clinician should perform a general physical exam, paying particular attention to the specific items listed below, entering comments for each indicated abnormality.

a. Weight in pounds: ☐☐☐ (90) 232-234 b. Height in inches: ☐☐ (91) 235-236

Area Examined	Comments
c. SKIN 237 (92) Abnormal ☐ 1 Normal ☐ 2	
d. HEAD, EARS, NOSE, THROAT 238 (93) Abnormal ☐ 1 Normal ☐ 2	
e. EYES Fundi: (1) 239 (94) Abnormal ☐ 1 / Normal ☐ 2 / Not Visualized ☐ 3 Other (Specify)? (95) 240 (2) Yes ☐ 1 No ☐ 2	

8. PHYSICAL EXAMINATION (continued)

Area Examined	Comments
f. NECK Raised jugular venous pressure? 241 96 (1) Yes ☐ 1 No ☐ 2 Carotid bruits? 97 (2) Yes ☐ 1 No ☐ 2 242 (3) 243 98 Right only ☐ 1; Left only ☐ 2; Bilateral ☐ 3 Carotid pulses absent or markedly diminished? 244 99 (4) Yes ☐ 1 No ☐ 2 245 100 (5) Right only ☐ 1; Left only ☐ 2; Bilateral ☐ 3 Thyroid abnormality? 246 101 (6) Yes ☐ 1 No ☐ 2 Other (Specify)? 102 (7) Yes ☐ 1 No ☐ 2 247	
g. LYMPH NODES 103 Abnormal ☐ 1 Normal ☐ 2 248	
h. CHEST, LUNGS Bilateral rales that do not clear with coughing? 249 104 (1) Yes ☐ 1 No ☐ 2 Respiratory rate 20+? 250 105 (2) Yes ☐ 1 No ☐ 2 Wheezing? 251 106 (3) Yes ☐ 1 No ☐ 2 Other (Specify)? 107 (4) Yes ☐ 1 No ☐ 2 252	

8. PHYSICAL EXAMINATION (continued)

Area Examined				Comments
i. HEART				
PMI more than 2 centimeters lateral to midclavicular line?	(1)	Yes ☐ 1	No ☐ 2 108 253	
Any murmur?	(2)	Yes ☐ 1	No ☐ 2 109 254	
Third heart sound?	(3)	Yes ☐ 1	No ☐ 2 110 255	
Fourth heart sound?	(4)	Yes ☐ 1	No ☐ 2 111 256	
Pulse irregular?	(5)	Yes ☐ 1	No ☐ 2 112 257	
Other (Specify)?	(6)	Yes ☐ 1	No ☐ 2 113 258	
j. BREASTS 259 114		Abnormal ☐ 1	Normal ☐ 2	
k. ABDOMEN				
Liver span 10 cm or more? 115 260	(1)	Yes ☐ 1	No ☐ 2	
Abnormal abdominal pulse? 261 116	(2)	Yes ☐ 1	No ☐ 2	
Any masses? 262 117	(3)	Yes ☐ 1	No ☐ 2	
Bruit?	(4)	Yes ☐ 1	No ☐ 2 118 263	
Other (Specify)? 119 264	(5)	Yes ☐ 1	No ☐ 2	
l. EXTREMITIES				
Pitting ankle edema?	(1)	Yes ☐ 1	No ☐ 2 120 265	
Femoral bruit? 121	(2)	Yes ☐ 1	No ☐ 2	
Any peripheral pulses absent or markedly diminished (specify location)? 267 122 266	(3)	Yes ☐ 1	No ☐ 2	
Other (Specify)?	(4)	Yes ☐ 1	No ☐ 2 123 268	

8. PHYSICAL EXAMINATION (continued)

Area Examined	Comments
m. NEUROLOGICAL (UA = unable to assess)	
Gait	
Left hemiparetic? (1) Yes ☐ 1 No ☐ 2 UA ☐ 3 124 269	
Right hemiparetic? (2) Yes ☐ 1 No ☐ 2 UA ☐ 3 125 270	
Walking on toes	
Left weakness? (3) Yes ☐ 1 No ☐ 2 UA ☐ 3 126 271	
Right weakness? (4) Yes ☐ 1 No ☐ 2 UA ☐ 3 127 272	
Walking on heels	
Left weakness? 128 273 (5) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Right weakness? 129 (6) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Stationary 30 seconds 274	
Eyes closed? 130 (7) Can do ☐ 1 Cannot do ☐ 2 UA ☐ 3	
Eyes open (only if unable to do with eyes closed) 275 131 (8) Can do ☐ 1 Cannot do ☐ 2 UA ☐ 3	
Cranial nerves 276	
Facial weakness left? 277 132 (9) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Facial weakness right? 278 133 (10) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Visual field deficit	
Left side? 279 134 (11) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Right side? (12) Yes ☐ 1 No ☐ 2 UA ☐ 3 135 280	
Motor wrist extensors 280	
Weakness left? 136 (13) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Weakness right? (14) Yes ☐ 1 No ☐ 2 UA ☐ 3	
Coordination 137 282 283	
Left hand patting? (15) Slowed ☐ 1 Normal ☐ 2 UA ☐ 3 138	
Right hand patting? (16) Slowed ☐ 1 Normal ☐ 2 UA ☐ 3 139	
Reflexes 284	
Assymetry of Patellar tendon 140 285 (17) L>R ☐ 1 Equal ☐ 3 R>L ☐ 2 UA ☐ 4	
Babinski sign left? (18) Yes ☐ 1 No ☐ 2 UA ☐ 3 141 286	
Babinski sign right? (19) Yes ☐ 1 No ☐ 2 UA ☐ 3 142 287	
Other	
Any speech or language problems (specify)? (20) Yes ☐ 1 No ☐ 2 143 288	

