

- 30-32 **(1)** FORM NUMBER  
 33 **(2)** VERSION  
 40 **(5/8)** SEQUENCE

COMPLIANCE EVALUATION

1. SHEP ID: **(3)**   - **(4)**     - **(5)**
2. Acrostic: **(6)** 41-46
3. Date of clinic visit:       **(7)**  
 Month Day Year
4. Sequence number: **(8)**

This form is required at every clinic visit after SHEP medications are started or increased, and at semi-annual and annual visits.

At the one-month visit: "We know that people sometimes miss a dose of their medicine for one reason or another, or they just forget. We are going to ask you a few questions at each clinic visit about taking your SHEP medicines. Your answers may help us to understand certain problems that can occur when people have to take medicines for a long period of time."

At other visits: "I am now going to ask you a few questions about taking your medicines since your last visit."

5. Have you missed taking your SHEP medicines anytime in the past 7 days? **(9)** 1  Yes 2  No  
 49 ↓

6. Which days did you miss? (Circle days mentioned.)  
 M T W Th F S S → Total days missed **(50)** **(10)**

7. Why did you miss taking the medicines?  
 (Push for answers, but do not mention specific categories.)

	<u>Mentioned</u>	<u>Not Mentioned</u>
a. Wasn't feeling well	51 <b>(11)</b> 1 <input type="checkbox"/>	2 <input type="checkbox"/>
b. Medicine made participant ill (Specify) _____	1 <input type="checkbox"/> <b>(12)</b> 52	2 <input type="checkbox"/>
c. Just forgot	53 <b>(13)</b> 1 <input type="checkbox"/>	2 <input type="checkbox"/>
d. Away from home/didn't have medicine	1 <input type="checkbox"/> <b>(14)</b> 54	2 <input type="checkbox"/>
e. Ran out of medicine	55 <b>(15)</b> 1 <input type="checkbox"/>	2 <input type="checkbox"/>
f. Didn't want to take (Reason) _____	1 <input type="checkbox"/> <b>(16)</b> 56	2 <input type="checkbox"/>
g. Doctor (usual source of care) told me to stop	57 <b>(17)</b> 1 <input type="checkbox"/>	2 <input type="checkbox"/>
h. Other (Specify) _____	1 <input type="checkbox"/> <b>(18)</b> 58	2 <input type="checkbox"/>

8. What did you do when you missed taking your SHEP medicines? (Push for answers, but do not provide specific categories.)

	<u>Mentioned</u>	<u>Not Mentioned</u>
a. Waited and doubled up the next dose	59 (19) 1 <input type="checkbox"/>	2 <input type="checkbox"/>
b. Did nothing/took usual dose next time	1 <input type="checkbox"/> (20) 60	2 <input type="checkbox"/>
c. Reports missed dose(s) at next clinic visit	61 (21) 1 <input type="checkbox"/>	2 <input type="checkbox"/>
d. Called SHEP clinic	1 <input type="checkbox"/> (22) 62	2 <input type="checkbox"/>
e. Recorded missed dose(s)	63 (23) 1 <input type="checkbox"/>	2 <input type="checkbox"/>
f. Took it later	1 <input type="checkbox"/>	2 <input type="checkbox"/>
g. Other (specify) _____	(24) 64	

9: How many times a day do you take your C1/C2? (Circle correct Step I drug.)

Every other day  1  
 Once per day  2 (25) 65  
 Other \_\_\_\_\_  3  
 (Specify)

10. How many do you take each time?

One  1 (26) 66  
 Other \_\_\_\_\_  2  
 (Specify)

11. When do you take it?

Morning when getting up  1 (27) 67  
 Other \_\_\_\_\_  2  
 (Specify)

If participant is not on Step II medications, go to 15.

12. How many times a day to your take your A1/A2/R? (Circle correct Step II drug.)

Once per day  1  
 Twice per day  2 (28) 68  
 Other \_\_\_\_\_  3  
 (Specify)

13. How many do you take each time?

One  1 (29) 69  
 Other \_\_\_\_\_  2  
 (Specify)

14. When do you take it?

Morning when getting up  1  
 Morning when getting up, and late afternoon or bedtime  2 (30) 70  
 Other \_\_\_\_\_  3  
 (Specify)

15. Was a pill count done at this visit? <sup>71</sup> (31) 1  Yes 2  No, SHEP medications not brought to clinic

RECORD TYPE (34) 80 a. Step I result: [72][73][74] . [75] % (32) DATE LAST PROCESSED 90-95 (37)  
 DATE RECEIVED (35) 81-86 b. Step II result: [76][77][78] . [79] % (33) PAPER COPY (38) 96  
 UPDATE NUMBER (36) 87-89 97 (39) EDIT STATUS CODE

If participant reports missing doses, or pill count result (if done) is less than 80% for either Step I or Step II, or participant is not taking drugs properly, reinforce instructions on how to take SHEP medications.

