30-32 (1) FORM NUMBER

33 (2) VERSION NUMBER

40 (518) SEQUENCE

CLINIC VISIT DOCUMENTATION

This form is to be used to document all clinic visits, and acts as a directory to all study procedures that are required at each visit.

Name: _____

1. SHEP ID: (3) 22-23 - (4) 24-27 - (5) 28-29

2. Acrostic: (6) 41-46

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

4. Sequence number: 47-48 (8)

5a. Type of visit: 49 (9)
- 1 ☐ One-month
- 2 ☐ Two-month
- 3 ☐ Quarterly
- 4 ☐ Other interim → 5b.

5b. Reason: 50 (10)
- 1 ☐ SBP or DBP at escape last visit
- 2 ☐ SBP above goal but not at escape levels last visit
- 3 ☐ Potassium re-check (local)
- 4 ☐ Other problem last visit (specify): _____
- 5 ☐ Medication refill only
- 6 ☐ Requested by participant
- 7 ☐ Other (specify): _____

6. Place of visit: 51 (11)
- 1 ☐ Clinic
- 2 ☐ Other

↓ Specify _____

7. Were Step I medications started or increased at last visit? 52 (12) 1 ☐ Yes 2 ☐ No

8. Were Step II medications started or increased at last visit? 53 (13) 1 ☐ Yes 2 ☐ No

Refer to following chart in determining procedures required at this visit.

	Procedure	Form	Comments	Required This Visit?	Done This Visit?
9.	Pulse, BP, Weight	SH08	Required every visit except telephone visits.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (14)
10.	Dipstick urinalysis	SH11	As required in clinician's judgment.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (15)
11.	Blood, central	SH12	Serum potassium required after Step 1 start or increase.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (16)
12.	Other lab work, local	SH11	As required in clinician's judgment; serum potassium re-check.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (17)
13.	Compliance	SH40	Required at visit after medications started or increased, and semi-annually.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (18)
14.	General well-being	SH41	Required every visit.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (19)
15.	Specific side effects	SH42	Required at visit after medications started or increased, and in response to any "Yes" on General Well-Being (SH41).	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (20)
16.	Medication and Scheduling Decision	SH43†	Required every visit except telephone visits.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (21)
17.	SHORTCARE/CES-D	SH30	Required quarterly.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (22)
18.	Social Network	SH34	Required at one-month visit.	Yes ☐ No ☐	Yes ☐ 1 No* ☐ 2 (23)

*Procedures required but not completed should be explained in Comments, Item 21.

†Fill in SHEP medication prescription at last visit (SH43, Item 16).

fields 14-23: 54-63

Review Items 20 and 21, and schedule next clinic visit (Item 22) at the termination of this visit, before participant leaves the SHEP Clinic.

19. a. Pulse: Beats in 30 seconds _____ x 2 = (24) 64-66 beats per minute.

b. Blood pressure:

Cuff Size:

(25) 67
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	(26) 68-70	(27) 71-73
Zero level	(28) 74-75	(29) 76-77
Corrected	(30) 78-80	(31) 81-83
+ Second	(32) 84-86	(33) 87-89
+ Zero level	(34) 90-91	(35) 92-93
+ Corrected	(36) 94-96	(37) 97-99
Sum of two corrected readings	(38) 100-102	(39) 103-105
Average of two corrected readings	(40) 106-108	(41) 109-111

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

(42) x 4 = 112-114 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(43) 115-117	(44) 118-120
Zero	(45) 121-122	(46) 123-124
Corrected	(47) 125-127	(48) 128-130

Three minutes

Pulse: Beats in 15 seconds _____

(49) x 4 = 131-133 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(50) 134-136	(51) 137-139
Zero	(52) 140-141	(53) 142-143
Corrected	(54) 144-146	(55) 147-149

c. Did the participant volunteer any symptoms on standing? (56) Yes ☐ 1 No ☐ 2 (150)

(1) Dizziness? Yes ☐ 1 (57) No ☐ 2 (151)

(2) Other (specify)? Yes ☐ 1 (58) No ☐ 2 (152)

_____

SKIP to 19d

d. Weight: (59) 153-155 pounds

e. Observer signature: _____ (60) 156-157 Code

Other procedures required at this visit should now be completed, in the order listed on the front of this form.

20. Action required as a result of this visit: (61) 1 ☐ None of 20a-20g required this visit (158)

a. (62) 1 ☐ Initial Notification of Morbid Event, SH20 (159)

b. (63) 1 ☐ Neurologic Exam for Stroke , SH27 (160)

c. (64) 1 ☐ Neurologic Exam for TIA, SH28 (161)

d. (65) 1 ☐ Deviation from Protocol, SH48 (162)

e. (66) 1 ☐ Dementia Referral, SH31 (163)

f. (67) 1 ☐ Depression Referral, SH32

g. (68) 1 ☐ Report of Unblinding, SH49 (165)

(164)

21. Comments on this visit: (166) (69) 01

_____

_____

_____

22. Next clinic visit: (70) (169 170) Month ☐☐ (171-172) Day ☐☐ (167 168) Year ☐☐ at (71) (173-176) Hour ☐☐ : Minute ☐☐ (177) (72) 1 ☐ a.m. 2 ☐ p.m.

If the next scheduled visit is an annual visit, participant may take home the Annual Medical History and Annual Medication and Habits History.

