30-32 (1) FORM NUMBER

33 (2) VERSION

SIDE EFFECTS QUESTIONNAIRE

(518) 40 SEQUENCE

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

2. Acrostic: (6) 41-46 [ ][ ][ ][ ][ ][ ]

3. Date of clinic visit to which this form applies: [36][37] Month [38][39] Day [34][35] Year (7)

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

This form is required at all clinic visits after a SHEP medication is started or increased; at all visits where the participant responds positively to any of the general side effects questions, and at all Annual visits.

Since your last visit, have you had:	(a)	New since last visit? (b) 1=Yes 2=No	Frequency: (c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	Severity: (d) 1=Not troublesome 2=Troublesome 3=Intolerable	In the opinion of the SHEP clinician, is this due to the use of SHEP medications? (e) 1=Yes 2=Possibly 3=No	
5. Unusual coldness or numbness of the hands or feet?	(9) Yes □ 1 No □ 2 49	→ (10) [50]	(11) [51]	(12) [52]	(13) [53]	
6. Unusual skin rash or bruising?	(14) Yes □ 1 No □ 2 54	→ (15) [55]	(16) [56]	(17) [57]	(18) [58]	→ (f) Is an acute skin rash present on physical exam? (19) Yes □ 1 Possibly □ 2 No □ 3 59
7. Any feelings of unsteadiness or imbalance?	(20) Yes □ 1 No □ 2 60	→ (21) [61]	(22) [62]	(23) [63]	(24) [64]	
8. Faintness or light headedness when you stand up quickly?	(25) Yes □ 1 No □ 2 65	→ (26) [66]	(27) [67]	(28) [68]	(29) [69]	→ (f) Is there an observable postural drop in blood pressure? (35) Yes □ 1 No □ 2 75
9. Loss of consciousness or passing out	70 (30) Yes □ 1 No □ 2	→ (31) [71]	(32) [72]	(33) [73]	(34) [74]	
10. Falls?	76 (36) Yes □ 1 No □ 2	→ (37) [77]	(38) [78]	(39) [79]	(40) [80]	
11. Fractures?	81 (41) Yes □ 1 No □ 2	→ (42) [82]	(43) [83]	(44) [84]	(45) [85]	→ (f) Hip? Yes □ 1 No □ 2 (46) 86 87 (47) (g) Spine? Yes □ 1 No □ 2 (h) Forearm? Yes □ 1 No □ 2 88 (48)

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12. Unusual pain in any joint?	49 Yes ☐ 1 → No ☐ 2 (89)	50 90	51 91	52 92	53 93	→ (f) Are there physical signs of acute arthritis? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 — 54 (94)
13. Muscle weakness or cramping?	95 55 Yes ☐ 1 → No ☐ 2	56 96	57 97	58 98	59 99	
14. Excessive thirst?	100 60 Yes ☐ 1 → No ☐ 2	61 101	62 102	63 103	64 104	
15. Loss of appetite?	105 65 Yes ☐ 1 → No ☐ 2	66 106	67 107	68 108	69 109	
16. Nausea or vomiting?	110 70 Yes ☐ 1 → No ☐ 2	71 111	72 112	73 113	74 114	
17. Unusual indigestion?	115 75 Yes ☐ 1 → No ☐ 2	76 116	77 117	78 118	79 119	
18. Change in bowel habits?	120 80 Yes ☐ 1 → No ☐ 2	81 121	82 122	83 123	84 124	
19. Tarry black stools or red blood in the stools?	125 85 Yes ☐ 1 → No ☐ 2 →	86 126	87 127	88 128	89 129	
20. Heart beating unusually fast or skipping beats?	130 90 Yes ☐ 1 → No ☐ 2	91 131	92 132	93 133	94 134	
21. Heart beating unusually slow?	135 95 Yes ☐ 1 → No ☐ 2	96 136	97 137	98 138	99 139	→ (f) Is an arrhythmia present on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 — 105 (145)
22. Episodes of chest pain or heaviness in the chest?	140 100 Yes ☐ 1 → No ☐ 2	101 141	102 142	103 143	104 144	

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23. Headaches so bad you had to stop what you were doing?	106 Yes □ 1 → No □ 2 146	107 147	108 148	149 109	150 110
24. Stuffy nose?	151 111 Yes □ 1 → No □ 2	112 152	113 153	154 114	155 115
25. Unusual shortness of breath or wheezing?	156 116 Yes □ 1 → No □ 2	117 157	118 158	159 119	160 120
26. Unusual tiredness or loss of pep?	162 122 Yes □ 1 → No □ 2	163 123	164 124	165 125	166 126
27. Swelling of the ankles?	127 167 Yes □ 1 → No □ 2	128 168	129 169	170 130	171 131
28. Feeling so depressed (sad or blue) that it interfered with your work, recreation or sleep?	173 133 Yes □ 1 → No □ 2	174 134	175 135	176 136	177 137
29. Any trouble with your memory or concentration?	178 138 Yes □ 1 → No □ 2	179 139	180 140	181 141	182 142
30. Nightmares?	183 143 Yes □ 1 → No □ 2	184 144	185 145	186 146	187 147
31. Any changes in your sexual activity?	148 188 Yes □ 1 → No □ 2	189 149	190 150	191 151	192 152

(f) Is there evidence for bronchospasm on auscultation of the chest?
161 121 Yes □ 1 Possibly □ 2 No □ 3

(f) Is there evidence of CHF on physical exam?
172 132 Yes □ 1 Possibly □ 2 No □ 3

(f) Loss of interest 193 153 Yes □ 1 No □ 2
194 154 (g) Decline in frequency? Yes □ 1 No □ 2
195 155 (h) Loss of enjoyment? Yes □ 1 No □ 2
196 156 (i) Functional impairment? Yes □ 1 No □ 2

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32. Trouble going to sleep, or waking early and having trouble getting back to sleep?	Yes ☐ 1 → No ☐ 2 (157) 197	(158) ☐ 198	(159) ☐ 199	(160) ☐ 200	(161) ☐ 201	
33. Waking up in the night more frequently to urinate?	Yes ☐ 1 → No ☐ 2 (162) 202	(163) ☐ 203	(164) ☐ 204	205 (165) ☐	206 (166) ☐	
34. More worry or anxiety than usual?	Yes ☐ 1 → No ☐ 2 207 (167)	(168) 208	(169) 209	210 (170) ☐	211 (171) ☐	
35. Weakness or numbness on one side, or unexpected difficulties talking or thinking?	Yes ☐ 1 → No ☐ 2 (172) 212	(173) ☐ 213	(174) ☐ 214	215 (175) ☐	216 (176) ☐ →	(f) Is there evidence of a stroke on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 217 (177)
36. Other relevant symptoms: Specify: _____	Yes ☐ 1 → No ☐ 2 (178) 218	☐ (179) 219	(180) ☐ 220	221 (181) ☐	222 (182) ☐ →	(f) Are there other relevant signs on physical exam? Yes ☐ 1 Possibly ☐ 2 No ☐ 3 Specify: _____ 223 (183)

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