Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial Preliminary Screening Form (Form # 10)

Prior to each individual participant's shipment (blood and/or urine) to Spectra, a hard copy of page 1 of this Form 10 **must** be included inside the shipping container. This step is for each first shipment (per participant) to Spectra. Also, this form should be entered within 24-hours into the Oracle database.

1. Participant ID number PID
2. Alpha code ALPHCDV
3. Visit Number VISN **B 0 1**

4. Date of birth ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ DOB
5. Gender ..... (1 = male, 2 = female) SEX
6. Race ..... RACE
   - 1 = Caucasian-non-Hispanic
   - 2 = Caucasian-Hispanic
   - 3 = Black-non-Hispanic
   - 4 = Black-Hispanic
   - 5 = Asian
   - 6 = Native Hawaiian or Other Pacific Islander
   - 7 = American Indian or Alaskan Native
   - 8 = Multi Racial
   - 9 = Other
7. Communication of participant:
   a. Primary language ..... (1 = English, 2 = Spanish, 3 = French, 4 = Other) P_LANG
   b. Can the participant speak English? ..... (0 = no, 1 = yes) SP_ENG
   c. Can the participant read English? ..... (0 = no, 1 = yes) RD_ENG
8. Age at onset of signs or symptoms of FSGS ..... (years) AGEONS, (months) MONONS
9. Height at onset of FSGS (before steroid exposure) ..... (UNK = unknown) (cm) ___ ___.HTP_STR
10. Estimated dry weight at onset of FSGS (before steroid exposure) ..... (UNK = unknown) (kg) ___ ___.DRY_WT
11. Body Mass Index at onset of FSGS (use estimated dry wt and measured height) ..... (kg/m^2) ___ ___.BMI
12. If Q9 and Q10 are unknown, was the participant obese before the onset of FSGS and before corticosteroid exposure? ..... (0 = no, 1 = yes, 8 = not applicable) OBESE
13. Date of biopsy diagnosis of FSGS ..... (mmm/yyyy) ___ ___ ___ /___ ___ BIOPDT
14. Is the biopsy consistent with idiopathic FSGS? ..... (0 = no, 1 = yes) BIOPSY
15. a. Is the participant currently pregnant? ..... (0 = no, 1 = yes, 8 = not applicable) PREG
    b. Is the participant currently breast-feeding? ..... (0 = no, 1 = yes, 8 = not applicable) BRSTFD
16. a. Does the participant have hypertension? ..... (0 = no, 1 = yes) HIGHBP
    b. Is blood pressure controlled to ≤140/95 and ≤95th percentile for age and height (age <18 years)? ..... (0 = no, 1 = yes 8 = not applicable) CTRLBP
    c. How many medicines is the participant taking for the primary purpose of blood pressure control? ..... BPMED

Questions 17 to 31 below are exclusion criteria. Code 0 = no, 1 = yes.

17. Is the participant currently participating in another therapeutic trial? ..... OTHTRL
18. Has the participant already received a transplant? ..... TXRECD
19. Does the participant have a malignancy? ..... MALIG
20. Does the participant have diabetes mellitus? ..... DIABET
21. Does the participant have cirrhosis or chronic active liver disease? ..... LIVERD
22. a. Does the participant currently have hepatitis B? ..... HEPB
    b. Does the participant currently have hepatitis C? ..... HEPC
23. Does the participant have a history of HIV? ..... HIV
24. Does the participant have a history of sickle cell disease? ..... SICKLE
25. Does the participant have a history of significant gastrointestinal disorder (e.g., severe chronic diarrhea or active peptic ulcer disease)? ..... GID
26. Does the participant have a known solitary kidney? ..... SOLKID
27. Does the participant have a history of reflux nephropathy? ..... REFNEP
28. Does the participant have another form of secondary FSGS? ..... OTFSGS
29. Does the participant have a known allergy to:
    a. Dexamethasone? ..... ALGDEX
    b. Angiotensin Converting Enzyme-Inhibitors? ..... ALGACE
    c. Angiotensin Receptor Blockers? ..... ALGARB
30. Has the participant ever been treated with:
    a. Cyclosporin? ..... CYCLOS
    b. Tacrolimus? ..... TACROL
    c. Azathioprine? ..... AZATHI
    d. Mycophenolate? ..... MYCOPH
    e. Sirolimus? ..... SIROLI

31. In the 30 days before this form was completed, was participant treated with:
    a. Cyclophosphamide?..... CYCLOP
    b. Levamisole?..... LEVAMI
    c. Chlorambucil?..... CHLORA
    d. Methotrexate?..... METHOT
    e. Nitrogen mustard?..... NIMUST
32. Current ACE/ARB status..... ACEARB
    1 = on ACE only, 2 = on ARB only and willing to come off ARB during follow up, 3 = on ARB only and not willing to come off ARB during follow up, 4 = on ACE and ARB both and willing to come off ARB during follow up, 5 = on ACE and ARB both and not willing to come off one of them during follow up, 6 = not on ACE or ARB

