

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) 8

5a. Type of visit: (49) (9) 1 One-month 2 Two-month 3 Quarterly 4 Other interim 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: 1 Clinic (11) 51 2 Other (11) 51 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.

Table with 5 columns: Procedure, Form, Comments, Required This Visit?, Done This Visit?. Rows include Pulse, BP, Weight; Dipstick urinalysis; Blood, central; Other lab work, local; Compliance; General well-being; Specific side effects; Medication and Scheduling Decision; SHORTCARE/CES-D; Social Network.

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

fields 14-23: 54-63

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

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 = 64-66 beats per minute.

b. Blood pressure:

Cuff Size:

Pulse Obliteration Pressure:

(25) 67	}	1 <input type="checkbox"/> Regular	Observed Value:	<input type="text"/>
		2 <input type="checkbox"/> Large arm	Subtract Zero Level:	- <input type="text"/>
		3 <input type="checkbox"/> Thigh	Corrected Value:	<input type="text"/>
		4 <input type="checkbox"/> Pediatric	Add Maximum Zero Level Plus 10:	+ <input type="text"/>
		Peak Inflation Level:	<input type="text"/>	

Seated Readings:

Standing Readings:

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

One minute		
Pulse:	Beats in <u>15</u> seconds _____	
	(42) x 4 = <input type="text" value="112-114"/>	beats per minute.
Blood Pressure:	<u>Systolic</u>	<u>Diastolic</u>
Reading	(43) <input type="text" value="115-117"/>	(44) <input type="text" value="118-120"/>
Zero	(45) <input type="text" value="121-122"/>	(46) <input type="text" value="123-124"/>
Corrected	(47) <input type="text" value="125-127"/>	(48) <input type="text" value="128-130"/>
Three minutes		
Pulse:	Beats in <u>15</u> seconds _____	
	(49) x 4 = <input type="text" value="131-133"/>	beats per minute.
Blood Pressure:	<u>Systolic</u>	<u>Diastolic</u>
Reading	(50) <input type="text" value="134-136"/>	(51) <input type="text" value="137-139"/>
Zero	(52) <input type="text" value="140-141"/>	(53) <input type="text" value="142-143"/>
Corrected	(54) <input type="text" value="144-146"/>	(55) <input type="text" value="147-149"/>

c. Did the participant volunteer any symptoms on standing?

- (1) Dizziness? Yes 1 57 ¹⁵¹ No 2
- (2) Other (specify)? Yes 1 58 ¹⁵² No 2

56 Yes 1 No 2
150 ↓

SKIP to 19d

d. Weight: 59 150-152 153-155 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: 61 ¹⁵⁸ None of 20a-20g required this visit

- 159 a. 62 Initial Notification of Morbid Event, SH20
- 160 b. 63 Neurologic Exam for Stroke, SH27
- 161 c. 64 Neurologic Exam for TIA, SH28
- 162 d. 65 Deviation from Protocol, SH48
- 163 e. 66 Dementia Referral, SH31
- f. 67 Depression Referral, SH32
- 165 g. 68 Report of Unblinding, SH49

21. Comments on this visit: 166 69 P 0/1 _____

22. Next clinic visit: 70 169 170 171-172 167 168 at 71 173-176 177
Month Day Year Hour Minute 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 BATCH DATE 514 3-8
- 179-184 74 DATE RECEIVED DATE MODIFIED 515 11-16
- 185-187 75 UPDATE NUMBER TIME MODIFIED 516 17-20
- 188-193 76 DATE LAST PROCESSED EDIT STATUS 517 21
- 194 77 PAPER COPY
- 195 78 Cross-Forms Edit Status

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** **38 39** **34 35** **7**
Month Day Year

4. Sequence number: **8** 47-48

5. Type of visit:

- 196 **79** Quarterly (Skip to 8)
- Other required (Skip to 8)
- Interim

6. Visit scheduled:

- 197 **80** by SHEP Clinic
- at participant's request

7. Reason for visit (check all that apply):

- 198 **81** a. BP check
- Potassium re-check (local) **199 82**
- 200 **83** c. Possible side effects
- d. Other (Specify in Comments, Item 12)

