

SHEP ANNUAL CLINIC VISIT

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

3. a. Today's Date: 34-39 7 Month Day Year b. Seq. #: 47-48 8 c. Year (1-6): 49 9

4. Location of Visit: 50 10 1 Clinic 2 Home 3 Telephone

5. Time visit begins: 11 51-52 : 53-54 12 1 a.m. 2 p.m. 13 55

PRIOR TO INITIATING PROCEDURES FOR THIS VISIT

- Collect, complete and review take-home Annual Medical and Medication and Habits History, SH44
Review and update original Participant Information Sheet, SH02

COMPLETE THE SECTION BELOW AT THE TERMINATION OF THIS VISIT BEFORE PARTICIPANT LEAVES; BE SURE THAT EVERY ITEM ON EACH PAGE IS COMPLETE AND LEGIBLE. THE SHEP ID AND ACROSTIC SHOULD MATCH THOSE ON THE SH06. CHECK YELLOW COPY FOR LEGIBILITY, ALSO. ANY ITEM THAT IS NOT COMPLETE ON THIS FORM, OR REQUIRED BUT NOT DONE, SHOULD BE EXPLAINED IN COMMENTS, ITEM 8.

Table with columns: Procedure, Auxiliary Form, Comment, Done this Visit? (Yes/No). Rows include Annual Medical and Medication and Habits History, ECG and two-minute rhythm strip, Dipstick urinalysis, etc.

[1] May omit for home visits
[2] May omit for telephone visits

- 7. Action required as a result of this visit: 25 1 None of 7a-7g required
a. 1 Initial Notification of Morbid Event, SH20
b. 27 1 SHEP Neurological Evaluation for Strokes, SH27
c. 28 1 SHEP Neurological Evaluation for TIA, SH28
d. 29 1 Dementia Referral, SH31
e. 30 1 Depression Referral, SH32
f. 31 1 Deviation from Protocol, SH48
g. 32 1 Report of Unblinding, SH49

8. Comments on this visit:

9. Next clinic visit: 33 75-80 Month Day Year at 34 81-82 : 35 83-84 36 85 1 a.m. 2 p.m.

10. Time visit is completed: 37 86-87 : 88-89 38 1 a.m. 2 p.m. 39 90

11. Signature of person reviewing this page: 40 91-92 Code

PULSE AND BLOOD PRESSURE--If any pulse or blood pressure is not obtained, enter all 9s in the appropriate spaces. If this is a telephone visit, complete only items 12d and 12e; leave cuff size and Item 12c blank.

12. a. Pulse: Beats in 30 seconds _____ x 2 = 41 | 93-95 beats per minute.

b. Cuff Size: { Regular Large arm Thigh Pediatric

Pulse Obliteration Pressure:

Observed Value: 43 | 97-99

Subtract Zero Level: 44 | 100-101

Corrected Value: 45 | 102-106

Add Maximum Zero Level Plus 20: + 46 | 105-106

Peak Inflation Level: 47 | 107-109

Seated Readings:

Standing Readings:

		<u>Systolic</u>		<u>Diastolic</u>
First	48	110-112	49	113-115
Zero level	50	116-117	51	118-119
Corrected	52	120-122	53	123-125
Second	54	126-128	55	129-131
Zero level	56	132-133	57	134-135
Corrected	58	136-138	59	139-141
Sum of two corrected readings	60	142-144	61	145-147
Average of two corrected readings	62	148-150	63	151-153

One minute

Pulse: Beats in 15 seconds _____

64 x 4 = 154-156 beats per minute.

Blood Pressure: Systolic Diastolic

Reading 65 157-159 66 160-162

Zero 67 163-164 68 165-166

Corrected 69 167-169 70 170-172

Three minutes

Pulse: Beats in 15 seconds _____

71 x 4 = 173-175 beats per minute.

Blood Pressure: Systolic Diastolic

Reading 72 176-178 73 179-181

Zero 74 182-183 75 184-185

Corrected 76 186-188 77 189-191

(If standing blood pressure not done, skip to 12e.)

c. Did the participant volunteer any symptoms on standing? 192 78 Yes 1 No 2

193 79 (1) Dizziness? Yes 1 No 2

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

80 194 SKIP to 12e.

d. To the participant, for telephone visits only:

Since the last time that you came to the SHEP clinic, have you had your blood pressure taken?

195
 Yes 1 No 2 DK 3

When was the last time?

81
 82 83
 196-197 198-199
 Month Year

Skip to 12e

What was your blood pressure at that time?
 (Interviewer: If participant does not know last blood pressure, fill in with 9's.)

84 85
 200-202 203-205
 SBP DBP

e. Observer: _____

86 206-207
 Code

PARTICIPANT SHOULD NOW BE SENT FOR ECG AND TWO-MINUTE RHYTHM STRIP, URINE SAMPLES, AND BLOOD SAMPLES, IN THAT ORDER, AS REQUIRED AT THIS ANNUAL VISIT. CHECK PAGE 1 FOR REQUIRED PROCEDURES.

COMPLIANCE EVALUATION--If participant was not prescribed any of the SHEP medications at last visit, skip to 24.

13. Have you missed taking your SHEP medicines anytime in the past 7 days?

87 1 Yes 2 No

208

Go to 17.

14. Which days did you miss? (Circle days mentioned.)

M T W Th F S S → Total days missed

88

209

15. Why did you miss taking the medicines?

(Push for answers, but do not mention specific categories.)

		Mentioned	Not Mentioned
a. Wasn't feeling well	210	89 1 <input type="checkbox"/>	2 <input type="checkbox"/>
b. Medicine made participant ill (Specify) _____		1 <input type="checkbox"/>	2 <input type="checkbox"/> 90 211
c. Just forgot	212	91 1 <input type="checkbox"/>	2 <input type="checkbox"/>
d. Away from home/didn't have medicine		1 <input type="checkbox"/>	2 <input type="checkbox"/> 92 213
e. Ran out of medicine	214	93 1 <input type="checkbox"/>	2 <input type="checkbox"/>
f. Didn't want to take (Reason) _____	216	95 1 <input type="checkbox"/>	2 <input type="checkbox"/> 94 215
g. Doctor (usual source of care) told me to stop		1 <input type="checkbox"/>	2 <input type="checkbox"/>
h. Other (Specify) _____		1 <input type="checkbox"/>	2 <input type="checkbox"/> 96 217

16. What did you do when you missed taking your SHEP medicines?
 (Push for answers, but do not provide specific categories.)

		Mentioned	Not Mentioned
a. Waited and doubled up the next dose	218	97 1 <input type="checkbox"/>	2 <input type="checkbox"/>
b. Did nothing/took usual dose next time		1 <input type="checkbox"/>	2 <input type="checkbox"/> 98 219
c. Reports missed dose(s) at next clinic visit	220	99 1 <input type="checkbox"/>	2 <input type="checkbox"/>
d. Called SHEP clinic		1 <input type="checkbox"/>	2 <input type="checkbox"/> 100 221
e. Recorded missed dose(s)	222	101 1 <input type="checkbox"/>	2 <input type="checkbox"/>
f. Took it later		1 <input type="checkbox"/>	2 <input type="checkbox"/> 102 223
g. Other (specify) _____	103		

224

If participant is not currently being prescribed C1 or C2, skip to 20.

17. How many times a day do you take your C1/C2?
(Interviewer: Circle correct Step 1 drug.) **225** (104) { Every other day 1
Once per day 2
Other _____ 3
(Specify)
18. How many do you take each time? **226** (105) { One _____ 1
Other _____ 2
(Specify)
19. When do you take it? **227** (106) { Morning when getting up 1
Other _____ 2
(Specify)
-

If participant is not currently being prescribed A1, A2 or R, skip to 23.

20. How many times a day to your take your A1/A2/R?
(Interviewer: Circle correct Step 2 drug.) **228** (107) { Once per day 1
Twice per day 2
Other _____ 3
(Specify)
21. How many do you take each time? **229** (108) { One _____ 1
Other _____ 2
(Specify)
22. When do you take it? **230** (109) { Morning when getting up 1
Morning when getting up,
and late afternoon
or bedtime 2
Other _____ 3
(Specify)
-

Item 23 for interviewer only. Skip pill count for home and telephone visits.

23. a. Was a pill count done at this visit? **231** (110) Yes 1 No 2
↓

Skip to 24.
- 232-235** (111) b. Step 1 result: · %
- 236-239** (112) c. Step 2 result: · %

If participant reports missing doses, or pill count result (if done) is less than 80% for either Step 1 or Step 2, or participant is not taking drugs properly, reinforce instructions on how to take SHEP medications.

GENERAL WELL-BEING

Interviewer: Questions in this section may be rephrased; use phraseology that you are comfortable with.

24. Have you felt unwell in any way since your last clinic visit; has anything been bothering you? (Specify): _____ **240** (113) Yes 1 No 2
↓
Go to 26.