3-8 (54) BATCH DATE (56) TIME MODIFIED 17-20 SH40/2  
 11-16 (55) DATE MODIFIED (57) EDIT STATUS 21



33 (2) VERSION (3) (4) COMPLIANCE EVALUATION

(6) 41-46

1. SHEP ID:   -     -   (5)
2. Acrostic:
3. Date of clinic visit:       (7) Month Day Year
4. Sequence number:   (8)

This form is required at the next scheduled visit after SHEP medications are started or increased, and at semi-annual visits. Do not administer if participant was not prescribed SHEP blinded medications at the last visit.

At the one-month visit: "We know that people sometimes miss a dose of their medicine for one reason or another, or they just forget. We are going to ask you a few questions at each clinic visit about taking your SHEP medicines. Your answers may help us to understand certain problems that can occur when people have to take medicines for a long period of time."

At other visits: "I am now going to ask you a few questions about taking your medicines since your last visit."

5. Have you missed taking your SHEP medicines anytime in the past 7 days? (9) 1  Yes 2  No  
49  
↓

6. Which days did you miss? (Circle days mentioned.)  
M T W Th F S S → Total days missed (50) (10)

7. Why did you miss taking the medicines? (Push for answers, but do not mention specific categories.)
- |  | <u>Mentioned</u>                   | <u>Not Mentioned</u>       |
|--|------------------------------------|----------------------------|
| a. Wasn't feeling well                           | 51 (11) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| b. Medicine made participant ill (Specify) _____ | 1 <input type="checkbox"/> (12) 52 | 2 <input type="checkbox"/> |
| c. Just forgot                                   | 53 (13) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| d. Away from home/didn't have medicine           | 1 <input type="checkbox"/> (14) 54 | 2 <input type="checkbox"/> |
| e. Ran out of medicine                           | 55 (15) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| f. Didn't want to take (Reason) _____            | 1 <input type="checkbox"/> (16) 56 | 2 <input type="checkbox"/> |
| g. Doctor (usual source of care) told me to stop | 57 (17) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| h. Other (Specify) _____                         | 1 <input type="checkbox"/> (18) 58 | 2 <input type="checkbox"/> |

8. What did you do when you missed taking your SHEP medicines? (Push for answers, but do not provide specific categories.)
- |  | <u>Mentioned</u>                   | <u>Not Mentioned</u>       |
|--|------------------------------------|----------------------------|
| a. Waited and doubled up the next dose         | 59 (19) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| b. Did nothing/took usual dose next time       | 1 <input type="checkbox"/> (20) 60 | 2 <input type="checkbox"/> |
| c. Reports missed dose(s) at next clinic visit | 61 (21) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| d. Called SHEP clinic                          | 1 <input type="checkbox"/> (22) 62 | 2 <input type="checkbox"/> |
| e. Recorded missed dose(s)                     | 63 (23) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |
| f. Took it later                               | 1 <input type="checkbox"/> (24) 64 | 2 <input type="checkbox"/> |
| g. Other (specify) _____                       | 98 (40) 1 <input type="checkbox"/> | 2 <input type="checkbox"/> |

If the participant is not currently being prescribed C1 or C2, skip to Item 12.

9. How many times a day do you take your C1/C2?  
(Circle correct Step 1 drug.)

Every other day  1  
Once per day  2 **(25)** 65  
Other  3  
(Specify) \_\_\_\_\_

10. How many do you take each time?

One  1  
Other  2 **(26)** 66  
(Specify) \_\_\_\_\_

11. When do you take it?

Morning when getting up  1  
Other  2 **(27)** 67  
(Specify) \_\_\_\_\_

If participant is not currently being prescribed A1, A2 or R, skip to Item 15.

12. How many times a day do you take your A1/A2/R?  
(Circle correct Step 2 drug.)

Once per day  1  
Twice per day  2 **(28)** 68  
Other  3  
(Specify) \_\_\_\_\_

13. How many do you take each time?

One  1  
Other  2 **(29)** 69  
(Specify) \_\_\_\_\_

14. When do you take it?

Morning when getting up  1  
Morning when getting up,  
and late afternoon  2 **(30)** 70  
or bedtime  3  
Other \_\_\_\_\_  
(Specify) \_\_\_\_\_

Item 15 for interviewer only. Skip pill count for home and telephone visits.

15. Was a pill count done at this visit?

71 **(31)** Yes  1 No  2

**(32)** a. Step 1 result:    .  %

**(33)** b. Step 2 result:    .  %

If participant reports missing doses, or pill count result (if done) is less than 80% for either Step 1 or Step 2, or participant is not taking drugs properly, reinforce instructions on how to take SHEP medications.

3-8 <b>(514)</b> BATCH DATE	RECORD TYPE <b>(34)</b> 80	DATE LAST PROCESSED <b>(37)</b> 90-95
11-16 <b>(515)</b> DATE MODIFIED	DATE RECEIVED <b>(35)</b> 81-86	PAPER COPY <b>(38)</b> 96
17-20 <b>(516)</b> TIME MODIFIED	UPDATE NUMBER <b>(36)</b> 87-89	97 <b>(39)</b> EDIT STATUS CODE
21 <b>(517)</b> EDIT STATUS		