178 (73) RECORD TYPE

179-184 (74) DATE RECEIVED

185-187 (75) UPDATE NUMBER

188-193 (76) DATE LAST PROCESSED

194 (77) PAPER COPY

195 (78) **Cross-Forms Edit Status**

BATCH DATE (514) 3-8

DATE MODIFIED (515) 11-16

TIME MODIFIED (516) 17-20

EDIT STATUS (517) 21

30-32 (1) FORM NUMBER

40 (518) SEQUENCE

33 (2) VERSION NUMBER

SHEP CLINIC VISIT

Name (3) (4) (5) (6)

1. SHEP ID: 22-23 - 24-27 - 28-29

2. Acrostic: 41-46

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

4. Sequence number: (8) 47-48

5. Type of visit: 196 (79)
   1 ☐ Quarterly (Skip to 8)
   2 ☐ Other required (Skip to 8)
   3 ☐ Interim

6. Visit scheduled: 197 (80)
   1 ☐ by SHEP Clinic
   2 ☐ at participant's request

7. Reason for visit (check all that apply): 198 (81)
   a. 1 ☐ BP check
   b. 1 ☐ Potassium re-check (local) 199 (82)
   c. 1 ☐ Possible side effects 200 (83)
   d. 1 ☐ Other (Specify in Comments, Item 12) 201 (84)

8. Place of visit: 51 (11)
   1 ☐ Clinic
   2 ☐ Home
   3 ☐ Telephone

9. a. Were Step 1 medications started or increased at last visit? 1 ☐ Yes 2 ☐ No (12) 52
   b. Were Step 2 medications started or increased at last visit? 1 ☐ Yes 2 ☐ No (13) 53

10. Refer to following chart in determining procedures required at this visit.

Procedure	Check if Required This Visit	Comments	Done This Visit? Yes	No
a. Pulse, BP, Weight	☐	Every visit except telephone visits.	☐ 1	☐ 2
b. Blood, central	☐	Serum potassium required at visit after Step 1 start or increase.	☐ 1	☐ 2
c. Local lab work (SH?	☐	As required in clinician's judgment; serum potassium re-check.	☐ 1	☐ 2
d. Compliance (SH40)	☐	Required at visit after SHEP medications started or increased, and semi-annually. Do not administer if SHEP medications were not prescribed at the last visit. Circle correct SHEP prescription in Items 9 and 12 on SH40.	☐ 1	☐ 2
e. General well-being	☐	Required every visit.	☐ 1	☐ 2
f. Specific side effects (SH42)	☐	Required at next regularly scheduled visit after SHEP medications started or increased, at interim visits for possible side effects, and in response to a "Yes" to Item 28b in the General Well-Being section. Do not administer if participant has been off of SHEP medications more than six months.	☐ 1	☐ 2
g. Protocol Review	☐	Required every visit. Fill in SHEP medication prescription at last visit (Item 12) prior to visit.	☐ 1	☐ 2
h. SHORTCARE/CES-D (SH30)	☐	Required quarterly. Do not administer over the telephone. Also required if the Behavioral Evaluation--Part II is being administered.	☐ 1	☐ 2
i. Social Network (SH34)	☐	Required at one-month after randomization. Do not administer over the telephone.	☐ 1	☐ 2
j. Behavioral Evaluation--Part I	☐	Required at next regularly scheduled visit after an annual visit, if not already administered at annual visit, in participating centers. Cannot be administered over the telephone.	☐ 1	☐ 2

54 (14) 56 (16) 58 (18) 57 (17) 59 (19) 202 (85) 60 (20) 62 (22) 63 (23) 203 (86)

REVIEW ITEMS 10 THROUGH 12, AND SCHEDULE NEXT CLINIC VISIT (ITEM 13) AT THE TERMINATION OF THIS VISIT, BEFORE THE PARTICIPANT LEAVES THE SHEP CLINIC. CHECK TO BE SURE THAT THE PARTICIPANT'S ID AND ACROSTIC ARE CORRECT--THE ACROSTIC SHOULD BE THE SAME AS THE ACROSTIC ON THE SH06. BE SURE THAT ALL REQUIRED SECTIONS OF THIS FORM ARE 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 12.

11. Action required as a result of this visit (61) 158
   1 ☐ None of 11a-11g required this visit.
   159 (62) a. 1 ☐ Initial Notification of Morbid Event, SH20
   b. 1 ☐ SHEP Neurological Evaluation for Strokes, SH27 (63) 160
   161 (64) c. 1 ☐ SHEP Neurological Evaluation for TIA, SH28
   d. 1 ☐ Dementia Referral, SH31 (65) 162
   163 (66) e. 1 ☐ Depression Referral, SH32
   f. 1 ☐ Deviation from Protocol, SH48 (67) 164
   165 (68) g. 1 ☐ Report of Unblinding, SH49

12. Comments on this visit: _____ 171-172 (71) 173-176

13. Next clinic visit: 167-172 (70) Month 169-170 Day Year 167-168 at Hour : Minute 1 ☐ a.m. 2 ☐ p.m. (72) 177

14. Signature of person reviewing this page: _____ Code (87) 204-205

If the next scheduled visit is an annual visit, participant may take home the Annual Medical, Medication and Habits History (SH44).

PULSE AND BLOOD PRESSURE--If any pulse or blood pressure or the participant's weight is not obtained, enter all 9s in the appropriate spaces. If this is a telephone visit, leave cuff size and Item 15c blank.