8. Place of visit:

- 51 **11** Clinic
- Home
- Telephone

- 9. a. Were Step 1 medications started or increased at last visit? Yes No **12 52**
- b. Were Step 2 medications started or increased at last visit? Yes 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	<input type="checkbox"/>	Every visit except telephone visits.	<input type="checkbox"/>	<input type="checkbox"/>
b. Blood, central	<input type="checkbox"/>	Serum potassium required at visit after Step 1 start or increase.	<input type="checkbox"/>	<input type="checkbox"/>
c. Local lab work (SH7)	<input type="checkbox"/>	As required in clinician's judgment; serum potassium re-check.	<input type="checkbox"/>	<input type="checkbox"/>
d. Compliance (SH40)	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
e. General well-being	<input type="checkbox"/>	Required every visit.	<input type="checkbox"/>	<input type="checkbox"/>
f. Specific side effects (SH42)	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
g. Protocol Review	<input type="checkbox"/>	Required every visit. Fill in SHEP medication prescription at last visit (Item 4) prior to visit.	<input type="checkbox"/>	<input type="checkbox"/>
h. SHORTCARE/CES-D (SH30)	<input type="checkbox"/>	Required quarterly. Do not administer over the telephone. Also required if Behavioral Evaluation--Part II is being administered.	<input type="checkbox"/>	<input type="checkbox"/>
i. Social Network (SH34)	<input type="checkbox"/>	Required at one-month after randomization. Do not administer over the telephone.	<input type="checkbox"/>	<input type="checkbox"/>
j. Behavioral Evaluation--Part I	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>

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

None of 11a-11g required this visit.

- 159 **62** a. Initial Notification of Morbid Event, SH20
- 161 **64** b. SHEP Neurological Evaluation for Strokes, SH27 **63 160**
- 66** c. SHEP Neurological Evaluation for TIA, SH28
- 67** d. Dementia Referral, SH31 **65 162**
- 163 **68** e. Depression Referral, SH32 **67 164**
- f. Deviation from Protocol, SH48
- 165 **68** g. Report of Unblinding, SH49

12. Comments on this visit:

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

14. Signature of person reviewing this page: **87**
Code

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
 1 Regular
 2 Large arm
 3 Thigh
 4 Pediatric
67

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

Seated Readings:

Standing Readings:

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

One minute
Pulse: Beats in 15 seconds _____
42 x 4 = 112-114 beats per minute.

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

Three minutes
Pulse: Beats in 15 seconds _____
49 x 4 = 131-133 beats per minute.

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

(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 Yes 1 No 2
 (2) Other (specify)? 57 Yes 1 No 2 58 152
 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
 How many times? **223-224** **97** ↓
 When? (Start with the first one after your last visit.) Go to 20.

(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? One 1 More than one 2 **108** ²⁵³
- c. How long did the attack(s) usually last? Less than 24 hours 1 More than 24 hours 2 **109** ²⁵⁴
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? Right eye only 1 **256**
 Left eye only 2 **111**
 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**
- b. Spinning sensation (vertigo) Yes 1 No 2 **118**
- c. Loss of balance **264** **119** Yes 1 No 2 **265**
- d. Difficulty walking Yes 1 No 2 **120**
- e. Blackouts or fainting **266** **121** Yes 1 No 2 **122**
- f. Frequent falls Yes 1 No 2 **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? (Specify): _____ Yes 1 No 2 **126** 271
- b. Have you increased or decreased any medications that you were taking? (Specify): _____ Yes 1 No 2 **127** 272
- c. Have you started taking any new medications? (Specify): _____ Yes 1 No 2 **128** 273

27. Interviewer:
Did the participant bring all non-SHEP medications to the clinic at this visit?
- Yes **274** **129** 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? Yes **276** **131** 1
 No 2
 Not on SHEP medications 3
- SH42 required

SPECIFIC SIDE EFFECTS (SH42)

Interviewer: The Side Effects Questionnaire (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 | |
|-----|---|--------------------------------------|----------------------------|----------------------------|--|
| 279 | (134) a. Stroke | 278 (133) <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Arrange for SHEP Neurological Examination for Stroke (SH27) as soon as possible. |
| | b. Acute myocardial infarction | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | |
| | c. Left ventricular failure | (135) <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | |
| | | 280 | | | |
| 282 | (137) d. Transient ischemic attack | 281 (136) <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Arrange for SHEP Neurological Examination for TIA (SH28) as soon as possible. |
| | e. Other cardiovascular hospitalization (specify: _____) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | |
| | f. Hospitalization for reason other than above (specify: _____) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | (138) 283 |
| | g. Intermediate or skilled care nursing home admission | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 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 290
Specify: _____

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

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) 1 Yes 2 No 192

↓
Initiate SH48 for this deviation.

Clinic Physician Initial

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

38. Have any other potentially serious conditions arisen since the last visit which are probably a result of the use of SHEP medications? (148) 294 { 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)? (149) 295 1 Yes 2 No

↓
Skip to 41.

fields 150-154: 296-300

40. Reason: (Check all that apply.)

- 150** a. Side effects judged to be severe enough to deviate from protocol
- 151** b. Participant has reached escape blood pressure
- 152** c. Private MD has prescribed alternative BP therapy
- 153** d. Participant request
- 154** e. 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.)?