25. Are any of these problems different from the way things were at your last clinic visit? **241** (114) Yes 1 No 2

26. Since your last visit, have you seen a doctor for any reason? (Specify): _____ **242** (115) Yes 1 No 2

27. Since your last visit, have you been in the hospital for any reason? **243** (116) Yes 1 No 2
How many times (117) **244-245**
When? (Start with the first one after your last visit.)
↓
Go to 28.

(If more than 3 hospitalizations, list rest on blank sheet of paper.)

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	(118) 246-251	(120) 254-259	(122) 262-267
Date of admission	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
Number of days	(119) <input type="text"/> 252-253	(121) <input type="text"/> 260-261	(123) <input type="text"/> 268-269
Reason	_____	_____	_____

28. Since your last SHEP visit, have you been told by a doctor or otherwise learned that you may have had a stroke? **270** (124) Yes 1 No 2

29. Thinking about the other medications that you might be taking now, or have taken since your last visit:

a. Have you stopped taking any medications? (Specify): _____ **271** (125) Yes 1 No 2

b. Have you increased or decreased any medications that you were taking? (Specify): _____ **272** (126) Yes 1 No 2

c. Have you started taking any new medications? (Specify): _____ **273** (127) Yes 1 No 2

30. Interviewer: Did the participant bring all non-SHEP medications to the clinic at this visit? **274** (128) Yes 1 No 2
Not on any non-SHEP medications 3

POSSIBLE SIDE EFFECTS--May not be re-phrased. If the participant has been off of SHEP medications more than six months, skip to Item 63.

Since your last visit, have you had:	(a)	New since last visit?		Frequency:		Severity:		In the opinion of the SHEP clinician, is this due to the use of SHEP medications?	
		1=Yes	2=No	(c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	(d) 1=Not 2=Troublesome 3=Intolerable	(e) 1=Yes 2=Possibly 3=No			
31. Unusual coldness or numbness of the hands or feet?	275 (129)	Yes <input type="checkbox"/> 1	(130) 276	(131) 277	(132) 278	(133) 279			
32. Unusual skin rash or bruising?	280 (134)	Yes <input type="checkbox"/> 1	(135) 281	(136) 282	(137) 283	(138) 284	(f) Is an acute skin rash present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	285 (139)	
33. Any feelings of unsteadiness or imbalance?	286 (140)	Yes <input type="checkbox"/> 1	(141) 287	(142) 288	(143) 289	(144) 290			
34. Faintness or light headedness when you stand up quickly?	291 (145)	Yes <input type="checkbox"/> 1	(146) 292	(147) 293	(148) 294	(149) 295	(f) Is there an observable postural drop in blood pressure? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(155) 301	
35. Loss of consciousness or passing out	296 (150)	Yes <input type="checkbox"/> 1	(151) 297	(152) 298	(153) 299	(154) 300			
36. Falls?	302 (156)	Yes <input type="checkbox"/> 1	(157) 303	(158) 304	(159) 305	(160) 306	(f) Hip? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (g) Spine? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (h) Forearm? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(166) 312	
37. Fractures?	307 (161)	Yes <input type="checkbox"/> 1	(162) 308	(163) 309	(164) 310	(165) 311	(f) Are there physical signs of acute arthritis? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	(167) 313	
38. Unusual pain in any joint?	315 (169)	Yes <input type="checkbox"/> 1	(170) 316	(171) 317	(172) 318	(173) 319		(168) 314	
39. Muscle weakness or cramping?	321 (175)	Yes <input type="checkbox"/> 1	(176) 322	(177) 323	(178) 324	(179) 325		320 (174)	
40. Excessive thirst?	326 (180)	Yes <input type="checkbox"/> 1	(181) 327	(182) 328	(183) 329	(184) 330			
41. Loss of appetite?	331 (185)	Yes <input type="checkbox"/> 1	(186) 332	(187) 333	(188) 334	(189) 335			
42. Nausea or vomiting?	336 (190)	Yes <input type="checkbox"/> 1	(191) 337	(192) 338	(193) 339	(194) 340			
43. Unusual indigestion?	341 (195)	Yes <input type="checkbox"/> 1	(196) 342	(197) 343	(198) 344	(199) 345			
44. Change in bowel habits?	346 (200)	Yes <input type="checkbox"/> 1	(201) 347	(202) 348	(203) 349	(204) 350			

Since your last visit, have you had:	(a)	New since last visit?		Frequency:				Severity:		In the opinion of the SHEP clinician, is this due to the use of SHEP medications?	
		(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) 1=Yes 2=Possibly 3=No					
45. Tarry black stools or red blood in the stools?	351 (205) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(206)	352	(207)	353	(208)	354	(209)	355		
46. Heart beating unusually fast or skipping beats?	356 (210) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(211)	357	(212)	358	(213)	359	(214)	360	(f) Is an arrhythmia present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	
47. Heart beating unusually slow?	361 (215) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(216)	362	(217)	363	(218)	364	(219)	365		
48. Episodes of chest pain or heaviness in the chest?	366 (220) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(221)	367	(222)	368	(223)	369	(224)	370		
49. Headaches so bad you had to stop what you were doing?	372 (226) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(227)	373	(228)	374	(229)	375	(230)	376	(225) 371	
50. Stuffy nose?	377 (231) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(232)	378	(233)	379	(234)	380	(235)	381		
51. Unusual shortness of breath or wheezing?	382 (236) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(237)	383	(238)	384	(239)	385	(240)	386	(f) Is there evidence for bronchospasm on auscultation of the chest? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	
52. Unusual tiredness or loss of pep?	388 (242) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(243)	389	(244)	390	(245)	391	(246)	392	(241)	
53. Swelling of the ankles?	393 (247) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(248)	394	(249)	395	(250)	396	(251)	397	(f) Is there evidence of CHF on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	
54. Feeling so depressed (sad or blue) that it interfered with your work, recreation or sleep?	399 (253) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(254)	400	(255)	401	(256)	402	(257)	403	(252) 398	
55. Any trouble with your memory or concentration?	404 (258) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(259)	405	(260)	406	(261)	407	(262)	408		
56. Nightmares?	409 (263) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(264)	410	(265)	411	(266)	412	(267)	413		

POSSIBLE SIDE EFFECTS (Continued)--May not be re-phrased.

Since your last visit, have you had:	New since last visit?		Frequency:					Severity:			In the opinion of the SHEP clinician, is this due to the use of SHEP medications?
	(a)	(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) 1=Yes 2=Possibly 3=No						
57. Any changes in your sexual activity? 414	(268) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(269) 415	(270) 416	(271)	417	(272)	418	(273) 419	(f) Loss of interest Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2		
								(g) Decline in frequency? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(274) 420		
								(h) Loss of enjoyment? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2			
								(i) Functional impairment? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(276) 422		
58. Trouble going to sleep, or waking early and having trouble getting back to sleep? 423	(277) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(278) 424	(279) 425	(280)	426	(281)	427				
59. Waking up in the night more frequently to urinate? 428	(282) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(283) 429	(284) 430	(285)	431	(286)	432				
60. More worry or anxiety than usual? 432	(287) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(288) 434	(289) 435	(290)	436	(291)	437				
61. Weakness or numbness on one side, or unexpected difficulties talking or thinking? 438	(292) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(293) 439	(294) 440	(295)	441	(296)	442	(f) Is there evidence of a stroke on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	(297) 443		
62. Other relevant symptoms Specify: 444	(298) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(299) 445	(300) 446	(301)	447	(302)	448	(f) Are there other relevant signs on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3 Specify: _____	(303) 449		

CLINICIAN REVIEW OF MEDICATION HISTORY--To be completed by clinician using information from the Annual Medical and Medication and Habits History, SH44.

63. Is the participant taking any of the drugs listed below?

	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)	450 (304) <input type="checkbox"/> 1	<input type="checkbox"/> 2
b. Digitalis	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (305) 451
c. Nitrates, including nitroglycerine, or other coronary vasodilator	452 (306) <input type="checkbox"/> 1	<input type="checkbox"/> 2
d. Propranolol or other beta blockers for other than treatment of blood pressure (excluding Timoptic eye drops)	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (307) 453
e. Timoptic eye drops	454 (308) <input type="checkbox"/> 1	<input type="checkbox"/> 2
f. Anti-arrhythmic drugs	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (309) 455
g. Lipid-lowering drugs, including clofibrate, cholestyramine, colestipol, nicotinic acid, etc.	456 (310) <input type="checkbox"/> 1	<input type="checkbox"/> 2
h. Agents for gout, including probenecid, allopurinol or colchicine	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (311) 457
i. Insulin	458 (312) <input type="checkbox"/> 1	<input type="checkbox"/> 2
j. Oral hypoglycemic agents	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (313) 459
k. Anticoagulants	460 (314) <input type="checkbox"/> 1	<input type="checkbox"/> 2
l. Antibiotics or anti-infection agents	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (315) 461
m. Cortisone or other gluco corticoids	462 (316) <input type="checkbox"/> 1	<input type="checkbox"/> 2
n. Amphetamines or other stimulant	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (317) 463
o. Flurazepam or other sedative	464 (318) <input type="checkbox"/> 1	<input type="checkbox"/> 2
p. Anti-depressants	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (319) 465
q. Librium, valium or other antianxiety agents	(320) <input type="checkbox"/> 1	<input type="checkbox"/> 2
r. Other psychotropic agents	466 (320) <input type="checkbox"/> 1	<input type="checkbox"/> 2 (321) 467
s. Potassium supplementation other than dietary recommendations	468 (322) <input type="checkbox"/> 1	<input type="checkbox"/> 2
t. Estrogen	<input type="checkbox"/> 1	<input type="checkbox"/> 2 (323) 469
u. Anturane® (Sulfinpyrazone) at least 4 weeks	470 (324) <input type="checkbox"/> 1	<input type="checkbox"/> 2
v. Persantine® (Dipyridamole) at least 4 weeks	<input type="checkbox"/> 1	<input type="checkbox"/> 2
w. Aspirin at least 4 weeks	472 (326) <input type="checkbox"/> 1	<input type="checkbox"/> 2 (325) 471
x. Non-steroidal anti-inflammatory drugs	<input type="checkbox"/> 1	<input type="checkbox"/> 2
y. Any experimental drug	474 (328) <input type="checkbox"/> 1	<input type="checkbox"/> 2 (327) 473

