DATASET: F60-F61

Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial
Adverse Event Report Form (Form # 60)

PID | ALPHCD | VISN

1. Participant ID number
2. Alpha code
3. Visit Number

4. a. Date of onset.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___ AEDT

   b. Source of adverse event..... AESRCE
   (1 = central lab results, 2 = local lab results, 3 = other, 4 = two consecutive high BP measurements documented on F16 or F79)

5. Date of initial report.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___ REPDT
   (Note: For high BP, enter the date of the second measurement)

Description: (record diagnoses and/or signs and or symptoms below)

6a. Condition:	MedDRA Code:
MDVT	MDC LLT

b. Prior history of similar event..... (0 = no, 1 = yes-describe in comments – 6j, 9 = unknown) ___ PEVENT

c. Severity of event..... SAESEV
   1 = mild, awareness of the sign or symptom, but easily tolerated
   2 = moderate, enough discomfort to interfere with usual activity
   3 = severe, incapacitating, with inability to do usual work or activity

d. Does the Principal Investigator believe that the event may have been caused by study drug?
   0 = no | 2 = possibly | 4 = definitely
   1 = unlikely | 3 = probably | 8 = not applicable

   d1. CSA..... SAEREL1
   d2. Dexamethasone SAEREL2
   d3. Lisinopril/Losartan..... SAEREL3
   d4. MMF SAEREL4
   d5. Prednisolone/Prednisone..... SAEREL5

e. If the event is related to study drug, what is the expectedness of the event?
   1 = unexpected – not mentioned in the drug labeling
   2 = expected, but of greater severity than mentioned in the drug labeling
   3 = expected and accurately described in the drug labeling

   e1. CSA..... AEEXP1
   e2. Dexamethasone AEEXP2
   e3. Lisinopril/Losartan..... AEEXP3

e4. MMF AEEXP4

e5. Prednisolone/Prednisone AEEXP5

f. Action taken

0 = none
1 = study drug reduced
2 = study drug temporarily held
3 = study drug discontinued
4 = other

f1. CSA AEACT1

f2. Dexamethasone AEACT2

f3. Lisinopril/Losartan AEACT3

f4. MMF AEACT4

f5. Prednisolone/Prednisone AEACT5

f6. If any of the items f1 to f5 is "Other", specify

_____ ACTOTH1

_____ ACTOTH2

ACTOTH3

g1. Outcome of event ..... AEOUT

0 = recovered without treatment
1 = recovered with treatment
2 = event continuing without treatment
3 = event continuing and controlled with treatment
4 = event continuing and not controlled with treatment
5 = participant died
6 = not yet available

g2. Outcome final as per discussion with Clinical Management Committee ..... (1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___ AECCDT

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

Note: for data entry purposes, the database screen is a REPEATING GROUP. Multiple entries are permitted for items a-j. Pressing the "enter" key will clear items a-j. for entry of another condition. To exit the repeating group, press the "page down" key to go to question 200.

7a. Condition:	MedDRA Code:

Use the codes from Q6c-g

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 7j, 9 = unknown) ___

c. Severity of event ..... ___

d. Does the PI believe that the event may have been caused by study drug?
   d1. CSA..... ___
   d2. Dexamethasone ..... ___
   d3. Lisinopril/Losartan..... ___
   d4. MMF ..... ___
   d5. Prednisolone/Prednisone..... ___

e. If the event is related to study drug, what is the expectedness of the event
   e1. CSA..... ___
   e2. Dexamethasone ..... ___
   e3. Lisinopril/Losartan..... ___
   e4. MMF ..... ___
   e5. Prednisolone/Prednisone..... ___

f. Action taken
   f1. CSA..... ___
   f2. Dexamethasone ..... ___
   f3. Lisinopril/Losartan..... ___
   f4. MMF ..... ___
   f5. Prednisolone/Prednisone..... ___
   f6. If any of the items f1 to f5 is "Other", specify

   _____

   _____

g1. Outcome of event..... ___
   0 = recovered without treatment
   1 = recovered with treatment
   2 = event continuing without treatment
   3 = event continuing and controlled with treatment
   4 = event continuing and not controlled with treatment
   5 = participant died
   6 = not yet available

g2. Outcome final as per discussion with Clinical Management Committee..... (1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

j. Comments: _____

_____

8a. Condition:	MedDRA Code:

Use the codes from Q6c-g

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 8j, 9 = unknown) ___

c. Severity of event ..... ___

d. Does the PI believe that the event may have been caused by study drug?

d1. CSA ..... ___

d2. Dexamethasone ..... ___

d3. Lisinopril/Losartan ..... ___

d4. MMF ..... ___

d5. Prednisolone/Prednisone ..... ___

e. If the event is related to study drug, what is the expectedness of the event

e1. CSA ..... ___

e2. Dexamethasone ..... ___

e3. Lisinopril/Losartan ..... ___

e4. MMF ..... ___

e5. Prednisolone/Prednisone ..... ___

f. Action taken

f1. CSA ..... ___

f2. Dexamethasone ..... ___

f3. Lisinopril/Losartan ..... ___

f4. MMF ..... ___

f5. Prednisolone/Prednisone ..... ___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event ..... ___

0 = recovered without treatment
1 = recovered with treatment
2 = event continuing without treatment

3 = event continuing and controlled with treatment
4 = event continuing and not controlled with treatment
5 = participant died
6 = not yet available

g2. Outcome final as per discussion with Clinical Management Committee..... (1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion.... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

9a. Condition:	MedDRA Code:

Use the codes from Q6c-g

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 9j, 9 = unknown) ___

c. Severity of event .....___

d. Does the PI believe that the event may have been caused by study drug?

d1. CSA.....___

d2. Dexamethasone .....___

d3. Lisinopril/Losartan.....___

d4. MMF .....___

d5. Prednisolone/Prednisone.....___

e. If the event is related to study drug, what is the expectedness of the event

e1. CSA.....___

e2. Dexamethasone .....___

e3. Lisinopril/Losartan.....___

e4. MMF .....___

e5. Prednisolone/Prednisone.....___

f. Action taken

f1. CSA.....___

f2. Dexamethasone .....___

f3. Lisinopril/Losartan.....___

f4. MMF .....___

f5. Prednisolone/Prednisone.....___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event.....___
0 = recovered without treatment
1 = recovered with treatment
2 = event continuing without treatment
3 = event continuing and controlled with treatment
4 = event continuing and not controlled with treatment
5 = participant died
6 = not yet available

g2. Outcome final as per discussion with Clinical Management Committee..... (1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

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

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

DATASET: F60-F61

Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial
Serious Adverse Event Report Form (Form # 61)

1. Participant ID number

2. Alpha code

3. Visit Number

4. Date of onset.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

5. Date of initial report.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

6. a. Study Physician reporting the event ....

   b. Phone number.....(___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Serious Criteria: Code 0 = no, 1 = yes

7. a. Fatal .....(if yes, complete Death Notification Form #63) ___ SERCRT1

   b. Immediately life-threatening ..... ___ SERCRT2

   c. Required hospitalization ..... (if yes, complete Hospitalization Form #62) ___ SERCRT3

   d. Prolonged existing hospitalization..... ___ SERCRT4

   e. Persistent or significant disability/incapacity ..... ___ SERCRT5

   f. Congenital anomaly/birth defect..... ___ SERCRT6
   (Pregnancy with or without resultant in a birth defect)

   g. Causes cancer..... ___ SERCRT7

   h. Overdose of study medication ..... ___ SERCRT8

8a. Condition:	MedDRA Code:

   b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 8j, 9 = unknown) ___

   c. Severity of event..... ___
   1 = mild, awareness of the sign or symptom, but easily tolerated
   2 = moderate, enough discomfort to interfere with usual activity
   3 = severe, incapacitating, with inability to do usual work or activity
   4 = life-threatening
   5 = fatal

d. Does the PI believe that the event may have been caused by study drug?

