

FORM271

FSGS Novel Therapies (FONT-II)

Study Exit Form After Randomization (Form # 271)

--	--	--	--	--	--

1. Participant ID Number
PID

--	--

2. Alpha Code
ALPHCD

--	--	--	--	--	--	--	--

3. Date (dd/mmm/yyyy)
CPEVENT / VISDT
VISIT_NUMBER /
SUBEVENT_NUMBER

REASON(S) FOR STUDY EXIT BEFORE STUDY DRUG EXPOSURE

- 4. Participant lost to follow-up?..... (0 = no, 1 = yes) ___ DSRSNY1
- 5. Personal physician choice? (0 = no, 1 = yes) ___ DSRSNY2
- 6. If yes, FONT study investigator choice? (0 = no, 1 = yes) ___ DSRSNY3
- 7. Participant/Parent choice? (0 = no, 1 = yes) ___ DSRSNY4
- 8. Specify reason (see list)..... ___ DSCRSN1

REASON(S) FOR STUDY EXIT AFTER STUDY DRUG EXPOSURE

- 9. Completion of study?..... (0 = no, 1 = yes) ___ DSRSNY5
- 10. Participant lost to follow-up?..... (0 = no, 1 = yes) ___ DSRSNY6
- 11. Personal physician choice? (0 = no, 1 = yes) ___ DSRSNY7
- 12. If yes, FONT study investigator choice? (0 = no, 1 = yes) ___ DSRSNY8
- 13. Participant/Parent choice? (0 = no, 1 = yes) ___ DSRSNY9
- 14. Specify reason (see list)..... ___ DSCRSN
- 15. Comments: _____ COMM

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) ___ / ___ / ___

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

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

c. "Username" of PI..... _____

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

REASON(S) FOR STUDY EXIT

- 01 = Work/school conflict
- 02 = Dependent care problem
- 03 = Transportation problem
- 04 = Too sick to come in
- 05 = In the hospital
- 10 = Refused; unhappy with frequency of protocol visits
- 11 = Refused; the participant is currently overwhelmed with personal problems
- 12 = Refused; does not like being part of a "research" study
- 13 = Refused; study participant feels there are too many study medications
- 14 = Refused; participant feels medications are causing side effects
- 15 = Refused; the participant's physician thinks the protocol is not good for his blood pressure control
- 16 = Refused; the participant thinks the study protocol is not good for his renal function
- 17 = Refused; the participant's physician thinks the protocol is not good for his renal function
- 18 = Refused; does not like the radioactivity related to bone densitometry
- 19 = Refused; does not like the study Clinical Center
- 20 = Refused; other reason
- 21 = Refused; reason unknown
- 30 = Scheduling conflict w/staff
- 31 = In jail or prison
- 32 = Participant moved away, current address known
- 33 = Participant moved away, current location unknown
- 34 = Study team has been unable to contact the participant
- 35 = Can no longer provide consent