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. For home and telephone visits, the participant should be asked to estimate their own height and weight; the remainder of the physical examination may be omitted.

64. Weight in pounds: 475-477 (329) 65. Height in inches: 478-479 (330)

Area Examined	Comments
66. SKIN 480 (331) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2	
67. HEAD, EARS, NOSE, THROAT 481 (332) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2	

PHYSICAL EXAMINATION (continued)

Area Examined	Comments
<p>68. EYES</p> <p>Fundi: 482 (333) a. { Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2 Not Visualized <input type="checkbox"/> 3</p> <p>Other (Specify)? 483 (334) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>69. NECK</p> <p>Raised jugular venous pressure? 484 (335) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Carotid bruits? 485 (336) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p style="text-align: center;">↓</p> <p>486 (337) c. { Right only <input type="checkbox"/> 1 Left only <input type="checkbox"/> 2 Bilateral <input type="checkbox"/> 3</p> <p>Carotid pulses absent or markedly diminished? 487 (338) d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p style="text-align: center;">↓</p> <p>488 (339) e. { Right only <input type="checkbox"/> 1 Left only <input type="checkbox"/> 2 Bilateral <input type="checkbox"/> 3</p> <p>Thyroid abnormality? 489 (340) f. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? 490 (341) g. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>70. LYMPH NODES 491 (342) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2</p>	
<p>71. CHEST, LUNGS</p> <p>492 (343) Bilateral rales that do not clear with coughing? a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>493 (344) Respiratory rate 20+? b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Wheezing? (345) 494 c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? (346) 495 d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>72. HEART</p> <p>PMI more than 2 centimeters lateral to midclavicular line? (347) 496 a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any murmur? 497 (348) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Third heart sound? (349) 498 c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Fourth heart sound? (350) 499 d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Pulse irregular? 500 (351) e. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? 501 (352) f. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>73. BREASTS 502 (353) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2</p>	

PHYSICAL EXAMINATION (Continued)

Area Examined	Comments
<p>74. ABDOMEN</p> <p>Liver span 10 cm or more? 503 (354) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Abnormal abdominal pulse? 504 (355) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any masses? 505 (356) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Bruit? a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (357) 506</p> <p>Other (Specify)? 507 (358) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>75. EXTREMITIES</p> <p>Pitting ankle edema? 508 (359) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Femoral bruit? 509 (360) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any peripheral pulses absent or markedly diminished (specify location)? (361) 510 c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? 511 (362) d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>76. NEUROLOGICAL (UA = unable to assess)</p> <p><u>Gait</u></p> <p>Left hemiparetic? 512 (363) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right hemiparetic? 413 (364) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Walking on toes</u></p> <p>Left weakness? 514 (365) c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right weakness? 515 (366) d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Walking on heels</u></p> <p>Left weakness? 516 (367) e. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right weakness? f. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 (368) 517</p> <p><u>Stationary 30 seconds</u></p> <p>Eyes closed? (369) 518 g. Can do <input type="checkbox"/> 1 Cannot do <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Eyes open (only if unable to do with eyes closed) (370) 519 h. Can do <input type="checkbox"/> 1 Cannot do <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Cranial nerves</u></p> <p>Facial weakness left? 520 (371) i. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Facial weakness right? (372) 521 j. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Visual field deficit</u></p> <p>Left side? 522 (373) k. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right side? 523 (374) l. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Motor wrist extensors</u></p> <p>Weakness left? 524 (375) m. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Weakness right? 525 (376) n. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p>	

PHYSICAL EXAMINATION (Continued)

Area Examined	Comments
<p>76. NEUROLOGICAL (Continued) (UA = Unable to assess)</p> <p><u>Coordination</u></p> <p>Left hand patting? ⁵²⁶ 377 o. Slowed <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right hand patting? ⁵²⁷ 378 p. Slowed <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Reflexes</u></p> <p>Assymetry ⁵²⁸ 379 q. L>R <input type="checkbox"/> 1 Equal <input type="checkbox"/> 3 of Patellar tendon R>L <input type="checkbox"/> 2 UA <input type="checkbox"/> 4</p> <p>Babinski sign left? ⁵²⁹ 380 r. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Babinski sign right? ⁵³⁰ 381 s. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Other</u></p> <p>Any speech or language ⁵³¹ 382 t. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 problems (specify)?</p>	

77. OTHER PHYSICAL FINDINGS (SPECIFY):

78. Clinician's signature: _____ ⁵³²⁻⁵³³ 383 Code

CLINICIAN'S JUDGMENT AND ENDPOINT 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 endpoint determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study endpoint questions are identified with ⊗. These questions must all be covered prior to termination of this visit. Pertinent items on the Medical History (SH44) are listed with the section headings. The "DK" option should be used only for home and telephone visits when pertinent information is not available.

Angina Pectoris - SH44 Items 3, 12

79. On the basis of your history and/or physical exam, do you believe that the participant has angina pectoris? ⁵³⁴ 384 Yes 1 No 2 DK 3 ⊗

Note: The Rose Questionnaire for angina (from SH44) is positive if:
 Either 12a or 12b is "Yes,"
 and either 12c or 12d is "Yes,"
 and 12e is "Stop or slow down,"
 and 12f is "Yes,"
 and 12g is "10 minutes or less,"
 and either 12h(1) is "Yes," (X placed in sternum upper, middle or lower) or both 12h(2) and 12h(3) are "Yes"
 (X in both left anterior chest and in left arm).

CLINICIAN'S JUDGMENT (Continued)

Myocardial Infarction (MI) - SH44 Items 2, 13, 14, 24, 25

80. a. On the basis of the ECG and/or your history and physical examination, do you believe the participant has had a myocardial infarction in the past year? **535** (385) Yes 1 No 2 DK 3 
- ↓ ↓
SKIP to 81. (387) **538-539**
- b. When was the most recent possible myocardial infarction? **536-537** (386) / **538-539** (387) / **538-539**
Month Year

81. a. Is there a history of coronary bypass in the past year? **540** (388) Yes 1 No 2 DK 3 
- ↓ ↓
SKIP to 82. **541-542** (389) / **543-544** (390) / **543-544**
Month Year
- b. Month and year of surgery:

Congestive Heart Failure - SH44 Item 17.

82. On the basis of your history and/or physical examination, do you believe that the participant has had congestive heart failure during the past year? **545** (391) 1 Yes, controlled 2 Yes, not controlled 3 No 4 DK 

ECG

83. Was an ECG performed this visit? **546** (392) Yes 1 No 2
↓
SKIP to 85. 
84. Are any of the following present?
 a. Atrial fibrillation or flutter? **547** (393) Yes 1 No 2 
 b. Second or third degree A-V block? Yes 1 No 2 (394) **548** 
 c. VPBs--multifocal, pairs or runs, or more than 10% of beats? **549** (395) Yes 1 No 2 
 d. Bradycardia (<50 beats/min.)? **551** (397) Yes 1 No 2 (396) **550** 
85. Does the participant currently have a pacemaker? Yes 1 No 2 DK 3 

Vascular System - SH44 Items 15, 18, 24, 25

86. a. Is there a history of vascular surgery in the past year? **552** (398) Yes 1 No 2 DK 3 
- ↓ ↓
SKIP to 87. **553** (399) Yes 1 No 2
- b. Aortic, iliac, popliteal or femoral bypass or graft? **553** (399) Yes 1 No 2
- c. Angioplasty? **554** (400) Yes 1 No 2
- Which vessel(s)? _____
- c. Other (Specify) _____ **555** (401) Yes 1 No 2

CLINICIAN'S JUDGMENT (Continued)

87. On the basis of your history and/or physical examination, does the participant have arterial disease with tissue necrosis or related loss of an extremity?

