FHN DAILY TRIAL - FORMS TABLE OF CONTENTS

Form #	Version Date	Form Name
104	01/MAY/2007	Co-Morbidity and Medical History Form
105	12/MAR/2006	Baseline Demographics, Employment, and Income Form
107	30/JUN/2006	Direct Patient Contact Form
108	26/MAR/2008	U.S. Patient Future Linkage Form
110	26/FEB/2008	Daily Trial Eligibility Confirmation (Screening) Form
111	16/MAR/2007	Documentation of Six Consecutive Days Form
112	16/MAY/2007	Daily Trial Pre-Randomization Drop-out Form
113	29/AUG/2007	Daily Study Ready for Randomization Confirmation
202	17/MAY/2006	Amputation Form
203	10/JAN/2006	Monthly IV Iron Therapy
204	10/FEB/2007	Injectable Medications Form
205	21/MAR/2007	Medications and Supplements Form
206	13/FEB/2009	Residual Renal Function
207	26/FEB/2008	Biochemistry Laboratory Data Form
208	10/FEB/2007	Participant In-Center Log Sheet (Non-dialytic Aspects of HD)
218	18/JAN/2007	Final MRI Scheduled
220	10/FEB/2007	SF-36 (English and Spanish), v1
221	14/JUL/2009	Beck Depression Inventory, v1
222	10/FEB/2007	Cousineau Self-Perceived Burden Scale
223	10/FEB/2007	Health Utilities Index 3 Form
224	10/FEB/2007	Central Interview Study Special Study Questions
225	10/FEB/2007	MOS Sleep Scale
230	16/MAR/2007	Feeling Thermometer Form
231	26/FEB/2008	Modified Mini Mental Status
232	17/JUL/2008	Trail Making B Form
233	25/JUL/2007	Clinical Center Miscellaneous Questions
234	01/MAY/2007	The FHN Combination Physical Function Tests Form
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242	16/MAR/2007	Single Frequency Bioelectrical Impedance (BIA) Assessment
250	10/FEB/2007	Dialysis Session Before MRI
251	16/JAN/2009	MRI Mailing Form
252A	03/SEP/2008	Central MRI Data Entry Results
252B	03/SEP/2008	Central MRI Data Entry Wall Motion Score
253	13/MAY/2008	Daily Trial Central Heart Rate Variability Mailing Form
254	30/MAY/2006	Daily Trial Central Holter Reading Facility Data Transmission Form
255	29/NOV/2006	U.S. Biological Specimen Repository Mailing Form
256	29/NOV/2006	International Biological Specimen Repository Mailing Form
257	10/FEB/2007	Canadian Repository Collection Date Form
271	13/JUN/2008	Access Used for Chronic Hemodialysis
273	09/OCT/2009	Monthly Kinetic Modeling Form
274	07/FEB/2007	Retrospective Kinetic Modeling Data
275	26/FEB/2008	Attendance at In-Center Dialysis Sessions Form
276	06/AUG/2010	Access Repair Procedure
277	06/AUG/2010	Permanent Access Failure or Access Removal Form

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Form #	Version Date	Form Name
278	10/JAN/2006	New Access Placement
302	26/FEB/2008	Clinical Center Hospitalization Notification Form
303	26/FEB/2008	Clinical Center Detailed Hospitalization Form
305	26/FEB/2008	Clinical Center Death Notification Form
306	26/FEB/2008	Clinical Center Detailed Death Form
307	01/FEB/2007	Adverse Event Reporting Form
308	15/APR/2009	Serious Adverse Event Reporting Form
309	16//OCT/2008	Planned Therapy Deviation
310	16//OCT/2008	Detected Therapy Deviations
311	11/MAY/2006	Daily Trial Central Holter Reading Facility Clinical Alerts Form
312	11/MAY/2006	Central Cardiac MRI Clinical Alerts Form
313	01/SEP/2006	Post Randomization Patient Transplant or Peritoneal Dialysis Form
400	05/DEC/2008	Patient Transfer Form
401	10/FEB/2007	Re-enrollment of Previously Enrolled Patient
404	23/SEPT/2009	Canadian Centers Vital Status
405	07/MAY/2010	End of Trial Patient Status
406	26/FEB/2008	Documentation of Consent for Repositories Form
501	13/FEB/2009	Outcome Committee Hospitalization Review Form
503	13/FEB/2009	Outcome Committee Death Review Form
700	17/JUN/2008	Thirty Days After F12 Data

Center-Specific Forms		
Form #	**Version Date**	**Form Name**
600	26/FEB/2008	Study Staff Information Form
601	26/FEB/2008	Clinical Center Form
602	26/FEB/2008	Other Study Facilities Form (Lab, Holter)
603	26/FEB/2008	Dialysis Unit Details Form
604	26/FEB/2008	Cardiac MRI Facility
605	11/OCT/2005	Consortium Core
606	24/JAN/2008	Documentation of Local Laboratory Method, Instrument, and Normal Ranges

FREQUENT HEMODIALYSIS NETWORK
Daily Study Baseline Visit Schedule

Daily Study - Screening/Baseline Visit B-01

Form #	Form Name
110	Eligibility Confirmation (Screening) Form
202	Amputation Form
206	Residual Renal Function (24-Hour Urine)
207	Biochemistry Laboratory Data Form
271	Access Used for Chronic Hemodialysis (patient's current access)
273	Monthly Kinetic Modeling
274	Retrospective Kinetic Modeling Data

Daily Study - Visit Number: B-02

107	Direct Patient Contact Form (Accessed at QOL center's website)
108	Patient Future Linkage (USRDS) for U.S. only
273	Monthly Kinetic Modeling
274	Retrospective Kinetic Modeling Data

These Forms can be completed at either B-01 or B-02

104	Comorbidity and Medical History Form
105	Baseline Demographics, Employment and Income Form
111	Documentation of Six Consecutive Days Form
113	Daily Trial Ready for Randomization Confirmation
203	Monthly IV Iron Therapy
204	Injectable Medications Form
205	Medications and Supplements Form
208	Participant In-Center Log Sheets (non-Dialytic Aspects of HD)
*220**	*SF-36, v1*
*221**	*Beck Depression Inventory, v1*
*222**	*Cousineau Self-Perceived Burden Scale*
*223**	*Health Utilities Index 3 (HUI3)*
*224**	*Special Study Questions*
*225**	*MOS Sleep Disturbance Survey*
230	Feeling Thermometer
231	Modified Mini Mental Status
232	Trail Making B
233	Clinical Center Miscellaneous Questions (Q4)
234	Physical Function Tests
242	Bioimpedance Form
250	Dialysis Session Before MRI
251	Cardiac MRI Mailing Form
253	Heart Rate Variability Mailing Form
255	U.S. Biological Specimen Repository Mailing Form
257	Canadian Repository Collection Data
406	Consent for Repository Form

**Forms completed by Central QOL Center and data securely transferred to DCC.*

FREQUENT HEMODIALYSIS NETWORK
Daily Study Baseline Visit Schedule

Forms completed on an as need basis:

Form #	Form Name
112	Pre-Randomization Drop-Out Form
271	Access Used for Chronic Hemodialysis (if access changed during baseline)
276/277/278	Access Related Forms
401	Re-enrollment of Previously Excluded Patient

(report)	Patient Suitability for Randomization Report

**Forms completed by Central QOL Center and data securely transferred to DCC.*

FREQUENT HEMODIALYSIS NETWORK
DAILY STUDY
Follow-Up Visit Schedule

Daily Follow-up Visit Number: F-0 (Month 0) - Randomization Month

Form #	Form Name
207	Local Biochemistry Form
273	Monthly Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Forms for Month 0-the month subject was randomized are not mandatory. However, they are strongly encouraged especially when the subject is randomized at the beginning of the month.

Daily Follow-up Visit Number: F-01 (Month 1)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
242	Bioimpedance Form (BIA) *(completed approx. 1 month from randomization)*
273	Monthly Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-up Visit Number: F-02 (Month 2)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Monthly Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-up Visit Number: F-03 (Month 3)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-Up Visit Number: F-04 (Month 4)

Form #	Form Name
203	Monthly IV Iron Therapy
204	Injectable Medications Form
205	Medications and Supplements
206	Residual Renal Function (24-hour Urine)
207	Biochemistry Laboratory Data Form (plus Q8 & 9)
208	Participant In-Center Log Sheets (non-Dialytic Aspects of HD)
*220**	*SF-36 v1*
*221**	*Beck Depression Inventory, v1*
*222**	*Cousineau Self-Perceived Burden Scale*
*223**	*Health Utilities Index-3 (HUI-3)*
*224**	*Central Interview Special Study Questions (Q12 only)*
*225**	*MOS Sleep Scale*
230	Feeling Thermometer
231	Modified Mini Mental
232	Trailmaking Test B
234	Physical Function Tests (Guralnik Battery)
242	Bioimpedance (BIA)
255	U.S. Biological Specimen Repository Mailing Form
257	Canadian Repository Collection Date Form
273	Monthly Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Session

Daily Follow-up Visit Number: F-05 (Month 5)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-up Visit Number: F-06 (Month 6)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-up Visit Number: F-07 (Month 7)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-Up Visit Number: F-08 (Month 8)

Form #	Form Name
203	Monthly IV Iron Therapy
204	Injectable Medications Form
205	Medications and Supplements
207	Biochemistry Laboratory Data Form (plus Q8 & 9)
208	Participant In-Center Log Sheets (non-Dialytic Aspects of HD)
273	Kinetic Modeling
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Session

Daily Follow-Up Visit Number: F-09 (Month 9)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Biochemistry Laboratory Data Form
273	Kinetic Modeling
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Session

Daily Follow-up Visit Number: F-10 (Month 10)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-up Visit Number: F-11 (Month 11)

Form #	Form Name
203	Monthly IV Iron Therapy
207	Local Biochemistry Form
218	Final MRI Scheduled
273	Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Sessions

Daily Follow-Up Visit Number: F-12 (Month 12)

Form #	Form Name
203	Monthly IV Iron Therapy
204	Injectable Medications Form
205	Medications and Supplements
206	Residual Renal Function (24-hour Urine)
207	Biochemistry Laboratory Data Form (plus Q8 & 9)
208	Participant In Center Log Sheets (non-Dialytic Aspects of HD)
*220**	*SF-36 v1*
*221**	*Beck Depression Inventory, v1*
*222**	*Cousineau Self-Perceived Burden Scale*
*223**	*Health Utilities Index-3 (HUI-3)*
*224**	*Central Interview Special Study Questions (all questions)*
*225**	*MOS Sleep Scale*
230	Feeling Thermometer
231	Modified Mini Mental
232	Trail Making B
233	Clinical Center Miscellaneous Questions (Q7-11 only)
234	Physical Function Tests (Guralnik Battery)
242	Bioimpedance (BIA)
250	Dialysis Session Before MRI
251	Cardiac MRI Mailing Form
253	Heart Rate Variability Mailing Form
255	U.S. Biological Specimen Repository Mailing Form
257	Canadian Repository Collection Date Form
273	Monthly Kinetic Modeling Form
274	Retrospective Dialysis Run Sheet Data
275	Attendance at In-Center Dialysis Session

FORMS COMPLETED DURING FOLLOW-UP, AS NEEDED
Follow-Up Visit Number is the same number as the month of the event

Form #	Form Name
202	Amputation Form
256	International Biological Specimen Repository Mailing Form

271	Access Used for Chronic Hemodialysis
276	Access Repair Procedure
277	Permanent Access Failure or Access Removal
278	New Access Placement

302	Clinical Center Hospitalization Notification Form
303	Clinical Center Detailed Hospitalization
305	Clinical Center Death Notification Form
306	Clinical Center Detailed Death Form

Form #	Form Name
307	Adverse Reaction Reporting Form
308	Serious Adverse Reaction Reporting Form
309	Planned Therapy Deviation
310	Detected Therapy Deviations
313	Post Randomization Patient Transplant or Peritoneal Dialysis Form

400	Patient Transfer Form (complete and fax to DCC)

Frequent Hemodialysis Network
CO-MORBIDITY ASSESSMENT and MEDICAL HISTORY - FORM #104

Instructions: The patient's primary physician should provide a list of the patient's medical history which should include any current diagnoses and past pertinent medical history. In the event this list is not prepared, the FHN study physician will review the patient's medical records. Medical records might include, but are not limited to: hospital discharge summaries, consultation letters, MD progress notes, problem lists, medication records and imaging reports [i.e. x-ray, ultrasound, CT].

