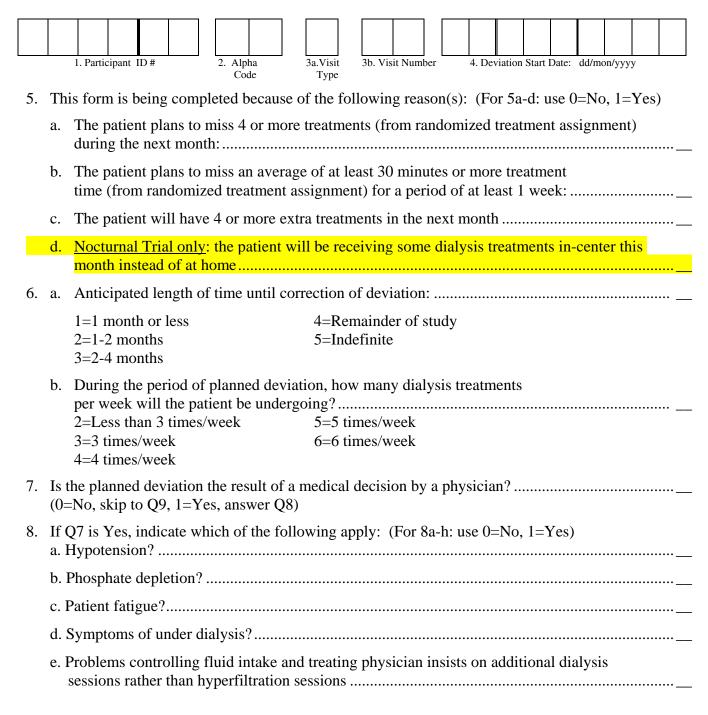
Frequent Hemodialysis Network PLANNED THERAPY DEVIATION - FORM #309

This form should be completed prior to planned <u>reductions</u> or <u>increases</u> 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 <u>each</u> month when the planned deviation will occur. Record the start date of the deviation in item #4.



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Page 2 of 2 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) 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 t	this form:		
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203. Date Entered: (dd/mon/yyyy) ___/___/____/