556 (402) Yes 1 No 2 DK 3



Note: The Rose Questionnaire for intermittent claudication (from SH44) is positive if:

- 15a is "Yes"
- and 15b is "No"
- and 15c is "Yes"
- and either 15d or 15e is "Yes"
- and 15f is "No"
- and 15g is "Stop or slow down"
- and 15h is "Yes"
- and 15i is "10 minutes or less"

Pulmonary - SH44 Items 16, 17

88. On the basis of the history and/or physical examination, does the participant have:

- a. Chronic bronchitis?
- b. Emphysema?

557 (403) Yes 1 No 2 DK 3
 558 (404) Yes 1 No 2 DK 3

Stroke/TIA - SH44 Items 5, 18-25

89. a. On the basis of your history and/or physical examination, and keeping the SHEP criteria in mind, do you believe the participant has had a stroke in the past year?

559 (405) Yes 1 No 2 DK 3



↓ ↓
 SKIP to 90.

b. When was the most recent episode of probable stroke (not TIA)?

560-561 (406) ≡ (407) 562-563
 [] []
 Month Year

c. Are any residual effects still present?

564 (408) Yes 1 No 2 DK 3

If not already accomplished, arrange for SHEP Neurological Evaluation for Stroke (SH27) as soon as possible.

90. On the basis of your history and/or physical examination, do you believe that the participant has had transient cerebral ischemic attacks within the past year?

565 (409)

- 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
- 5 DK



If "Yes, based on history and presence of carotid bruit" or "Yes, based on history of two or more TIA in same location," or "Yes, based on other combinations of evidence," arrange for SHEP Neurological Evaluation for TIA (SH28) as soon as possible if not already accomplished.

CLINICIAN'S JUDGMENT (Continued)

100. Other than possible stroke, TIA, left ventricular failure, myocardial infarction and vascular surgeries, was the participant hospitalized or admitted to an intermediate or skilled care nursing home in the past year? (421) Yes 1 No 2 DK 3

101. On the basis of your history and/or physical examination is there any other life-threatening disease, or any other reason which might seriously impair the individual's participation in the SHEP over the next year? 577 (422) Yes 1 No 2 DK 3

Specify: _____

102. Comments: _____

103. Clinician's signature: _____ 579-580 (423)
Code

For new possible strokes, acute myocardial infarctions, left ventricular failures, and transient ischemic attacks, obtain complete hospital/physician visit record for that event. For new other hospitalizations and new admissions to skilled or intermediate care nursing homes, obtain discharge summary or admission record only. Have participant sign consent to obtain medical records. Fill out Form SH20, Initial Report of Morbid Event.

PROTOCOL REVIEW

104. a. At the last visit, were SHEP medications prescribed in dosages specified in the protocol? (424) 1 Yes 2 No

b. Since the last visit, have SHEP medications been altered to dosages other than prescribed at the last visit? 581 (425) 1 Yes 2 No 3 DK
Specify: _____ 582

c. Since the last visit, have open-label antihypertensive medications been prescribed or taken? (426) 1 Yes 2 No 3 DK
Specify: _____ 583

If 104a is "Yes" and both 104b and 104c are "No" or "DK," skip to 110.

PROTOCOL REVIEW (Continued)

105. Has this deviation already been reported on a Deviation from Protocol form, SH48?

427

1 Yes 2 No

584

Initiate SH48 for this deviation.

Clinic Physician Initial

106. What has happened with respect to the problem which caused this deviation from the protocol?

Comment: _____

428

585

- 1 Resolved
- 2 Improved
- 3 Worse
- 4 Unchanged

107. Have any other potentially serious conditions arisen since the last visit which are probably a result of the use of SHEP medications?

429

586

- 1 Yes
- 2 No
- 3 Not on SHEP meds

108. At this visit, do you plan to restore the participant to the SHEP drugs and doses specified in the protocol (including discontinuing open-label antihypertensives, if any)?

430

587

1 Yes 2 No

Skip to 110.

109. Reason: (Check all that apply.)

- 588 431 a. 1 Side effects judged to be severe enough to deviate from protocol
- 589 432 b. 590 1 Participant has reached escape blood pressure
- 591 434 c. 433 1 Private MD has prescribed alternative BP therapy
- d. 1 Participant request
- e. 435 1 Other (Specify): _____

592

110. In the judgment of the SHEP clinician, are any of the positive or abnormal responses in the General Well-Being or Side Effects sections related to the current use of SHEP medications?

593

436

- 1 Yes
- 2 Possibly
- 3 No
- 4 No positive or abnormal responses

Skip to 112.

111. a. In the judgment of the SHEP clinician and physician, do any of these responses require deviation from protocol in prescribing SHEP medication?

437

594

1 Yes 2 No

Skip to 112.

b. Are any of these conditions possibly harmful to the participant?

Initiate SH48 for Deviation from Protocol.

438

595

1 Yes 2 No

Clinic Physician Initial

PROTOCOL REVIEW (Continued)

112. Are there reasons other than those in Questions 104-111 that require a deviation from protocol in prescribing SHEP medications (e.g., interference from other medicine, etc.)?

439 1 Yes 2 No

(Specify): _____

596

Skip to next section.

Initiate SH48 for Deviation from Protocol.

Clinic Physician Initial

BLOOD PRESSURE REVIEW--Goal SBP: _____ BP today: _____

Please review attached chart for treatment and scheduling decision based on blood pressure status. For participants already on open-label therapy, skip to Item 113 (medication prescription last visit).

MEDICATION PRESCRIPTION--Take into account all of Items 104 through 112 and the participant's blood pressure status.

113. Medication prescription last visit:

440 a. Step 1: 1 C1 3 C1, dose 1/2 2 C2 4 None (Skip to 113c)

441 b. Bottle #: 598-600

597

601 442 c. Step 2: 1 A1 3 R, Dose 1 5 None 2 A2 4 R, Dose 2 (Skip to 113e)

443 d. Bottle #: 602-604

605 444 e. 1 Open-label antihypertensives -> Specify: _____

606 445 f. 1 Potassium supplement -> 446 g. 607-608 meq/day

609 447 h. 1 Uric acid agent -> Specify drug and dose: _____

114. Medication prescription this visit: 1 No change 448 -> 610

Go to 115

611 449 a. Step 1: 1 C1 3 C1, dose 1/2 2 C2 4 None (Skip to 114c)

450 b. Bottle #: 612-614

615 451 c. Step 2: 1 A1 3 R, Dose 1 5 None 2 A2 4 R, Dose 2 (Skip to 114e)

452 d. Bottle #: 616-618

619 453 e. 1 Open-label antihypertensives -> Specify: _____

620 454 f. 1 Potassium supplement -> 455 g. 621-622 meq/day

623 456 h. 1 Uric acid agent -> Specify drug and dose: _____

115. Signature of Clinician completing this section: _____ 457 624-625

BEHAVIORAL EVALUATIONS

The participant should now be administered:

- SHEP SHORTCARE (SH30, SH36)
- Activities of Daily Life (SH33)
- Social Network (SH34)
- Behavioral Evaluation--Part II (SH35)

626 458 RECORD TYPE

627-632 459 DATE RECEIVED

633-635 460 UPDATE NUMBER

3-8 514 BATCH DATE PLEASE REVIEW PAGE 1 636-641 461 DATE LAST PROCESSED

Version 1 - 1/86 17-20 516 TIME MOD. 642 462 PAPER COPY SH09/18

11-16 515 DATE MODIFIED 21 517 EDIT STATUS 643 463 CROSS FORM EDIT STATUS

30-32 1 FORM NUMBER

SHEP ANNUAL CLINIC VISIT

518 SEQUENCE

33 2 VERSION NUMBER

3 22-23 4 24-27 5 28-29

2. Acrostic: 41-46 6

3. a. Today's Date: Month Day Year 7

b. Seq. #: 47-48 8

c. Year (1-6): 49 9

50 10 4a. Place of visit: 1 Clinic (skip to 5) 2 Home (skip to 5) 3 Telephone (skip to 5) 4 No visit

b. Vital status: 1 Alive 2 Dead 3 Unknown 4 464 644

5. Time visit begins: 11 12 51-52 53-54 1 a.m. 2 p.m. 13

55

PRIOR TO INITIATING PROCEDURES FOR THIS VISIT

- Collect, complete and review take-home Annual Medical and Medication and Habits History, SH44
Review and update original Participant Information Sheet, SH02

COMPLETE THE SECTION BELOW AT THE TERMINATION OF THIS VISIT BEFORE PARTICIPANT LEAVES; BE SURE THAT EVERY ITEM ON EACH PAGE IS COMPLETE AND LEGIBLE. THE SHEP ID AND ACROSTIC SHOULD MATCH THOSE ON THE SH06. CHECK YELLOW COPY FOR LEGIBILITY, ALSO. ANY ITEM THAT IS NOT COMPLETE ON THIS FORM, OR REQUIRED BUT NOT DONE, SHOULD BE EXPLAINED IN COMMENTS, ITEM 8.

