

Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial Baseline Visit Form (Form # 11)

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1. Participant ID Number

PID

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2. Alpha Code

ALPHCD

B	0	1
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3. Visit Number

VISN

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4. Date of Visit (dd/mmm/yyyy)

VISDT

Symptoms in the past month. Code 0 = no, 1 = yes.

- 5. Edema (10014210)..... EDEMA
- 6. Fainting (10016169)..... FAIN
- 7. Dizzy on standing (10013581)..... DIZZY
- 8. Nausea (10028813)..... NAUSEA
- 9. Vomiting (10047700)..... VOMIT
- 10. Diarrhea (10012727)..... DIARRH
- 11. Cough (10011224)..... COUGH

Other Symptoms:	MedDRA Code:
12. MDVT	MDCLLT
13.	
14.	
15.	

SYMPTOM 1 -
SYMPTOM 2 2

16. Current menarche status?..... MNSTAT
1 = pre menarche female
2 = currently menstruating female
3 = post menopausal
8 = not applicable (male)

17. For menstruating females: birth control status?..... BIRCON
1 = pre pubertal, post menopausal
2 = abstinent
3 = agrees to use two forms of birth control
4 = none of the above
8 = not applicable (male)

Study Medications: code 1 = pills, 2 = liquid

18. Participant preference for study medication formulation
a. CSA..... MEDFRM 1
b. Dexamethasone..... MEDFRM 2
c. Lisinopril/Losartan MEDFRM 3
d. MMF MEDFRM 4
e. Prednisolone/Prednisone..... MEDFRM 5

PPD/Tuberculosis History Information

19. History of a positive PPD?(0 =no, 1 = yes) POS PPD
If no, place PPD (no controls needed) and enter PPD results using Form 91 TB Skin Test Form.

20. If the participant had a positive PPD/Tuberculosis, was a Chest X-ray done? CHSTX
0 = no, 1 = yes, 8 = not applicable

21. Date of Chest X-ray(dd/mmm/yyyy) _____ / _____ / _____ CHSDT

22. Results of Chest X-ray CHSRES
1 = normal
2 = abnormal & probable TB/Tuberculosis related
3 = abnormal but not TB/Tuberculosis related
8 = not applicable
9 = unknown

23. TB Medicine – therapy history TBTHER
1 = completed 6 months preventative therapy (INH, rifampin, etc)
2 = incomplete preventative therapy
3 = TB/Tuberculosis not treated
8 = not applicable

Socioeconomic status

24. Health insurance: HLTINS
1 = private
2 = Medicaid/Medicare
3 = none
98 = participant declines
99 = can't ask

25. What is the highest level of education the participant completed? EDLEV
00 = ≤ kindergarten
01 - 11 = specify grade
12 = high school graduate/GED
13 = some college
14 = graduated college
15 = some graduate school
16 = advanced degree
98 = participant declines
99 = can't ask

26. What is the participant's gross household income per year? INCOME
1 = \$0 - \$14,999
2 = \$15,000 - \$24,999
3 = \$25,000 - \$34,999
4 = \$35,000 - \$49,999
5 = \$50,000 - \$79,999
6 = \$80,000 +
98 = participant declines
99 = can't ask

27. Number of adults (≥ 19 years) in the same household (not counting the participant).... NUMADL
(Enter 98 = participant declines, 99 = can't ask)

28. Number of children (< 19 years) in the same household (not counting the participant) NUMCHL
(Enter 98 = participant declines, 99 = can't ask)

29. a. How did the participant hear of this study? PTHEAR
1 = Personal physician
2 = Study brochure or other literature
3 = Website
4 = Study physician, if different from your personal physician
5 = Study coordinator
6 = Study participant
7 = Other OTHSPE1

b. Who first approached the participant with information of the study? PTAPAR
1 = Personal physician
2 = Study physician, if different from your personal physician
3 = Study coordinator
4 = Other OTHSPE2

200. Date this form completed.....(dd/mmm/yyyy) _____/_____/_____

201. Username of person completing this form..... _____

Automatically stored:

202. Date this form entered (dd/mmm/yyyy) ("Created On")

203. Username of person entering this form ("By")