8. PHYSICAL EXAMINATION (continued)

n. OTHER PHYSICAL FINDINGS (SPECIFY):

144 289 7 1/0

o. Clinician's signature: _____ 145 290-291 [ ][ ] Code

9. CLINICIAN'S JUDGMENT AND EXCLUSION CRITERIA REVIEW

To be completed by the clinician using information from the participant's history and from the physical examination. These are clinical data for study eligibility determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study eligibility questions are identified with ✱. These questions must all be covered prior to scheduling the participant to return for Baseline Visit 2. Pertinent items on the Baseline Medical History (SH04) are listed with the section headings.

Hypertension - SH04 Items 2, 55

a. On the basis of your history and physical exam, do you believe that the participant has ever had malignant hypertension? 292 146 Yes ☐ 1 No ☐ 2 ✱

Angina Pectoris - SH04 Items 4, 42

b. On the basis of your history and physical exam, do you believe that the participant has angina pectoris? 293 147 Yes ☐ 1 No ☐ 2

Note: The Rose Questionnaire for angina (from SH04) is positive if:

Either 42a or 42b is "Yes,"
and either 42c or 42d is "Yes,"
and 42e is "Stop or slow down,"
and 42f is "Yes,"
and 42g is "10 minutes or less,"
and either 42h(1) is "Yes," (X placed in Sternum upper, middle or lower) or both 42h(2) and 42h(3) are "Yes"
(X in both left anterior chest and in left arm).

9. CLINICIAN'S JUDGMENT (continued)

Myocardial Infarction (MI) - SH04 Items 3, 43, 44, 54

c. On the basis of the ECG and your history and physical examination, do you believe the participant has ever had a myocardial infarction? 294 148 Yes ☐ 1 No ☐ 2 ↓ SKIP to e.

d. Was it in the past 6 months? 295 149 Yes ☐ 1 No ☐ 2

e. Is there a history of coronary bypass? 150 Yes ☐ 1 No ☐ 2 ↓ 296 SKIP to g.

f. Was it in the past six months? 297 151 Yes ☐ 1 No ☐ 2

Congestive Heart Failure - SH04 Item 47

g. On the basis of your history and physical examination, do you believe that the participant has had congestive heart failure during the past year? 298 152
☐ 1 Yes, controlled
☐ 2 Yes, not controlled
☐ 3 No

ECG

h. Are any of the following present? 153 299
(1) Atrial fibrillation or flutter? Yes ☐ 1 No ☐ 2
(2) Second or third degree A-V block? 154 Yes ☐ 1 No ☐ 2
(3) VPBs--multifocal, pairs or runs, or more than 10% of beats? 300 Yes ☐ 1 No ☐ 2 155 301
(4) Bradycardia (<50 beats/min.)? 302 156 Yes ☐ 1 No ☐ 2

i. Does the participant currently have a pacemaker? 303 157 Yes ☐ 1 No ☐ 2

Vascular System - SH04 Items 45, 48, 54

j. Is there a history of vascular surgery? 158 Yes ☐ 1 No ☐ 2 ↓ 304 SKIP to k.

(1) Aortic, iliac, popliteal or femoral bypass or graft? 159 305 Yes ☐ 1 No ☐ 2
(2) Other (Specify) _____ 306 160 Yes ☐ 1 No ☐ 2

k. On the basis of your history and physical examination, does the participant have arterial disease with tissue necrosis or related loss of an extremity? 161 307 Yes ☐ 1 No ☐ 2

9. CLINICIAN'S JUDGMENT (continued)

Pulmonary - SH04 Items 18, 46, 47

l. On the basis of the history and physical examination, does the participant have:

(1) Chronic bronchitis? 308 (162) Yes ☐ 1 No ☐ 2

(2) Emphysema? 309 (163) Yes ☐ 1 No ☐ 2

Stroke/TIA - SH04 Items 8, 48-55

m. On the basis of your history and physical examination, and keeping the SHEP criteria in mind, do you believe the participant has ever had a stroke? 310 (164) Yes ☐ 1 No ☐ 2 → SKIP to n.