Table with columns: Procedure, Auxiliary Form, Comment, Done this Visit? (Yes/No). Rows include Annual Medical and Medication and Habits History, ECG and two-minute rhythm strip, Dipstick urinalysis, Blood sample, Fasting blood sample, Non-fasting blood sample, SHORTCARE/CES-D, Activities of Daily Life, Social Network, Behavioral Evaluation.

[1] May omit for home visits. [2] May omit for telephone visits; SH33 and SH34 should be completed if participant is willing.

7. Action required as a result of this visit: 1 None of 7a-7f required 25

- 70 71 72 74 a. Initial Notification of Morbid Event, SH20
b. SHEP Neurological Evaluation for Strokes, SH27
c. SHEP Neurological Evaluation for TIA, SH28
d. Dementia Referral, SH31
e. Depression Referral, SH32
f. Report of Unblinding, SH49

8. Comments on this visit:

9. Next clinic visit: 33 75-80 Month Day Year at 34 35 81-82 83-84 1 a.m. 2 p.m. 36 85

10. Time visit is completed: 37 38 86-87 88-89 1 a.m. 2 p.m. 39 90

11. Signature of person reviewing this page: 40 91-92 Code

PULSE AND BLOOD PRESSURE--If any pulse or blood pressure is not obtained, enter all 9s in the appropriate spaces. If this is a telephone visit, complete only items 12d and 12e; leave cuff size and Item 12c blank.

12. a. Pulse: Beats in 30 seconds _____ x 2 = 41 beats per minute.

93-95

b. Cuff Size: 42 Regular Large arm Thigh Pediatric

Pulse Obliteration Pressure:
 Observed Value: 43 97-99
 Subtract Zero Level: 44 100-101
 Corrected Value: 45 102-104
 Add Maximum Zero Level Plus 20: 46 105-106
 Peak Inflation Level: 47 107-109

Seated Readings:

Standing Readings:

		<u>Systolic</u>		<u>Diastolic</u>
First	48	110-112	49	113-115
Zero level	50	116-117	51	118-119
Corrected	52	120-122	53	123-125
Second	54	126-128	55	129-131
Zero level	56	132-133	57	134-135
Corrected	58	136-138	59	139-141
Sum of two corrected readings	60	142-144	61	145-147
Average of two corrected readings	62	148-150	63	151-153

One minute
 Pulse: Beats in 15 seconds _____
64 x 4 = 154-156 beats per minute.

Blood Pressure: Systolic Diastolic
 Reading 65 157-159 66 160-162
 Zero 67 163-164 68 165-166
 Corrected 69 167-169 70 170-172

Three minutes
 Pulse: Beats in 15 seconds _____
71 x 4 = 173-175 beats per minute.

Blood Pressure: Systolic Diastolic
 Reading 72 176-178 73 179-181
 Zero 74 182-183 75 184-185
 Corrected 76 186-188 77 189-191

(If standing blood pressure not done, skip to 12e.)

c. Did the participant volunteer any symptoms on standing?

(1) Dizziness?	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	79 193	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	78 192
(2) Other (specify)? _____	Yes <input type="checkbox"/> 1	No <input type="checkbox"/> 2	80 194	SKIP to 12e.		

d. To the participant, for telephone visits only:

Since the last time that you came to the SHEP clinic, have you had your blood pressure taken?

81 195
Yes 1 No 2 DK 3

When was the last time?

82 83
196-197 198-199
Month Year

Skip to 12e.

What was your blood pressure at that time?
(Interviewer: If participant does not know last blood pressure, fill in with 9s.)

84 85
200-202 203-205
SBP DBP

e. Observer: _____

86 206-207
Code

PARTICIPANT SHOULD NOW BE SENT FOR ECG AND TWO-MINUTE RHYTHM STRIP, URINE SAMPLES, AND BLOOD SAMPLES, IN THAT ORDER, AS REQUIRED AT THIS ANNUAL VISIT. CHECK PAGE 1 FOR REQUIRED PROCEDURES.

COMPLIANCE EVALUATION--If participant was not prescribed any of the SHEP medications at last visit, skip to 24.

13. Have you missed taking your SHEP medicines anytime in the past 7 days?

208 87 Yes 1 No 2

Go to 17.

14. Which days did you miss? (Circle days mentioned.)

M T W Th F S S → Total days missed

88 209

15. Why did you miss taking the medicines?

(Push for answers, but do not mention specific categories.)

		<u>Mentioned</u>		<u>Not Mentioned</u>
a. Wasn't feeling well		1 <input type="checkbox"/>	89 210	2 <input type="checkbox"/>
b. Medicine made participant ill (Specify) _____	211	1 <input type="checkbox"/>	90	2 <input type="checkbox"/>
c. Just forgot		1 <input type="checkbox"/>	91 212	2 <input type="checkbox"/>
d. Away from home/didn't have medicine	213	1 <input type="checkbox"/>	92	2 <input type="checkbox"/>
e. Ran out of medicine		1 <input type="checkbox"/>	93 214	2 <input type="checkbox"/>
f. Didn't want to take (Reason) _____	215	1 <input type="checkbox"/>	94	2 <input type="checkbox"/>
g. Doctor (usual source of care) told me to stop		1 <input type="checkbox"/>	95 216	2 <input type="checkbox"/>
h. Other (Specify) _____	217	1 <input type="checkbox"/>	96	2 <input type="checkbox"/>

16. What did you do when you missed taking your SHEP medicines?
(Push for answers, but do not provide specific categories.)

		<u>Mentioned</u>		<u>Not Mentioned</u>
a. Waited and doubled-up the next dose	218	1 <input type="checkbox"/>	97	2 <input type="checkbox"/>
b. Did nothing/took usual dose next time		1 <input type="checkbox"/>	98 219	2 <input type="checkbox"/>
c. Reports missed dose(s) at next clinic visit	220	1 <input type="checkbox"/>	99	2 <input type="checkbox"/>
d. Called SHEP clinic		1 <input type="checkbox"/>	100 221	2 <input type="checkbox"/>
e. Recorded missed dose(s)	222	1 <input type="checkbox"/>	101	2 <input type="checkbox"/>
f. Took it later		1 <input type="checkbox"/>	102 223	2 <input type="checkbox"/>
g. Other (specify) _____	224	1 <input type="checkbox"/>	103	2 <input type="checkbox"/>

If participant is not currently being prescribed C1 or C2, skip to 20.

17. How many times a day do you take your C1/C2?
(Interviewer: Circle correct Step 1 drug.)

Every other day 1 } **104**
Once per day 2 } 225
Other _____ 3 }
(Specify)

18. How many do you take each time?

One _____ 1 } **105**
Other _____ 2 } 226
(Specify)

19. When do you take it?

Morning when getting up 1 } **106**
Other _____ 2 } 227
(Specify)

If participant is not currently being prescribed A1, A2 or R, skip to 23.

20. How many times a day to you take your A1/A2/R?
(Interviewer: Circle correct Step 2 drug.)

Once per day 1 } **107**
Twice per day 2 } 228
Other _____ 3 }
(Specify)

21. How many do you take each time?

One _____ 1 } **108**
Other _____ 2 } 229
(Specify)

22. When do you take it?

Morning when getting up 1 } **109**
Morning when getting up, 2 } 230
and late afternoon
or bedtime
Other _____ 3 }
(Specify)

Item 23 for interviewer only. Skip pill count for home and telephone visits.

23. a. Was a pill count done at this visit?

Yes 1 No 2 **110**
↓ 231

Skip to 24.

b. Step 1 result: **232-235** · % **111**

c. Step 2 result: **236-239** · % **112**

If participant reports missing doses, or pill count result (if done) is less than 80% for either Step 1 or Step 2, or participant is not taking drugs properly, reinforce instructions on how to take SHEP medications.

GENERAL WELL-BEING

Interviewer: Questions in this section may be rephrased; use phraseology that you are comfortable with.

24. Have you felt unwell in any way since your last clinic visit; has anything been bothering you? (Specify): _____ **113** Yes 1 No 2
240 ↓ Go to 26.
25. Are any of these problems different from the way things were at your last clinic visit? **241** **114** Yes 1 No 2
26. Since your last visit, have you seen a doctor for any reason? (Specify): _____ **242** **115** Yes 1 No 2
27. Since your last visit, have you been in the hospital for any reason? **116** Yes 1 No 2
How many times? **117** 244-245 **243** ↓
When? (Start with the first one after your last visit.) Go to 28.

(If more than 3 hospitalizations, list rest on blank sheet of paper.)