15. a. Pulse: Beats in 30 seconds (24) x 2 = 64-66 beats per minute.

b. Cuff Size: (25) 67

1 ☐ Regular
2 ☐ Large arm
3 ☐ Thigh
4 ☐ Pediatric

Pulse Obliteration Pressure:

Observed Value:	(88)	206-208
Subtract Zero Level:	(89)	209-210
Corrected Value:		211-213 (90)
Add Maximum Zero Level Plus 20:	(91)	214-215
Peak Inflation Level:	(92)	216-218

Seated Readings:

	Systolic	Diastolic
First	(26) 68-70	(27) 71-73
Zero level	(28) 74-75	(29) 76-77
Corrected	(30) 78-80	(31) 81-83
Second	(32) 84-86	(33) 87-89
Zero level	(34) 90-91	(35) 92-93
Corrected	(36) 94-96	(37) 97-99
Sum of two corrected readings	(38) 100-102	(39) 103-105
Average of two corrected readings	(40) 106-108	(41) 109-111

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

(42) x 4 = 112-114 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(43) 115-117	(44) 118-120
Zero	(45) 121-122	(46) 123-124
Corrected	(47) 125-127	1289-130 (48)

Three minutes

Pulse: Beats in 15 seconds _____

(49) x 4 = 131-133 beats per minute.

Blood Pressure:	Systolic	Diastolic
Reading	(50) 134-136	137-139 (51)
Zero	(52) 140-141	142-143 (53)
Corrected	(54) 144-146	147-149 (55)

(If standing blood pressure not done, skip to 15d.)

c. Did the participant volunteer any symptoms on standing? Yes ☐ 1 No ☐ 2 (56) 150

(1) Dizziness 151 (57) Yes ☐ 1 No ☐ 2

(2) Other (specify)? _____ (58) 152 Yes ☐ 1 No ☐ 2

↓ SKIP to 15d.

d. Weight: [ ] pounds (59) 153

e. Observer signature: _____ [ ] (60) 154 Code

COMPLIANCE EVALUATION

Interviewer: If any SHEP medication was started or increased at the last clinic visit, or if this is a semi-annual visit, the compliance evaluation (SH40) should be administered (refer to Items 9a, 9b and 10d). Do not administer if SHEP medications were not prescribed at the last visit. If required, administer the compliance evaluation and then return to this form.

GENERAL WELL-BEING - Interviewer: Questions in this section are to be asked at every visit; use phraseology that you are comfortable with.

16. Have you felt unwell in any way since your last clinic visit; has anything been bothering you? (Specify): _____ (93) 219 Yes □ 1 No □ 2 → Go to 18.

17. Are any of these problems different from the way things were at your last clinic visit? (94) 220 Yes □ 1 No □ 2

18. Since your last visit, have you seen a doctor for any reason? (Specify): _____ (95) 221 Yes □ 1 No □ 2

19. Since your last visit, have you been in the hospital for any reason? (96) 222 Yes □ 1 No □ 2 → Go to 20.

How many times? 223-224 (97)

When? (Start with the first one after your last visit.)

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

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	(98) 225-230	(100) 233-238	(102) 241-246
Date of admission	Month Day Year	Month Day Year	Month Day Year
Number of days	(99) 231-232	(101) 239-240	(103) 247-248
Reason			

20. a. Since your last SHEP visit, have you had any sudden feeling of numbness, tingling or loss of feeling in either arm, hand, leg, foot or face? (104) 249 Yes □ 1 No □ 2 → SKIP to 21.

b. How many attacks of such numbness or tingling have you had? (105) 250 One □ 1 More than one □ 2

c. How long did each of the attack(s) usually last? (106) 251 Less than 24 hours □ 1 More than 24 hours □ 2

21. a. Since your last SHEP visit, have you had any sudden attacks of paralysis or loss of use of either arm, hand, leg or foot? Yes □ 1 No □ 2 (107) 252

↓

SKIP to 22.

b. How many attacks of such paralysis have you had? 253 (108)
One □ 1
More than one □ 2

c. How long did the attack(s) usually last? 254 (109)
Less than 24 hours □ 1
More than 24 hours □ 2

22. a. Since your last SHEP visit, have you had any sudden loss of eyesight or blurring of vision for a short period of time? Yes □ 1 No □ 2 (110) 255

↓

SKIP to 23.

b. What part of your vision was affected? 256 (111)
Right eye only □ 1
Left eye only □ 2
Both eyes □ 3
Vision to the right side □ 4
Vision to the left side □ 5

c. How many attacks of loss of eyesight or blurring of vision have you had? 257 (112)
One □ 1
More than one □ 2

d. How long did the attack(s) usually last? 258 (113)
Less than 24 hours □ 1
More than 24 hours □ 2

23. a. Since your last SHEP visit, have you had any sudden attacks of changes in speech, loss of speech or inability to say words? Yes □ 1 No □ 2 (114) 259

↓

SKIP to 24.

b. How many attacks of loss of speech have you had? 260 (115)
One □ 1
More than one □ 2

c. How long did the attack(s) usually last? 261 (116)
Less than 24 hours □ 1
More than 24 hours □ 2

24. Since your last SHEP visit, have you had any of the following:

a. Dizziness 262 (117) Yes □ 1 No □ 2 263 (118)
b. Spinning sensation (vertigo) Yes □ 1 No □ 2
c. Loss of balance 264 (119) Yes □ 1 No □ 2
d. Difficulty walking Yes □ 1 No □ 2 (120) 265
e. Blackouts or fainting 266 (121) Yes □ 1 No □ 2
f. Frequent falls Yes □ 1 No □ 2 (122) 267

If none of 24a-f are answered "Yes," skip to 25.

g. About how many total attacks of all of these conditions do you think you ever had? 268 (123)
One □ 1
More than one □ 2

h. How long did the attack(s) usually last? 269 (124)
Less than 24 hours □ 1
More than 24 hours □ 2