(1) When was the most recent episode of probable stroke (not TIA)? 311-314 (165) ☐☐ Month ☐☐ Year

(2) Are any residual effects still present? 315 (166) Yes ☐ 1 No ☐ 2

n. On the basis of your history and physical examination, do you believe that the participant has had transient cerebral ischemic attacks within the past 12 months? 316 (167)

- ☐ 1 Yes, based on history and presence of carotid bruit
- ☐ 2 Yes, based on history of two or more TIA in same location
- ☐ 3 Yes, based on other combinations of evidence
- ☐ 4 No

o. Is there a history of carotid endarterectomy? 317 (168) Yes ☐ 1 No ☐ 2

Contraindications to Study Drugs

p. On the basis of your history and physical examination, does this participant have any contraindication to chlorthalidone? (169) Yes ☐ 1 No ☐ 2 318

q. On the basis of your history and physical examination, does this participant have any contraindication to atenolol? (170) Yes ☐ 1 No ☐ 2 319

r. On the basis of your history and physical examination, does this participant have any contraindication to reserpine? 320 (171) Yes ☐ 1 No ☐ 2

s. Are both Question q and Question r answered "Yes?" 321 (172) Yes ☐ 1 No ☐ 2

9. CLINICIAN'S JUDGMENT (continued)

Other Exclusion Criteria

t. Alcohol--on the basis of your history and physical examination, do you believe the participant currently drinks 6 or more drinks/day, or that alcoholism or alcoholic liver disease have been present in the past? 322 (173) Yes ☐ 1 No ☐ 2

u. Dementia--on the basis of your history and physical examination, do you believe the participant definitely has any form of dementia? 323 (174) Yes ☐ 1 No ☐ 2

v. Allergy--on the basis of your history and physical examination, do you believe the participant is allergic to one of the SHEP medications? 324 (175) Yes ☐ 1 No ☐ 2

w. On the basis of your history and physical examination is there any life-threatening disease, or other reason which might seriously impair the individual's participation in the SHEP over the next five years? 325 (176) Yes ☐ 1 No ☐ 2

If "yes," specify what conditions or diseases are present: _____

Falls and Fractures

x. Do you believe that the participant has ever had a fracture of:

(1) Hip? 326 (177) Yes ☐ 1 No ☐ 2

(2) Spine? 327 (178) Yes ☐ 1 No ☐ 2

(3) Forearm? 328 (179) Yes ☐ 1 No ☐ 2

y. Do you believe that the participant has had a problem with frequent falls? 329 (180) Yes ☐ 1 No ☐ 2

9. CLINICIAN'S JUDGMENT (continued)

Result

Items marked with ⊛ are exclusions if answer is "Yes," or, in the case of CHF (Question 9g), answered "Yes, not controlled," or, in the case of TIA (Question 9n), answered "Yes, based on history and presence of carotid bruit" or "Yes, based on history of two or more TIAs in same location."

z. Based on the information contained in this review:

181 ☐ 1 The participant remains eligible for the SHEP.
☐ 2 The participant is not eligible for the SHEP.

330

331-332

182 aa. Clinician's Signature: _____ ☐☐ Code

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process. Only eligible persons should proceed with serum sample, if required. Baseline Visit 2 may then be scheduled.

10. Does the participant have a history of kidney disease, or protein (at least trace) or blood (at least non-hemolyzed trace) in urine?

Yes ☐ 1 ↓ 183 No ☐ 2

333

A blood sample may be drawn at local option for local determination of serum creatinine. Document blood draw on front of this form.

334 184 RECORD TYPE

185 DATE RECEIVED 335-340

186 UPDATE NUMBER 341-343

187 DATE LAST PROCESSED 344-349

188 PAPER COPY 350

189 CROSS FORM EDIT

351

514 BATCH DATE 3-8

515 DATE MODIFIED 11-16

516 TIME MODIFIED 17-20

517 EDIT STATUS 21

Keypuncher code 1-2
Verifyer code 9-10

1 FORM NUMBER 30-32

518 SEQUENCE 40

BASELINE VISIT 1

2 VERSION NUMBER 33

Name: 3 4

1. SHEP ID: 22-23 - 24-27 - 28-29 5 2. Acrostic: 6 41-46

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

PRIOR TO INITIATING PROCEDURES FOR THIS VISIT, COLLECT, REVIEW AND COMPLETE THE FOLLOWING ITEMS.

