Frequent Hemodialysis Network
NOCTURNAL TRIAL ELIGIBLITY CONFIRMATION FORM - FORM #100

Instructions: This form is to be completed and entered into the FHN database. The first 4 digits in the patient id need to be the number assigned to the dialysis unit where this patient is being enrolled. The last two digits will be assigned by the study coordinator. The alpha code (item 2) will be generated automatically by the database when the form is key entered and saved. You will need to record this alpha code as it will be used in combination with the patient's ID number throughout the trial.

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

5. Date trial consent form signed (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

Mandatory Section (Questions 6-21): **Complete for all consenting patients**

Demographics

6. Date of birth (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   Note: Age less than 18 is an exclusion.

7. Gender? (1=Male, 2=Female).....__

8. a. Race.....__
   1=Native American, Aboriginal Canadian or Alaskan Native, First Nation, Aboriginal Australian
   2=Asian
   3=Native Hawaiian or Other Pacific Islander
   4=Black, African American, African
   5=White/Caucasian
   6=More than one race (multiracial)
   9=Unknown or not reported

   b. Hispanic or Latino ethnicity? (0=No, 1=Yes, 9=Unknown or not reported).....__

Communication

9. a. Patient's primary language? (1=English, 2=Spanish, 3=French, 4=Other) .....__
   Note: Inability to verbally communicate in English or Spanish is an exclusion.

   b. Can the patient speak English? (0=No, 1=Yes).....__

   c. Can the patient read English? (0=No, 1=Yes) .....__

   d. Can the patient speak Spanish? (0=No, 1=Yes) .....__

   e. Can the patient read Spanish? (0=No, 1=Yes).....__

10. Can the patient him/herself communicate over a standard telephone? (0=No, 1=Yes).....__

Height and Weight

11. a. Lowest weight recently achieved post dialysis (kg) .....__ __ __.__

    b. Most recent height (measure supine length in those unable to stand) (cm).....___ __ __.__
    For bilateral amputees, use historic height.
    Be sure to note on the Amputation Form #202, if the patient is a bilateral amputee.

Kidney Failure and Dialysis Treatment

12. a. Month and year patient was first treated for ESRD (with hemodialysis, peritoneal dialysis, or kidney transplantation) (mon/yyyy) ..... __ __ __/__ __ __ __

    b. Has patient had at least one week of 3x a week, in-center chronic hemodialysis? (0=No, 1=Yes) .....__
    (Note: Incident patients who have not been on dialysis for at least 1 week are excluded.)

13. Patient currently requires an additional ultrafiltration session beyond the 3x a week hemodialysis? (0=No, 1=Yes, occasionally, 2=Yes, always) .....__
    (*Note: The need for extra ultrafiltration treatments is not an exclusion.)*

14. Currently using a non-tunneled catheter for hemodialysis? (0=No, 1=Yes) .....__
    (*Note: Use of a non-permanent access is an exclusion.)*

15. If randomized to receive home nocturnal hemodialysis, patient seems willing and able to perform such treatments? (0=No, 1=Yes) ..... __
    (Note: More detailed assessment of home/patient suitability etc. to be performed during baseline assessment).

16. Does the patient have someone who could help him/her with home nocturnal hemodialysis if randomized to this therapy? (0=No, 1=Yes) .....__
    (Note: More detailed assessment of caregiver suitability etc. to be performed during baseline assessment. Answering "NO" to both questions 15 and 16 is an exclusion.)

17. On the basis of the physician's best clinical judgment, is the patient adherent to his or her hemodialysis regimen? (0=No, non-adherent, 1=Yes, adherent, 9=Unknown, patient is so new to HD –unable to evaluate) .....__

18. Able to have a cardiac MRI at beginning of trial and one year later? .....__
    (*Note: Inability to have MRI at baseline and at 1 year is an exclusion.)*
    1=Yes
    2=No, reason: patient is unwilling or unable to travel to MRI facility.
    3=No, reason: patient has a pacemaker or implanted defibrillator or is scheduled for placement.
    4=No, reason: patient has another metallic object in body or is scheduled for such placement. (Metallic objects include certain mechanical heart values, brain aneurysm clips.
    5=No, reason: patient is claustrophobic even if receives mild sedative.
    6=No, reason: patient is unable to lie still on back for 30 minutes even if receives mild sedative.
    7=No, reason: patient is too large to fit into MRI machine (*usually > 300 pounds but depends on .. patient's height and machine used*)

