

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 - 24 25 26 27 - 28 29 (5) 2. Acrostic: [] [] [] [] [] (6)

3. Date of clinic visit: 36 37 38 39 34 35 (7) 4. Sequence #: 47 48 (8) 41-46

5. a. Study medications: 1 [] Discontinue 2 [] Increase 3 [] Decrease 4 [] Delay of required change (9) 5 [] No change b. Initiation of open-label therapy this visit?: 1 [] Yes 2 [] No (10) 49 (9) 50

6. Reason: Check one only; provide details in Comments, Item 9. 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 (11)

7. For drug discontinuations only - Is this participant still willing to be followed in the SHEP clinic? 1 [] Yes (12) 2 [] No 52

Complete SH50 - Refusal or Lost to Follow-up Documentation

8. For participants reaching escape blood pressure: Date Month Day 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) RECORD TYPE (25) 94 DATE RECEIVED (26) 95-100

9. Comments: (22) ↑ 0/1 89 104-109 (28) DATE LAST PROCESSED UPDATE NUMBER (27) 101-103 PAPER COPY (29) 110

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

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

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