

30-32 (1) FORM NUMBER

SIDE EFFECTS QUESTIONNAIRE

(58) <sup>40</sup> SEQUENCE

33 (2) VERSION

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:

(7) 36 37  
Month

38 39  
Day

34 35  
Year

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

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)	(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	(e) 1=Yes 2=Possibly 3=No	In the opinion of the SHEP clinician, is this due to the use of SHEP medications?
5. Unusual coldness or numbness of the hands or feet? 49	(9) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(10) 50	(11) 51	(12) 52	(13) 53	
6. Unusual skin rash or bruising? 54	(14) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(15) 55	(16) 56	(17) 57	(18) 58	(f) Is an acute skin rash present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3
7. Any feelings of unsteadiness or imbalance? 60	(20) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(21) 61	(22) 62	(23) 63	(24) 64	
8. Faintness or light headedness when you stand up quickly? 65	(25) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(26) 66	(27) 67	(28) 68	(29) 69	(f) Is there an observable postural drop in blood pressure? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2
9. Loss of consciousness or passing out 70	(30) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(31) 71	(32) 72	(33) 73	(34) 74	
10. Falls? 76	(36) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(37) 77	(38) 78	(39) 79	(40) 80	
11. Fractures? 81	(41) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(42) 82	(43) 83	(44) 84	(45) 85	(f) Hip? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (g) Spine? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2 (h) Forearm? Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2

Since your last visit, have you had:	New since last visit?		Frequency:	Severity:	In the opinion of the SHEP clinician, is this due to the use of SHEP medications?	
	(a)	(b) 1=Yes 2=No	(c) 1=once only 2=<weekly 3=2-6 x weekly 4=daily 5=constantly	(d) 1=Not troublesome 2=Troublesome 3=Intolerable	(e) 1=Yes 2=Possibly 3=No	(f)
12. Unusual pain in any joint?	89 (49) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(50) 90	(51) 91	(52) 92	(53) 93	(f) Are there physical signs of acute arthritis? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3 94 (54)
13. Muscle weakness or cramping?	95 (55) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(56) 96	(57) 97	(58) 98	(59) 99	
14. Excessive thirst?	100 (60) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(61) 101	(62) 102	(63) 103	(64) 104	
15. Loss of appetite?	105 (65) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(66) 106	(67) 107	(68) 108	(69) 109	
16. Nausea or vomiting?	110 (70) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(71) 111	(72) 112	(73) 113	(74) 114	
17. Unusual indigestion?	115 (75) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(76) 116	(77) 117	(78) 118	(79) 119	
18. Change in bowel habits?	120 (80) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(81) 121	(82) 122	(83) 123	(84) 124	
19. Tarry black stools or red blood in the stools?	125 (85) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(86) 126	(87) 127	(88) 128	(89) 129	
20. Heart beating unusually fast or skipping beats?	130 (90) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(91) 131	(92) 132	(93) 133	(94) 134	
21. Heart beating unusually slow?	135 (95) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2	(96) 136	(97) 137	(98) 138	(99) 139	(f) Is an arrhythmia present on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3 145 (105)
22. Episodes of chest pain or heaviness in the chest?	140 (100) Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 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? 146	(106) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(107) 147	(108) 148	149 (109) <input type="checkbox"/>	150 (110) <input type="checkbox"/>			
24. Stuffy nose? 151	(111) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(112) 152	(113) 153	154 (114) <input type="checkbox"/>	155 (115) <input type="checkbox"/>			
25. Unusual shortness of breath or wheezing? 156	(116) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(117) 157	(118) 158	159 (119) <input type="checkbox"/>	160 (120) <input type="checkbox"/>			
26. Unusual tiredness or loss of pep? 162	(122) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(123) 163	(124) 164	165 (125) <input type="checkbox"/>	166 (126) <input type="checkbox"/>			
27. Swelling of the ankles? 167	(127) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(128) 168	(129) 169	170 (130) <input type="checkbox"/>	171 (131) <input type="checkbox"/>			
28. Feeling so depressed (sad or blue) that it interfered with your work, recreation or sleep? 173	(133) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(134) 174	(135) 175	176 (136) <input type="checkbox"/>	177 (137) <input type="checkbox"/>			
29. Any trouble with your memory or concentration? 178	(138) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(139) 179	(140) 180	181 (141) <input type="checkbox"/>	182 (142) <input type="checkbox"/>			
30. Nightmares? 183	(143) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(144) 184	(145) 185	186 (146) <input type="checkbox"/>	187 (147) <input type="checkbox"/>			
31. Any changes in your sexual activity? 188	(148) Yes <input type="checkbox"/> 1 → No <input type="checkbox"/> 2	(149) 189	(150) 190	191 (151) <input type="checkbox"/>	192 (152) <input type="checkbox"/>			
						(f) Is there evidence for bronchospasm on auscultation of the chest? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3		
						(f) Is there evidence of CHF on physical exam? Yes <input type="checkbox"/> 1 Possibly <input type="checkbox"/> 2 No <input type="checkbox"/> 3		
						(f) Loss of interest <input type="checkbox"/> 153 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2		
						(g) Decline in frequency? <input type="checkbox"/> 154 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2		
						(h) Loss of enjoyment? <input type="checkbox"/> 155 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2		
						(i) Functional impairment? <input type="checkbox"/> 156 Yes <input type="checkbox"/> 1 No <input type="checkbox"/> 2		

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

RETURN TO SH41

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- DATE RECEIVED (185) 225-230
- UPDATE NUMBER (186) 232-233
- DATE LAST PROCESSED (187) 234-239
- PAPER COPY (188) 240
- (189) Cross-Forms Edit Status
- 241

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