FORM210
FSGS Novel Therapies (FONT-II)
Screening Form (Form # 210)

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.

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1. Participant ID number PID
2. Alpha code ALPHCD
3. Visit Number CPEVENT / VISIT_NUMBER / SUBEVENT_NUMBER

4. a. Was this participant enrolled in the FSGS-CT Study? ..... (0=no, 1=yes)___FSGSCT

   b. If Q4a is yes, FSGS-CT PID Number..... ___ ___ ___ ___ ___ ___FSGSID

5. Date of birth ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___DOB

6. Gender.....(1=male, 2=female) ___SEX

7. a. Ethnicity.....___ETHNIC
   1 = Not Hispanic or Latino, 2 = Hispanic or Latino, 8 = Unknown/Not reported

   b. Race .....___RACE
   1 = American Indian/Alaska Native 2 = Asian
   3 = Black or African American 4 = White
   5 = More than one race 8 = Unknown/Not reported

Inclusion Criteria – all must be completed

8. FSGS confirmed by renal biopsy?..... ___BIOPSY
   1 = FONT pathologist confirmed, 2 = FSGS-CT pathologist confirmed, 3 = not confirmed, pending

9. Age at onset of proteinuria ..... Years ___ ___AGEONS Months ___ ___MONONS

10. Locally estimated GFR ..... (ml/min/1.73 m^2) ___ ___ ___.___GFR
    [Estimated GFR using Schwartz (age <18 yr) or Cockroft-Gault (age ≥ 18 yr)]

11. Local Up/c > 1.0 g/g creatinine on first morning void? ..... (0=no, 1=yes)___UPCGTI

12. Practicing acceptable forms of birth control (female) ..... ___BIRCON
    1 = pre pubertal, post menopausal or surgically sterile 4 = none of the above
    2 = abstinent 8 = not applicable (male)
    3 = agrees to use two forms of birth control

13. Blood pressure is controlled <140/90 (≥ 18 yrs) or <95th percentile

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for age and height (< 18 yrs)..... (0=no, 1=yes)___CTRLBP

14. Resistant to prior prescribed immunomodulatory therapy ..... (0=no, 1=yes)___RESIMM

Exclusion Criteria – all must be completed

15. Is the patient currently pregnant or breastfeeding?..... (0=no, 1=yes, 8=Male, N/A)___PREGBF
16. Ever diagnosed with or received: (0=no, 1=yes)
    a. Transplant organ or bone marrow?..... ___RCVTX
    b. Malignancy (history of)? ..... ___DXMLG
    c. Diabetes Mellitus? ..... ___DXDM
    d. Hepatic Disease, Cirrhosis, Hepatitis, or chronic <u>active</u> liver disease?..... ___DXHEP
    e. HIV or AIDS?..... ___DXHIV
    f. Other active serious infection? ..... ___DXINF
    g. Congestive Heart Failure? ..... ___DXCHF
    h. Myocardial Infarction (history of)? ..... ___DXMYOC
    i. Multiple Sclerosis? ..... ___DXMS
    j. Systemic Lupus Erythematosus? ..... ___DXSLE
17. Participation in another therapeutic trial involving protocol mandated Administration of a immunosuppressive medication concurrently or 30 days prior to randomization? ..... (0=no, 1=yes)___OTHTRL
18. Has the participant ever been treated with the following agents:
    a. Adalimumab or other TNFα antagonist?..... (0=no, 1=yes)___TNFA
    b. Galactose.....(0=no, 1=yes)___GALACT
19. Has participant received <u>any</u> immunosuppressive agents other than steroids in the past 30 days? .....(0=no, 1=yes)___IMMRX
20. Has participant received Rituximab in the past 90 days?.....(0=no, 1=yes)___RITUX

Medical History

21. Has the patient ever been treated with:
    [0=no, 1=yes, 9=unknown (a-j), enter UNK= unknown (a1 – j1)]
    a. Cyclosporine? ..... ___CSA
        1. Estimated cumulative exposure (in months)..... ___ ___ ___CSAMON
    b. Tacrolimus? ..... ___TACROL
        1. Estimated cumulative exposure (in months)..... ___ ___ ___TACMON
    c. Azathioprine?..... ___AZATHI
        1. Estimated cumulative exposure (in months)..... ___ ___ ___AZAMON
    d. Mycophenolate?..... ___MMF

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1. Estimated cumulative exposure (in months)..... ___ ___ ___MMFMON

e. Sirolimus?.....___SIROL

1. Estimated cumulative exposure (in months)..... ___ ___ ___SIRMON

f. Rituximab?.....___RTX

1. Estimated cumulative exposure (in months)..... ___ ___ ___RTXMON

g. Steroids? .....___STROID

1. Estimated cumulative exposure (in months)..... ___ ___ ___STRMON

h. Cyclophosphamide?.....___CYTXN

1. Estimated cumulative exposure (in months)..... ___ ___ ___CYTMON

i. Chlorambucil?..... ___CHLORM

1. Estimated cumulative exposure (in months)..... ___ ___ ___CHLMON

j. Other immunosuppressives.....___IMMSUP

1. Estimated cumulative exposure (in months)..... ___ ___ ___IMMMON

22. Current and chronic health conditions in the past 5 years for which medical care was received?

Condition:	**MedDRA Code:**
a. MDVT	MDCLLT
b.	
c.	
d.	