- 304** **158**
- 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 1/2 (159) 305
2 C2 4 None (Skip to 44c)

b. Bottle #: (160) 306-308

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

d. Bottle #: (162) 310-312

(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 1/2 (168) 319
2 C2 4 None (Skip to 45c)

b. Bottle #: (169) 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 #: (171) 324-326

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

328 (173) f. 1 Potassium supplement → (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

195 (78) CROSS FORM EDIT STATUS

185-187 (75) UPDATE NUMBER

3-8 (514) BATCH DATE

188-193 (76) DATE LAST PROCESSED

11-16 (515) DATE MODIFIED

Version 2 - 2/86

17-20 (516) TIME MODIFIED SH08/9

194 (77) PAPER COPY

21 (517) EDIT STATUS

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 38 39 34 35 7 4. Sequence number: 47-48 8
Month Day Year

5. Type of visit: 196 79 Quarterly (Skip to 8) Other required (Skip to 8) Interim
 6. Visit scheduled: 30-32 1 FORM NUMBER by SHEP Clinic at participant's request
197 80 33 2 VERSION NUMBER

7. Reason for visit (check all that apply): 81 82 83 84 BP check Potassium re-check (local) Possible side effects Other (Specify in Comments, Item 12)
 8. Place of visit: 51 11 40 58 SEQUENCE Clinic Home Telephone

9. a. Were Step 1 medications started or increased at last visit? Yes No 12 52
 b. Were Step 2 medications started or increased at last visit? Yes 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	<input type="checkbox"/>	Every visit except telephone visits.	<input type="checkbox"/>	<input type="checkbox"/>
b. Blood, central	<input type="checkbox"/>	Serum potassium required at visit after Step 1 start or increase.	<input type="checkbox"/>	<input type="checkbox"/>
c. Local lab work (SH11)	<input type="checkbox"/>	Local re-check of central laboratory results; as required in clinician's judgment.	<input type="checkbox"/>	<input type="checkbox"/>
d. Compliance (SH40)	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
e. General well-being	<input type="checkbox"/>	Required every visit.	<input type="checkbox"/>	<input type="checkbox"/>
f. Specific side effects (SH42)	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
g. Medication and Scheduling Decision	<input type="checkbox"/>	Required every visit. Fill in SHEP medication prescription at last visit (Item 39) prior to visit.	<input type="checkbox"/>	<input type="checkbox"/>
h. SHORTCARE/CES-D (SH30)	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
i. Social Network (SH34)	<input type="checkbox"/>	Required at one-month after randomization. Do not administer over the telephone.	<input type="checkbox"/>	<input type="checkbox"/>
j. Behavioral Evaluation--Part II	<input type="checkbox"/>	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.	<input type="checkbox"/>	<input type="checkbox"/>
k. Activities of Daily Life (SH33)	<input type="checkbox"/>	Required if Behavioral Evaluation--Part II is being administered.	<input type="checkbox"/>	<input type="checkbox"/>

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 None of 11a-11f required this visit.
62 Initial Notification of Morbid Event, SH20 **fields 61-66: 158-163**
63 SHEP Neurological Evaluation for Strokes, SH27
64 SHEP Neurological Evaluation for TIA, SH28
65 Dementia Referral, SH31
66 Depression Referral, SH32
68 Report of Unblinding, SH49

12. Comments on this visit: _____

13. Next clinic visit: 70 a.m. p.m. 72 177
 Month Day Year at Hour Minute

14. Signature of person reviewing this page: _____ 71 173-176 87 Code

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: Pulse Obliteration Pressure: 24

1 Regular Observed Value: 206-208 88

25 2 Large arm Subtract Zero Level: 209-210 89

67 3 Thigh Corrected Value: 211-213 90

4 Pediatric Add Maximum Zero Level Plus 20: + 214-215 91

Peak Inflation Level: 216-218 92

Seated Readings:

Standing Readings:

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

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

(1) Dizziness Yes 1 57 No 2

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

d. Weight: 153-155 59 pounds

e. Observer signature: _____

151 152 SKIP to 15d.

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): _____

219
 93 Yes 1 No 2

↓
 Go to 18.

17. Are any of these problems different from the way things were at your last clinic visit?

220
 94 Yes 1 No 2

18. Since your last visit, have you seen a doctor for any reason? (Specify): _____

221
 95 Yes 1 No 2

19. Since your last visit, have you been in the hospital for any reason?

222
 96 Yes 1 No 2

How many times? [] 97 223-224

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

↓
 Go to 20.

(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	[] 101	103 []
Reason	231-232	239-240	247-248

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?

249
 Yes 1 No 2 104

↓
 SKIP to 21.

b. How many attacks of such numbness or tingling have you had?

250 105 { One 1
 More than one 2

c. How long did each of the attack(s) usually last?