- ☐ Consent for Baseline Visit 1 (and Baseline Visit 2, if allowed)
- ☐ SH02, Participant Information Sheet
- ☐ SH03, Demographic Information and Medication History
- ☐ Item 5 (page 2 of this form), Summary of Initial Contact and Drug Evaluation Visits

COMPLETE SECTION BELOW AT TERMINATION OF VISIT BEFORE PARTICIPANT LEAVES. CHECK TO BE SURE THAT THE ACROSTIC (ITEM 2) IS CORRECT. BE SURE THAT EVERY ITEM ON EACH PAGE IS COMPLETE (IF REQUIRED) AND LEGIBLE. CHECK YELLOW COPY FOR LEGIBILITY, ALSO. ANY ITEMS OR PROCEDURES REQUIRED BUT NOT COMPLETED SHOULD BE EXPLAINED IN COMMENTS, ITEM 4d.

4. a. Procedures completed: ☐ 1 None, participant not BP eligible (skip to 4b). 21 100

		Yes	No		
352 190	(1)	☐ 1	☐ 2	101	Baseline Medical History (SH04)
	(2)	☐ 1	☐ 2	22	ECG and two-minute rhythm strip
103 24	(3)	☐ 1	☐ 2		Dipstick urinalysis (SH11)
	(4)	☐ 1	☐ 2	23	Physical examination
104 25	(5)	☐ 1	☐ 2	102	Local determination of serum creatinine (SH11) --not required

b Result of this visit--please check entire form carefully for eligibility:

105 26
- ☐ 1 Participant is not eligible for Baseline Visit 2 (skip to 4d).
- ☐ 2 Participant is eligible but currently refuses Baseline Visit 2 (skip to 4d)
- ☐ 3 Participant is eligible and Baseline Visit 2 scheduled.
- ☐ 4 Participant was eligible and scheduled for BV2 but became ineligible or died or refused prior to BV2 (explain in Comments, Item 4d).

c. Baseline Visit 2 scheduled:

106-111 27 Month ___ Day ___ Year ___ at 28 Hour ___ : Minute ___ a.m. ☐ 1 p.m. ☐ 2 29 116

112-115

d. Comments: _____

e. Signature of person completing this section: _____ 191 353-354 Code

SUMMARY OF INITIAL CONTACT AND DRUG EVALUATION VISITS--
Copy from Initial Contact Form SH01, Participant Information Sheet SH02 and, if applicable, Drug Evaluation Visit Summary SH05:

5. a. Date of birth: 8 47-50 [ ] Month [ ] Day [ ] Year 9 51-54

b. Social Security Number (leave blank if no number):

80-88 18 [ ] - [ ] - [ ]

c. Medicare Number (leave blank if no number):

19 89-91 - 92-93 - 94-97 - 98-99 20

d. Initial Contact Visit date: 192 [ ] - [ ] - [ ]
355-360 Month Day Year

e. Initial Contact Visit blood pressure readings:

	Systolic		Diastolic
Reading 1:	193 361-363	194	364-366
Reading 2:	195 367-369	196	370-372
Reading 3:	197 373-375	198	376-378

f. Using most up-to-date information available, was participant on antihypertensive medications at the Initial Contact Visit?

55 10 Yes ☐ 1 No ☐ 2 → (Skip to Item 6.)

g. Date antihypertensive medications completely withdrawn:

379-384 199 [ ] - [ ] - [ ]
Month Day Year

h. Blood pressure readings on day medications completely withdrawn:

	Systolic		Diastolic
Reading 1:	200 385-387	201	388-390
Reading 2:	202 391-393	203	394-396
Reading 3:	204 397-399	205	400-402

i. Date of most recent Drug Evaluation Visit:

403-408 206 [ ] - [ ] - [ ]
Month Day Year

j. Blood pressure readings at most recent Drug Evaluation Visit:

	Systolic		Diastolic
Reading 1:	207 409-411	208	412-414
Reading 2:	209 415-419	210	418-420
Reading 3:	211 421-423	212	424-426

PULSE AND BLOOD PRESSURE--If any pulse or blood pressure is not obtained, enter all 9s in the appropriate spaces.

6. a. Pulse: Beats in 30 seconds _____ (30) × 2 = 117-119 beats per minute.

b. Cuff Size:

120 (31)
1 ☐ Regular
2 ☐ Large arm
3 ☐ Thigh
4 ☐ Pediatric

Pulse Obliteration Pressure:

Observed Value: (213) 427-429

Subtract Zero Level: 430-431 (214) - ____

Corrected Value: (215) 432-434

Add Maximum Zero Level Plus 20: (216) ____

435-436

Peak Inflation Level: (217) 437-439

Seated Readings:

	Systolic	Diastolic
First	(32) 121-123	(33) 124-126
Zero level	(34) 127-128	(35) 129-130
Corrected	(36) 131-133	(37) 134-136
Second	(38) 137-139	(39) 140-142
Zero level	(40) 143-144	(41) 145-146
Corrected	(42) 147-149	(43) 150-152
Sum of two corrected readings	(44) 153-155	(45) 156-158
Average of two corrected readings	(46) 159-161	(47) 162-164

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

(48) × 4 = 165-167 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(49) 168-170	(50) 171-173
Zero	(51) 174-175	(52) 176-177
Corrected	(53) 178-180	(54) 181-183

Three minutes

Pulse: Beats in 15 seconds _____

(55) × 4 = 184-186 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(56) 187-189	(57) 190-192
Zero	(58) 193-194	(59) 195-196
Corrected	(60) 197-199	(61) 200-202

(If standing blood pressure not done, skip to 6d.)

c. Did the participant volunteer any symptoms on standing? 203 (62) Yes ☐ 1 No ☐ 2 → SKIP to 6d.

(1) Dizziness? 204 (63) Yes ☐ 1 No ☐ 2

(2) Other (specify)? Yes ☐ 1 No ☐ 2 (64) 205

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

206 (65)
- ☐ 1 SBP 150-219 and DBP <95 mm Hg → Eligible
- ☐ 2 SBP < 150 or SBP ≧ 220 or DBP ≧ 95 mm Hg → Not blood pressure eligible

e. Observer: _____ 207-208 (66) ☐ Code

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process.

Only blood pressure eligible participants should proceed with the remaining items in Baseline Visit 1. If the Baseline Medical History (SH04) has not been completed, it must be completed at this time.

PARTICIPANT SHOULD NOW BE SENT FOR ECG, TWO-MINUTE RHYTHM STRIP AND DIPSTICK URINALYSIS.

7. a. Does the participant have a history of kidney disease, or protein (at least trace) or blood (at least non-hemolyzed trace) in urine?

333 (183) Yes ☐ 1 No ☐ 2

A blood sample may be drawn at local option for local determination of serum creatinine. Document result on Local Laboratory Results, SH11, with dipstick urinalysis results. If a blood sample is drawn, hold this form and final determination of eligibility until local creatinine result is obtained.

b. Was a blood sample drawn for local determination of serum creatinine?

440 (218) Yes ☐ 1 No ☐ 2 → SKIP to 8.

c. Local creatinine result:

441 (219)
- 1 ☐ Creatinine >2.0 mg/dl → Ineligible
- 2 ☐ Creatinine ≦ 2.0 mg/dl → Eligible

CLINICIAN REVIEW OF MEDICATION HISTORY--To be completed by clinician using information from the Baseline Demographic Information and Medication History Form, SH03. Do not count drugs that the participant discontinued in order to participate in the SHEP.

8. Is the participant taking any of the drugs listed below? Drugs marked with an * are exclusions if checked "Current."

	Current (last 2 weeks)	Not Current or Not Sure
* a. Any medication for blood pressure, or any drugs with antihypertensive action (including Neptazene and Diamox)	209 (67) ☐ 1	210 (68) ☐ 2
b. Digitalis	☐ 1	☐ 2
c. Nitrates, including nitroglycerine, or other coronary vasodilator	211 (69) ☐ 1	☐ 2

(Continued on next page)

CLINICIAN REVIEW OF MEDICATION HISTORY (Continued)

		Current (last 2 weeks)	Not Current or Not Sure
* d.	Propranolol or other beta blockers for other than treatment of blood pressure (excluding Timoptic eye drops) 212 70	□ 1 220 442	□ 2
e.	Timoptic eye drops 213 71	□ 1	□ 2
f.	Anti-arrhythmic drugs	□ 1	□ 2
g.	Lipid-lowering drugs, including clofibrate, cholestyramine, colestipol, nicotinic acid, etc. 214 72	□ 1	□ 2
h.	Agents for gout, including probenecid, allopurinol or colchicine 216 73	□ 1 215	□ 2
* i.	Insulin 74	□ 1	□ 2
j.	Oral hypoglycemic agents	□ 1 217	□ 2
* k.	Anticoagulants 218 76	□ 1	□ 2
l.	Antibiotics or anti-infection agents	□ 1 77 219	□ 2
m.	Cortisone or other gluco corticoids 220 78	□ 1	□ 2
n.	Amphetamines or other stimulant	□ 1 79 221	□ 2
o.	Flurazepam or other sedative 222 80	□ 1	□ 2
p.	Anti-depressants	□ 1 81 223	□ 2
q.	Librium, valium or other antianxiety agents	□ 1	□ 2
r.	Other psychotropic agents 224 82	□ 1 83 225	□ 2
s.	Potassium supplementation other than dietary recommendations 226 84	□ 1	□ 2
t.	Estrogen	□ 1 85 227	□ 2
u.	Anturane® (Sulfinpyrazone) at least 4 weeks	□ 1	□ 2 86 228
v.	Persantine® (Dipyridamole) at least 4 weeks 87	□ 1	□ 2
w.	Aspirin at least 4 weeks 229	□ 1	□ 2 89 231
x.	Non-steroidal anti-inflammatory drugs 88	□ 1	□ 2
* y.	Any experimental drug 230	□ 1 221 443	□ 2

If any of 8a, 8d, 8i, 8k, or 8y are marked "Current," the participant is not eligible for participation in the SHEP. Ineligible persons should proceed to the scheduling area for termination of their participation in the SHEP screening process. Only eligible participants should proceed with the physical examination.