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

5. Medical history reviewed from what period: .. __ __ __ /__ __ __ __ to __ __ __ /__ __ __ __
(mon/yyyy) (mon/yyyy)

History of Any of the Following Medical Conditions:
For Questions 6-33: 0=No, 1=Yes, *except where indicated otherwise*

6. a. Myocardial infarction (MI) [by history not only by EKG changes]? (from Charlson).....__
If No, skip to Q6d, if Yes, continue:

b. Myocardial infarction in past year? .....__

c. Myocardial infarction before the past year? .....__

d. Atrial fibrillation? .....__

7. a. Congestive Heart Failure (CHF)? (from Charlson) .....__
If No, skip to Q8, if Yes, continue:

b. Admitted to hospital <u>once</u> in the past year for CHF/fluid overload (post-ESRD)?.....__

c. Admitted to hospital <u>more than once</u> in the past year for CHF/fluid overload (post-ESRD)?__

8. Connective Tissue Disease? (from Charlson) .....__
(e.g., lupus, Wegener's granulomatosis, other vasculitis, scleroderma; <u>exclude</u> rheumatoid arthritis-see Q17)

9. Peripheral vascular disease (includes aortic aneurysm > 6 cm)? (from Charlson) .....__
(Includes intermittent claudication, history of bypass, gangrene, untreated abdominal aortic aneurysm of 6 cm of more [AAA] or thoraco-abdominal aneurysm [TAA].)

10. History of abdominal aortic aneurysm <u>repair</u> or bypass grafting?.....__

11. A previous history of amputation and location: question moved to Form 202-needed for KM reports

12. Current infection, ulceration or gangrene of a digit or limb? .....__

For Questions 6-33: 0=No, 1=Yes, continued:

13. Cerebrovascular disease? (from Charlson) .....__
(Includes history of CVA with minor or no residua and transient ischemic attacks)

14. Hemiplegia? (from Charlson).....__
(Includes paraplegia/hemiplegia resulting from CVA or other condition)

15. Dementia? (from Charlson) .....__

16. Chronic pulmonary disease? (from Charlson) .....__

17. Rheumatologic condition? .....__

18. Ulcer disease? (from Charlson) .....__

19. Diabetes without end-organ damage? (from Charlson).....__
(*For example, a diabetic where diabetes is not listed as the cause for ESRD*).

20. Diabetes with end-organ damage (retinopathy, neuropathy or kidney failure)? (from Charlson) .....__

21. Hepatitis B surface antigen positive?.....__

22. Hepatitis C positive?.....__

23. Mild Liver Disease (without portal hypertension, includes chronic hepatitis)? (from Charlson) .....__

24. Moderate or Severe Liver Disease (such as portal hypertension or jaundice)? (from Charlson).....__

25. Leukemia (acute or chronic)? (from Charlson).....__

26. Lymphoma? (from Charlson).....__

27. Multiple myeloma?.....__

28. Tumor without metastases (exclude if 5 years from diagnosis)? (from Charlson).....__

29. Metastatic solid tumor? (from Charlson) .....__

30. Gout?.....__

31. Human immunodeficiency virus (HIV)? .....__

32. Uses nasal CPAP at night? .....__

33. Legally blind? .....__
Note: A patient is legally blind if he or she has central visual acuity of 20/200 or less in his or her better eye, even when his vision is measured using the best possible correction.

34. History of cigarette smoking? .....__
1=Never smoked, 2=Used to smoke, 3=Currently smokes

35. History of excess alcohol use? .....__
0=No history 2=Yes, currently
1=Yes, used to drink in excess

36. History of illicit drug use? .....__
0=No history, 2=Yes, in the past 5 years, 1=Yes, but more than 5 years ago

37. In the past year, how many times was the patient admitted to an intensive care unit?.....__
0=Not admitted, 1=Admitted once, 2=Admitted more than once

38. In the past year, how many times was the patient admitted to a cardiac/coronary care unit (0=Not admitted, 1=Admitted once, 2=Admitted more than once)? .....__

39. Primary reason kidneys failed:.....__ __
01=Diabetic nephropathy
02=Hypertensive nephrosclerosis
03=Glomerulonephritis (includes, but not limited to: membranous nephropathy, focal sclerosis, membranoproliferative glomerulonephritis, mesangial proliferative glomerulonephritis, chronic renal failure with proteinuria, nephritic syndrome without biopsy, IGA nephropathy, other glomerulonephritis)
04=Polycystic kidney disease
05=Physical trauma
06=Analgesic nephropathy
07=Obstructive uropathy (includes, but not limited to: obstructive uropathy-acquired, obstructive uropathy-congenital, urinary tract stones)
88=Other (includes, but not limited to: hereditary nephritis, pyelonephritis, other interstitial nephritis, vesico-ureteral reflux, renal artery stenosis)
99=Unknown

40. Is the patient currently on the cadaveric transplant waiting list? .....__
0=No, patient is currently being assessed to be on the list
1=No, possibility of transplant was never discussed with patient
2=No, patient refuses a transplant or is not interested in being assessed for transplant
3=No, patient was assessed and told he/she was medically ineligible
4=No, patient is expecting a living donor to come forward
5=No, reason unknown or other
6=Yes

41. Number of previous kidney transplants? (0 for none, 1 for one, etc.) .....__

42. Has the patient previously received peritoneal dialysis? (0=No, 1=Yes) .....__

43. Generally uses a wheelchair to move around? (0=No, 1=Yes) ……..__

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

Frequent Hemodialysis Network
BASELINE DEMOGRAPHICS, EMPLOYMENT, and INCOME - FORM #105

Instructions: This form is completed at baseline.

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

5. Marital status:.....__

1=Never been married	4=Separated
2=Married	5=Divorced
3=Common law marriage/partnered/ living together unmarried	6=Widowed

6. Household Size: (For Questions 6 a-d: 0=No, 1=Yes)
   a. Lives with family (e.g., spouse, children, parents):.....__
   b. Lives alone:.....__
   c. Lives with others (e.g., retirement community, rooming house):.....__
   d. Homeless:.....__

7. Highest level of formal education achieved?..... __ __

1=Nursery school - 8th Grade	6=Associate degree
2=9th-12th grade, no diploma	7=Bachelor's degree
3=High school graduate	8=Refused
4=Vocational/technical/business	9=Unknown
5=Some college, no degree	10=Master's/Doctorate

8. Has the patient ever been employed for pay? (0=No, 1=Yes).....__

9. What was the last year the patient was employed?.....__ __ __ __
   (Enter current year if currently employed)

10. Current work status:.....__ __

01=Student, not employed	07=Not working, seeking work, not disabled
02=Student, employed	08=Employed full-time
03=Homemaker	09=Employed part-time
04=Not working, not seeking work, disabled	10=Retired
05=Not working, not seeking work, not disabled	06=Not working, seeking work, disabled
	99=Unknown

11. Current household gross annual income (in your own country's currency)?.....__

1=<$10,000	6=$40,000-$49,000
2=$10,000-$14,999	7=$50,000-$99,000
3=$15,000-$19,999	8=>$100,000
4=$20,000-$29,999	9=Unknown or refused
5=$30,000-$39,000	

Patient Health Insurance: (For questions 12a-h: 0=No, 1=Yes, 8=Not Applicable)

12. **Column A:** What type of health insurance does the patient have?
Column B: Are any of the insurance plans the patient listed an HMO (Health Maintenance Organization)?

		A Have?	**B HMO?**
a.	Medicare:	__	__
b.	Medicaid or State Medical Assistance:	__	__
c.	State or county program other than Medicaid:	__	__
d.	Employer-sponsored or retiree health plan:	__	__
e.	Privately-purchased policy (e.g., Medigap or Medicare supplement):	__	__
f.	Veterans benefit, TriCare or military health plan:	__	__
g.	Canadian health care benefits:	__	__
h.	None:	__	

13. a. Is Medicare paying for this patient's hemodialysis? .....__
0=No, answer Question 13b
1=Yes, skip to Question 200.
(Note: This question may need to be completed by your Billing Department.)

b. If no to Question 13a, why not?.....__
1=Patient recently started hemodialysis
2=Patient is Canadian
3=U.S. Patient has alternative insurance

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

Frequent Hemodialysis Network
PATIENT CONTACT - FORM #107

This form is completed as soon as the patient signs the consent form for participation in the FHN Trials. The DCC does **not** have access to this form. You will need to login to the QOL website at https://surveyweb2.ucsur.pitt.edu/DialysisQOL/index.php. Your center's login information can be obtained by writing to survey@pitt.edu.

1. Participant ID #	2. Alpha Code	3. Date dd/mon/yyyy

4. Patient's Full Name:
   a. Last Name: _____
   b. First Name: _____
   c. Middle Initial: _____

5. Trial:
   a. Daily Study _____
   b. Nocturnal Study _____

6. Visit:
   a. Baseline _____
   b. First Follow-up (F4 or F5) _____
   c. Final Follow-up (F12 or F14) _____

7. Status:
   a. Baseline _____
   b. Still in Trial _____
   c. Withdrew from Trial, agreed to be contacted for QOL interview _____
   d. Withdrew from Trial, do not contact for QOL interview _____
   e. Deceased _____

8. Age:
   a. Adult 18 years old and over _____
   b. 17 years old and younger _____

9. Preferred Interview Language:
   a. English _____
   b. Spanish _____

10. Best times to Call:

    Phone 1: ..... _____

    Time 1 ..... _____

    Phone 2 ..... _____

    Time 2 ..... _____

    Phone 3 ..... _____

    Time 3 ..... _____

11. Emergency contacts:

    Name 1 ..... _____

    Phone 1 ..... __ __ __-__ __ __-__ __ __ __

    Name 2 ..... _____

    Phone 2 ..... __ __ __-__ __ __-__ __ __ __

    Name 3 ..... _____

    Phone 3 ..... __ __ __-__ __ __-__ __ __ __

Frequent Hemodialysis Network
PATIENT FUTURE LINKAGE - FORM #108

This form is for U.S. patients only. This form is completed as soon as the patient signs the consent form for participation in the FHN Trial. It is ideal for the subject to provide his/her social security number (SSN). However, if the subject refuses to provide SSN but is willing to submit other key data items, then complete the appropriate data items below. The DCC does **not** have access to this form.

This information is sent directly to the USRDS: Attn: Shu-Cheng Chen, M.S.
Director of Information Systems
USRDS
914 South 8th Street, Suite D-206
Minneapolis, MN 55404

1. Participant ID # 2. Alpha Code 3. Date dd/mon/yyyy

4. Did patient agree to provide this information for future linkage with USRDS?..... __
0=No, patient refused - *complete question on Form 233. (Do not send to USRDS.)*
1=Yes, patient agreed, continue.
2=Yes, patient agreed but does not want to provide SSN.

Print the following:

5. Clinical Center name: _____

6. Patient name: a) *Last name: _____
b) *First name: _____
c) Middle initial: _____

7. *Date of Birth: (dd/mon/yyyy) .....__ __/__ __ __/__ __ __ __

8. *Gender: (1=Male, 2=Female) ..... __

United States:

9. a. Social Security Number: (numeric) ..... __ __ __-__ __-__ __ __ __

b. *Month and year patient was first treated for ESRD (with hemodialysis, peritoneal dialysis, or kidney transplantation) (mon/yyyy).....__ __ __/__ __ __ __
(Note: This date should be the same date that appears on Form 100/110, Q12a)

10. Medicare/HIC Number: (alphanumeric).....__ __ __ -__ __- __ __ __ __ -__ __
(Note: Do not complete item 10 if patient refused to provide SSN.)

*Must be completed if SSN is not provided.

Frequent Hemodialysis Network
DAILY TRIAL ELIGIBILITY CONFIRMATION FORM - FORM #110

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 6-19): **Complete for all consenting patients**

Demographics

6. Date of birth (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   Note: Age less than 13 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 been on 3x a week, in-center chronic hemodialysis for at least 2 weeks? (0=No, 1=Yes) .....__
    (Note: Incident patients who have not been on dialysis for at least 2 weeks 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 short-daily hemodialysis, is patient willing and able to come to dialysis unit six times per week up to 2.75 hours per treatment? (0 = No, 1=Yes).....__
    (*This would include ability to arrange adequate transportation for the patient*).

16. 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) .....__

17. 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*).

18. How many **minutes** would it take the patient to travel from his/her place of residence to the dialysis unit where he/she would receive daily hemodialysis if randomized to the daily arm? (one-way trip) .....__ __ __

19. Would the patient or his/her family have any out of pocket transportation costs (i.e., gas, parking, fares for public transportation, other) traveling to the dialysis unit for daily hemodialysis, if the patient were randomized to the daily arm? (0=No, 1=Yes)..__

Exclusion Criteria:
(0=No, 1=Yes) *Note: Any response of "1=Yes" is a reason for exclusion.*
You may skip to Question 41 if any reason(s) for study exclusion are identified.