106 { Less than 24 hours 1
 More than 24 hours 2

251

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? Right eye only **256** **111** { 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? One **257** **112** { 1
 More than one 2
- d. How long did the attack(s) usually last? Less than 24 hours 1 **113**
 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** 258
 ↓
 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 | 117 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
| b. Spinning sensation (vertigo) | 118 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
| c. Loss of balance | 119 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
| d. Difficulty walking | 120 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
| e. Blackouts or fainting | 121 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
| f. Frequent falls | 122 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 |
- fields 117-122:
262-267**
- 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? (Specify): _____ Yes 1 No 2 **126** 271
- b. Have you increased or decreased any medications that you were taking? (Specify): _____ Yes 1 No 2 **127** 272
- c. Have you started taking any new medications? (Specify): _____ Yes 1 No 2 **128** 273

27. Interviewer: Did the participant bring all non-SHEP medications to the clinic at this visit?

Yes **274** **129** 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? **131** **276** Yes 1
 No 2
 Not on SHEP medications 3

SH42 required

SPECIFIC SIDE EFFECTS (SH42)

Interviewer: The Side Effects Questionnaire (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 <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Arrange for SHEP |
| b. Acute myocardial infarction | | <input type="checkbox"/> 1 | 134 <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Neurological Examination |
| c. Left ventricular failure | 280 | 135 <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | for Stroke (SH27) as soon as possible. |
| | | | 279 | | |
| d. Transient ischemic attack | | 136 <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Arrange for SHEP |
| e. Other cardiovascular hospitalization (specify: _____) | 281 | <input type="checkbox"/> 1 | 137 <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | Neurological Examination for TIA (SH28) as soon as possible. |
| | | | 282 | | |
| f. Hospitalization for reason other than above (specify: _____) | | <input type="checkbox"/> 1 | 138 <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | |
| | | | 283 | | |
| g. Intermediate or skilled care nursing home admission | 284 | 139 <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 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? (179) Yes 1 No 2 DK 3
336 ↓ Go to 36a.
- c. Were there any other changes made in the SHEP blinded medications since the last visit? (190) Yes 1 No 2 DK 3
337
(Specify _____)
36. a. Were open-label antihypertensive medications prescribed at the last visit (any source)? (191) Yes 1 No 2 DK 3
338 ↓ Go to 37a.
- b. Were open-label antihypertensive medications prescribed since the last visit (any source)? (192) 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 **381** **(197)** Yes 1 **(196)** 380
- e. Perceived side effects in the judgment of the participant **383** **(199)** Yes 1 **(198)** 382
- f. Stroke **385** **(201)** Yes 1 **(200)** 384
- g. MI **387** **(203)** Yes 1 **(202)** 386
- h. LVF **389** **(205)** Yes 1 **(204)** 388
- i. Angina
- j. Other medical (specify) _____
- k. Participant refusal or preference
- l. Private MD request
- m. Other (specify) _____

MEDICATION PRESCRIPTION AND SCHEDULING

39. Medication prescription last visit:

- a. Step 1 **(206)** 390
- C1 1
C2 2
 $\frac{1}{2}$ C1 3
Other C _____ 4
No Step 1 (go to 39c) 5
- b. Step 1 bottle number **(160)** 306-308
- c. Step 2 **(207)** 391
- 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
- d. Step 2 bottle number **(162)** 310-312
- e(1) Open-label drugs (specify drug and dose) **(208)** 392
- Yes 1 No 2 DK 3
↓ ↓
Go to 39f.
- e(2) Source of open-label drugs **(209)** 393
- Prescribed by SHEP 1
Prescribed by other source 2
Both 3
- f(1) K supplement **(210)** 394
- Yes 1 No 2 DK 3
↓ ↓
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:

a. Step 1

No change (go to 41) 1 **167** 318
 C1 1
 C2 2 **212**
 1/2 C1 3
 Other C 4 396
 No Step 1 (go to 40c) 5

b. Step 1 bottle number

169

320-322

c. Step 2

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

d. Step 2 bottle number

171 324-326

e(1) Open-label drugs (specify drug and dose)

214 Yes 1 No 2 DK 3 398
 ↓ ↓
 Go to 40f.

e(2) Source of open-label drugs

Prescribed by SHEP 1
 Prescribed by other source 2 **215** 399
 Both 3

f(1) K supplement

216 Yes 1 No 2 DK 3 400
 ↓ ↓
 Go to 40g.

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

174

g. Uric acid drug (specify drug and dose)

217 Yes 1 No 2 DK 3 329-330 401

41. Schedule:

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

42. Comments

185-187

178 **13** RECCRD TYPE

75 UPDATE NUMBER

194 **77** PAPER COPY

188-193

179-184 **74** DATE RECEIVED

76 DATE LAST PROCESSED

195 **78** EDIT STATUS CODE

332-333

43. Signature of Clinician completing this section:

176
Code

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.)