25. 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 (125) **270**

26. 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? Yes ☐ 1 No ☐ 2 (126) **271**
(Specify): _____

b. Have you increased or decreased any medications that you were taking? Yes ☐ 1 No ☐ 2 (127) **272**
(Specify): _____

c. Have you started taking any new medications? Yes ☐ 1 No ☐ 2 (128) **273**
(Specify): _____

27. Interviewer:
Did the participant bring all non-SHEP medications to the clinic at this visit? **274** (129)

Yes ☐ 1
No ☐ 2
Not on any non-SHEP medications ☐ 3

28. Interviewer:

a. Did the participant volunteer any complaints or problems in Items 16-25? (130) **275** Yes ☐ 1 No ☐ 2

↓

Skip to next section.

b. Are these problems that, in your opinion, may be related to study medications? **276** (131)

Yes ☐ 1
No ☐ 2
Not on SHEP medications ☐ 3

↓

SH42 required

SPECIFIC SIDE EFFECTS (SH42)

Interviewer: The Side Effects Quesionnaire (SH42) is required at the first required visit after SHEP medications are started or increased, in response to a "Yes" to Item 28b, and at interim visits for possible side effects. It is not required under any condition for participants who have been off of SHEP medications more than six months. If required, administer the SH42, and then return to this form.

POSSIBLE EVENTS

29. Are there any positive responses to Items 16-25 or on the Side Effects Questionnaire (SH42)? (132) 277 Yes □ 1 No □ 2 → Go to 33.

30. In the judgment of the SHEP clinician, are any of these positive or abnormal responses a result of:

		Yes	Possibly	No	
278 (133)					
279 (134) a.	Stroke	□ 1	□ 2	□ 3	Arrange for SHEP
b.	Acute myocardial infarction	□ 1	□ 2	□ 3	Neurological Examination
c.	Left ventricular failure (135)	□ 1	□ 2	□ 3	for Stroke (SH27) as soon as possible.
280					
281 (136)					
282 (137) d.	Transient ischemic attack	□ 1	□ 2	□ 3	Arrange for SHEP
e.	Other cardiovascular hospitalization (specify: _____)	□ 1	□ 2	□ 3	Neurological Examination for TIA (SH28) as soon as possible.
f.	Hospitalization for reason other than above (specify: _____)	□ 1	□ 2	□ 3 (138) 283	
g.	Intermediate or skilled care nursing home admission	□ 1	□ 2	□ 3 (139) 284	

31. Was the participant hospitalized or seen by a physician for any event in 30a-30g?

285 (140) Yes □ 1 → No □ 2 Not sure □ 3

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

For any event in 30a-30g checked "Yes" or "Possibly," fill out Form SH20, Initial Report of Morbid Event.

32. Does the participant think that any of these conditions are due to the SHEP medications? 286 (141) Yes □ 1 No □ 2 DK □ 3

33. Comments (note pertinent history and physical exam findings and diagnostic impressions): _____

34. Signature of person completing this section: _____ (142) 287-288 Code

PROTOCOL REVIEW--To be filled out by SHEP Clinician

35. a. At the last visit, were SHEP medications prescribed in dosages specified in the protocol? 1 ☐ Yes 2 ☐ No (143) 289

b. Since the last visit, have SHEP medications been altered to dosages other than prescribed at the last visit? (144) 1 ☐ Yes 2 ☐ No 3 ☐ DK
Specify: _____ 290

_____

c. Since the last visit, have open-label antihypertensive medications been prescribed or taken? (145) 1 ☐ Yes 2 ☐ No 3 ☐ DK
Specify: _____ 291

_____

If 35a is "Yes" and both 35b and 35c are "No" or "DK," skip to 41.

36. Has this deviation already been reported on a Deviation from Protocol form, SH48? (146) 192 1 ☐ Yes 2 ☐ No

↓

Initiate SH48 for this deviation.

_____
Clinic Physician Initial

37. What has happened with respect to the problem which caused this deviation from the protocol?
Comment: _____
_____ 293 (147)
1 ☐ Resolved
2 ☐ Improved
3 ☐ Worse
4 ☐ Unchanged

38. Have any other potentially serious conditions arisen since the last visit which are probably a result of the use of SHEP medications? 294 (148)
1 ☐ Yes
2 ☐ No
3 ☐ Not on SHEP meds

39. 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)? 295 (149) 1 ☐ Yes 2 ☐ No

↓

Skip to 41.

fields 150-154: 296-300

40. Reason: (Check all that apply.)

150 a. 1 ☐ Side effects judged to be severe enough to deviate from protocol

151 b. 1 ☐ Participant has reached escape blood pressure

152 c. 1 ☐ Private MD has prescribed alternative BP therapy

153 d. 1 ☐ Participant request

154 e. 1 ☐ Other (Specify): _____

41. 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? **301** 155

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

→ Skip to 43.

42. a. In the judgment of the SHEP clinician and physician, do any of these responses require deviation from protocol in prescribing SHEP medication? **302** 156 1 ☐ Yes 2 ☐ No

↓

Skip to 43.

b. Are any of these conditions possibly harmful to the participant? **303** 157 1 ☐ Yes 2 ☐ No

Initiate SH48 for Deviation from Protocol.

_____
Clinic Physician Initial

43. Are there reasons other than those in Questions 35-42 that require a deviation from protocol in prescribing SHEP medications (e.g., interference from other medicine, etc.)? 158 **304** 1 ☐ Yes 2 ☐ No

(Specify): _____

↓

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 44 (medication prescription last visit).

MEDICATION PRESCRIPTION--Take into account all of Items 35 through 43 and the participant's blood pressure status.