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

Exclusion criteria, continued:
(0=No, 1=Yes) Note: Any response of "1=Yes" is a reason for exclusion.

21. 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)?.....__

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

23. Currently on nocturnal dialysis? .....__

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

25. 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.)?.....__

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

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

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

29. 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.)

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

31. Actively planning to become pregnant in the next year? (8=Not applicable) .....__

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

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

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

Within the next year: *(0=No, 1=Yes)*

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

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

37. Scheduled to start home hemodialysis? .....__

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

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

40. 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*)?…….....__

---

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

---

42. **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)*

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

---

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

Frequent Hemodialysis Network
DAILY STUDY DOCUMENTATION OF SIX CONSECUTIVE DAYS - FORM #111

This form is completed by study staff to determine if a consented patient demonstrates ability to attend the daily dialysis treatment. This form is completed once during baseline. The patient should use the same transportation that will be used during the follow-up period and must be done six days in a row.

1. Participant ID # 2. Alpha Code

3. Record six consecutive visit dates within one week (three of these dates will be dialysis days)

   a. Date of visit #1: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __
   b. Date of visit #2: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __
   c. Date of visit #3: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __
   d. Date of visit #4: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __
   e. Date of visit #5: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __
   f. Date of visit #6: (dd/mon/yyyy)..... __ __ / __ __ __/ __ __ __ __

4. Did the patient demonstrate the ability to come into the unit: (0=No, 1=Yes) .....__

5. In the opinion of the Study Staff, is this patient capable of coming into the participating dialysis unit six (6) days per week for the duration of the trial? (0=No, 1=Yes) .....__

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

Frequent Hemodialysis Network
DAILY TRIAL PRE-RANDOMIZATION DROPOUT - FORM #112

This form is completed when it is determined that a patient who appeared to be eligible for the *daily* trial enrolled in baseline and was subsequently found to be ineligible. So 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 residual renal urea clearance >3 mL/min per 35L
05=For transportation or associated costs reasons, was unable or unwilling to come to the dialysis unit 6 days per week.
06=For reasons *other than* transportation, was unable or unwilling to come to the dialysis unit 6 days per week.
07=Based on physician or health care provider judgment, patient would not be adherent to daily hemodialysis
08=Unable to have a baseline cardiac MRI
09=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
10=Unable to have baseline quality of life assessment
11=Lowest weight achieved post-dialysis <30kg
12=Admitted to an acute or chronic care hospital with no planned discharge in near future
16=Family does not support patient joining the study
17=Dialyzing 6x per week conflicts with the patient's personal schedule
18=The unit where the patient would be dialyzed has no room for a patient at this time

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: systemic 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)
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 13 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 12 weeks passed since baseline data collection, and new data could not be collected
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 drop-out 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) __ __/__ __ __/__ __ __ __

Frequent Hemodialysis Network
DAILY STUDY - READY FOR RANDOMIZATION
CONFIRMATION FORM - #113

Instructions: This form should be completed in the two weeks prior to the date of a patient's randomization into the Daily Study.

1. Participant ID # | 2. Alpha Code | 3a. Visit Type | 3b. Visit Number

5. Does the patient's planned dialysis unit have an open slot available so this patient can dialyze six times a week? (0=No, 1=Yes).....__

Items 6 through 11 document the discussion between an FHN Study staff member and the patient. (The staff member may be from the clinical center or from the Core. It is strongly recommended that this be a different person than the person who has interacted with this patient the most.)

6. Is the dialysis unit's open time slot acceptable to the patient? (0=No, 1=Yes).....__

7. a. Does the patient have a plan for reliable and convenient transportation to the patient's planned dialysis unit for dialysis sessions six times a week? (0=No, 1=Yes)....__
   (Please keep a note in the local file for this patient regarding the patient's plan for transportation.)

   b. Now that the patient has experienced the baseline MRI, is the patient still willing to do an F12 MRI? ..... __

8. Does the patient still want to be in the study? (0=No, 1=Yes).....__

9. Spouse/partner/caregiver status: .....__
   (1=The patient has no spouse or partner or caregiver; 2=There is a spouse or partner or caregiver and that person supports this patient being in the study; 3=There is a spouse or partner or caregiver and that person IS NOT in favor of this patient possibly being randomized to six times a week dialysis.)

10. FHN username of the staff member who talked with the patient: .....__ __ __ __ __ __ __ __
    (Hint: The username is usually the first 6 letters of the person's last name followed by the first letter of the person's first name. You can also check Form 600.)

11. Date of discussion: (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __

---

12. Did the team of staff who will be following the patient meet to discuss whether they feel the patient should be randomized? (0=No, 1= Yes, complete 13) .....__

13. Date of team meeting: (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __
    (Please keep a note in the local file for this patient documenting that this meeting was held and who attended.)

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

Frequent Hemodialysis Network
AMPUTATION FORM #202

Baseline: This form is **required by all study participants once during baseline**. It is needed for the kinetic modelling reporting program and must be entered at baseline before a KM report can be generated.

Follow-up: Complete this form during follow-up every time it is identified that a patient has undergone an amputation.

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

5. Location of amputation:

   a. Left leg (0=none, 1=toe(s), 2=below ankle, 3=below knee, 4=above knee) ....__

   b. Right leg (0=none, 1=toe(s), 2=below ankle, 3=below knee, 4=above knee) ....__

   c. Left arm (0=none, 1=finger(s), 2=below wrist, 3=below elbow, 4=above elbow) ....__

   d. Right arm (0=none, 1=finger(s), 2=below wrist, 3=below elbow, 4=above elbow) ....__

   If amputation occurred during follow-up, please be sure to complete the hospitalization forms 302 and 303.

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

Frequent Hemodialysis Network
MONTHLY IV IRON THERAPY FORM #203

Instructions:

Review patient medication records for **monthly** IV Iron use. Record only intravenous (IV) iron on this form.

For EPO and other injectable medications, use Form 204.

For all other medications, over-the-counter meds, and supplements, use Form 205. Oral (po) iron should also be recorded on Form 205.

Schedule for form completion: For both daily and nocturnal studies, this form is completed at baseline and monthly during follow-up.

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

5. Has the participant used any IV Iron during the last **1** month? .....__
   0=No, skip to question 200.
   1=Yes, complete Table 1

TOTAL IV IRON USE FOR ONE MONTH

IV Iron Medication Name	Medication Code*	Route of Administration 0=Not IV 1=IV	Number of *times* given during month being reported	TOTAL *milligrams* given during month being reported
6.		__	__ __	__ __ __ __

*The medication code is electronically found on the code list accessed during data entry.

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

Frequent Hemodialysis Network
INJECTABLE MEDICATIONS *(other than IV Iron)* - FORM #204

Instructions: Record only the IV medications listed below. *Use Form #203 to record IV iron use.*

Schedule: Daily: Baseline, F-4, F-8 and F-12.
Nocturnal v3.0: Baseline, F-4, F-8, and F-12. (*Nocturnal v2.1: Baseline, F-5, F-9, and F-14).*

On this form, record only the following medications:

IV or SC erythropoietin (Procrit, Epogen)
IV or SC darbepoetin (Aranesp)
IV vitamin D/vitamin D analogues:
- IV calcitriol (Calcijex)
- IV alfacalcidol (One-Alpha)
- IV doxercalciferol (Hectorol)
- IV paricalcitol (Zemplar)

Use Form #205 to record all other medications, over-the-counter medications, and supplements.

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

5. Has the participant used any of the medications identified above during the last 4 weeks? .....__
   0=No, skip to question 200
   1=Yes, continue with Q6a.

6. a. Has the participant used any Erythropoietin (EPO, Procrit, or Epogen) during the last 4 weeks? .....__
   0=No, skip to Q7a
   1=Yes, continue with Q6b

ERYTHROPOIETIN (PROCRIT, EPOGEN) USE DURING THE LAST 4 WEEKS:

Medication Name	Medication Code**	Route of administration 1=IV 2=SC	How many *times* was erythropoietin given during the last ONE WEEK?	What was the TOTAL number of *units* given during the last ONE WEEK?	What was the TOTAL number of *units* given during the last FOUR WEEKS?
6b.					
6c.					

**The medication code is electronically found on the code list accessed during data entry.

7. a. Has the participant used any darbepoetin (Aranesp) during the last 4 weeks? .....__
(0=No, skip to Q8a, 1=Yes, continue with Q7b.)

DARBEPOETIN (ARANESP) USE DURING THE LAST 4 WEEKS:

Medication Name	Medication Code**	Route of admini-stration 1=IV 2=SC	How many *times* was Aranesp given during the last FOUR WEEKS?	What was the TOTAL number of *micrograms* given during the last FOUR WEEKS?
7b.				

8. a. Has the participant taken any IV vitamin D/vitamin D analogues during the last week? (0=No, 1=Yes, continue with Q8b, 2=Pt. received IV Vit.D within last month but not within the last week.) .....__
These include: IV calcitriol (Calcijex, Rocaltrol)
IV alfacalcidol (1-Alpha)
IV doxercalciferol (Hectorol)
IV paricalcitol (Zemplar)

IV VITAMIN D/VITAMIN D ANALOGUES USE DURING THE LAST 1 WEEK:

Medication Name	Medication Code**	How many *times* was the medication given during the last <u>ONE</u> WEEK?	What was the TOTAL number of *micrograms* given during the last ONE WEEK?
8b.			
8c.			

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

**The medication code is electronically found on the code list accessed during data entry.

Frequent Hemodialysis Network

MEDICATIONS AND SUPPLEMENTS FORM #205

For all meds <u>other than</u> Erythropoietin, Darbopoetin, IV Iron, and IV Vitamin D Analogues

Instructions: Record all prescription medications, over-the-counter (OTC) medications, and supplements on this form (include prn medications). *Use Form 203 to record IV Iron use. Use Form 204 to record EPO, Procrit, Epogen, Aranesp, and IV vitamin D analogues.*

Schedule: Daily: Baseline, F-4, F-8 and F-12.
Nocturnal v3.0: Baseline, F-4, F-8, and F-12. (*Nocturnal v2.1: Baseline, F-5, F-9, and F-14).*

On this form, please be especially sure to capture:

- oral vitamin D and calcimimetic use
- blood pressure medications

You may write additional medications on a separate attached page. The computer will allow you to enter as many medications as needed.

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

5. Is the participant prescribed/currently taking any <u>prescription</u> medications *(other than EPO/Epogen, Procrit, Aranesp, IV Iron, IV vitamin D analogues)*, <u>over-the-counter meds</u>, or <u>supplements</u>? .....___
(0=No, go to Q200, 1=Yes, complete Q6)

6. Is the participant prescribed any oral phosphate binders? .....___
(0=No, skip to Q11, 1=Yes, go to Q7, 2=Yes, but not taking, go to Q7)

<u>Oral Phosphate Binder</u> Name (Enter generic name or U.S. or Canadian trade name)	**Medication Code***	**Total *Prescribed* <u>Daily</u> Dose (in milligrams)**
7.		___ ___ ___ ___ ___
8.		___ ___ ___ ___ ___
9.		___ ___ ___ ___ ___
10.		___ ___ ___ ___ ___

PARTICIPANT'S MEDICATIONS: ***continued on the following page***

*The medication code is electronically found on the code list accessed during data entry.

PARTICIPANT'S MEDICATIONS: ***continued,***
You may write additional medications on a separate attached page. The computer will allow you to enter as many medications as needed. Include medications taken on a prn basis.

.**Medication/Supplement Name (Enter generic name or U.S. or Canadian trade name)**	**Medication Code***
11.	
12.	
13.	
14.	
15.	
16.	
17.	
18.	
19.	
20.	
21.	
22.	
23.	
24.	
25.	
26.	
27.	
28.	
29.	
30.	

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

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

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

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

*The medication code is electronically found on the code list accessed during data entry.

Frequent Hemodialysis Network
RESIDUAL RENAL FUNCTION - FORM #206

Instructions: This form is to be completed with the results received from your local laboratory.

Schedule: Daily: Baseline and at months 4 and 12
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

Urine collections should be obtained over an 18 hour period for the daily study and a 24 hour period for the nocturnal study ending with a kinetic modeling session.

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

5. Does the patient currently produce urine? (0=No, 1=Yes)..__
(*Note: If No, skip to Q200. If Yes, continue with the next question.)*

6. a. Start date of urine collection: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. Start time of urine collection: (24-hour clock) .... __ __: __ __

7. a. End date of urine collection: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. End time of urine collection: (24-hour clock)... __ __: __ __

8. Volume of urine collection: (ml) ....__ __ __ __
If patient produces less than 80 ml, then analysis need not be done; skip to Q200.
Be sure to mix the urine throroughly beforedrawing off an aliquot and sending to the lab for analysis.

