SIDE EFFECTS

SLOS Simvastatin Study

☐ NIH
☐ KKI

Subject Number ☐☐☐☐☐

Subject Initials ☐☐☐

Study Month: (circle one):
0, 0.5, 1, 3, 6, 9, 12, 14, 15, 17, 20, 23, 26
Other: ____

Date Assessment Completed: ___ ___ / ___ ___ / ___ ___ ___ ___
m m d d y y y y

Staff ID: ☐☐☐

Was any data collected for this form? (Circle one) **Yes** **No** (If **YES,** continue.)

Your Initials: ☐☐☐

Relationship to Child:____

1= Mother
2= Grandmother
3= Guardian, female
4= Other female
5= Father
6= Grandfather
7= Guardian, male
8= Other male

Directions: For each behavior, please check the box corresponding to the degree of the behavior as observed over the *past week*. If absent, or if you have not seen the problem, check the box marked absent.

Mild = causes little or no interference in every day life (e.g., behavior occurs occasionally and is low in intensity)
Moderate = causes some interference in every day life (e.g., behavior occurs occasionally and is high in intensity *or* behavior occurs frequently and is low in intensity)
Severe = causes clear and substantial interference in every day life (e.g. behavior occurs frequently and is high in intensity)

**If the behavior was present prior to starting this protocol, indicate the degree of this behavior by writing mild, moderate or severe in this column , using the above definitions.

BEHAVIOR	Absent	Present prior**	Mild	Moderate	Severe	Office Use
1. Irritable, easily annoyed, touchy (emotionally over-reactive)						
2. Crabby, whiny						
3. Tearful, prone to crying						
4. Sad, unhappy, depressed						
5. Social withdrawal, talks or interacts little						
6. Staring, daydreaming						
7. Dull, not alert						
8. Drowsy, sleepy						
9. Insomnia						
10. Eating less						
11. Eating more						
12. Diarrhea, loose bowel movements						
13. Change in urine color						
14. Change in skin or whites of eye color						
15. Dizzy, balance unstable						
16. Headaches						
17. Weakness						
18. Stomachaches, nausea, vomiting						

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BEHAVIOR	Absent	Present prior**	Mild	Moderate	Severe	Office Use
18. Anxiety, fear, nervousness						
19. Restless, high activity level						
20. Easily excited						
21. Excessive talking						
22. Excessively happy, silly						
23. Bizarre behavior						
24. Weakness						
25. Muscle cramping						
26. Gets stuck on repetitive activities						
27. Stereotypic movements (deliberate, repetitive movements with no apparent function: e.g., rocks body back and forth; shakes hand(s) in front of eyes)						
28. Self injury (deliberately hurts self – e.g., bites, hits, scratches, or otherwise injures self)*						
29. Repetitive picking at hair, skin, fingernails or biting fingernails*						
30. Other (specify) ____________ ____________						
31. Other (specify) ____________ ____________						

* If picking or nail biting causes self-injury, rate the degree of self-injury on item 28. Also rate the picking or nail biting on item 29.

Do you have any additional comments about possible side effects? (Since last form)

____

For Clinician:

	YES	NO
32. Current heath complaints	1	2
33. Recent injuries, illness requiring medical attention	1	2
34. Recent illness	1	2
35. Concurrent medication	1	2

If **yes,** complete Concomitant Medication Form

Review each item, score 0 for absent, 1 for mild, 2 for moderate, and 3 for severe. Enter a final score in the shaded column.