

# Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial Study Exit Before Randomization Form (Form # 31)

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1. Participant ID Number

ALPHCD

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2. Alpha Code

VISN

B	0	1
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3. Visit Number

VISIT DATE: VISDT  
Auto calculated

Please respond with a code of "1=Yes" to any new exclusion criteria detected during baseline. Other items can be left blank.

- 5. Participant is moving out of the area? ..... MOVING
- 6. Participant/guardian no longer wants to participate?..... PTOUT
- 7. Participant's personal physician no longer wants the patient to participate? ..... PHYOUT
- 8. FSGS Study Team no longer thinks the patient should be enrolled? ..... FSGOUT
- 9. Age – Pt ≥ 41 years prior to randomization? ..... OLDAGE  
(before randomization, database will confirm patient has not yet reached 41<sup>st</sup> birthday)
- 10. a. GFR <40 ml/min/1.73m<sup>2</sup>? ..... LOWGFR
- b. Date of blood draw for Serum Creatinine measurement that determined  
    ineligibility.....(dd/mmm/yyyy) \_\_\_/\_\_\_/\_\_\_ DRAWDT1
- 11. a. Absolute neutrophil count (ANC) < 2000? ..... LDWANC
- b. Date of blood draw for ANC measurement that determined  
    ineligibility.....(dd/mmm/yyyy) \_\_\_/\_\_\_/\_\_\_ DRAWDT2
- 12. a. Hematocrit < 28%? ..... LOWHCT
- b. Date of blood draw for Hematocrit measurement that determined  
    ineligibility.....(dd/mmm/yyyy) \_\_\_/\_\_\_/\_\_\_ DRAWDT3
- 13. a. Serum Potassium ≥ 5.5 mEq/L measured on a non-hemolyzed sample? ..... HIGHSK
- b. Date of blood draw for Serum Potassium measurement that determined  
    ineligibility.....(dd/mmm/yyyy) \_\_\_/\_\_\_/\_\_\_ DRAWDT4
- 14. FSGS Clinical Trial age stratum full? ..... STFULL
- 15. BMI too high? ..... HIBMI
- 16. a. Baseline Protein to creatinine ratio(s) ineligible? ..... INUPC
- b. Date of last urine collection that determined  
    ineligibility.....(dd/mmm/yyyy) \_\_\_/\_\_\_/\_\_\_ COLDT
- 17. Biopsy ineligible? ..... INBIOP
- 18. Currently participating in another therapeutic trial? ..... OTHTRL

19. Pregnant? ..... PREG
20. Breastfeeding? ..... BRSTFD
21. Currently menstruating female who does not practice abstinence and refuses to use two forms of birth control? ..... BIRCON
22. Transplant recipient? ..... TXRCPT
23. History of malignancy? ..... MALIG
24. Uncontrolled hypertension? ..... HIGHBP
25. Participant requires 4 or more antihypertensive medicines? ..... MEDBP
26. Diabetes Mellitus? ..... DIABET
27. Cirrhosis or chronic active liver disease found? ..... LIVERD
28. Hepatitis B? ..... HEPB
29. Hepatitis C? ..... HEP C
30. HIV? ..... HIV
31. Sickle cell disease? ..... SICKLE
32. Significant GI disorder detected? ..... GID
33. Solitary kidney? ..... SOLKID
34. Anemia? ..... ANEMIA
35. Reflux nephropathy? ..... REFNEP
36. Allergic to dexamethasone? ..... ALGDEX
37. Allergic to both ACE-I and ARB? ..... ALGARB
38. Treated with cyclosporin? ..... TRTCYC
39. Treated with tacrolimus? ..... TRTTAC
40. Treated with azathioprine? ..... TRTAZA
41. Treated with mycophenolate? ..... TRTMYC
42. Treated with sirolimus? ..... TRTSIR
43. Treated with cyclophosphamide in the past 30 days? ..... TRTCPP
44. Treated with levamisole in the past 30 days? ..... TRTLEV
45. Treated with chlorambucil in the past 30 days? ..... TRTCHL
46. Treated with methotrexate in the past 30 days? ..... TRTMET
47. Treated with nitrogen mustard in the past 30 days? ..... TRTINIT
48. Other? ..... OTHER

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")**