9. a. Start date of preceding dialysis: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. Start time of preceding dialysis (24-hour clock).. __ __: __ __

10. a. End date of preceding dialysis: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. End time of preceding dialysis (24-hour clock).. __ __: __ __

Note: This day must be a kinetic modeling day (Form 273, item 4)

11. a. Start date of subsequent dialysis: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. Start time of subsequent dialysis (24-hour clock)... __ __: __ __

12. a. End date of subsequent dialysis: (dd/mon/yyyy) .... __ __/__ __ __ /__ __ __ __
   b. End time of subsequent dialysis (24-hour clock).. __ __: __ __

Results:

13. Urine urea nitrogen (mg/dL) ..... __ __ __

or in SI units (mmol/dl) .....__ __ __

or in SI units (mmol/day) .....__ __ __

b. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

14. Urine creatinine (mg/dL) ..... __ __ __.__

or in SI units (mmol/dl) .....__ __ __

or in SI units (mmol/day) .....__ __ __

b. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

15. a. Urine phosphorus (mg/dL) *(database will calculate 24 hour result)* .....__ __ __ __.__

or in SI units (mmol/dl) .....__ __ __

or in SI units (mmol/day) .....__ __ __

b. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

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

Frequent Hemodialysis Network
BIOCHEMISTRY LABORATORY DATA FORM - FORM #207

This form is completed with the results received from your local laboratory. Use the most recent blood test value available. Follow-up values must be after randomization.

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

Local Serum Values *Baseline and once per month*

5. a. Pre-dialysis Bicarbonate (HCO_3) or Total CO_2 (mmol/L=mEqL) .....__ __ __
   b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

6. a. Pre-dialysis Sodium (mmol/L=mEqL) .....__ __ __
   b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

7. a. Pre-dialysis Potassium (mmol/L=mEqL) .....__. __
   b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

8. a. Pre-dialysis Calcium (mg/dL) ..... __ __.__
   or in SI units (mmol/L) .....__ . __ __
   b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

9. a. Pre-dialysis Hemoglobin (g/dL) .....__ __. __
   or in SI units (g/L) .....__ __ __
   b. Date sample drawn (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __
   c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

Local Iron and PTH Profile Baseline (i.e., up to 4 months before randomization) and once every 3-4 months post randomization. *[For retrospective baseline values for Q10-12, you will need to fax this completed form to the DCC after all other baseline forms have been entered.]*

(For centers obtaining these values more often than every 3 months, please enter value obtained closest to: F4, F8, and F12 for daily study and nocturnal study v3.0. *In nocturnal study v2.1, values should be obtained closest to F5, F9, and F14*).

Report transferrin saturation as a percent (%) *OR* in SI units *OR* iron and TIBC.

10. a. Pre-dialysis Transferrin saturation (%).....__ __ __

or in SI units (mmol/L) .....__ . __ __

b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

c. Lab where test was performed: (use lab number identified in Form 602) ..... __ _

If you completed item 10a - do not complete items 10d & e. The database will not allow the form to be saved.

d. Pre-dialysis iron (ug/dL).....__ __ __

e. Total iron binding capacity (ug/dL).....__ __ __

11 b. Pre-dialysis Ferritin (ng/mL = µg/L) .....__ __ __ __ __

or in SI units (pmol/L) .....__ __ __ __.__

b. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

c. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

12. a. Pre-dialysis Parathyroid hormone (pg/mL = ng/L) .....__ __ __ __. __

or in SI units (pmol/L) .....__ __ __ __.__

b. Method used to measure PTH (1=Intact, 2=Bi-PTH).....__

c. Date sample drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

d. Lab where test was performed: (use lab number identified in Form 602) ..... __ __

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

Frequent Hemodialysis Network
PARTICIPANT IN-CENTER LOG SHEET - FORM #208

Study Coordinator Instructions: This form is filled out by all participants dialyzing in center (conventional, daily, and any participants who failed home nocturnal). The study coordinator should explain to the participant how to fill out the following log sheet for a 1week period. For participants receiving conventional dialysis, fill out sessions 1, 2, and 3.

Schedule: Daily: Baseline, F-4, F-8 and F-12.
Nocturnal v3.0: Baseline, F-4, F-8, and F-12. (*Nocturnal v2.1: Baseline, F-5, F-9, and F-14*).

For Daily participants, fill out sessions 1 - 6. Please LEAVE THE FORM ON THE FRONT OF THE CHART so that the participant can be reminded to fill it out at each dialysis session during the week. The Study Coordinator should pick up the form at the end of the week or beginning of the next week.

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

Participant to complete this section on pages 1 and 2:

Dialysis Session Number	**Date of Session (dd/mon/yyyy)**	**Travel Time to and from dialysis unit** (minutes)	**Waiting time before dialysis** (minutes)	**Waiting time before leaving dialysis unit** (minutes)	**Dietician Visits** – number of minutes (put 0 if did not talk to dietician)	**Physiotherapist Visits** - number of minutes (put 0 if did not talk to physiotherapist)
1						
2						
3						
4						
5						
6						
TOTAL MINUTES*:		________	________	________	__________	__________
Number of times participant communicated with health care professional:					_____	_____

The computer will calculate the numbers in the grey area.

Continued on page 2

Dialysis Session Number	**Date of Session (dd/mon/yyyy)**	**Social Worker Visits-** number of minutes (put 0 if did not talk to social worker)	**Nurse Practitioner /Physician Assistant Visits-** number of minutes (put 0 if did not talk to nurse practitioner)	**Physician Visits -** number of minutes (put 0 if did not talk to physician)
1				
2				
3				
4				
5				
6				
TOTAL MINUTES*:		_____	_____	_____
Number of times participant communicated with health care professional:		_____	_____	_____

For Study Coordinator Completion:

Total number of dialysis sessions for which this form was completed	_____

The computer will calculate the numbers in the grey areas. The data entry person should copy down the numbers into spaces provided.

7. How was this form completed? .....__
1=Participant filled it out and mailed form in
2=Participant filled it out and coordinator picked it up from unit
3=Coordinator filled it out

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

Frequent Hemodialysis Network
FINAL MRI SCHEDULED - FORM #218

Instructions: MRI data are one of two co-primary outcomes for the FHN study. A final MRI is required for each randomized patient, whether he or she is complying to the randomized treatment or not.

It is vital that the F-12 MRIs be done while a patient is receiving his/her randomized treatment. Centers are strongly encouraged to schedule each patient in the beginning of the patient's month 12. If you have any doubts as to whether you can do an MRI during month 12, you should schedule the patient's MRI toward the end of the patient's F-11 month. Please enter this form into the FHN database by Day 15 of each patient's F-11 month.

Nocturnal Study only: If a patient originally consented to protocol version 2.1 and continues to follow the schedule of protocol 2.1, the MRI should be done in the F-14 window. If you have any doubts as to whether you can do this during the month14, you should schedule the patient's MRI toward the end of the patient's F-13 window. For these patients, please enter this form into the FHN database by Day 15 of each patient's F-13 month.

1. Participant ID # 2. Alpha Code

3. Date final MRI scheduled: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

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

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

For Clinical Center Use Only:

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

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

g. Walking more than a mile.....__

h. Walking several blocks.....__

i. Walking one block.....__

j. Bathing or dressing yourself.....__

8. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your *physical* health? (0=No, 1=Yes)

a. Cut down on the amount of time you spent on work or other activities .....__

b. Accomplished less than you would like .....__

c. Were limited to the kind of work or other activities.....__

d. Had difficulty performing the work or other activities.....__ (for example, it took extra effort)

9. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any *emotional* problems (such as feeling depressed or anxious)? (0=No, 1=Yes)

a. Cut down the amount of time you spent on work or other activities .....__

b. Accomplished less than you would like .....__

c. Did not do work or other activities as carefully as usual.....__

10. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? .....__

1=Not at all
2=Slightly
3=Moderately
4=Quite a bit
5=Extremely

11. How much bodily pain have you had during the past 4 weeks?.....__

1=None
2=Very Mild
3=Mild
4=Moderate
5=Severe
6=Very Severe

For items 5-15, possible responses may include: 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)

12. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? .....__
    1=Not at all
    2=Slightly
    3=Moderately
    4=Quite a bit
    5=Extremely

    These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.
    1=All of the time
    2=Most of the time
    3=A Good bit of the time
    4=Some of the time
    5=A little bit of the time
    6=None of the time

13. How much of the time during the past 4 weeks:
    a. Did you feel full of pep? .....__
    b. Have you been a very nervous person? .....__
    c. Have you felt so down in the dumps that nothing could cheer you up? .....__
    d. Have you felt calm and peaceful? .....__
    e. Did you have a lot of energy? .....__
    f. Have you felt downhearted and blue? .....__
    g. Did you feel worn out? .....__
    h. Have you been a happy person? .....__
    i. Did you feel tired? .....__

14. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? .....__
    1=All of the time
    2=Most of the time
    3=Some of the time
    4=A little of the time
    5=None of the time

15. How TRUE or FALSE is each of the following statements for you?
    1=Definitely True
    2=Mostly True

For items 5-15, possible responses may include: 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)

3=Don't Know
4=Mostly False
5=Definitely False

a. I seem to get sick a little easier than other people .....__

b. I am as healthy as anybody I know.....__

c. I expect my health to get worse .....__

d. My health is excellent.....__

QOL Center Only

100. Language used to complete this form? (1=English, 2=Spanish) .....__

101. Setting where this form was completed? .....__
1=Telephoned person at home (or patient returned QOL phone call shortly after)
2=Telephoned person when he or she was at the dialysis unit
3=Telephoned person at another location
4=Patient phone in at his/her convenience

102. Identify reason this QOL instrument was not completed? .....__
0=N/A, instrument was completed
1=Not completed due to patient logistics (phone disconnected, on vacation)
2=Attempted but unable to be completed - patient too sick
3=Attempted but unable to be completed - patient in hospital
4=Unable. Patient withdrew consent.
5=Study Staff logistics

201. Username of person completing interview .....__ __ __ __ __ __ __

Please contact the DCC for further information.

Frequent Hemodialysis Network
COUSINEAU SELF-PERCEIVED BURDEN SCALE - FORM #222

Instructions: This form is completed by Central Interview.

Schedule: Daily: Baseline, F-4 and F-12.
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

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

4b. Time of interview? (hh:mm:ss)..... __ __:__ __:__ __

We are interested in how you feel about the relationship that you have with the person (or people) who helps you out with your day-to-day activities. You may need a little bit or a lot of help with things like driving, carrying groceries, preparing meals and getting dressed or bathed. The person who helps you may be a friend, neighbor, or a member of your family – someone who is NOT paid to help you. We will refer to this person as your caregiver.

Please rate each statement on a scale of how often you feel this way, from "none of the time" to "all of the time".

For Questions 5 - 14, use the following codes: 1=None of the time, 2=A little of the time
3=Some of the time, 4=Most of the time, 5=All of the time

5. I worry that the health of my caregiver could suffer as a result of caring for me.....__
6. I worry that my caregiver is overextending him/herself in helping me.....__
7. I am concerned that it costs my caregiver a lot of money to care for me.....__
8. I feel guilty about the demands that I make on my caregiver.....__
9. I am concerned that my caregiver is helping me beyond their capacity.....__
10. I am concerned that I am "too much trouble" to my caregiver.....__
11. I am concerned that because of my illness, my caregiver is trying to do too many things at once.....__
12. I am confident that my caregiver can handle the demands of caring for me.....__
13. I think that I make things hard on my caregiver.....__
14. I feel that I am a burden to my caregiver.....__

For items 5-14, possible responses may include: 7=Does not have unpaid caregiver, 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)

13. During the past week, have you been able to hear what is said in a conversation with one other person in a quiet room *without* a hearing aid? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 15.

14. Have you been able to hear what is said in a conversation with one other person in a quiet room *with* a hearing aid? .....__
0=No, 1=Yes, 8=Don't know /Didn't wear a hearing aid, 9=Refused

SPEECH

15. During the past week, have you been able to be understood *completely* when speaking your own language with people who do not know you? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 20.

16. Have you been able to be understood *partially* when speaking with people who do not know you?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused

17. During the past week, have you been able to be understood *completely* when speaking with people who know you well? .....__
0= No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 20.

18. Have you been able to be understood *partially* when speaking with people who know you well? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 20.

19. During the past week, have you been able to speak at all?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused

GETTING AROUND

20. During the past week, have you been able to bend, lift, jump and run *without difficulty* and *without help or equipment* of any kind? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 28.