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	118 246-251	120 254-259	122 262-267
Date of admission	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
Number of days	119 <input type="text"/> 252-253	121 <input type="text"/> 260-261	123 <input type="text"/> 268-269
Reason	_____	_____	_____

28. Since your last SHEP visit, have you been told by a doctor or otherwise learned that you may have had a stroke? Yes 1 No 2 **270** **124**
29. Thinking about the other medications that you might be taking now, or have taken since your last visit:
- a. Have you stopped taking any medications? (Specify): _____ Yes 1 No 2 **271** **125**
- b. Have you increased or decreased any medications that you were taking? (Specify): _____ Yes 1 No 2 **272** **126**
- c. Have you started taking any new medications? (Specify): _____ Yes 1 No 2 **273** **127**
30. Interviewer: Did the participant bring all non-SHEP medications to the clinic at this visit? Yes 1 No 2 **128**
Not on any non-SHEP medications 3 **274**

CLINICIAN REVIEW OF MEDICATION HISTORY--To be completed by clinician using information from the Annual Medical and Medication and Habits History, SH44. Medications may fit into more than one category.

63. Is the participant taking any of the drugs listed below?

	Current (last 2 weeks)	Not Current or Not Sure
a. Any medication for blood pressure, or any drugs with antihypertensive action (see list in Manual of Operations)	<input type="checkbox"/> 1 304 450	<input type="checkbox"/> 2 305 451
b. Digitalis	<input type="checkbox"/> 1	<input type="checkbox"/> 2
c. Nitrates, including nitroglycerine, or other coronary vasodilator	<input type="checkbox"/> 1 306 452	<input type="checkbox"/> 2 453
d. Propranolol or other beta blockers for other than treatment of blood pressure (excluding eye drops containing beta-blockers)	<input type="checkbox"/> 1	<input type="checkbox"/> 2 307
e. Eye drops containing beta-blockers	<input type="checkbox"/> 1 308 454	<input type="checkbox"/> 2
f. Anti-arrhythmic drugs	<input type="checkbox"/> 1	<input type="checkbox"/> 2 309
g. HMG CoA reductase inhibitors (e.g., Lovastatin, Mevicor)	<input type="checkbox"/> 1 465 645	<input type="checkbox"/> 2 455
h. Other lipid-lowering drugs, including clofibrate, cholestyramine, colestipol, nicotinic acid, etc.	<input type="checkbox"/> 1 507 714	<input type="checkbox"/> 2
i. Agents for gout, including probenecid, allopurinol or colchicine	<input type="checkbox"/> 1	<input type="checkbox"/> 2 311 457
j. Insulin	<input type="checkbox"/> 1 312 458	<input type="checkbox"/> 2
k. Oral hypoglycemic agents	<input type="checkbox"/> 1	<input type="checkbox"/> 2 313 459
l. Anticoagulants	<input type="checkbox"/> 1 314 460	<input type="checkbox"/> 2
m. Antibiotics or anti-infection agents	<input type="checkbox"/> 1	<input type="checkbox"/> 2 315 461
n. Cortisone or other gluco corticoids	<input type="checkbox"/> 1 316 462	<input type="checkbox"/> 2
o. Amphetamines or other stimulant	<input type="checkbox"/> 1	<input type="checkbox"/> 2 317 463
p. Flurazepam or other sedative	<input type="checkbox"/> 1 318 464	<input type="checkbox"/> 2
q. Anti-depressants	<input type="checkbox"/> 1	<input type="checkbox"/> 2 319 465
r. Librium, valium or other antianxiety agents	<input type="checkbox"/> 1	<input type="checkbox"/> 2
s. Other psychotropic agents	<input type="checkbox"/> 1 320 466	<input type="checkbox"/> 2 321 467
t. Potassium supplementation other than dietary recommendations	<input type="checkbox"/> 1 322 468	<input type="checkbox"/> 2
u. Estrogen	<input type="checkbox"/> 1	<input type="checkbox"/> 2 323 469
v. Anturane [®] (Sulfinpyrazone) at least 4 weeks	<input type="checkbox"/> 1 324 470	<input type="checkbox"/> 2
w. Persantine [®] (Dipyridamole) at least 4 weeks	<input type="checkbox"/> 1	<input type="checkbox"/> 2 325 471
x. Aspirin at least 4 weeks	<input type="checkbox"/> 1 326 472	<input type="checkbox"/> 2
y. Non-steroidal anti-inflammatory drugs	<input type="checkbox"/> 1	<input type="checkbox"/> 2 327 473
z. Any experimental drug	<input type="checkbox"/> 1 328 474	<input type="checkbox"/> 2

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. For home and telephone visits, the participant should be asked to estimate their own height and weight; the remainder of the physical examination may be omitted.

64. Weight in pounds: **475-477** **329** 65. Height in inches: **478-479** **330**

Area Examined	Comments
66. SKIN ⁴⁵⁰ 331 Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2	
67. HEAD, EARS, NOSE, THROAT ⁴⁵¹ 332 Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2	
68. EYES	
Fundi:	a. Abnormal <input type="checkbox"/> 1 333 452 Normal <input type="checkbox"/> 2 Not Visualized <input type="checkbox"/> 3
Other (Specify)?	b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 334 453

POSSIBLE SIDE EFFECTS--May not be re-phrased. If the participant has been off of SHEP medications more than six months, skip to Item 63.

Since your last visit, have you had:	(a)	(b) 1=Yes 2=No	New since last visit? Frequency:			Severity:			In the opinion of the SHEP clinician, is this due to the use of SHEP medications?
			(c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	(d) 1=Not troublesome 2=Troublesome 3=Intolerable	(e) 1=Yes 2=Possibly 3=No				
31. Unusual coldness or numbness of the hands or feet?	275 (129)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(130) 276	(131) 277	(132) 278	(133) 279			
32. Unusual skin rash or bruising?	280 (134)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(135) 281	(136) 282	(137) 283	(138) 284	(f) Is an acute skin rash present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	(139) 285	
33. Any feelings of unsteadiness or imbalance?	286 (140)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(141) 287	(142) 288	(143) 289	(144) 290			
34. Faintness or light headedness when you stand up quickly?	291 (145)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(146) 292	(147) 293	(148) 294	(149) 295	(f) Is there an observable postural drop in blood pressure? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(155) 301	
35. Loss of consciousness or passing out	296 (150)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(151) 297	(152) 298	(153) 299	(154) 300			
36. Falls?	302 (156)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(157) 303	(158) 304	(159) 305	(160) 306		(166) 312	
37. Fractures?	307 (161)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(162) 308	(163) 309	(164) 310	(165) 311	(f) Hip? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (g) Spine? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (h) Forearm? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(167) 313	
38. Unusual pain in any joint?	315 (169)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(170) 316	(171) 317	(172) 318	(173) 319	(f) Are there physical signs of acute arthritis? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	(174) 320	
39. Muscle weakness or cramping?	321 (175)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(176) 322	(177) 323	(178) 324	(179) 325			
40. Excessive thirst?	326 (180)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(181) 327	(182) 328	(183) 329	(184) 330			
41. Loss of appetite?	331 (185)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(186) 332	(187) 333	(188) 334	(189) 335			
42. Nausea or vomiting?	336 (190)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(191) 337	(192) 338	(193) 339	(194) 340			
43. Unusual indigestion?	341 (195)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(196) 342	(197) 343	(198) 344	(199) 345			
44. Change in bowel habits?	346 (200)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(201) 347	(202) 348	(203) 349	(204) 350			

POSSIBLE SIDE EFFECTS (Continued)--May not be re-phrased.

Since your last visit, have you had:	(a)	(b) 1=Yes 2=No	Frequency:				Severity:		In the opinion of the SHEP clinician, is this due to the use of SHEP medications?	
			(c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	(d) 1=Not troublesome 2=Troublesome 3=Intolerable	(e) 1=Yes 2=Possibly 3=No					
45. Tarry black stools or red blood in the stools?	351 (205)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(206) 352	(207) 353	(208) 354	(209) 355				
46. Heart beating unusually fast or skipping beats?	356 (210)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(211) 357	(212) 358	(213) 359	(214) 360				
47. Heart beating unusually slow?	361 (215)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(216) 362	(217) 363	(218) 364	(219) 365				
48. Episodes of chest pain or heaviness in the chest?	366 (220)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(221) 367	(222) 368	(223) 369	(224) 370	(225) 371			(f) Is an arrhythmia present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3
49. Headaches so bad you had to stop what you were doing?	372 (226)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(227) 373	(228) 374	(229) 375	(230) 376				
50. Stuffy nose?	377 (231)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(232) 378	(233) 379	(234) 380	(235) 381				
51. Unusual shortness of breath or wheezing?	382 (236)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(237) 383	(238) 384	(239) 485	(240) 386	(241) 387			(f) Is there evidence for bronchospasm on auscultation of the chest? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3
52. Unusual tiredness or loss of pep?	388 (242)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(243) 389	(244) 390	(245) 391	(246) 392	(247) 393			
53. Swelling of the ankles?	393 (247)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(248) 394	(249) 395	(250) 396	(251) 397	(252) 398			(f) Is there evidence of CHF on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3
54. Feeling so depressed (sad or blue) that it interfered with your work, recreation or sleep?	399 (253)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(254) 400	(255) 401	(256) 402	(257) 403				
55. Any trouble with your memory or concentration?	404 (258)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(259) 405	(260) 406	(261) 407	(262) 408				
56. Nightmares?	409 (263)	Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(264) 410	(265) 411	(266) 412	(267) 413				

POSSIBLE SIDE EFFECTS (Continued)--May not be re-phrased.