PHYSICAL EXAMINATION--The clinician should perform a general physical examination, paying particular attention to the specific items listed below, entering comments for each indicated abnormality.

9. a. Weight in pounds: 232-234 90 b. Height in inches: 91 235-236

	Area Examined		Comments
10.	SKIN 237 92	Abnormal □ 1 Normal □ 2	
11.	HEAD, EARS, NOSE, THROAT 238 93	Abnormal □ 1 Normal □ 2	
12.	EYES Fundi: a. Abnormal □ 1 / Normal □ 2 / Not Visualized □ 3 94 239 Other (Specify)? 240 95 b. Yes □ 1 No □ 2		

(Physical examination continued on the next page)

Area Examined				Comments
13. NECK				
Raised jugular venous pressure? 241 96	a.	Yes ☐ 1	No ☐ 2	
Carotid bruits?	b.	Yes ☐ 1	No ☐ 2 97	242
243 98	c.	Right only ☐ 1 Left only ☐ 2 Bilateral ☐ 3		
Carotid pulses absent or markedly diminished?	d.	Yes ☐ 1	No ☐ 2 99	244
245 100	e.	Right only ☐ 1 Left only ☐ 2 Bilateral ☐ 3		
Thyroid abnormality?	f.	Yes ☐ 1	No ☐ 2 101	246
Other (Specify)?	g.	Yes ☐ 1	No ☐ 2 102	247
14. LYMPH NODES		Abnormal ☐ 1	Normal ☐ 2 103	248
15. CHEST, LUNGS				
Bilateral rales that do not clear with coughing?	a.	Yes ☐ 1	No ☐ 2 104	249
Respiratory rate 20+? 105	b.	Yes ☐ 1	No ☐ 2	
Wheezing? 250	c.	Yes ☐ 1	No ☐ 2 106	251
Other (Specify)? 252 107	d.	Yes ☐ 1	No ☐ 2	
16. HEART				
PMI more than 2 centimeters lateral to midclavicular line? 253 108	a.	Yes ☐ 1	No ☐ 2	
Any murmur?	b.	Yes ☐ 1	No ☐ 2 109	254
Third heart sound? 255 110	c.	Yes ☐ 1	No ☐ 2	
Fourth heart sound?	d.	Yes ☐ 1	No ☐ 2 111	256
Pulse irregular? 257 112	e.	Yes ☐ 1	No ☐ 2	
Other (Specify)?	f.	Yes ☐ 1	No ☐ 2 113	258
17. BREASTS 259 114		Abnormal ☐ 1	Normal ☐ 2	
18. ABDOMEN				
Liver span 10 cm or more? 260 115	a.	Yes ☐ 1	No ☐ 2	
Abnormal abdominal pulse? 261 116	b.	Yes ☐ 1	No ☐ 2	
Any masses?	c.	Yes ☐ 1	No ☐ 2 117	262
Bruit? 263 118	d.	Yes ☐ 1	No ☐ 2	
Other (Specify)?	e.	Yes ☐ 1	No ☐ 2 119	264

Area Examined					Comments
19. EXTREMITIES					
Pitting ankle edema? 265 (120)	a.	Yes ☐ 1	No ☐ 2		
Femoral bruit?	b.	Yes ☐ 1	No ☐ 2	(121) 266	
Any peripheral pulses absent or markedly dimished? (specify location) 267 (122)	c.	Yes ☐ 1	No ☐ 2		
Other (Specify)? 268 (123)	d.	Yes ☐ 1	No ☐ 2		
20. NEUROLOGICAL (UA = unable to assess)					
Gait					
Left hemiparetic? 269 (124)	a.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Right hemiparetic?	b.	Yes ☐ 1	No ☐ 2	UA ☐ 3	(125) 270
Walking on toes					
Left weakness? 271 (126)	c.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Right weakness?	d.	Yes ☐ 1	No ☐ 2	UA ☐ 3	(127) 272
Walking on heels					
Left weakness? 273 (128)	e.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Right weakness?	f.	Yes ☐ 1	No ☐ 2	UA ☐ 3	(129) 274
Stationary 30 seconds					
Eyes closed? (130)	g.	Can do ☐ 1	Cannot do ☐ 2	UA ☐ 3	
Eyes open (only if unable to do with eyes closed) 275	h.	Can do ☐ 1	Cannot do ☐ 2	UA ☐ 3	(131) 276
Cranial nerves					
Facial weakness left? 277 (132)	i.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Facial weakness right? 278 (133)	j.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Visual field deficit					
Left side? 279 (134)	k.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Right side?	l.	Yes ☐ 1	No ☐ 2	UA ☐ 3	(135) 280
Motor wrist extensors					
Weakness left? 281 (136)	m.	Yes ☐ 1	No ☐ 2	UA ☐ 3	
Weakness right?	n.	Yes ☐ 1	No ☐ 2	UA ☐ 3	(137) 282
Coordination					
Left hand patting?	o.	Slowed ☐ 1	Normal ☐ 2	UA ☐ 3	(138) 283
Right hand patting?	p.	Slowed ☐ 1	Normal ☐ 2	UA ☐ 3	(139) 284