33. a. Most recent weight..... (kg) ___ ___ ___.WEIGHT
    b. Date measured.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ WT_DT
    c. Most recent height ..... (cm) ___ ___ ___.HEIGHT
    d. Date measured.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ HT_DT
34. a. Most recent serum creatinine.....(mg/dl) ___.CREAT
    b. Date measured.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ CREADT
    c. Estimated GFR.....(ml/min/1.73 m^2) ___ ___ ___.___ GFR

FINAL ELIGIBILITY CRITERIA

Previous Therapy for FSGS

35. Participant had at least 4 consecutive weeks of corticosteroid therapy?.....(0 = no, 1 = yes) CORTRX1
36. Was the cumulative dose for the duration of that corticosteroid therapy at least 56 mg/kg or 1680 mg of prednisone or equivalent?.....(0 = no, 1 = yes, 8 = not applicable) CORTRX5
37. Did the participant demonstrate steroid resistance defined as a failure to achieve a sustained urine protein/creatinine ratio $\leq$ 1.0 during the treatment course referred to in Q35-36? .....(0 = no, 1 = yes, 8 = not applicable) RATYN
38. Has the participant ever had a complete remission of proteinuria (UP/Cr <0.2 or UA protein 0/trace) after the treatment course referred to in Q35-38? ..... CR
    0 = no, 1 = yes, 8 = not applicable
39. Estimate the number of doses of IV pulse methylprednisolone used in the past?..... (UNK = unknown) NMDOSE

Consent

40. Date of FSGS study consent.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ / CONSDT1

41. Date of assent.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ / CONSDT2

100. Is the participant eligible based on the data on this form?.....(0 = no, 1 = yes) ELIG

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")

Participant Information
(May be written on another sheet.)

Stored locally. Not key entered into the study database:

Name of participant/parents: _____

Address: _____

Address: _____

Phone number: _____

Alternate contact not living with this participant: _____

Alternate contact phone number: _____

Physicians' names: _____

_____

Contact information: _____

Note: Old Eligibility criteria provided for informational purposes - see #35-41

31. In the 30 days before this form was completed, was participant treated with:
    a. Cyclophosphamide? ..... ___
    b. Levamisole? ..... ___
    c. Chlorambucil? ..... ___
    d. Methotrexate? ..... ___
    e. Nitrogen mustard? ..... ___

32. Current ACE/ARB status ..... ___
    1 = on ACE only, 2 = on ARB only and willing to come off ARB during follow up, 3 = on ARB only and not willing to come off ARB during follow up, 4 = on ACE and ARB both and willing to come off ARB during follow up, 5 = on ACE and ARB both and not willing to come off one of them during follow up, 6 = not on ACE or ARB

33. a. Most recent weight ..... (kg) ___ ___ ___.___
    b. Date measured ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___
    c. Most recent height ..... (cm) ___ ___ ___.___
    d. Date measured ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

34. a. Most recent serum creatinine ..... (mg/dl) ___.___
    b. Date measured ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___
    c. Estimated GFR ..... (ml/min/1.73 m^2) ___ ___ ___.___

OLD ELIGIBILITY CRITERIA

Previous Therapy for FSGS

35. Participant had at least 8 consecutive weeks of corticosteroid therapy? ..... (0 = no, 1 = yes) ___ CORTRX1

36. During the 8 consecutive weeks of corticosteroids, were at least 4 consecutive weeks dosed daily? ..... (0 = no, 1 = yes, 2 = no but overall dose was equivalent, 8 = not applicable) ___ CORTRX2
    (4 of the 8 weeks can be alternate day corticosteroids, or equivalent dose met)

37. Was the daily corticosteroid dose during the 4 consecutive weeks of daily therapy *at least* 2 mg/kg, 60 mg/m^2 or 60 mg?
    ..... (0 = no, 1 = yes, 2 = no but overall dose was equivalent, 8 = not applicable) ___ CORTRX3

38. In the remaining 4 weeks, was the dose at least alternate day, 1 mg/kg, 40mg or 40 mg/m^2? ..... (0 = no, 1 = yes, 2 = no but overall dose was equivalent, 8 = not applicable) ___ CORTRX4

39. Did the participant demonstrate steroid resistance defined as a failure to achieve a sustained urine protein/creatinine ratio ≤ 2 (U/A protein $\leq$ 1+) during the treatment course referred to in Q35-38? ..... (0 = no, 1 = yes, 8 = not applicable) ___ RATYN

40. Has the participant ever had a complete remission of proteinuria (UP/Cr <0.2 or UA protein 0/trace) after the treatment course referred to in Q35-38? ..... ___ CR
    0 = no, 1 = yes, 8 = not applicable

41. Number of doses of IV pulse methylprednisolone used in the past? ..... ___ NMDOSE
    0 = none, 1 = one, 2 = two, 3 = three, 4 = four or more