

VIEW: PHYS

DCMNAME: PHYSICAL\_EXAM

DCMSUBNM: PHYEXAM

# Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial

## Physical Exam Form (Form # 46)

PID

--	--	--	--	--	--

1. Participant ID number

ALPHCD

--	--

2. Alpha code

VISN

--	--	--	--	--	--

3. Visit Number

4. a. Date of Examination .....(dd/mmm/yyyy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ VISDT  
 b. Username of person completing the exam..... \_\_\_\_\_ UNEXAM
5. a. Height/length .....(cm) \_\_\_\_\_ . HEIGHT  
 b. Weight.....(kg) \_\_\_\_\_ . WEIGHT
6. Blood Pressure:  
 a. Sitting.....(systolic/diastolic) \_\_\_\_\_ / BPSYS1/BPDIA1  
 b. Standing.....(systolic/diastolic) \_\_\_\_\_ / BPSYS2/BPDIA2
7. Edema ..... EDEMA  
 Enter highest code. Code 0 = none, 1 = pretibial, 2 = above knee, 3 = presacral, 4 = ascites, 5 = anasarca
8. Heart rate per minute ..... HRTR

*This question will be completed for all participants.*

9. a. Is this a menstruating female? .....(0 = no, 1 = yes, 8 = not applicable, male) BIRCON6  
 If Q9a=1 (yes), respond to items b1-4 below.
- b. For menstruating females, what forms of birth control is the participant using as reported at this visit (a response to 1 – 4 is required):
1. Barrier methods.....(0 = no, 1 = yes) BIRCON1  
 a. If yes to item b1, how many forms of barrier methods are used..... BCFMS
2. Oral contraceptive.....(0 = no, 1 = yes) BIRCON2
3. Injectable contraceptive.....(0 = no, 1 = yes) BIRCON4
4. Abstinent.....(0 = no, 1 = yes) BIRCON5

For visits labeled B01, W00, W14, W26, W38, W52, and W78 and the participant was not considered a treatment failure at W26 or W52, continue. For all other follow-up visits (or a semi-annual visit held for a participant identified as a W26 or W52 treatment failure), record abnormalities only.

10. a. Respiratory rate per minute..... RESPR  
 b. Temperature.....(°C) \_\_\_\_\_ . TEMP

11. Cushingoid.....(0 = no, 1 = yes) SYMNY1
12. a. Eyes..... (0 = normal, 1 = abnormal) SYMNA1  
b. If abnormal, were there cataracts.....(0 = no, 1 = yes) SYMNY2  
c. If other abnormality, description ..... SYMDS1  
d. MedDRA code ..... SYMMD1
13. a. Pharynx/mouth..... (0 = normal, 1 = abnormal) SYMNA2  
b. If abnormal, was there gingival hyperplasia.....(0 = no, 1 = yes) SYMNY2  
c. If abnormal, description..... SYMDS2  
d. MedDRA code ..... SYMMD2
14. a. Chest/Breast..... (0 = normal, 1 = abnormal) SYMNA3  
b. If abnormal, description..... SYMDS3  
c. MedDRA code ..... SYMMD3
15. a. Lung..... (0 = normal, 1 = abnormal) SYMNA4  
b. If abnormal, description..... SYMDS4  
c. MedDRA code ..... SYMMD4
16. a. Heart..... (0 = normal, 1 = abnormal) SYMNA5  
b. If abnormal, description..... SYMDS5  
c. MedDRA code ..... SYMMD5
17. a. Abdomen..... (0 = normal, 1 = abnormal) SYMNA6  
b. If abnormal, description..... SYMDS6  
c. MedDRA code ..... SYMMD6
18. a. Genitourinary..... (0 = normal, 1 = abnormal, 2 = not done) SYMNA7  
b. If abnormal, description..... SYMDS7  
c. MedDRA code ..... SYMMD7
19. Is the participant pre pubertal?.....(0 = no, 1 = yes) SYMNY4

- 20. a. Lymph nodes..... (0 = normal, 1 = abnormal) SYMNA8
- b. If abnormal, description..... SYMDS8
- c. MedDRA code..... SYMMD8
- 21. a. Skin..... (0 = normal, 1 = abnormal) SYMNA9  
    If skin is abnormal, complete items b – f.
- b. Hirsutism.....(0 = no, 1 = yes) SYMNY5
- c. Striae.....(0 = no, 1 = yes) SYMNY6
- d. Acne.....(0 = no, 1 = yes) SYMNY7
- e. If other abnormality, description..... SYMDS9
- f. MedDRA code..... SYMMD9
- 22. a. Neurologic..... (0 = normal, 1 = abnormal) SYMNA10  
    If neurologic is abnormal, complete items b – e.
- b. Tremor..... (0 = no, 1 = yes) SYMNY8
- c. Muscle strength..... (0 = normal, 1 = decreased) SYMNA11
- d. If other abnormality, description..... SYMDS10
- e. MedDRA code..... SYMMD10
- 23. a. Any other abnormal findings.....(0 = no, 1 = yes) SYMNY9
- b. If abnormal, description..... SYMDS11
- c. MedDRA code..... SYMMD11

200. Date this form reviewed..... (dd/mmm/yyyy) \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ COMPUT

201. Username of person reviewing this form..... COMBY

**Automatically stored:**

**202. Date this form entered (dd/mmm/yyyy) (“Created On”)**

**203. Username of person entering this form (“By”)**