44. Medication prescription last visit:

a. Step 1: 1 □ C1 3 □ C1, dose ½ (159) 305
2 □ C2 4 □ None (Skip to 44c)

(160) 306-308 b. Bottle #: ____

c. Step 2: 1 □ A1 3 □ R, Dose 1 5 □ None (161) 309
2 □ A2 4 □ R, Dose 2 (Skip to 44e)

d. Bottle #: 310-312 (162)

(163) 313 e. 1 □ Open-label antihypertensives → Specify: _____

f. 1 □ Potassium supplement (164) 314 → g. ____ meq/day (165) 315-316

(166) h. 1 □ Uric acid agent → Specify drug and dose: _____

317

45. Medication prescription this visit: 1 □ No change (167) 318 → Go to 46

a. Step 1: 1 □ C1 3 □ C1, dose ½ (168) 319
2 □ C2 4 □ None (Skip to 45c)

(169) b. Bottle #: 320-322

c. Step 2: 1 □ A1 3 □ R, Dose 1 5 □ None (170) 323
2 □ A2 4 □ R, Dose 2 (Skip to 45e)

d. Bottle #: 324-326 (171)

327 (172) e. 1 □ Open-label antihypertensives Specify: _____

328 f (173) 1 □ Potassium supplement → g. (174) ____ 329-330 meq/day

h. 1 □ Uric acid agent (175) 331 → Specify drug and dose: _____

46. Signature of Clinician completing this section: _____ (176) 332-333

OTHER PROCEDURES

Interviewer: If the SHORTCARE (SH30) or the Social Network Questionnaire (SH34) or the Behavioral Evaluation--Part II (SH35) are required at this visit, they should be administered at this time.

The participant may now be sent for any lab work that may be required at this visit. Document lab work on the front of this form (Items 10b and 10c.)

178 (73) RECORD TYPE PLEASE REVIEW PAGE 1.

179-184 (74) DATE RECEIVED

185-187 (75) UPDATE NUMBER

188-193 (76) DATE LAST PROCESSED

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21 (517) EDIT STATUS

SH08/9

SHEP CLINIC VISIT

Name: (3) (4) (5)

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

3. Today's date: 36 37 (Month) 38 39 (Day) 34 35 (Year) (7)
4. Sequence number: 47-48 (8)

5. Type of visit: (196) (79)
   1 ☐ Quarterly (Skip to 8)
   2 ☐ Other required (Skip to 8)
   3 ☐ Interim

6. Visit scheduled: (197) (80)
   1 ☐ by SHEP Clinic
   2 ☐ at participant's request

30-32 (1) FORM NUMBER
33 (2) VERSION NUMBER
40 (518) SEQUENCE

7. Reason for visit (check all that apply): fields 81-84: 198-201
   a. (81) 1 ☐ BP check
   b. (82) 1 ☐ Potassium re-check (local)
   c. (83) 1 ☐ Possible side effects
   d. (84) 1 ☐ Other (Specify in Comments, Item 12)

8. Place of visit: 51 (11)
   1 ☐ Clinic
   2 ☐ Home
   3 ☐ Telephone

9. a. Were Step 1 medications started or increased at last visit? 1 ☐ Yes 2 ☐ No (12) 52
   b. Were Step 2 medications started or increased at last visit? 1 ☐ Yes 2 ☐ No (13) 53

10. Refer to following chart in determining procedures required at this visit.

Procedure	Check if Required This Visit	Comments	Done This Visit? Yes	No
a. Pulse, BP, Weight	☐	Every visit except telephone visits.	☐ 1	☐ 2 (14) fields 14-20: 54-60
b. Blood, central	☐	Serum potassium required at visit after Step 1 start or increase. (16)	☐ 1	☐ 2
c. Local lab work (SH11)	☐	Local re-check of central laboratory results; as required in clinician's judgment.	☐ 1	☐ 2 (17)
d. Compliance (SH40)	☐	Required at visit after SHEP medications started or increased, and semi-annually. Do not administer if SHEP medications were not prescribed at the last visit. Circle correct SHEP prescription in Items 9 and 12 on SH40. (18)	☐ 1	☐ 2
e. General well-being	☐	Required every visit.	☐ 1	☐ 2 (19)
f. Specific side effects (SH42)	☐	Required at next regularly scheduled visit after SHEP medications started or increased, at interim visits for possible side effects, and in response to a "Yes" to Item 28b in the General Well-Being section. Do not administer if participant has been off of SHEP medications more than six months. (20)	☐ 1	☐ 2
g. Medication and Scheduling Decision	☐	Required every visit. Fill in SHEP medication prescription at last visit (Item 39) prior to visit.	☐ 1	☐ 2 (85) 202
h. SHORTCARE/CES-D (SH30)	☐	Required at the next quarterly visit after SHEP medications are started or increased, and semi-annually. Also required at other quarterly visits if participant reached criterion score at last SHORTCARE but did not qualify for referral at that time. Also required if the Behavioral Evaluation--Part II is being administered. Do not administer over the telephone. (22) 62	☐ 1	☐ 2
i. Social Network (SH34)	☐	Required at one-month after randomization. Do not administer over the telephone.	☐ 1	☐ 2 (23) 63
j. Behavioral Evaluation--Part II	☐	Required at next regularly scheduled visit after an annual visit, if not already administered at annual visit, in participating centers. Cannot be administered over the telephone. (86) 203	☐ 1	☐ 2
k. Activities of Daily Life (SH33)	☐	Required if Behavioral Evaluation--Part II is being administered.	☐ 1	☐ 2 (177) 334

REVIEW ITEMS 10 THROUGH 12, AND SCHEDULE NEXT CLINIC VISIT (ITEM 13) AT THE TERMINATION OF THIS VISIT, BEFORE THE PARTICIPANT LEAVES THE SHEP CLINIC. CHECK TO BE SURE THAT THE PARTICIPANT'S ID AND ACROSTIC ARE CORRECT--THE ACROSTIC SHOULD BE THE SAME AS THE ACROSTIC ON THE SH06. BE SURE THAT ALL REQUIRED SECTIONS OF THIS FORM ARE 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 12.