21. Have you been able to walk around the neighborhood *without difficulty* and *without help or equipment* of any kind?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 28.

22. Have you been able to walk around the neighborhood *with difficulty* but *without help or equipment* of any kind? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 28

23. During the past week, have you been able to walk at all? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If no, interviewer go to item 26.

24. Have you needed mechanical support, such as braces or a cane or crutches, to be able to walk around the neighborhood? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused

25. Have you needed the help of another person to walk? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused

26. Have you needed a wheelchair to get around the neighborhood? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused

27. Have you needed the help of another person to get around in the wheelchair?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused

HANDS AND FINGERS

28. During the past week, have you had the *full use* of both hands and ten fingers? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 32.

29 Have you needed the help of another person because of limitations in the use of your hands or fingers? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If no, interviewer go to item 31.

30. Have you needed the help of another person with some tasks, most tasks, or all tasks?
1= Some tasks, 2= Most tasks, 3= All tasks, 8= Don't know, 9= Refused

31. Have you needed special equipment, for example special tools to help with dressing or eating, because of limitations in the use of your hands or fingers? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused

SELF-CARE

32. During the past week, have you been able to eat, bathe, dress and use the toilet without difficulty?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If yes, interviewer go to item 35.

33. Have you needed the help of another person to eat, bathe, dress or use the toilet?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused

34. Have you needed special equipment or tools to eat, bathe, dress or use the toilet? .....__
0=No, 1=Yes, 8=Don't know, 9=Refused

FEELINGS

35. During the past week, have you been feeling happy or unhappy?.....__
1=Happy, 2= Unhappy, 8=Don't know, 9=Refused
If unhappy, interviewer go to item 37.

For items 5-45, possible responses may include: 8=Don’t know, 9=Refused to answer (these responses will be considered as missing data.)

36. Would you describe yourself as having felt: ?.....__
1=Happy and interested in life, 2=Somewhat happy, 8=Don't know, 9=Refused
If happy and interested in life or somewhat happy, interviewer go to item 38.

37. Would you describe yourself as having felt: ?.....__
1=Somewhat unhappy 8=Don't know
2=Very unhappy 9=Refused
3=So unhappy that life is not worthwhile

38. During the past week, did you ever feel fretful, angry, irritable, anxious or depressed?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If no, interviewer go to item 41.

39. How often did you feel fretful, angry, irritable, anxious or depressed: rarely, occasionally, often, or almost always? .....__
1=Rarely, 2=Occasionally, 3=Often, 4=Almost always, 8=Don't know, 9=Refused

40. During the past week did you feel *extremely* fretful, angry, irritable, anxious or depressed; to the point of needing professional help?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused

MEMORY

41. How would you describe your ability to remember things, during the past week?.....__
1=Able to remember most things, 2=Somewhat forgetful, 3=Very forgetful,
4=Unable to remember anything at all, 8=Don't know, 9=Refused

THINKING

42. How would you describe your ability to think and solve day-to-day problems, during the past week? ?.....__
1=Able to think clearly and solve problems 5=Unable to think or solve problems
2=Had a little difficulty 8=Don't know
3=Had some difficulty 9=Refused
4=Had a great deal of difficulty

PAIN AND DISCOMFORT

43. Have you had any trouble with pain or discomfort, during the past week?.....__
0=No, 1=Yes, 8=Don't know, 9=Refused
If no, interviewer go to item 45.

44. How many of your activities, during the past week, were limited by pain or discomfort: none, a few, some, most, all? .....__
1=None, 2=A few, 3= Some, 4=Most, 5=All, 8=Don't know, 9=Refused

45. Overall, how would you rate your health during the past week?.....__

1=Excellent,
2=Very good
3=Good
4=Fair
5=Poor
8=Don't know
9=Refused

QOL Center Only

100. Language used to complete this form? (1=English, 2=Spanish) .....__

101. Setting where this form was completed? .....__

1=Telephoned person at home (or patient returned QOL phone call shortly after)
2=Telephoned person when he or she was at the dialysis unit
3=Telephoned person at another location
4=Patient phone in at his/her convenience

102. Identify reason this QOL instrument was not completed?.....__

0=N/A, instrument was completed
1=Not completed due to patient logistics (phone disconnected, on vacation)
2=Attempted but unable to be completed - patient too sick
3=Attempted but unable to be completed - patient in hospital
4=Unable. Patient withdrew consent.
5=Study Staff logistics

201. Username of person completing interview .....__ __ __ __ __ __ __

Frequent Hemodialysis Network
CENTRAL SPECIAL STUDY QUESTIONS – FORM #224

Instructions: This form is completed by Central Interview.
Schedule: Questions are asked at Baseline and F12 for the Daily Trial and at Baseline and F12/F14 in the Nocturnal Trial unless otherwise indicated. *Note Question 12 is also asked at F4 in the Daily Trial and at F4/F5 in the Nocturnal Trial.*

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

4b. Time of interview?(hh:mm:ss).. __ __:__ __:__ __

Impact of Treatment

5. a. How long does it take you to recover from a dialysis session and resume your normal, usual activities? (Record the participant's actual response)....................__ __ __

   b. Units of measure in Q5a: (1=Minutes, 2=Hours, 3=Days)..__

6. On a scale from 0 to 100, with 0 being "no inconvenience" and 100 being "extreme inconvenience," how inconvenient do you find dialysis?..__ __ __

Medication Compliance

7. a. Have you missed any pills in the last week?..__
   (0=No, go to Question 8, 1=Yes, answer Q7b)

   b. EXCEPT for your phosphate binders, have you missed any pills in the last week? ....__
   (0=No, 1=Yes) *(Note: phosphate binders include, but are not limited to: Tums, calcium carbonate, Renagel, etc)*

Sex

The next three questions are personal and relate to your sexual activity, but your answers are important in understanding how kidney disease impacts on people's lives.

8. Have you had any sexual activity in the past 4 weeks? ....__
   (0=No, skip to question 11, 1=Yes, continue with Question 9.)

How much of a problem was each of the following in the past 4 weeks?

9. Enjoying sex?..__
   1=Not a problem
   2=A little problem
   3=Somewhat of a problem
   4=Very much a problem
   5=Severe problem
   9=Refused

For items 5-12, possible responses may include: 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)
If the patient is under 18 years old, questions 8, 9, and 10 will not be asked and the questions will appear blank in the database.

10. Becoming sexually aroused?.....__

1=Not a problem
2=A little problem
3=Somewhat of a problem
4=Very much a problem
5=Severe problem
9=Refused

Modality Preference. These questions are asked at the end of the study (Daily at F12, Nocturnal at F14).

11. a. There are a number of different treatment options for patients with kidney failure. If you were eligible for all of the following treatments, which would you rank as your 1st preference?.....__

1= Peritoneal dialysis
2=In-center 3 times weekly hemodialysis
3=In-center 6 times weekly hemodialysis
4=Home 6 times weekly daily hemodialysis
5=Home 6 times weekly nocturnal hemodialysis
6=Kidney transplant

b. Which would be your 2nd preference? .....__

1= Peritoneal dialysis
2=In-center 3 times weekly hemodialysis
3=In-center 6 times weekly hemodialysis
4=Home 6 times weekly daily hemodialysis
5=Home 6 times weekly nocturnal hemodialysis
6=Kidney transplant

c. Which would be your 3rd preference? .....__

1= Peritoneal dialysis
2=In-center 3 times weekly hemodialysis
3=In-center 6 times weekly hemodialysis
4=Home 6 times weekly daily hemodialysis
5=Home 6 times weekly nocturnal hemodialysis
6=Kidney transplant

For all patients at:
Daily: Baseline, F4 and F12
Nocturnal: Baseline, F5 and F14

12. Number of hours since the end of your last dialysis session: .....__ __.__

For items 5-12, possible responses may include: 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)
If the patient is under 18 years old, questions 8, 9, and 10 will not be asked and the questions will appear blank in the database.

QOL Center Only

100. Language used to complete this form? (1=English, 2=Spanish) .....__

101. Setting where this form was completed? .....__
1=Telephoned person at home (or patient returned QOL phone call shortly after)
2=Telephoned person when he or she was at the dialysis unit
3=Telephoned person at another location
4=Patient phone in at his/her convenience

102. Identify reason this QOL instrument was not completed?.....__

0=N/A, instrument was completed
1=Not completed due to patient logistics (phone disconnected, on vacation)
2=Attempted but unable to be completed - patient too sick
3=Attempted but unable to be completed - patient in hospital
4=Unable. Patient withdrew consent.
5=Study Staff logistics

201. Username of person completing interview .....__ __ __ __ __ __ __

For items 5-12, possible responses may include: 8=Don't know, 9=Refused to answer (these responses will be considered as missing data.)
If the patient is under 18 years old, questions 8, 9, and 10 will not be asked and the questions will appear blank in the database.

Frequent Hemodialysis Network
MOS SLEEP SCALE - FORM #225

Instructions: This form is completed by Central Interview.
Schedule: Daily: Completed at Baseline, F4 and F12
Nocturnal: Completed at Baseline, F5 and F14.

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

4b. Time of interview?(hh:mm:ss)... __ __:__ __:__ __

5. How long did it usually take for you to fall asleep during the past 4 weeks? ....__
   1=0–15 minutes
   2=16–30 minutes
   3=31–45 minutes
   4=46–60 minutes
   5=More than 60 minutes

6. On the average, how many hours did you sleep each night during the past 4 weeks? (Write in the number of hours per night) ....__ __.__

Use the following codes to answer questions 7-16:
1=All of the time
2=Most of the time
3=A good bit of the time
4=Some of the time
5=A little of the time
6=None of the time

7. How often during the past 4 weeks did you feel that your sleep was not quiet?.....................__
   (moving restlessly, feeling tense, speaking, etc., while sleeping)

8. How often during the past 4 weeks did you get enough sleep to feel rested upon waking in the morning? ....__

9. How often during the past 4 weeks did you awaken short of breath or with a headache? ......__

10. How often during the past 4 weeks did you feel drowsy or sleepy during the day? ....__

11. How often during the past 4 weeks did you have trouble falling asleep?...............................__

12. How often during the past 4 weeks did you awaken during your sleep time and have trouble falling asleep again? ....__

13. How often during the past 4 weeks did you have trouble staying awake during the day? ......__

14. How often during the past 4 weeks did you snore during your sleep? ....__

15. How often during the past 4 weeks did you take naps (5 minutes or longer) during the day?...__

16. How often during the past 4 weeks did you get the amount of sleep you needed? ....__

For items 5-16, possible responses may include: 8/88=Don't know, 9/99=Refused to answer (these responses will be considered as missing data.)

QOL Center Only

100. Language used to complete this form? (1=English, 2=Spanish) .....__

101. Setting where this form was completed? .....__
1=Telephoned person at home (or patient returned QOL phone call shortly after)
2=Telephoned person when he or she was at the dialysis unit
3=Telephoned person at another location
4=Patient phone in at his/her convenience

102. Identify reason this QOL instrument was not completed?.....__
0=N/A, instrument was completed
1=Not completed due to patient logistics (phone disconnected, on vacation)
2=Attempted but unable to be completed - patient too sick
3=Attempted but unable to be completed - patient in hospital
4=Unable. Patient withdrew consent.
5=Study Staff logistics

201. Username of person completing interview .....__ __ __ __ __ __ __

Frequent Hemodialysis Network
FEELING THERMOMETER RESULTS – FORM #230

Instructions: This form is completed by Study Staff based on the rating provided by the patient. This rating a scale from 0 to 100 with 0 = "Worst imaginable health state" and 100="Best imaginable health state". The patient is to use the form provided to answer the question, "How good or bad is your health today."

It is recommended that the patient complete this test before the other physical function tests. It is also recommended that test be done greater than 6 hours following the end of hemodialysis.

Schedule: Daily: Baseline, F-4 and F-12.
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

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

4b. Time of interview? (24 hr clock) ..... __ __:__ __

5. What rating did the patient record on the worksheet? (000 to 100).....__ __ __
(Note: leave blank if unable to complete test. Go to Q101.)

