30-32 (1) FORM NUMBER

40 (518) SEQUENCE

33 (2) VERSION

REPORT OF DEVIATION FROM PROTOCOL

To be used at initiation of individual therapy, discontinuation of study medications, or other deviation from protocol in prescribing study medications for any reason (e.g., escape BP).

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

2. Acrostic: ☐☐☐☐☐☐ (6) 41-46

3. Date of clinic visit: 36 37 (Month) 38 39 (Day) 34 35 (Year) (7)

4. Sequence #: 47 48 (8)

5. a. Study medications: (9) 49
   1 ☐ Discontinue
   2 ☐ Increase
   3 ☐ Decrease
   4 ☐ Delay of required change
   5 ☐ No change

   b. Initiation of open-label therapy this visit?: (10) 50
   1 ☐ Yes 2 ☐ No

6. Reason: Check one only; provide details in Comments, Item 9.

   (11) 51
   1 ☐ Escape blood pressure criteria met (document escape in Item 8).
   2 ☐ Major side effects
   3 ☐ Morbid event
   4 ☐ Request of participant
   5 ☐ Request of participant's private physician
   6 ☐ Other; specify in Comments, Item 9

7. For drug discontinuations only - Is this participant still willing to be followed in the SHEP clinic?
   1 ☐ Yes (12) 52 2 ☐ No
   ↓
   Complete SH50 - Refusal or Lost to Follow-up Documentation

8. For participants reaching escape blood pressure:

	Date Month	Date Day	Date Year	SBP (14)	DBP
Visit 1 (13)	55 56	57 58	53 54	59 60 61	62 63 64 (15)
Visit 2 (16)	67 68	69 70	65 66	71 72 73 (17)	74 75 76 (18)
Visit 3 (19)	79 80	81 82	77 78	83 84 85 (20)	86 87 88 (21)

RECORD TYPE (25) 94

DATE RECEIVED (26) 95-100

UPDATE NUMBER (27) 101-103

DATE LAST PROCESSED (28) 104-109

PAPER COPY (29) 110

9. Comments: (22) 89 P 0/1

10. Signature of person completing form: _____ (23) 90 91 Code

11. Signature of clinic physician: _____ (24) 92 93 Code

3-8 (514) BATCH DATE

11-16 (515) DATE MODIFIED

17-20 (516) TIME MODIFIED

21 (517) EDIT STATUS

SH48/1