PHYSICAL EXAMINATION (Continued)

Area Examined	Comments
Neurological (Continued) (UA = unable to assess)	
Reflexes 285 (140)	
Assymetry of Patellar tendon 286 (141) q. L>R ☐ 1 Equal ☐ 3 R>L ☐ 2 UA ☐ 4	
Babinski sign left? r. Yes ☐ 1 No ☐ 2 UA ☐ 3	
Babinski sign right? s. Yes ☐ 1 No ☐ 2 UA ☐ 3	
Other 287 (142)	
Any speech or language problems (specify)? t. Yes ☐ 1 No ☐ 2 (143) 288	

21. OTHER PHYSICAL FINDINGS (SPECIFY):

22. Clinician's signature: _____ (145) 290-291 Code

CLINICIAN'S JUDGMENT AND EXCLUSION CRITERIA REVIEW--To be completed by the clinician using information from the participant's history and from the physical examination. These are clinical data for study eligibility determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study eligibility questions are identified with ⊛. These questions must all be covered prior to scheduling the participant to return for Baseline Visit 2. Pertinent items on the Baseline Medical History (SH04) are listed with the section headings.

Hypertension - SH04 Items 2, 55

23. On the basis of your history and physical exam, do you believe that the participant has ever had malignant hypertension? 292 (146) Yes ☐ 1 No ☐ 2 ⊛

Angina Pectoris - SH04 Items 4, 42

24. On the basis of your history and physical exam, do you believe that the participant has angina pectoris? 293 (147) Yes ☐ 1 No ☐ 2

Note: The Rose Questionnaire for angina (from SH04) is positive if:

Either 42a or 42b is "Yes,"
and either 42c or 42d is "Yes,"
and 42e is "Stop or slow down,"
and 42f is "Yes,"
and 42g is "10 minutes or less,"
and either 42h(1) is "Yes," (X placed in sternum upper, middle or lower) or both 42h(2) and 42h(3) are "Yes"
(X in both left anterior chest and in left arm).

CLINICIAN'S JUDGMENT (Continued)

Myocardial Infarction (MI) - SH04 Items 3, 43, 44, 54

25. a. On the basis of the ECG and your history and physical examination, do you believe the participant has ever had a myocardial infarction? 294 148 Yes ☐ 1 No ☐ 2 ↓ SKIP to 26.

b. Was it in the past 6 months? 295 149 Yes ☐ 1 No ☐ 2

26. a. Is there a history of coronary bypass? 296 150 Yes ☐ 1 No ☐ 2 ↓ SKIP to 27.

b. Was it in the past six months? 297 151 Yes ☐ 1 No ☐ 2

Congestive Heart Failure - SH04 Item 47

27. On the basis of your history and physical examination, do you believe that the participant has had congestive heart failure during the past year? 298 152
☐ 1 Yes, controlled
☐ 2 Yes, not controlled
☐ 3 No

ECG

28. Are any of the following present? 299 153

a. Atrial fibrillation or flutter? Yes ☐ 1 No ☐ 2 154 300
b. Second or third degree A-V block? Yes ☐ 1 No ☐ 2
c. VPBs--multifocal, pairs or runs, or more than 10% of beats? 301 155 Yes ☐ 1 No ☐ 2 156 302
d. Bradycardia (<50 beats/min.)? Yes ☐ 1 No ☐ 2

29. Does the participant currently have a pacemaker? Yes ☐ 1 No ☐ 2 157 303

Vascular System - SH04 Items 45, 48, 54

30. a. Is there a history of vascular surgery? 304 158 Yes ☐ 1 No ☐ 2 ↓ SKIP to 31.