Since your last visit, have you had:	(a)	(b) 1=Yes 2=No	(c) Frequency:				(d) 1=Not 2=Troublesome 3=Intolerable	(e) 1=Yes 2=Possibly 3=No	In the opinion of the SHEP clinician, is this due to the use of SHEP medications?
			1=once only	2=<weekly	3=2-6 x weekly	4=daily			
57. Any changes in your sexual activity?	414 (268) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(269) 415 (270) 416	(271)	417	(272)	418	419	(273) (f) Loss of interest Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (g) Decline in frequency? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (h) Loss of enjoyment? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (i) Functional impairment? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	
58. Trouble going to sleep, or waking early and having trouble getting back to sleep?	423 (277) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(278) 424 (279) 425	(280)	426	(281)	427	422	(274) 420	
59. Waking up in the night more frequently to urinate?	428 (282) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(283) 429 (284) 430	(285)	431	(286)	432			
60. More worry or anxiety than usual?	433 (287) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(288) 434 (289) 435	(290)	436	(291)	437			
61. Weakness or numbness on one side, or unexpected difficulties talking or thinking?	438 (292) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(293) 439 (294) 440	(295)	441	(296)	442	(f) Is there evidence of a stroke on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3	(297) 443	
62. Other relevant symptoms: Specify:	444 (298) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(299) 445 (300) 446	(301)	447	(302)	448	(f) Are there other relevant signs on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3 Specify: _____	(303) 449	

PHYSICAL EXAMINATION (Continued)

Area Examined	Comments
<p>69. NECK</p> <p>Raised jugular venous pressure? a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (335) 484</p> <p>Carotid bruits? b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (336) 485</p> <p style="padding-left: 100px;">↓</p> <p>c. Right only <input type="checkbox"/> 1 (337) 486 Left only <input type="checkbox"/> 2 Bilateral <input type="checkbox"/> 3</p> <p>Carotid pulses absent or markedly diminished? d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (338) 487</p> <p style="padding-left: 100px;">↓</p> <p>e. Right only <input type="checkbox"/> 1 (339) 488 Left only <input type="checkbox"/> 2 Bilateral <input type="checkbox"/> 3</p> <p>Thyroid abnormality? f. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (340) 489</p> <p>Other (Specify)? g. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (341) 490</p>	
<p>70. LYMPH NODES 491 (342) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2</p>	
<p>71. CHEST, LUNGS</p> <p>Bilateral rales that do not clear with coughing? a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (343) 492</p> <p>Respiratory rate 20+ (344) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 493</p> <p>Wheezing? c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (345) 494</p> <p>Other (Specify)? 495 (346) d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>72. HEART</p> <p>PMI more than 2 centimeters lateral to midclavicular line? 496 a (347) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any murmur? b (348) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 497</p> <p>Third heart sound? 398 c (349) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Fourth heart sound? d (350) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 499</p> <p>Pulse irregular? 500 e (351) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? f (352) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 501</p>	
<p>73. BREASTS 502 (353) Abnormal <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2</p>	
<p>74. ABDOMEN</p> <p>Liver span 10 cm or more? 503 (354) a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Abnormal abdominal pulse? 504 (355) b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any masses? c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (356) 505</p> <p>Bruit? 506 (357) d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Other (Specify)? e. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (358) 507</p>	

PHYSICAL EXAMINATION (Continued)

Area Examined	Comments
<p>75. EXTREMITIES</p> <p>Pitting ankle edema? a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 359 508</p> <p>Femoral bruit? 509 360 b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p> <p>Any peripheral pulses absent or markedly diminished (specify location)? 511 361 c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 510</p> <p>Other (Specify)? 362 d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2</p>	
<p>76. NEUROLOGICAL (UA = unable to assess)</p> <p><u>Gait</u></p> <p>Left hemiparetic? 513 363 a. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 512</p> <p>Right hemiparetic? 364 b. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Walking on toes</u></p> <p>Left weakness? 514 365 c. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 515</p> <p>Right weakness? 366 d. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Walking on heels</u> 516</p> <p>Left weakness? 367 e. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right weakness? 368 f. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 517</p> <p><u>Stationary 30 seconds</u></p> <p>Eyes closed? 518 369 g. Can do <input type="checkbox"/> 1 Cannot do <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Eyes open (only if unable to do with eyes closed) 370 519 h. Can do <input type="checkbox"/> 1 Cannot do <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Cranial nerves</u> 520</p> <p>Facial weakness left? 371 i. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Facial weakness right? 372 j. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Visual field deficit</u> 521</p> <p>Left side? 522 373 k. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Right side? 374 l. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 523</p> <p><u>Motor wrist extensors</u> 524</p> <p>Weakness left? 375 m. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p>Weakness right? 376 n. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 525</p> <p><u>Coordination</u> 527</p> <p>Left hand patting? 378 o. Slowed <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 377 526</p> <p>Right hand patting? 378 p. Slowed <input type="checkbox"/> 1 Normal <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Reflexes</u></p> <p>Assymetry of Patellar tendon 528 379 q. L>R <input type="checkbox"/> 1 Equal <input type="checkbox"/> 3 R>L <input type="checkbox"/> 2 UA <input type="checkbox"/> 4</p> <p>Babinski sign left? 381 r. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3 380 529</p> <p>Babinski sign right? 381 s. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 UA <input type="checkbox"/> 3</p> <p><u>Other</u> 530</p> <p>Any speech or language problems (specify)? 382 t. Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 531</p>	

77. OTHER PHYSICAL FINDINGS (SPECIFY):

78. Clinician's signature: _____

532-533

383

Code

CLINICIAN'S JUDGMENT AND ENDPOINT 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 endpoint determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study endpoint questions are identified with . These questions must all be covered prior to termination of this visit. Pertinent items on the Medical History (SH44) are listed with the section headings. The "DK" option should be used only for home and telephone visits when pertinent information is not available.

Angina Pectoris - SH44 Items 3, 12

79. On the basis of your history and/or physical exam, do you believe that the participant has angina pectoris?

384 534

Yes 1 No 2 DK 3



Note: The Rose Questionnaire for angina (from SH44) is positive if:

Either 12a or 12b is "Yes,"
 and either 12c or 12d is "Yes,"
 and 12e is "Stop or slow down,"
 and 12f is "Yes,"
 and 12g is "10 minutes or less,"
 and either 12h(1) is "Yes," (X placed in sternum upper, middle or lower) or both 12h(2) and 12h(3) are "Yes"
 (X in both left anterior chest and in left arm).

Myocardial Infarction (MI) - SH44 Items 2, 13, 14, 24, 25

80. a. On the basis of the ECG and/or your history and physical examination, do you believe the participant has had a myocardial infarction in the past year?

385 535

Yes 1 No 2 DK 3



SKIP to 81.

b. When was the most recent possible myocardial infarction?

386 536-537 538-539 387
 Month Year

81. a. Is there a history of coronary bypass in the past year?

388 540

Yes 1 No 2 DK 3



SKIP to 82.

b. Month and year of surgery:

389 Month Year 390

Congestive Heart Failure - SH44 Item 17

82. On the basis of your history and/or physical examination, do you believe that the participant has had congestive heart failure during the past year? 391 1 Yes, controlled 2 Yes, not controlled 3 No 4 DK 545

ECG

83. Was an ECG performed this visit? 392 Yes 1 No 2 546
↓
SKIP to 85.

84. Are any of the following present?
 a. Atrial fibrillation or flutter? 548 393 Yes 1 No 2 547
 b. Second or third degree A-V block? 394 Yes 1 No 2
 c. VPBs--multifocal, pairs or runs, or more than 10% of beats? 550 395 Yes 1 No 2 549
 d. Bradycardia (<50 beats/min.)? 396 Yes 1 No 2

85. Does the participant currently have a pacemaker? Yes 1 No 2 DK 3 397 551

Vascular System - SH44 Items 15, 18, 24, 25

86. a. Is there a history of vascular surgery in the past year? 552 398 Yes 1 No 2 DK 3 551
↓
SKIP to 87.

b. Aortic, iliac, popliteal or femoral bypass or graft? 553 399 Yes 1 No 2
 c. Angioplasty? 400 Yes 1 No 2 554
 Which vessel(s)? _____
 d. Other (Specify) _____ 555 401 Yes 1 No 2

87. On the basis of your history and/or physical examination, does the participant have arterial disease with tissue necrosis or related loss of an extremity? 556 402 Yes 1 No 2 DK 3 558

Note: The Rose Questionnaire for intermittent claudication (from SH44) is positive if:
 15a is "Yes"
 and 15b is "No"
 and 15c is "Yes"
 and either 15d or 15e is "Yes"
 and 15f is "No"
 and 15g is "Stop or slow down"
 and 15h is "Yes"
 and 15i is "10 minutes or less"

Pulmonary - SH44 Items 16, 17

88. On the basis of the history and/or physical examination, does the participant have:
 a. Chronic bronchitis? 557 403 Yes 1 No 2 DK 3 558
 b. Emphysema? 404 Yes 1 No 2 DK 3

CLINICIAN'S JUDGMENT (Continued)

96. Do you believe that the participant has had a problem with frequent falls in the past year?

417 Yes 1 No 2 DK 3
573

Other

97. Alcohol--on the basis of your history and/or 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 year?

418 Yes 1 No 2 DK 3
574

98. Dementia--on the basis of your history and physical examination, do you believe the participant definitely has any form of dementia?