11. Action required as a result of this visit: (61) 1 ☐ None of 11a-11f required this visit. fields 61-66: 158-163
    a. (62) 1 ☐ Initial Notification of Morbid Event, SH20
    b. (63) 1 ☐ SHEP Neurological Evaluation for Strokes, SH27
    c. (64) 1 ☐ SHEP Neurological Evaluation for TIA, SH28
    d. (65) 1 ☐ Dementia Referral, SH31
    e. (66) 1 ☐ Depression Referral, SH32
    f. (68) 1 ☐ Report of Unblinding, SH49
    165

12. Comments on this visit: _____

13. Next clinic visit: (70) Month ____ Day ____ Year ____ at Hour ____ : Minute ____ 1 ☐ a.m. 2 ☐ p.m. (72) 177
    169-170 171-172 167-168 (71) 173-176

14. Signature of person reviewing this page: _____ Code (87) 204-205

If the next scheduled visit is an annual visit, participant may take home the Annual Medical, Medication and Habits History (SH44).

PULSE AND BLOOD PRESSURE--If any pulse or blood pressure or the participant's weight is not obtained, enter all 9s in the appropriate spaces. If this is a telephone visit, leave cuff size and Item 15c blank.

15. a. Pulse: Beats in 30 seconds _____ x 2 = 64-66 beats per minute.

b. Cuff Size: (25) 67

1 ☐ Regular
2 ☐ Large arm
3 ☐ Thigh
4 ☐ Pediatric

Pulse Obliteration Pressure: (24)

Observed Value:	206-208	(88)
Subtract Zero Level:	- 209-210	(89)
Corrected Value:	211-213	(90)
Add Maximum Zero Level Plus 20:	+ 214-215	(91)
Peak Inflation Level:	216-218	(92)

Seated Readings:

	Systolic		Diastolic	
First	(26)	68-70	(27)	71-73
Zero level	(28)	74-75	(29)	76-77
Corrected	(30)	78-80	(31)	81-83
+ Second	(32)	84-86	(33)	87-89
+ Zero level	(34)	90-91	(35)	92-93
Corrected	(36)	94-96	(37)	97-99
Sum of two corrected readings	(38)	100-102	(39)	103-105
Average of two corrected readings	(40)	106-108	(41)	109-111

Standing Readings:

One minute

Pulse: Beats in 15 seconds _____

(42) x 4 = 112-114 beats per minute.

Blood Pressure:	Systolic		Diastolic	
Reading	(43)	115-117	(44)	118-120
Zero	(45)	121-122	(46)	123-124
Corrected	(47)	125-127	(48)	128-130

Three minutes

Pulse: Beats in 15 seconds _____

(49) x 4 = 131-133 beats per minute.

Blood Pressure:	Systolic		Diastolic	
Reading	(50)	134-136	(51)	137-139
Zero	(52)	140-141	(53)	142-143
Corrected	(54)	144-146	(55)	147-149

(If standing blood pressure not done, skip to 15d.)

c. Did the participant volunteer any symptoms on standing? (56) 150 Yes ☐ 1 No ☐ 2 ↓ SKIP to 15d.

(1) Dizziness Yes ☐ 1 (57) No ☐ 2

(2) Other (specify)? Yes ☐ 1 No ☐ 2 (58)

151 _____ 152

d. Weight: (59) 153-155 pounds

e. Observer signature: _____ (60) 156-157 Code

COMPLIANCE EVALUATION

Interviewer: If any SHEP medication was started or increased at the last clinic visit, or if this is a semi-annual visit, the compliance evaluation (SH40) should be administered (refer to Items 9a, 9b and 10d). Do not administer if SHEP medications were not prescribed at the last visit. If required, administer the compliance evaluation and then return to this form.

GENERAL WELL-BEING - Interviewer: Questions in this section are to be asked at every visit; use phraseology that you are comfortable with.

16. Have you felt unwell in any way since your last clinic visit; has anything been bothering you? (Specify): _____ (93) 219 Yes ☐ 1 No ☐ 2 → Go to 18.

17. Are any of these problems different from the way things were at your last clinic visit? (94) 220 Yes ☐ 1 No ☐ 2

18. Since your last visit, have you seen a doctor for any reason? (Specify): _____ (95) 221 Yes ☐ 1 No ☐ 2

19. Since your last visit, have you been in the hospital for any reason? (96) 222 Yes ☐ 1 No ☐ 2 → Go to 20.

How many times? ☐ (97) 223-224

When? (Start with the first one after your last visit.)