b. Aortic, iliac, popliteal or femoral bypass or graft? 305 159 Yes ☐ 1 No ☐ 2

c. Angioplasty? Yes ☐ 1 No ☐ 2 222 444
Which vessel(s)? _____ 306

d. Other (Specify) _____ 160 Yes ☐ 1 No ☐ 2

CLINICIAN'S JUDGMENT (Continued)

31. On the basis of your history and physical examination, does the participant have arterial disease with tissue necrosis or related loss of an extremity? 307 161 Yes ☐ 1 No ☐ 2

Note: The Rose Questionnaire for intermittent claudication (from SH04) is positive if:

Item 45a is "Yes"
and 45b is "No"
and 45c is "Yes"
and 45d or 45e is "Yes"
and 45f is "No"
and 45g is "Stop or slow down"
and 45h is "Yes"
and 45i is "10 minutes or less."

Pulmonary - SH04 Items 18, 46, 47

32. On the basis of the history and physical examination, does the participant have: 308 162

a. Chronic bronchitis? Yes ☐ 1 No ☐ 2
b. Emphysema? Yes ☐ 1 No ☐ 2 163 309

Stroke/TIA - SH04 Items 8, 48-55

33. a. On the basis of your history and physical examination, and keeping the SHEP criteria in mind, do you believe the participant has ever had a stroke? 310 164 Yes ☐ 1 No ☐ 2

↓

SKIP to 34.

b. When was the most recent episode of probable stroke (not TIA)? 311-314 165 ☐ Month ☐ Year

c. Are any residual effects still present? 166 Yes ☐ 1 No ☐ 2

34. On the basis of your history and physical examination, do you believe that the participant has had transient cerebral ischemic attacks within the past 12 months? 315 167 316

☐ 1 Yes, based on history and presence of carotid bruit
☐ 2 Yes, based on history of two or more TIA in same location
☐ 3 Yes, based on other combinations of evidence
☐ 4 No

35. Is there a history of carotid endarterectomy? 168 Yes ☐ 1 No ☐ 2

317

CLINICIAN'S JUDGMENT (Continued)

Contraindications and Allergies to Study Drugs

36. On the basis of your history and physical examination, does this participant have any contraindication or allergy to chlorthalidone? 169 318 Yes ☐ 1 No ☐ 2

37. On the basis of your history and physical examination, does this participant have any contraindication or allergy to atenolol? 170 319 Yes ☐ 1 No ☐ 2

38. On the basis of your history and physical examination, does this participant have any contraindication or allergy to reserpine? 171 320 Yes ☐ 1 No ☐ 2

39. Are both Question 37 and Question 38 answered "Yes?" 172 Yes ☐ 1 No ☐ 2

Other Exclusion Criteria 321

40. Alcohol--on the basis of your history and physical examination, do you believe the participant currently drinks 6 or more drinks/day, or that alcoholism has been a problem in the past year, or alcoholic liver disease is currently present? 173 322 Yes ☐ 1 No ☐ 2

41. Dementia--on the basis of your history and physical examination, do you believe the participant definitely has any form of dementia? 174 323 Yes ☐ 1 No ☐ 2

42. On the basis of your history and physical examination is there any life-threatening disease, or any other reason which might seriously impair the individual's participation in the SHEP over the next five years? 176 325 Yes ☐ 1 No ☐ 2

Specify: _____

Falls and Fractures

43. Do you believe that the participant has ever had a fracture of: 326

a. Hip? 177 Yes ☐ 1 No ☐ 2

b. Spine? Yes ☐ 1 No ☐ 2 178 327

c. Forearm? 328 179 Yes ☐ 1 No ☐ 2

44. Do you believe that the participant has had a problem with frequent falls? Yes ☐ 1 No ☐ 2 180 329

Result

Items 23 through 44 that are marked with ⊛ are exclusions if answer is "Yes," or, in the case of CHF (Question 27), answered "Yes, not controlled," or, in the case of TIA (Question 34), answered "Yes, based on history and presence of carotid bruit" or "Yes, based on history of two or more TIAs in same location." Please review these criteria very carefully before answering Item 45.

45. Based on the information contained in this review:

181 330

- ☐ 1 The participant remains eligible for the SHEP.
- ☐ 2 The participant is not eligible for the SHEP.

46. Clinician's signature: _____ 182 331-332 [ ] Code

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process. Baseline Visit 2 may then be scheduled for eligible persons.

PLEASE REVIEW PAGE 1

334	184	RECORD TYPE
335-340	185	DATE RECEIVED
341-343	186	UPDATE NUMBER
344-349	187	DATE LAST PROCESSED
350	188	PAPER COPY
351	189	CROSS FORM EDIT
3-8	514	BATCH DATE
11-16	515	DATE MODIFIED
17-20	516	TIME MODIFIED
21	517	EDIT STATUS

Keypuncher Code 1-2

Verifyer Code 9-10