419 Yes 1 No 2 DK 3
575

99. a. Has the participant had cancer (except basal cell cancer) diagnosed within the past year?

420 Yes 1 No 2 DK 3
576

↓
SKIP to 100.
↓

b. What was (were) the primary sites?

100. Other than possible stroke, TIA, left ventricular failure, myocardial infarction and vascular surgeries, was the participant hospitalized or admitted to an intermediate or skilled care nursing home in the past year?

421 Yes 1 No 2 DK 3 
577

101. On the basis of your history and/or physical examination is there any other life-threatening disease, or any other reason which might seriously impair the individual's participation in the SHEP over the next year?

422 Yes 1 No 2 DK 3
578

Specify: _____

102. Comments: _____

103. Clinician's signature: _____ 579-580 423 Code

For new possible strokes, acute myocardial infarctions, left ventricular failures, and transient ischemic attacks, obtain complete hospital/physician visit record for that event. For new other hospitalizations and new admissions to skilled or intermediate care nursing homes, obtain discharge summary or admission record only. Have participant sign consent to obtain medical records. Fill out Form SH20, Initial Report of Morbid Event.

MEDICATION REVIEW

104. a. Were any SHEP blinded medications prescribed at the last visit? (466) Yes 1 No 2
646 ↓ Go to 105a.
- b. Were all SHEP blinded medications discontinued since the last visit? (467) Yes 1 No 2 DK 3
647 ↓ Go to 105a.
- c. Were there any other changes made in the SHEP blinded medications since the last visit?
 (Specify _____) (468) Yes 1 No 2 DK 3
648
105. a. Were open-label antihypertensive medications prescribed at the last visit (any source)? (469) Yes 1 No 2 DK 3
649 ↓ Go to 106a.
- b. Were open-label antihypertensive medications prescribed since the last visit (any source)? (470) Yes 1 No 2 DK 3
650

BLOOD PRESSURE REVIEW - Goal SBP: _____ BP today: _____ Last visit: _____

Please review the attached chart for treatment and scheduling decision based on blood pressure status.

106. a. Has the participant reached escape blood pressure at this visit? 651 (471) Yes 1 No 2 DK 3
↓ Go to 107a.
- b. List the escape blood pressure sequence:

	Month	Day	Year	SBP	DBP
Visit 1	(472) 652-657			(473)	(474)
Visit 2	(475) 664-669			(476)	(477)
Visit 3	(478) 676-681			(479)	(480)

field 473: 658-660
 field 474: 661-663
 field 476: 670-672
 field 477: 673-675
 field 479: 682-684
 field 480: 685-687

107. a. Will you be prescribing SHEP medications according to the prescribed SHEP blood pressure treatment regimen at this visit? 688 **481** Yes 1 No 2 DK 3
- b. Will you be prescribing open-label antihypertensive medications at this visit? 689 **482** Yes 1 No 2 DK 3

If Item #107a is "Yes" and Item #107b is "No," skip to #108.

Reasons (check all that apply):

- c. Participant has reached escape blood pressure at this visit or a previous visit 690 **483** Yes 1
- d. Possible or probable side effects in the judgment of the SHEP clinician 691 **484** Yes 1 **485** 692
- e. Perceived side effects in the judgment of the participant 693 **486** Yes 1 **487** 694
- f. Stroke 695 **488** Yes 1 **489** 696
- g. MI 697 **490** Yes 1 **491** 698
- h. LVF 699 **492** Yes 1 **493** 700
- i. Angina
- j. Other medical (specify) _____
- k. Participant refusal or preference
- l. Private MD request
- m. Other (specify) _____

MEDICATION PRESCRIPTION AND SCHEDULING

108. Medication prescription last visit:

- a. Step 1 C1 1
C2 2 **494** 701
 $\frac{1}{2}$ C1 3
Other C _____ 4
No Step 1 (go to 108c) 5
- b. Step 1 bottle number **441** 598
- c. Step 2 A1 1
A2 2 **495** 702
Other A _____ 3
R Dose 1 4
R Dose 2 5
Other R _____ 6
No Step 2 (go to 108e) 7
- d. Step 2 bottle number **602-604** **443**
- e(1) Open-label drugs (specify drug and dose) Yes 1 No 2 DK 3 **496** 703

↓ ↓
 Go to 108f.
- e(2) Source of open-label drugs Prescribed by SHEP 1 **497** 704
Prescribed by other source 2
Both 3
- f(1) K supplement 705 **498** Yes 1 No 2 DK 3
↓ ↓
 Go to 108g.
- f(2) Meq/day (unknown = 99) 706 **499** 1 2 3 **607-608** **446**
- g. Uric acid drug (specify drug and dose) Yes 1 No 2 DK 3

109. Medication prescription this visit:

610 (448) No change (go to 110) 1

a. Step 1

707 (500) C1 1
C2 2
1/2 C1 3

Other C 4
No Step 1 (go to 109c) 5

612-614 (450)

b. Step 1 bottle number

c. Step 2

708 (501) A1 1
A2 2

Other A 3
R Dose 1 4
R Dose 2 5

Other R 6
No Step 2 (go to 109e) 7

616 (452)

d. Step 2 bottle number

e(1) Open-label drugs (specify drug and dose) (502) Yes 1 No 2 DK 3

709 Go to 109f.

e(2) Source of open-label drugs

Prescribed by SHEP 1 (710)
Prescribed by other source 2 (503)
Both 3

f(1) K supplement

Yes 1 No 2 DK 3 (504)

Go to 109g. 711

f(2) Meq/day (unknown = 99)

621-622 (455)

g. Uric acid drug (specify drug and dose) 712 (505) Yes 1 No 2 DK 3

110. Schedule:

626 (458) RECORD TYPE 642 (462) PAPER COPY Next quarterly 1 (506)
One month 2
1-2 weeks 3
1 week 4 713
Other (specify) 5

111. Comments

633 (465) UPDATE NUMBER 643 (463) CROSS FORM
EDIT STATUS CODE

636-640 (461) DATE LAST PROCESSED

112. Signature of Clinician completing this section: 491 624-625 Code

BEHAVIORAL EVALUATIONS

The participant should now be administered:

- SHEP SHORTCARE (SH30, SH36)
- Social Network (SH34)
- Activities of Daily Life (SH33)
- Behavioral Evaluation--Part II (SH35)

 Combinations 1-8 assume DBP < 90 mm Hg at this visit:

SBP [1] at Consecutive Visits On Same Step & Dose		On Maximum SHEP Meds?	Prescription This Visit [2]	Schedule [3]
Visit 1	Visit 2			
1	<=110 [4]		SD [5]	CD
2	111-goal	111-goal	N	NC
3	111-189	111-189	Y	NC
4	>goal-219	220-239	N	SU
5	>goal-239	>goal-219	N	SU
6	220-239	220-239	N Y	SU [5] OL [5]
7	>=240 [4]		OL [5]	CD
8	Other		NC	SBP 111-219 ->1M SBP 220-239 ->2W

 For DBP < 90 mm Hg this visit, skip Combinations 9-14.

DBP [1] at Consecutive Visits On Same Step & Dose			On Maximum SHEP Meds?	Prescription This Visit [2]	Schedule [3]
Visit 1	Visit 2	Visit 3			
9	90-94	90-94	N	SU [5]	1M
10	90-94	95-114	N	SU [5]	1-2W
11	90-94	90-114	>= 90	Y	OL [5]
12	95-114	95-114	N Y	SU [5] OL [5]	1-2W CD
13	115+ [4]			OL [5]	CD
14	Other			NC	DBP 90- 94 ->1M DBP 95-114 ->1-2W

- [1] Average of two seated corrected readings
 [2] OL = open label, SU = step up, SD = step down at clinician discretion
 [3] W = weeks, M = month, Q = next quarterly, CD = clinician discretion
 [4] Any single visit
 [5] Escape blood pressure reached

If DBP >=90 mm Hg at this visit, treatment prescribed this visit should reflect the largest change in medication prescribed above for the appropriate blood pressure levels. For example, the choice between "No Change" and "Step Up" should be "Step Up"; the choice between "Step Up" and "Open Label" should be "Open Label". The next visit should be scheduled according to the shortest suggested interval.

For additional detail on specific blood pressure combinations, refer to the SHEP Manual of Operations, Chapter 3.