For Center Use:

100. Language used to complete this form? (1=English, 2=Spanish) .....__

101. Identify reason this instrument was not completed?.....__
1=N/A, instrument was completed
2=Attempted but unable to be completed - patient too sick
3=Attempted but unable to be completed - patient did not want to be bothered at this time
4=Attempted but patient cannot grasp how to do the test
5=Unable. Patient in hospital.
6=Patient forgot to bring eyeglasses or other visual aid
7=Unable. Patient withdrew consent.
8=Staff logistics

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

201. Username of certified person who performed this test .....__ __ __ __ __ __ __

For Clinical Center Use Only:
202. Username of person entering this form: __ __ __ __ __ __ __

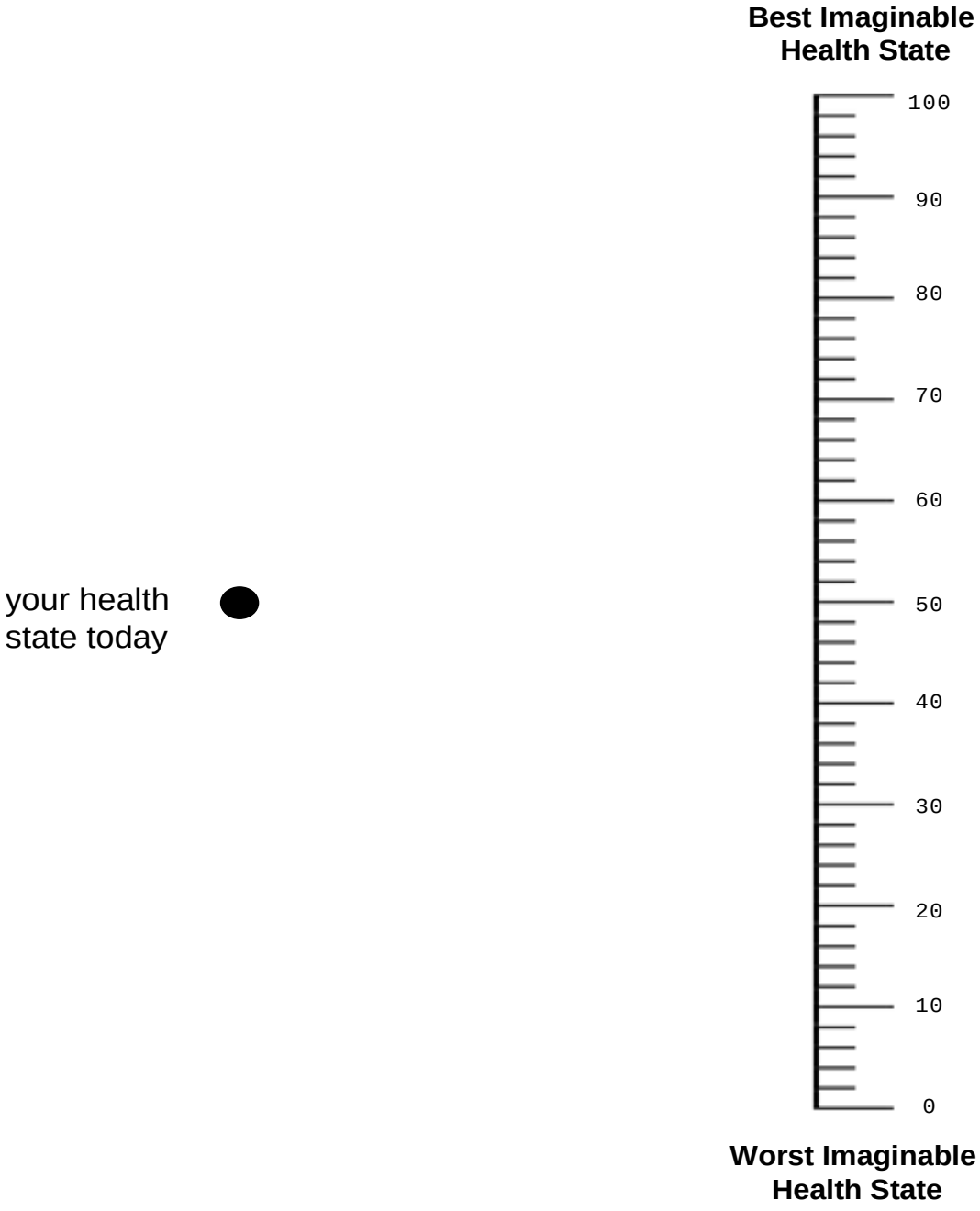
203. Date Entered: (dd/mon/yyyy) __ __/__ __ __ /__ __ __ __

Feeling Thermometer

1. Participant ID # 2. Alpha 4a. Date of Questionnaire: dd/mon/yyyy

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the *best* state you can imagine is marked by 100, and the *worst* state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad your health is today. Please do this by drawing a straight line from the black dot to whichever point on the scale that indicates how good or bad your health is currently.



Frequent Hemodialysis Network
MODIFIED MINI-MENTAL STATUS QUESTIONNAIRE - FORM #231

Instructions: Review all instructions in MOP on how to properly administer this test. It is strongly recommended that this test be done pre-dialysis or should not be done within the 1st six hours from end of hemodialysis. The study coordinator should conduct the test with the patient first and then go back later to score it.

Schedule: Daily: Baseline, F-4 and F-12.
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

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

4b. Time of test? (24-hr clock) ..... __ __:__ __

Items 4c and d can be patient reported:

c. Date of last dialysis treatment (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

d. End time of last dialysis treatment? (24-hr clock) ..... __ __:__ __

Examiner: **"Are you comfortable? I would like to ask you a few questions that require concentration and memory. Some are a little bit more difficult than others. Some questions will be asked more than once."**

5. Examiner: **"When were you born?"** (For 5a-c: Record 0=Incorrect, 1=Correct)

   a. Month: _____ .....__

   b. Day: _____ .....__

   c. Year: _____ .....__

6. Examiner: **"Where were you born?"** (For 6a-b: Record 0=Incorrect, 1=Correct)

   a. City/town:_____ .....__

   b. State/country: _____ .....__

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continued on next page

Examiner**: "I am going to say three words for you to remember. Repeat them after I have said all three words: Shirt, Blue, Honesty"**

Examiner note: Do not repeat the words for the participant until after the first trial. The participant may give the words in any order. If there are errors on the first trial, repeat the items up to six times until they are learned. Record responses to first attempt.

For items 7a-c: Record 0=Incorrect, 1=Correct

7. a. Shirt: _____.....__

   b. Blue: _____.....__

   c. Honesty:_____.....__

   d. Number of presentations necessary for the participant to repeat the presentation: .....__

Examiner: **"I would like you to count from 1 - 5.** If unable to count forward correctly**: say 1-2-3-4-5."**

8. a. Counting from 1-5:_____.....__
   (0=Unable to count forward, 1=Able to count forward)

Examiner: "**Now I would like you to count backwards from 5 to 1."**

b. Counting backwards from 5 to 1: (write in participant's response) .....__ __ __ __ __
(Start recording in the first dash. If participant is unable to complete the series, fill in the rest of the dashes with asterisks. The database will allow you to enter the asterisks and will score this item automatically once the participant's responses are entered.)

Examiner: **"Spell the word, 'world'."** Record letters in the order given.

9. a. Spelling "world":_____.....__
   (0=Unable to spell forward, 1=Able to spell forward)
   Examiner note: If unable to spell correctly: say "It's spelled W O R L D."

Examiner: **"Now spell 'world' backwards."**

b. Spelling "world" backwards: (write in participant's response).....__ __ __ __ __
(Record the first five letters in the order given starting with the first dash. If participant is unable to complete the series, fill in the rest of the dashes with asterisks. The database will allow you to enter the asterisks and will score this item automatically once the participant's responses are entered.)

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continued on next page

Examiner: **"What three words did I ask you to remember earlier?"**

Examiner note: The words may be repeated in any order. If the participant cannot give the correct answer after a category cue, provide the three choices listed. If the participant still cannot give the correct answer from the three choices, record "Unable to recall/refused" and provide the correct answer. Examiner should allow 3 seconds between promptings.

10. a. Shirt: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"Something to wear"**
4=After **"Was it shirt, shoes, or socks?"**

b. Blue: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"A color"**
4=After **"Was it blue, black or brown?"**

c. Honesty: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"A good personal quality"**
4=After **"Was it honesty, charity or modesty?"**

Examiner: **"What is today's date?" (month/day/year)**

Examiner note: Record response verbatim. If no response, enter '9'.

11 a. Month: _____.....__
0=Incorrect
1=Within 1 month
2=Correct response

b. Day: _____.....__
0=Incorrect
1=Within 2 days
2=Within 3-5 days
3=Correct response

c. Year: _____.....__
0=Incorrect
1=Within 1 years
2=Within 2-5 years
3=Correct response

Examiner: **"What day of the week is it?"**

11d. Day of the week: _____ .....__
0=Incorrect
1=Correct

Examiner: **"What season of the year is it?"** *(see MOP for instructions on 'season')*

e. Season: _____ .....__
0=Incorrect
1=Correct

Examiner: **"What state (province) are we in?"**

12 a. State: _____ .....__
0=Incorrect
1=Correct

Examiner: **"What county (parish) are we in?"**

b. County: _____.....__
0=Incorrect
1=Correct

Examiner: **"What city/town are we in?"**

c. City/town:_____ .....__
0=Incorrect
1=Correct

Examiner: **"Are we in a clinic, store or home?"** *(substitute actual location, if needed)*

d. Clinic, store, home:_____.....__
0=Incorrect
1=Correct

Examiner: Point to forehead: **"What do you call this part of the face?"**

13. a. Forehead:_____.....__
0=Incorrect
1=Correct

Examiner: Point to chin: **"And this part of the body?"**

b. Chin: _____.....__
0=Incorrect
1=Correct

Examiner: Point to shoulder: **"And this part of the body?"**

c. Response to shoulder:_____ .....__
0=Incorrect
1=Correct

Examiner: Point to elbow: **"And this part of the body?"**

d. Elbow:_____.....__
0=Incorrect
1=Correct

Examiner: Point to knuckle: **"And this part of the hand?"**

e. Knuckle: _____.....__
0=Incorrect
1=Correct

Examiner: **"What animals have 4 legs? Tell me as many as you can."**

*Examiner Note: Discontinue after 30 seconds. Record the total number of correct responses. If the participant gives no response in 10 seconds and there are still at least 10 seconds remaining, gently remind them (once only) "**What other animals have four legs?**"*

*The first time an incorrect answer is provided, say **"I want four legged animals."***

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

14. Participant's total correct responses to animals:.....__ __

Examiner Note: If the initial response is scored "lesser correct answer" or "Error," coach the participant by saying: "An arm and a leg are both limbs or extremities" to reinforce the correct answer. Coach only for Question #15a. No other prompting or coaching is allowed.

Examiner: **"In what way are an arm and leg alike?"**

15 a. Arm/leg: _____.....__
0=Error (states differences, gives unrelated answer)
1=Lesser correct response (e.g., body parts, both bend, have joints)
2=Correct response (limbs, extremities, appendages)

Examiner**: "In what way are laughing and crying alike?"**

b: Laughing/crying: _____.....__

0=Error (states differences, gives unrelated answer)
1=Lesser correct response (e.g., sounds, other similar responses)
2=Expressions or feelings, emotions

Examiner: **"In what way are eating and sleeping alike?"**

c. Eating/sleeping:_____.....__

0=Error (states differences, gives unrelated answer)
1=Lesser correct response (e.g. bodily functions, relaxing, "good for you")
2=Necessary bodily functions, essential for life

Examiner: **"Repeat what I say: "I would like to go out."**

Examiner Note: Pronounce the individual words distinctly but with normal tempo of a spoken sentence.

16. Participant's response: _____ .....__

0=3 or more words missing
1=1 or 2 words missed
2=Correct

Examiner: **"Now repeat: "No ifs, ands or buts."**

Examiner Note: Pronounce the individual words distinctly but with normal tempo of a spoken sentence. Give no credit if the participant misses the 's.'

17. a. 'No ifs':_____ .....__

0=Incorrect
1=Correct

b. 'Ands':_____.....__

0=Incorrect
1=Correct

c. 'Or buts':_____ .....__

0=Incorrect
1=Correct

Examiner: Hold up Card#1 (card says: CLOSE YOUR EYES) and say: **"Please do this."**

*Examiner note: If the subject does not close their eyes within five seconds, prompt by pointing to the sentence and saying: "**Read and do what this says.**" If the subject has already read the sentence aloud spontaneously, simply say "**Do what this says.**"*

*Allow five seconds for the response. Record "1" if the subject reads the sentence aloud, either spontaneously or after your request, but does not close their eyes. As soon as the subject closes their eyes, say "**Open.**"*

18. Participant response:_____ .....__
0=Does not read aloud or closes eyes/refuses
1=Reads aloud, but does not close eyes
2=Obeys with prompting
3=Obeys without prompting

Examiner: **"Please write the following sentence: 'I would like to go out.'"**

Examiner note: Give the participant a piece of paper and a pencil. Note which hand the participant uses to write. Allow a maximum of 1 minute after the first reading of the sentence for the scored response. Assign 1 for each correct word, but no credit for "I". For each word, mark "0" if there are spelling errors. Do not penalize self-corrected errors. If this task is not done, ask the participant if they are right or left handed {for use in Questions 20 and 21}.