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

	Hospitalization #1	Hospitalization #2	Hospitalization #3
Hospital name	(98) 225-230	(100) 233-238	(102) 241-246
Date of admission	☐ Month ☐ Day ☐ Year	☐ Month ☐ Day ☐ Year	☐ Month ☐ Day ☐ Year
Number of days	☐ (99) 231-232	☐ (101) 239-240	(103) ☐ 247-248
Reason			

20. a. Since your last SHEP visit, have you had any sudden feeling of numbness, tingling or loss of feeling in either arm, hand, leg, foot or face? Yes ☐ 1 (104) 249 No ☐ 2 → SKIP to 21.

b. How many attacks of such numbness or tingling have you had? (105) 250 One ☐ 1 More than one ☐ 2

c. How long did each of the attack(s) usually last? (106) 251 Less than 24 hours ☐ 1 More than 24 hours ☐ 2

21. a. Since your last SHEP visit, have you had any sudden attacks of paralysis or loss of use of either arm, hand, leg or foot? Yes ☐ 1 No ☐ 2 (107) 252

SKIP to 22.

b. How many attacks of such paralysis have you had? 253 (108) One ☐ 1 More than one ☐ 2

c. How long did the attack(s) usually last? 254 (109) Less than 24 hours ☐ 1 More than 24 hours ☐ 2

22. a. Since your last SHEP visit, have you had any sudden loss of eyesight or blurring of vision for a short period of time? Yes ☐ 1 No ☐ 2 (110) 255

SKIP to 23.

b. What part of your vision was affected? 256 (111)
Right eye only ☐ 1
Left eye only ☐ 2
Both eyes ☐ 3
Vision to the right side ☐ 4
Vision to the left side ☐ 5

c. How many attacks of loss of eyesight or blurring of vision have you had? 257 (112) One ☐ 1 More than one ☐ 2

d. How long did the attack(s) usually last? Less than 24 hours ☐ 1 More than 24 hours ☐ 2 (113) 258

23. a. Since your last SHEP visit, have you had any sudden attacks of changes in speech, loss of speech or inability to say words? Yes ☐ 1 No ☐ 2 (114) 259

SKIP to 24.

b. How many attacks of loss of speech have you had? 260 (115) One ☐ 1 More than one ☐ 2

c. How long did the attack(s) usually last? 261 (116) Less than 24 hours ☐ 1 More than 24 hours ☐ 2

24. Since your last SHEP visit, have you had any of the following:

fields 117-122: 262-267

a. Dizziness (117) Yes ☐ 1 No ☐ 2
b. Spinning sensation (vertigo) (118) Yes ☐ 1 No ☐ 2
c. Loss of balance (119) Yes ☐ 1 No ☐ 2
d. Difficulty walking (120) Yes ☐ 1 No ☐ 2
e. Blackouts or fainting (121) Yes ☐ 1 No ☐ 2
f. Frequent falls (122) Yes ☐ 1 No ☐ 2

If none of 24a-f are answered "Yes," skip to 25.

g. About how many total attacks of all of these conditions do you think you ever had? 268 (123) One ☐ 1 More than one ☐ 2

h. How long did the attack(s) usually last? 269 (124) Less than 24 hours ☐ 1 More than 24 hours ☐ 2

25. 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 (125) 270

26. 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? Yes ☐ 1 No ☐ 2 (126) 271
(Specify): _____

b. Have you increased or decreased any medications that you were taking? Yes ☐ 1 No ☐ 2 (127) 272
(Specify): _____

c. Have you started taking any new medications? Yes ☐ 1 No ☐ 2 (128) 273
(Specify): _____

27. Interviewer:
Did the participant bring all non-SHEP medications to the clinic at this visit? 274 (129)
Yes ☐ 1
No ☐ 2
Not on any non-SHEP medications ☐ 3

28. Interviewer:

a. Did the participant volunteer any complaints or problems in Items 16-25? (130) 275 Yes ☐ 1 No ☐ 2
→ Skip to next section.

b. Are these problems that, in your opinion, may be related to study medications? 276 (131)
Yes ☐ 1
No ☐ 2
Not on SHEP medications ☐ 3
→ SH42 required

SPECIFIC SIDE EFFECTS (SH42)

Interviewer: The Side Effects Quesionnaire (SH42) is required at the first required visit after SHEP medications are started or increased, in response to a "Yes" to Item 28b, and at interim visits for possible side effects. It is not required under any condition for participants who have been off of SHEP medications more than six months. If required, administer the SH42, and then return to this form.

POSSIBLE EVENTS

29. Are there any positive responses to Items 16-25 or on the Side Effects Questionnaire (SH42)? 132 Yes ☐ 1 No ☐ 2 277

Go to 33.

30. In the judgment of the SHEP clinician, are any of these positive or abnormal responses a result of:

		Yes	Possibly	No	
a.	Stroke 278 133	☐ 1	☐ 2	☐ 3	Arrange for SHEP Neurological Examination for Stroke (SH27) as soon as possible.
b.	Acute myocardial infarction	☐ 1	134 ☐ 2	☐ 3	
c.	Left ventricular failure 135 280	☐ 1	☐ 2 279	☐ 3	
d.	Transient ischemic attack 136	☐ 1	☐ 2	☐ 3	Arrange for SHEP Neurological Examination for TIA (SH28) as soon as possible.
e.	Other cardiovascular hospitalization 281 (specify:_____)	☐ 1	137 ☐ 2 282	☐ 3	
f.	Hospitalization for reason other than above (specify:_____)	☐ 1	138 ☐ 2 283	☐ 3	
g.	Intermediate or skilled care nursing home admission 139	☐ 1 284	☐ 2	☐ 3	

31. Was the participant hospitalized or seen by a physician for any event in 30a-30g?

285 140 Yes ☐ 1 → No ☐ 2 Not sure ☐ 3

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

For any event in 30a-30g checked "Yes" or "Possibly," fill out Form SH20, Initial Report of Morbid Event.