Does the participant meet the criteria of:

23. a. Steroid resistance (failure to achieve sustained Up/c <1.0 following a standard course of prednisone/prednisolone/methylprednisolone prescribed for FSGS therapy___STRRES
1 = steroid resistant 2 = established intolerance to steroids
3 = anticipated intolerance to steroids 4 = none of the above (not eligible)

b. Patient immunosuppressive status:.....___IMSTAT
1 = off all immunosuppressives including steroids
2 = on minimal dose of corticosteroids for stability/discussed with Drs. Trachtman or Gipson
3 = on minimal dose of corticosteroids for stability/not yet discussed with Drs. Trachtman or Gipson
4 = currently using more than a minimal dose of immunosuppressives (including steroids)

24. a. Is the participant taking ACEi/ARB therapy? (0=no; 1=ACEi only; 2=ARB only; 3=both)
___ACEARB1

b. In the judgment of the site PI, has participant been on a full and steady dose of ACEi and/or ARB for at least 2 weeks, at the time of B01 visit?

(0 = no, 1 = yes, 2 = yes, but on ACEi only, 3 = yes, but on ARB only,8 = not applicable) ___ACEARB2

25. Has ACEi or ARB ever been stopped due to intolerance? (0=no; 1=ACEi; 2=ARB; 3=both) ___OFFAA

26. Does the participant have a known allergy to:
    a. Angiotensin Converting Enzyme Inhibitors (ACEi)?..... (0=no 1=yes)___ALGACE
    b. Angiotensin Receptor Blockers (ARB)? ..... (0=no 1=yes)___ALGARB
    c. Atorvastatin (Lipitor)..... (0=no 1=yes)___ALGLIP
    d. Adalimumab?.....(0=no 1=yes)___ALGADA

27. Past Medical History:
    a. Birth weight of participant (enter UNK = unknown).....(kg)___ ___ ___.___BIRTHWT
    b. Was the participant born prematurely?..... (0=no, 1=yes, 9=unknown)___PRBORN
    c. If yes, how many weeks prematurely
    (enter UNK = unknown, NA = not applicable)..... (wks)___ ___PBWKS

Have participant ever had:

28. Seizures?.....(0=no 1=yes)___SEIZUR

29. Blood clot?.....(0=no 1=yes)___BDCLOT

30. Hypertension?.....(0=no 1=yes)___HIGHBP

Heart Condition:

31. a. Arrhythmia?.....(0=no 1=yes)___ARRHY
    b. LVH? .....(0=no 1=yes)___LVH
    c. Congenital deformality? .....(0=no 1=yes)___DEFRM
    d. Valvular disease?.....(0=no 1=yes)___VALVDS
    e. Other condition?.....(0=no 1=yes)___OTHCON
        1. If Other, specify:

Condition:	MedDRA Code:
MDVT	MDCLLT

32. a. Smoking History.....(0=never, 1=former smoker, 2=current smoker, 9=unknown)___ SMOKE
    b. If current smoker, estimate number of cigarettes per day .....(NA=not applicable)___ ___ SMKNUM

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c. Do you live or work with someone who smokes regularly? ..... ___ ___ SNDSMK
0 = no, 1 = yes, 9 = unknown, 98 = declines

33. How many first degree relatives [including mother, father, sister(s), brother(s), son(s), daughter(s)] ever had: (enter UNK = unknown)
a. Kidney Disease (other than kidney stones or urinary tract infections)..... ___ ___ RLKIDY
b. Dialysis or Kidney Transplant ..... ___ ___ RLDIAL

c. Proteinuria..... ___ ___RLPROT

d. FSGS..... ___ ___RLFSGS

34. Health insurance ..... ___ ___HLTINS

1 = private	4 = National Health Insurance (Canadian)
2 = Medicaid/Medicare	98 = participant declines
3 = none	99 = can't ask

35. What is the highest level of education the participant completed? ..... ___ ___EDLEV

00 = ≤ kindergarten	15 = some graduate school
01 – 11 = specify grade	16 = advanced degree
12 = high school graduate/GED	98 = participant declines
13 = some college	99 = can't ask
14 = graduated college	

36. What is the participant's gross household income per year?..... ___ ___INCOME

1 = $0 - $14,999	5 = $50,000 - $79,999
2 = $15,000 - $24,999	6 = $80,000 +
3 = $25,000 - $34,999	98 = participant declines
4 = $35,000 - $49,999	99 = can't ask

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

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

39. Appropriate FONT study consent date ..... dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___CONSDT

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

200. a. Form Completed By .....(Print name)_____
Q200a is not entered into database

b. "Username" of person completing this form ..... ___ ___ ___ ___ ___ ___ ___ ___

c. Date this form completed.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

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201. a. Principal Investigator (PI) Signature ..._____
Q201a is not entered into database

b. F210 signed by PI ..... (0=no, 1=yes) ___PISIGN

c. "Username" of PI..... ___ ___ ___ ___ ___ ___ ___ ___

d. Date form signed by PI ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___PIDT

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