19. a. '**would**': _____.....__
0=Incorrect
1=Correct

b. '**like**': _____.....__
0=Incorrect
1=Correct

c. '**to**': _____.....__
0=Incorrect
1=Correct

d. '**go**': _____.....__
0=Incorrect
1=Correct

e. '**out**': _____ .....__
0=Incorrect
1=Correct

f. What hand did the participant use to write the sentence?.....__
1=Right
2=Left

Examiner: **"Here is a drawing. Please copy the drawing onto this piece of paper."**

Examiner's Note: Hand the participant Card #2 (pentagon drawing) and a blank piece of paper. Allow 1 minute for copying. For right-handed participants, present the sample on the left side; the left-handed participants present the sample on the right side. Do not penalize for self-corrected errors, tremors, minor gaps, or overshoots. Do not allow patient to trace drawing.

20. a. Pentagon 1:.....__
0=Less than 2 lines / refused
1=2 or more lines, but it is not an enclosed figure
2=Non pentagon enclosed figure
3=5 sides, but longest: shortest side>2:1
4=5 sides, approximately equal sized

b. Pentagon 2:.....__
0=Less than 2 lines / refused
1=2 or more lines, but it is not an enclosed figure
2=Non pentagon enclosed figure
3=5 sides, but longest: shortest side>2:1
4=5 sides, approximately equal sized

c. Intersection of pentagons: .....__
0=No enclosure / refused
1=Other than 4-corned enclosure
2=4-cornered enclosure

Examiner: Refer back to Question 19f to determine the participant's dominant hand. Hold up a piece of white paper in plain view of the subject but out of reach, and say:

"Take this paper with your left (right *for left-handed person*) hand, fold it in half using both hands, and hand it back to me."

21. a. Takes paper in correct hand: .....__
0=Incorrect
1=Correct

b. Fold paper in half correctly:.....__
0=Incorrect
1=Correct

c. Hands paper back:.....__
0=Incorrect
1=Correct

Examiner: **"What three words did I ask you to remember earlier?**

Examiner note: The words may be repeated in any order. If the participant cannot give the correct answer after a category cue, provide the three choices listed. If the participant still cannot give the correct answer from the three choices, record "0" and provide the correct answer.

22. a. Shirt: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"Something to wear"**
4=After **"Was it shirt, shoes, or socks?"**

b. Blue: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"A color"**
4=After **"Was it blue, black or brown?"**

c. Honesty: _____.....__
0=Unable to recall/refused (provide the correct answer)
1=Spontaneous recall
2=Correct word/incorrect form
3=After **"A good personal quality"**
4=After **"Was it honesty, charity or modesty?"**

Examiner: **"Would you please tell me again where were you born?"**

23. Participant response: .....
Examiner note: Do not score this item. If the answer matches the answer given in Items 6a & b, mark those responses correct.

If physical/functional disabilities or other problems exist which cause the participant difficulty in completing any of the tasks, record the nature of the problem from the following problems codes.

24. a. Did the participant have any physical/functional disabilities as stated above?..... __
0=No, test completed, go to Q200; 1=Yes, complete 23 b-f.

Identify the following disabilities: Use codes: 0= No, 1=Yes
b. Vision:..... __
c. Hearing:..... __
d. Writing problems due to injury or illness or amputation: ..... __
e. Illiteracy or lack of education: ..... __
f. Language:..... __

---

100. Language used to complete this form? (1=English, 2=Spanish)..... __

---

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

201. Username of certified person who performed this test..... __ __ __ __ __ __ __

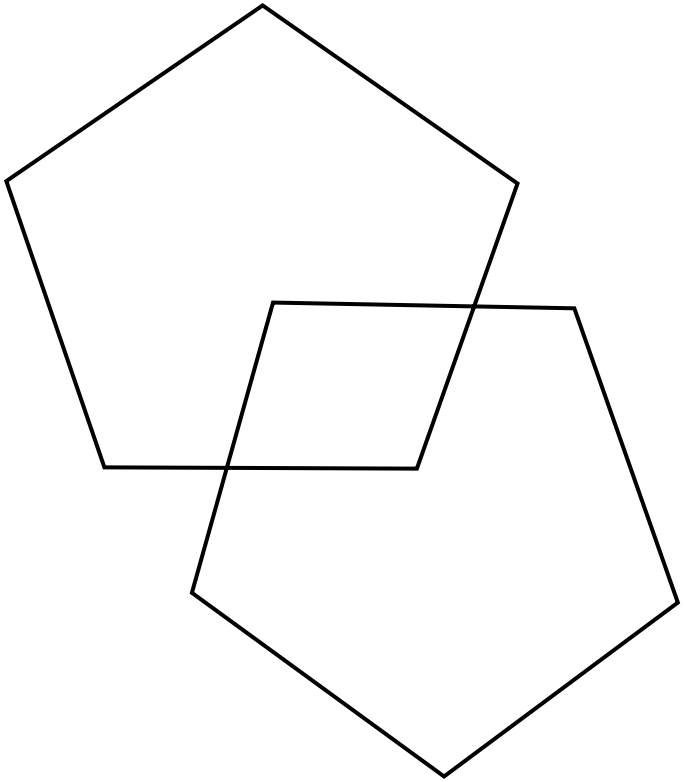
For Clinical Center Use Only:
202. Username of person entering this form: __ __ __ __ __ __ __

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

CLOSE YOUR EYES

Modified Mini Mental, Form 231, Question 20

Card #2



Frequent Hemodialysis Network
TRAILMAKING B SCORE SHEET - FORM #232

Instructions: Review all instructions in MOP/Forms Manual on how to properly administer this test. It is recommended that test be done more than 6 hours following the end of hemodialysis.
Note: Time allowed for test has been extended from 4 to 10 minutes; maximum score for the FHN Trial is 23 connecting lines.

Schedule: Daily: Baseline, F-4 and F-12.
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

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

4b. Time of test? (24 hr clock)... __ __:__ __

TRAILMAKING B: Number to Letter Test **Time allowed: 10 minutes**

<u>Sample test</u>: "You will notice that this page has both numbers and letters. Begin at number one, and draw a line from number one to the letter A, A to two, two to B, B to three, three to C, and so on, until you reach the end. Draw the lines as fast as you can. Go."

<u>Test</u>: "Good. Now do this test the same way. Begin at number one, and draw a line from number one to the letter A, A to two, two to B, B to three, three to C, and so on, until you have reached the end. Remember, first you have a number, then a letter, and so on. Draw the lines as fast as you can. Go."

Scoring:

5. Time required for patient to complete Trailmaking Test B:.................................. __ __:__ __
   If the subject is unable to complete the test in the time allotted, record a maximum time of 10 minutes. minutes:seconds

6. Number of correct responses: ....__ __
   If the subject completes the test correctly in the time allotted, record a maximum score of 23. If the subject does not complete the test correctly in under 10 minutes, record the number of correct responses.

**For the purposes of the FHN Trial, the best score is 23 lines*

---

100. Language used to complete this form? (1=English, 2=Spanish)... __

101. Identify reason this instrument was not completed?.. __
   1=N/A, instrument was completed, complete Q102.
   2=Attempted but unable to be completed - patient too sick.
   3=Attempted but unable to be completed - patient did not want to be bothered at this time
   4=Patient forgot glasses or hearing aid (had difficulty seeing or hearing)
   5=Unable. Patient in hospital.
   6=Unable. Patient withdrew consent.
   7=Staff logistics

102. Did test administrator catch an error too late? (0=No, 1=Yes)... __

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

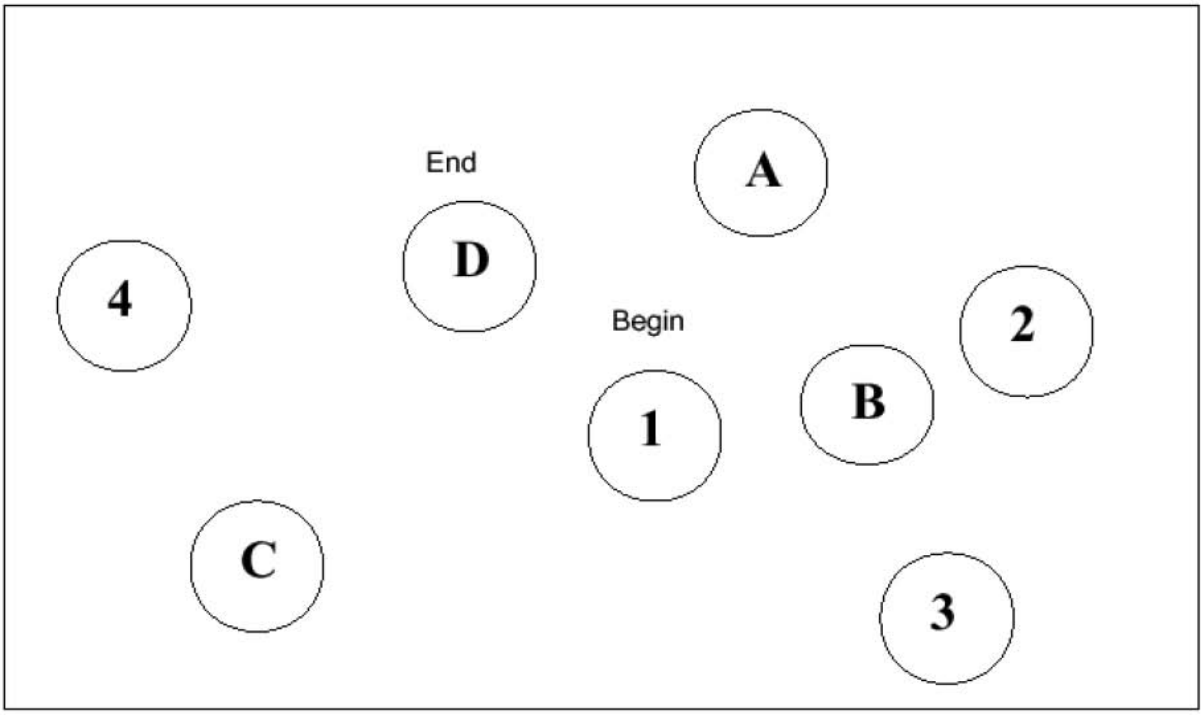
201. Username of certified person who performed this test .... __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Trail Making (Part B) – *SAMPLE*

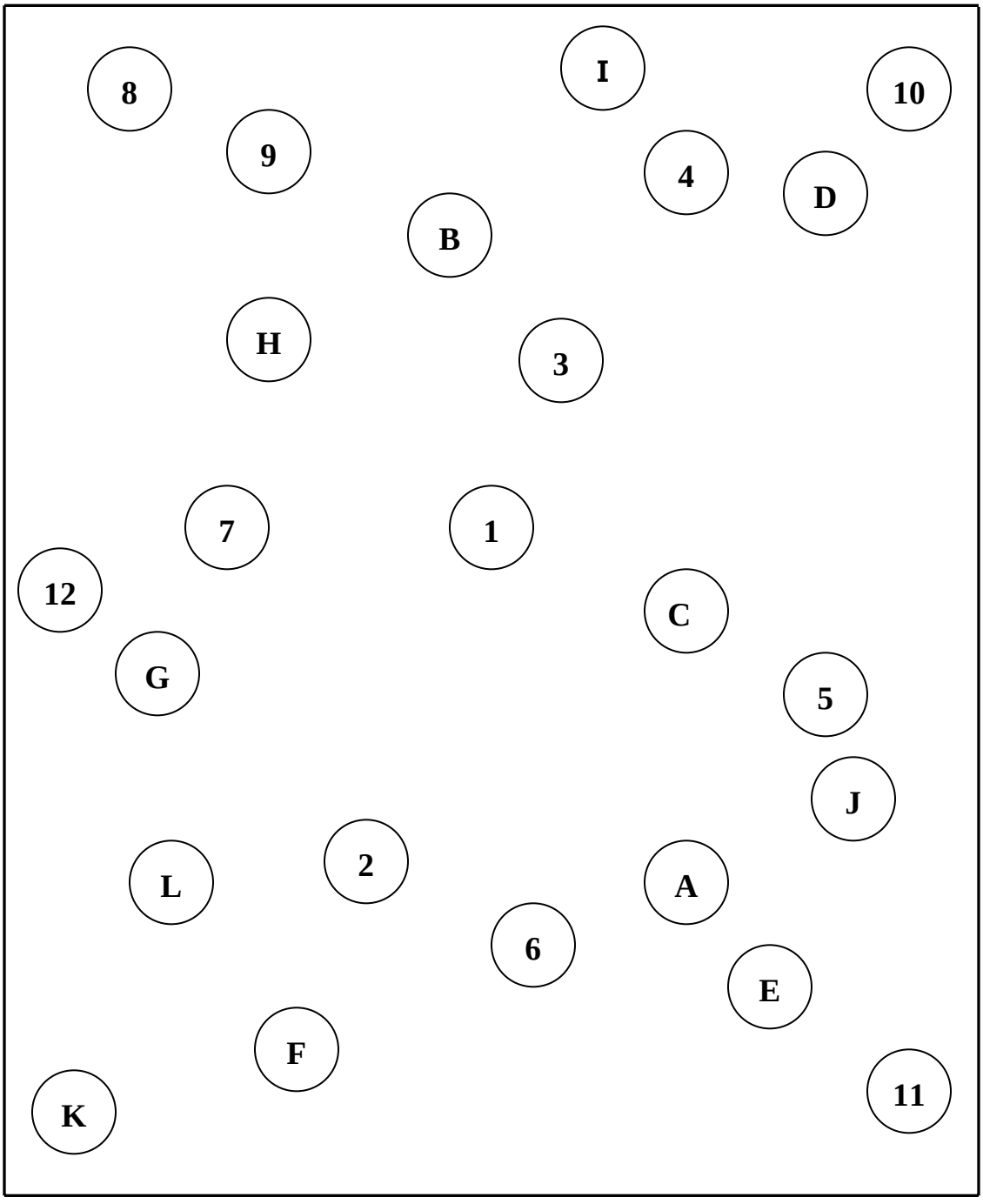


Trail Making (Part B)