0 = no 2 = possibly 4 = definitely
1 = unlikely 3 = probably 8 = not applicable

d1. CSA ..... ___

d2. Dexamethasone ..... ___

d3. Lisinopril/Losartan ..... ___

d4. MMF ..... ___

d5. Prednisolone/Prednisone ..... ___

e. If the event is related to study drug, what is the expectedness of the event

1 = unexpected – not mentioned in the drug labeling
2 = expected, but of greater severity than mentioned in the drug labeling
3 = expected and accurately described in the drug labeling

e1. CSA ..... ___

e2. Dexamethasone ..... ___

e3. Lisinopril/Losartan ..... ___

e4. MMF ..... ___

e5. Prednisolone/Prednisone ..... ___

f. Action taken

0 = none 2 = study drug temporarily held 4 = other
1 = study drug reduced 3 = study drug discontinued (complete F45)

f1. CSA ..... ___

f2. Dexamethasone ..... ___

f3. Lisinopril/Losartan ..... ___

f4. MMF ..... ___

f5. Prednisolone/Prednisone ..... ___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event ..... ___

0 = recovered without treatment
1 = recovered with treatment
2 = event continuing without treatment
3 = event continuing and controlled with treatment
4 = event continuing and not controlled with treatment
5 = participant died
6 = not yet available

g2. Outcome final as per discussion with Clinical Management Committee ..... (1=yes blank o/w) ___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

Note: for data entry purposes, the database screen is a REPEATING GROUP. Multiple entries are permitted for items a-j. Pressing the "enter" key will clear (scroll) items a-j. for entry of another condition. To exit the repeating group, press the "page down" key to go to question 200.

9a. Condition:	MedDRA Code:

Use the codes from Q8c-g

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 9j, 9 = unknown) ___

c. Severity of event ..... ___

d. Does the PI believe that the event may have been caused by study drug?

d1. CSA..... ___

d2. Dexamethasone ..... ___

d3. Lisinopril/Losartan..... ___

d4. MMF ..... ___

d5. Prednisolone/Prednisone..... ___

e. If the event is related to study drug, what is the expectedness of the event

e1. CSA..... ___

e2. Dexamethasone ..... ___

e3. Lisinopril/Losartan..... ___

e4. MMF ..... ___

e5. Prednisolone/Prednisone..... ___

f. Action taken

f1. CSA..... ___

f2. Dexamethasone ..... ___

f3. Lisinopril/Losartan..... ___

f4. MMF ..... ___

f5. Prednisolone/Prednisone..... ___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event.....___

g2. Outcome final as per discussion with Clinical Management Committee..... (1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

10a. Condition:	MedDRA Code:

Use the codes from Q8c-g

b. Prior history of similar event .....(0 = no, 1 = yes-describe in comments – 10j, 9 = unknown) ___

c. Severity of event .....___

d. Does the PI believe that the event may have been caused by study drug?

d1. CSA.....___

d2. Dexamethasone .....___

d3. Lisinopril/Losartan.....___

d4. MMF .....___

d5. Prednisolone/Prednisone.....___

e. If the event is related to study drug, what is the expectedness of the event

e1. CSA.....___

e2. Dexamethasone .....___

e3. Lisinopril/Losartan.....___

e4. MMF .....___

e5. Prednisolone/Prednisone.....___

f. Action taken

f1. CSA.....___

f2. Dexamethasone .....___

f3. Lisinopril/Losartan.....___

f4. MMF .....___

f5. Prednisolone/Prednisone.....___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event.....___

g2. Outcome final as per discussion with Clinical Management Committee .....(1=yes blank o/w)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

11a. Condition:	MedDRA Code:

Use the codes from Q8c-g

b. Prior history of similar event .....(0 = no, 1 = yes-describe in comments – 11j, 9 = unknown) ___

c. Severity of event .....___

d. Does the PI believe that the event may have been caused by study drug?

d1. CSA.....___

d2. Dexamethasone .....___

d3. Lisinopril/Losartan.....___

d4. MMF .....___

d5. Prednisolone/Prednisone.....___

e. If the event is related to study drug, what is the expectedness of the event

e1. CSA.....___

e2. Dexamethasone .....___

e3. Lisinopril/Losartan.....___

e4. MMF .....___

e5. Prednisolone/Prednisone.....___

f. Action taken

f1. CSA.....___

f2. Dexamethasone .....___

f3. Lisinopril/Losartan.....___

f4. MMF .....___

f5. Prednisolone/Prednisone.....___

f6. If any of the items f1 to f5 is "Other", specify

_____

_____

g1. Outcome of event.....___

g2. Outcome final as per discussion with Clinical Management Committee..... (1=yes **blank o/w**)___

g3. Date of the Clinical Man. Comm discussion..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

h. Date of outcome.....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___

j. Comments: _____

_____

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

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