19. How many **minutes** does it take the patient to travel from his/her place of residence to the dialysis unit where he/she receives conventional hemodialysis? (one-way trip)..... __ __ __

20. Does the patient or his/her family have any out of pocket transportation costs (i.e., gas, parking, fares for public transportation, other) related to traveling to the dialysis unit for his/her hemodialysis? (0=No, 1=Yes) .....__

21. If randomized to receive nocturnal HD, how many **minutes** would it take the patient to travel from his/her place of residence to the unit where he/she would receive his/her nocturnal hemodialysis TRAINING sessions? (one-way trip).....__ __ __

Exclusion Criteria:
(For Questions 22-43: 0=No, 1=Yes) *Note: Any response of "1=Yes" is a reason for exclusion.* You may skip to Question 44 if any reason(s) for study exclusion is identified.

22. Life expectancy less than six months?.....__

23. Has a medical history that might limit his/her ability to undergo the study treatments for 12 months? 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)?.....__

24. Currently on short-daily dialysis?.....__

25. Currently on nocturnal dialysis?.....__

26. Less than 3 months since the patient returned to HD after acute rejection resulting in allograft failure .....__

27. Currently requires hemodialysis more than 3 times per week for a medical indication other than ultrafiltration (such as, but not limited to: systemic oxalosis, or requiring total parenteral nutrition)?.....__

28. Native kidney function expected to recover without need for long-term dialysis? .....__

29. Currently admitted to an acute or chronic care hospital? .....__

30. Currently uses one or more investigational drugs?.....__

31. Currently participating in another clinical trial that contradicts or interferes with therapies or measured outcomes in this trial? .....__
    0=Not currently in another trial
    1=Currently in another trial that contradicts or interferes with FHN therapies or outcomes
    2=Currently in another trial but the trial does not contradict or interfere with FHN therapies or outcomes (requires Executive Committee endorsement.)

32. Currently pregnant? (8=Not applicable).....__

33. Actively planning to become pregnant in the next 12 months? (8=Not applicable) .....__

34. Has contraindications to heparin, including allergy or heparin-induced thrombocytopenia?.....__

35. Unable or unwilling to follow the *study* protocol for any reason (including reasons such as mental incompetence)? .....__

36. Unable or unwilling to follow the *training* protocol for any reason? .....__

(For Questions 22-43: 0=No, 1=Yes), continued:

37. Based on clinical staff's best clinical judgment, is the patient's residual renal function estimated to be too high? .....__

Within the next 12 months:

38. Scheduled for a living donor kidney transplant? .....__

39. Scheduled to start peritoneal dialysis?.....__

40. Scheduled to start home hemodialysis? .....__
(0=No, 1=Yes, 2=Already doing home dialysis – not an exclusion)

41. Plans to relocate to another hemodialysis center not participating in this study? ..... __

42. Expects to be geographically unavailable for more than 2 consecutive weeks? .....__
Note: Frequent HD patients who leave for brief vacations are allowed to use conventional HD while he/she is on vacation.

43. Anticipates not having his/her hemodialysis in a unit participating in the study for more than 4 weeks total (*excludes unavailability due to scheduled hospitalizations, or the use of home nocturnal hemodialysis*)?……. .....__

44. Eligible to be randomized based on the data on this form? (0=No, 1=Yes).....__
(Note: do not enter form if patient is ineligible)

45. **Emergency Contact Information**: You must provide three names and phone numbers. It is recommended that the persons listed on this contact form be physicians who have access to the patients at this location and are aware of emergency mental health resources. Information will be used by a number of sources, especially the Central Quality of Life Interviewing Center. Choose people with answering services or pagers so they will be available in the evening, if necessary. One emergency contact should be the study PI.

For column c, use: 1=Physician, 2=Other Health Care Professional

(a) Last Name	(b) First Name	(c) Role	(d) Phone Number (xxx-xxx-xxxx)	(e) E-Mail Address
1.				
2.				
3.				

For all subjects: *(Use of Central Lab needed only if pt's blood work will not be analyzed at the same lab during both baseline and follow-up)*

46. Does this pt's blood work need to be shipped to the FHN central laboratory? (0=No, 1=Yes)..__

DCC Use Only:

47. For patient randomized before 10/2006 to in-center dialysis, date home training began (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __

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