30-32 (1) FORM NUMBER

40 (5/8) SEQUENCE

PROTOCOL REVIEW AND MEDICATION AND SCHEDULING DECISION

33 (2) VERSION

(6) 41-46

1. SHEP ID: (3) [22][23] - (4) [24][25][26][27] - [28][29] (5)

2. Acrostic: [ ][ ][ ][ ][ ][ ]

3. Date of Clinic Visit: [36][37] Month [38][39] Day [34][35] Year (7)

4. Sequence number: [47][48] (8)

REVIEW OF PROTOCOL

5. At the last clinic visit, were SHEP medications prescribed in dosages specified in the protocol? 49 (9)
   1 ☐ Yes → Skip to 11
   2 ☐ No

6. What has happened with respect to the problem which caused this deviation from the protocol? 50 (10)
   Comment: _____
   _____
   1 ☐ Resolved
   2 ☐ Improved
   3 ☐ Worse
   4 ☐ Unchanged

7. Have any other potentially serious conditions arisen since the last visit which are probably a result of the use of SHEP medications? 51 (11)
   1 ☐ Yes
   2 ☐ No
   3 ☐ Not on SHEP meds

8. At this visit, do you plan to restore the participant to the SHEP drugs and doses specified in the protocol? 52 (12)
   1 ☐ Yes → Skip to 11
   2 ☐ No

9. Reason: (Check all that apply.)
   53 (13) 1 ☐ Side effects judged to be severe enough to deviate from protocol
   54 (14) 1 ☐ Participant has reached escape blood pressure and requires deviation from protocol
   55 (15) 1 ☐ Other (Specify): _____

10. Has this decision already been reported on a Deviation from Protocol form, SH48? (16) 56
    1 ☐ Yes
    2 ☐ No → Initiate SH48 for this decision.

    _____
    Clinic Physician Initial

11. 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? (17) 57
    1 ☐ Yes
    2 ☐ Possibly
    3 ☐ No
    4 ☐ No positive or abnormal responses → Skip to 14

12. In the judgment of the SHEP clinician and physician, do any of these responses require deviation from protocol in prescribing SHEP medication? (18) 58
    1 ☐ Yes
    2 ☐ No → Skip to 14

13. Are any of these conditions possibly harmful to the participant? (19) 59

1 ☐ Yes 2 ☐ No

Initiate SH48 for Deviation from Protocol.

Clinic Physician Initial

14. Are there reasons other than those in Questions 5-13 that require a deviation from protocol in prescribing SHEP medications (e.g., interference from other medicine, etc.)? (20) 60
(Specify): _____

1 ☐ Yes 2 ☐ No
↓

Initiate SH48 for Deviation from Protocol.

Skip to next section

Clinic Physician Initial

SHEP MEDICATION AND SCHEDULING DECISION

SBP today: _____ Goal SBP: _____
DBP today: _____

15. Blood pressure review:

a. 1 ☐ SBP above 110 and at or below goal, with DBP <90 mm Hg (61) (21) → b. At least second consecutive visit at these levels on same dose and Step? (62) (22)
1 ☐ Yes Remain on same Step and dose. Schedule next quarterly visit.
2 ☐ No Remain on same Step and dose. Schedule next visit in one month.

a. 2 ☐ SBP above goal and <220, with DBP <90 mm Hg (61) (21) → b. At least second consecutive visit at these levels on same Step and dose? (63) (23)
1 ☐ Yes Move to next dose or Step. If already on Step II Dose 2, continue current regimen. Schedule next visit in one month.
2 ☐ No Continue same dose and Step. Schedule next visit in one month.

a. 3 ☐ SBP ≧240 or DBP ≧115 mm Hg (61) (21) → b. Initiate open-label antihypertensive therapy at this visit. (Initiate Deviation from Protocol, SH48.) If already on open-label therapy, step up according to clinician judgment. Schedule next visit according to clinician judgment. (Visits must be at least quarterly.)

a. 4 ☐ SBP ≦110 mm Hg (61) (21) → b. SHEP medications may be stepped down to the next lower dose or step, at the discretion of the SHEP clinician. Schedule next visit according to clinician judgment (visits must be at least quarterly). If drugs are stepped down, initiate SH48, Deviation from Protocol. Are drugs being stepped down this visit? (64) (24)
1 ☐ Yes
2 ☐ No

a. 5 ☐ SBP 220-239 or DBP 90-114 mm Hg → b. Monitor for escape BP according to following table; has escape BP criteria been reached?

61 (21)

65 (25)
1 ☐ Yes Move to next Step or dose; if on maximum Step and Dose, initiate open-label therapy. Initiate Deviation from Protocol, SH48. If already on open-label therapy, adjust treatment and schedule next visit according to clinician judgment.
2 ☐ No Remain on same Step and dose.

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c. Schedule next visit at earliest interval:

66 (26)
1 ☐ DBP 95-114 → 1-2 weeks
2 ☐ SBP 220-239 → 2 weeks
3 ☐ DBP 90-94 → 1 month
4 ☐ Other schedule → Specify: _____

Escape Criteria for SBP 220-239 or DBP 90-114 mm Hg (visits on same Step and Dose)

	1st Visit	2nd Visit	3rd Visit	Comment
SBP:	220-239	220-239		
DBP:	95-114	95-114		
	95-114	90-94	≧90	
	90-94	≧90		Not on maximum study meds
	90-94	90-114	≧90	On maximum study meds

16. SHEP medication prescription last visit:

67 (27) a. Step I: 3 ☐ C1, dose ½ 1 ☐ C1 2 ☐ C2 4 ☐ None b. Bottle #: (28) 68 69 70

71 (29) c. Step II: 1 ☐ A1 2 ☐ A2 3 ☐ R, Dose 1 4 ☐ R, Dose 2 5 ☐ None d. Bottle #: (30) 72 73 74

75 (31) e. 1 ☐ Open-label antihypertensives → Specify: _____

76 (32) f. 1 ☐ Potassium supplement → g. 77 78 meq/day (33)

79 (34) h. 1 ☐ Uric acid agent → Specify drug and dose: _____

17. SHEP medication prescription this visit: (35) 80 1 ☐ No change → Go to 18.

81 (36) a. Step I: 3 ☐ C1, dose ½ 1 ☐ C1 2 ☐ C2 4 ☐ None b. (37) Bottle #: 82 83 84

85 (38) c. Step II: 1 ☐ A1 2 ☐ A2 3 ☐ R, Dose 1 4 ☐ R, Dose 2 5 ☐ None d. Bottle #: 86 87 88 (39)

89 (40) e. 1 ☐ Open-label antihypertensives → Specify: _____

90 (41) f. 1 ☐ Potassium supplement → g. (42) 91 92 meq/day

93 (43) h. 1 ☐ Uric acid agent → Specify drug and dose: _____

18. Clinician: _____ (44) 94 95
Signature Code

(514) 3-8 BATCH DATE (515) 11-16 DATE MODIFIED (516) 17-20 TIME MODIFIED (517) 21 EDIT STATUS

Keypuncher's code 1-2
Verifyier's code 9-10