Frequent Hemodialysis Network
PLANNED THERAPY DEVIATION - FORM #309

This form should be completed prior to planned reductions or increases in number of dialysis treatments or in treatment time: planned average time per session 30 minutes or different from prescribed time under the study protocol for a period of at least one week or received four or more treatments or greater as designated under the FHN protocol or for a nocturnal trial patient who dialyzed in-center rather than at home. Treatment deviations due to hospitalizations are not counted.

This form should be completed at the beginning of each month when the planned deviation will occur. Record the start date of the deviation in item #4.

1. Participant ID # | 2. Alpha Code | 3a. Visit Type | 3b. Visit Number | 4. Deviation Start Date: dd/mon/yyyy

5. This form is being completed because of the following reason(s): (For 5a-d: use 0=No, 1=Yes)

   a. The patient plans to miss 4 or more treatments (from randomized treatment assignment) during the next month: ..... __

   b. The patient plans to miss an average of at least 30 minutes or more treatment time (from randomized treatment assignment) for a period of at least 1 week: ..... __

   c. The patient will have 4 or more extra treatments in the next month ..... __

   d. Nocturnal Trial only: the patient will be receiving some dialysis treatments in-center this month instead of at home ..... __

6. a. Anticipated length of time until correction of deviation: ..... __

   1=1 month or less
   2=1-2 months
   3=2-4 months
   4=Remainder of study
   5=Indefinite

   b. During the period of planned deviation, how many dialysis treatments per week will the patient be undergoing? ..... __

   2=Less than 3 times/week
   3=3 times/week
   4=4 times/week
   5=5 times/week
   6=6 times/week

7. Is the planned deviation the result of a medical decision by a physician? ..... __
   (0=No, skip to Q9, 1=Yes, answer Q8)

8. If Q7 is Yes, indicate which of the following apply: (For 8a-h: use 0=No, 1=Yes)
   a. Hypotension? ..... __

   b. Phosphate depletion? ..... __

   c. Patient fatigue? ..... __

   d. Symptoms of under dialysis? ..... __

   e. Problems controlling fluid intake and treating physician insists on additional dialysis sessions rather than hyperfiltration sessions ..... __

Q8 (deviation due to medical reason continued: Code 0=No, 1=Yes)

f. Vascular access problem made no hemodialysis possible ..... __

g. Moderate vascular access problem was judged to make dialysis possible no more than 3x per week ..... __

h. Other medical indication described in text field (Q13) ..... __
(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)

9. Is the planned deviation the result of patient non-adherence? ..... __
(0=No, skip to Q11, 1=Yes, answer Q10)

10. If Q9 is Yes, indicate which of the following apply: (For 10a-g: use 0=No, 1=Yes)

a. Transportation difficulties? ..... __

b. Inadequate caregiver assistance? ..... __

c. Employment constraints? ..... __

d. Concern over vascular access? ..... __

e. Other time commitments? ..... __

f. Patient burn-out? ..... __

g. Patient symptoms suspected by patient to be due to over dialysis? ..... __

(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)

11. Is the planned deviation the result of logistical or scheduling issues with the dialysis unit? (0=No, skip to Q13, 1=Yes, answer Q12) ..... __

12. If Q11 is Yes, indicate which of the following apply: (For 12a-b: use 0=No, 1=Yes)

a. Staffing shortage? ..... __

b. Scheduling issues preclude the designated dialysis treatment schedule? ..... __
(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)

13. Other Comments: Please describe what is going on with this patient (database will allow up to 2000 characters)

_____

_____

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_____

200. Date this form completed (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

201. Username of person reviewing completeness of this form ..... __ __ __ __ __ __ __

For Clinical Center Use Only:

202. Username of person entering this form: __ __ __ __ __ __ __

203. Date Entered: (dd/mon/yyyy) __ __/__ __ __ /__ __ __ __