Frequent Hemodialysis Network
NOCTURNAL TRIAL PRE-RANDOMIZATION DROPOUT - FORM #103

This form is completed when it is determined that a patient who appeared to be eligible for the nocturnal study, enrolled in baseline and subsequently found to be ineligible. This patient consented but was not randomized.

1. Participant ID #	2. Alpha Code	3. Pre-Randomization Dropout Date (dd/mon/yyyy)

4. Primary Reason for Pre-Randomization Dropout .....__ __

Note: These choices are in rank order. Please enter the first reason that applies.

Primary - 1st Tier Reasons:

00=Patient died
01=Patient received a kidney transplant
02=Permanent access failed and was not replaced during baseline period, i.e., patient continues to use a non-tunneled catheter for HD
03=Unable to achieve a mean eKt/V of $\geq$ 1.0 on at least two baseline sessions
04=Baseline GFR greater than 10 ml/min/1.73m2 as measured by the average of urea and creatinine clearances obtained from a 24-hour urine collection
05=For reasons of home suitability, would be unable to perform hemodialysis at home
06=Patient unable or unwilling to have home hemodialysis
07=Patient would be unwilling or unable to complete training protocol
08=Based on physician or health care provider judgment, patient would not be adherent to home hemodialysis
09=Unable to have a baseline cardiac MRI
10=Unexpected finding was identified on cardiac MRI (such as a tumor), which limits the patient's ability to take trial treatments for the 12 month duration of the study
11=Unable to have baseline quality of life assessment
12=Admitted to an acute or chronic care hospital with no planned discharge in near future
14=No longer eligible under nocturnal protocol v3.0 - patient cannot do home dialysis.
15=Patient not interested in nocturnal protocol v3.0.
19=Neither home monitoring nor family support are available.

Secondary - Tier 2 Reasons

30=Currently requires HD more than 3 times per week for a medical indication other than ultrafiltration (such as, but not limited to: system oxalosis, or required total parenteral nutrition)
31=Native kidney function recovered or expected to recover without need for long-term dialysis
32=Life expectancy is less than six months
33=Has a medical history that limits the patient's ability to take trial treatments for the 12 month duration of the study. Examples include but are not limited to: currently receiving chemo or radiotherapy for a malignant neoplastic disease other than localized non-melanoma skin cancer, active systemic infection, AIDS (but not HIV)
34=Less than 3 months since returned to conventional HD after any other renal replacement modality (such as, failed transplant, short-daily HD, nocturnal HD, peritoneal dialysis)

(reasons continued on next page)

35=Currently uses one or more investigational drugs

36=Currently participates in another clinical trial that contradicts or interferes with therapies or measured outcomes in this trial
37=Patient unable to verbally communicate in either English or Spanish
38=Patient's age less than 18 years
39=Currently pregnant
40=Actively planning to become pregnant in the next 12 months
41=Has contraindications to heparin, including allergy or heparin-induced thrombocytopenia
42=Unable or unwilling to follow the ***study*** protocol for any reason (including reasons such as mental incompetence)
43=Scheduled for living donor kidney transplant within next year
44=Currently on or scheduled to go on peritoneal dialysis
45=Currently on short-daily dialysis
46=Currently on nocturnal dialysis
47=Scheduled to start home hemodialysis
48=Plans to relocate to another HD center not participating in this study
49=Expects to be geographically unavailable at the dialysis unit for >2 consecutive weeks in the next 12 months
50=Anticipates not having his/her HD in a unit participating in the study in the next 12 months
51=More than 15 weeks passed since baseline data collection, and new data could not be obtained
52=Logistics reasons
96=DCC use only: Study site dropped
97=Patient was lost to follow-up
98=Patient preference
99-Study team preference

If you have a reason for dropout not found on this listing, please contact the DCC for a new code.

5. Secondary Reason for Pre-Randomization Dropout..... __ __
(Use codes from Q4)

6. If Q4 or Q5 is "52=Logistics reasons", describe what happened.

_____

_____

_____

_____

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) __ __/__ __ __ /__ __ __ __