32. Does the participant think that any of these conditions are due to the SHEP medications? 286 141 Yes ☐ 1 No ☐ 2 DK ☐ 3

33. Comments (note pertinent history and physical exam findings and diagnostic impressions): _____

_____

_____

_____

_____

34. Signature of person completing this section: _____ 287-288 142 ☐ Code

MEDICATION REVIEW

35. a. Were any SHEP blinded medications prescribed at the last visit? (178) Yes ☐ 1 No ☐ 2
335
↓ Go to 36a.

b. Were all SHEP blinded medications discontinued since the last visit? 336 (179) Yes ☐ 1 No ☐ 2 DK ☐ 3
↓ Go to 36a.

c. Were there any other changes made in the SHEP blinded medications since the last visit? (180) Yes ☐ 1 No ☐ 2 DK ☐ 3
337
(Specify_____)

36. a. Were open-label antihypertensive medications prescribed at the last visit (any source)? 338 (181) Yes ☐ 1 No ☐ 2 DK ☐ 3
↓ Go to 37a.

b. Were open-label antihypertensive medications prescribed since the last visit (any source)? (182) Yes ☐ 1 No ☐ 2 DK ☐ 3
339

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

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

37. a. Has the participant reached escape blood pressure at this visit? (183) Yes ☐ 1 No ☐ 2 DK ☐ 3
340
↓ ↓ Go to 38a.

b. List the escape blood pressure sequence:

		Month	Day	Year	SBP	DBP
fields 184-186: 341-352	Visit 1	(184)			(185)	(186)
fields 187-189: 353-364	Visit 2	(187)			(188)	(189)
fields 190-192: 365-376	Visit 3	(190)			(191)	(192)

38. a. Will you be prescribing SHEP medications according to the prescribed SHEP blood pressure treatment regimen at this visit? (193) 377 Yes □ 1 No □ 2 DK □ 3

b. Will you be prescribing open-label antihypertensive medications at this visit? (194) 378 Yes □ 1 No □ 2 DK □ 3

If Item #38a is "Yes" and Item #38b is "No," skip to #39.

Reasons (check all that apply):

c. Participant has reached escape blood pressure at this visit or a previous visit — 379 (195) Yes □ 1
d. Possible or probable side effects in the judgment of the SHEP clinician — Yes □ 1 (196) 380
e. Perceived side effects in the judgment of the participant — 381 (197) Yes □ 1
f. Stroke — Yes □ 1 (198) 382
g. MI — 383 (199) Yes □ 1
h. LVF — Yes □ 1 (200) 384
i. Angina — 385 (201) Yes □ 1
j. Other medical (specify) _____ — Yes □ 1 (202) 386
k. Participant refusal or preference — 387 (203) Yes □ 1
l. Private MD request — Yes □ 1 (204) 388
m. Other (specify) _____ — 389 (205) Yes □ 1

MEDICATION PRESCRIPTION AND SCHEDULING

39. Medication prescription last visit:

a. Step 1

C1 □ 1
C2 □ 2
½ C1 □ 3
Other C _____ □ 4
No Step 1 (go to 39c) □ 5
(206) 390

b. Step 1 bottle number (160) 306-308

c. Step 2

A1 □ 1
A2 □ 2
Other A _____ □ 3
R Dose 1 □ 4
R Dose 2 □ 5
Other R _____ □ 6
No Step 2 (go to 39e) □ 7
(207) 391

d. Step 2 bottle number (162) 310-312

e(1) Open-label drugs (specify drug and dose) (208) Yes □ 1 No □ 2 DK □ 3
392
Go to 39f.

_____

e(2) Source of open-label drugs

Prescribed by SHEP □ 1
Prescribed by other source □ 2
Both □ 3
(209) 393

f(1) K supplement (210) Yes □ 1 No □ 2 DK □ 3
394
Go to 39g.

315-316
f(2) Meq/day (unknown = 99) (165)

g. Uric acid drug (specify drug and dose) Yes □ 1 No □ 2 DK □ 3 (211) 395

_____

40. Medication prescription this visit:

No change (go to 41) □ 1 (167) 318

a. Step 1

C1 □ 1
C2 □ 2
½ C1 □ 3
Other C _____ □ 4
No Step 1 (go to 40c) □ 5
(212) 396

b. Step 1 bottle number (169) 320-322 ____

c. Step 2

A1 □ 1
A2 □ 2
Other A _____ □ 3
R Dose 1 □ 4
R Dose 2 □ 5
Other R _____ □ 6
No Step 2 (go to 40e) □ 7
(213) 397

d. Step 2 bottle number (171) 324-326 ____

e(1) Open-label drugs (specify drug and dose) (214) 398 Yes □ 1 No □ 2 DK □ 3

_____

Go to 40f.

e(2) Source of open-label drugs

Prescribed by SHEP □ 1
Prescribed by other source □ 2
Both □ 3
(25) 399

f(1) K supplement (216) 400 Yes □ 1 No □ 2 DK □ 3

Go to 40g.

f(2) Meq/day (unknown = 99) ____ (174) 329-330

g. Uric acid drug (specify drug and dose) (217) 401 Yes □ 1 No □ 2 DK □ 3

_____

41. Schedule:

Next quarterly □ 1
One month □ 2
1-2 weeks □ 3
1 week □ 4
Other (specify) _____ □ 5
(218) 402

42. Comments

178 (13) RECORD TYPE

185-187 (75) UPDATE NUMBER

194 (77) PAPER COPY

179-184 (14) DATE RECEIVED

188-193 (76) DATE LAST PROCESSED

195 (78) EDIT STATUS CODE

(176) 332-333 ____ Code

43. Signature of Clinician completing this section: _____

OTHER PROCEDURES

Interviewer: If the SHORTCARE (SH30), the Activities of Daily Life (SH33), or the Social Network Questionnaire (SH34) or the Behavioral Evaluation --Part II (SH35) are required at this visit, they should be administered at this time.

The participant may now be sent for any lab work that may be required at this visit. Document lab work on the front of this form (Items 10b and 10c.)

PLEASE REVIEW PAGE 1.