1. Participant ID #

2. Alpha Code

4a. Date of test dd/mon/yyyy



Frequent Hemodialysis Network
CLINICAL CENTER MISCELLANEOUS QUESTIONS - FORM #233

Instructions: Clinical Center staff completes these questions at intervals specified in each section.

Follow-up Extension Study: For all patients consenting to the Follow-up Extension Study, only complete Questions 12a - 13b at the end of this form.

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

For all U.S. patients at baseline:

4b. Did patient agree to provide health insurance identification numbers for future linkage with USRDS? ..... __
0=No, patient refused (*Do not complete Form 108*)
1=Yes, patient agreed. (*Complete Form 108*)
8=Not applicable

For Daily Trial: skip questions 5 and 6.

Nocturnal Trial Blood Pressure - at baseline only:

5. Mid-arm circumference for BP cuff (in cm) ..... __ __.__

6. a. Cuff size provided to the patient for the OMRON machine ..... __
1=Pediatric 3=Large
2=Regular 4=X-large (thigh sized)

b. How much is patient's electric bill per month? ..... $ __ __ __.__ __

c. How much is patient's water bill per month? ..... $ __ __ __.__ __

d. What currency are Items 6b & c reported in? ..... __
(1=American, 2=Canadian, 3=Australian)

Items 7 - 11 For All Patients At End of Trial

Employment Status Change

7. Current work status: ..... __ __
01=Student, not employed
02=Student, employed
03=Homemaker
04=Not working, not seeking work, disabled
05=Not working, not seeking work, not disabled
06=Not working, seeking work, disabled
07=Not working, seeking work, not disabled
08=Employed full-time
09=Employed part-time
10=Retired
99=Unknown

8. Has there been a change in employment status since baseline? ..... __
(0=No, skip to Q10, 1=Yes, complete Q9)

(questions continued on next page)

9. Primary reason for work status change (between trial baseline and current)? .....__
   1=Due to time constraints of chronic kidney failure treatment
   2=Due to complications of chronic kidney failure
   3=Due to illness other than chronic kidney failure
   4=Due to retirement
   5=Patient now working more hours.
   6=Due to other reasons
   If other reason for change in work status, contact DCC for new code.

For All Patients At The End of the Study
Patient Health Insurance: (For questions 10a-h: 0=No, 1=Yes, 8=Not Applicable)

10. **Column A:** What type of health insurance does the patient have?
    Column B: Are any of the insurance plans the patient listed an HMO (Health Maintenance Organization)?

		A Have?	**B HMO?**
a.	Medicare:	__	__
b.	Medicaid or State Medical Assistance:	__	__
c.	State or county program other than Medicaid:	__	__
d.	Employer-sponsored or retiree health plan:	__	__
e.	Privately-purchased policy (e.g., Medigap or Medicare supplement):	__	__
f.	Veterans benefit, TriCare or military health plan:	__	__
g.	Canadian health care benefits:	__	__
h.	None:	__	

11. a. Is Medicare paying for this patient's hemodialysis? .....__
    0=No, answer Question 11b
    1=Yes, skip to Question 200.
    (Note: This question may need to be completed by your Billing Department.)

    b. If no to Question 11a, why not?.....__
    1=Patient recently started hemodialysis
    2=Patient is Canadian
    3=U.S. Patient has alternative insurance
    4=Patient is Australian

****

Follow-up Extension Study Final Visit Only: *Modality Preference.*

12. a. There are a number of different treatment options for patients with kidney failure. If you (patient) were eligible for all of the following treatments, which would you rank as your 1st preference?.....__
    1= Peritoneal dialysis
    2=In-center 3 times weekly hemodialysis
    3=In-center 6 times weekly hemodialysis
    4=Home 6 times weekly daily hemodialysis
    5=Home 6 times weekly nocturnal hemodialysis
    6=Kidney transplant
    7=Home 3 times weekly hemodialysis
    8=Home 3 times weekly nocturnal hemodialysis

Frequent Hemodialysis Network
CLINICAL CENTER MISCELLANEOUS QUESTIONS - FORM #233

b. Which would be your 2nd preference? .....__
1= Peritoneal dialysis
2=In-center 3 times weekly hemodialysis
3=In-center 6 times weekly hemodialysis
4=Home 6 times weekly daily hemodialysis
5=Home 6 times weekly nocturnal hemodialysis
6=Kidney transplant
7=Home 3 times weekly hemodialysis
8=Home 3 times weekly nocturnal hemodialysis

c. Which would be your 3rd preference? .....__
1= Peritoneal dialysis
2=In-center 3 times weekly hemodialysis
3=In-center 6 times weekly hemodialysis
4=Home 6 times weekly daily hemodialysis
5=Home 6 times weekly nocturnal hemodialysis
6=Kidney transplant
7=Home 3 times weekly hemodialysis
8=Home 3 times weekly nocturnal hemodialysis

13. a. What is primary reason patient would prefer dialysis modality indicated in Q12a? .....__ __
1=Convenience for patient's schedule
2=Convenience for caregiver's schedule
3=Pt feels best using this modality
4=Pt believes he/she will feels feel better using this modality
5=Pt concern for access
8=Other reason (complete Q13b)

b. If Q13a=8, provide other reason in comment section:

_____

_____

_____

_____

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

201. Username of person completing this form.....__ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
PHYSICAL FUNCTION MEASURES QUESTIONS - FORM #234

Instructions: Review detailed instructions in MOP on how to conduct these physical function tests. A stopwatch is needed. The computer will calculate the number of points assigned to each test and report the scores in items 13a-e.
Schedule: Daily: Baseline, F-4 and F-12.
Nocturnal v3.0: Baseline, F-4 and F-12. (*Nocturnal v2.1: Baseline, F-5 and F-14).*

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

4b. Time of assessment? (24 hr clock).. __ __:__ __

c. How does this patient ambulate/move around? ....__
(1=Unassisted, 2=Walker, 3=Cane, 4=Wheelchair)

All of the tests should be performed in the same order as they are presented. Instructions to the participant are shown in bold italic and should be given exactly as they are written in this script.

BALANCE TESTS (Record number of seconds each position is held.)
The participant must be able to stand unassisted without the use of a cane or walker.
You may help the participant to get up.

Examiner: "Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe"

"Do you have any questions before we begin?"

- ***"Now I will show you the first movement"*** (Demonstrate) ***"I want you to try to stand with your feet together, side-by-side, for about 10 seconds."***
- ***"You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop."***
-
- Stand next to the participant to help him/her into the side-by-side position. Supply just enough support to the participant's arm to prevent loss of balance.
-
- When the participant has his/her feet together, ask ***"Are you ready?***
-
- Then let go and begin timing as you say, ***"Ready, begin."***

- Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

- If participant is unable to hold the position for 10 seconds, record result in Item #5 and go to the gait speed test.

5. Results: Side-by-side stand (seconds).....__ __.__ __
(Ideal is to hold position for 10 seconds. If balance test is not attempted, record '99.99' and answer question 8. End balance tests.)

- ***"Now I will show you the second movement.*** (Demonstrate) ***I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you."***

- ***"You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop."***

- Stand next to the participant to help him/her into the semi-tandem position. Supply just enough support to the participant's arm to prevent loss of balance.

- When the participant has his/her feet together, ask ***"Are you ready?"***

- Then let go and begin timing as you ***"Ready, begin."***

- Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

- If participant is unable to hold the position for 10 seconds, record result in Item #6 and go to the gait speed test.

6. Results: Semi-tandem stand (seconds).....__ __.__ __
(Ideal is to hold position for 10 seconds. If balance test is not attempted, record '99.99' and answer question 8. End balance tests.)

- ***"Now I will show you the third movement".*** (Demonstrate) ***"I want you to try to stand with heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you."***

- ***"You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop."***

- Stand next to the participant to help him/her into the tandem position. Supply just enough support to the participant's arm to prevent loss of balance.

- When the participant has his/her feet together, ask ***"Are you ready?"***

- Then let go and begin timing as you say, ***"Ready, begin."***

- Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

- Record the number of seconds in item #7.

7. Results: Tandem stand (seconds).....__ __.__ __
(Ideal is to hold position for 10 seconds. If balance test is not attempted, record '99.99' and answer question 8. End balance tests.)

8. If participant did not attempt test or failed the test, identify reason why:.....__
0=N/A, patient completed test.
1=Tried but unable to perform test
2=Participant could not hold position unassisted
3=Not attempted, you (person conducting test) felt unsafe
4=Not attempted, participant felt unsafe
5=Participant unable to understand instructions
6=Participant refused

GAIT SPEED TEST Observe participant's normal walk. A cane or other walking aid may be used, if needed.

- ***"Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it."***

- ***"This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***

- Demonstrate the walk for the participant.

- ***"Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?"***

- Have the participant stand with both feet touching the starting line.

- ***"When I want you to start, I will say: Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***

- Press the start/stop button to start the stopwatch as the participant begins walking. Walk behind and to the side of the participant.

- Stop timing when one of the participant's feet is completely across the end line and record the number of seconds in Item 9a.

First Gait Test

9. a. Results: Time (in seconds) for first gait speed test over 4 meters .....__ __.__ __
If unable to complete test or test refused, enter "00.00"

b. Did patient not attempt or failed test? (0=No, 1=Yes) .....__

c. Why did patient not attempt or failed test?.....__
0=N/A, patient completed test
1=Tried but unable
2=Participant could not walk unassisted
3=Not attempted, you (examiner) felt unsafe
4=Not attempted, participant felt unsafe
5=Participant unable to understand instructions
6=Participant refused

d. Aids used for first walk?.....__
0=None
1=Cane
2=Walker
3=Other, specify:_____
4=N/A, patient did not attempt test

e. Does examiner have any comments? (0=No, 1=Yes).....__

Specify: _____

_____

Second Gait Speed Test

- ***"Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course."***
- Have the participant stand with both feet touching the starting line.
- ***"When I want you to start, I will say: Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
- Press the start/stop button to start the stopwatch as the participant begins walking. Walk behind and to side of the participant.
- Stop timing when one of the participant's feet is completely across the end line. Record results in Item 10a.

10. a. Results: time (in seconds) for second gait speed test over 4 meters .....__ __.__ __
If unable to complete test or test refused, enter "00.00"

b. Did patient not attempt or failed test? (0=No, 1=Yes) .....__

c. Why did patient not attempt or failed test?.....__
0=N/A, patient completed test
1=Tried but unable
2=Participant could not walk unassisted
3=Not attempted, you (examiner) felt unsafe
4=Not attempted, participant felt unsafe
5=Participant unable to understand instructions
6=Participant refused

d. Aids used for second walk? .....__
0=None
1=Cane
2=Walker
3=Other, specify:_____
4=N/A, patient did not attempt test

e. Does examiner have any comments? (0=No, 1=Yes).....__

Specify: _____

CHAIR STAND TEST This test measures the strength of the participant's legs. Arms should be folded across chest. If participant cannot rise without using arms, the test is finished. See also other reasons for discontinuing test.

Single Chair Stand

- "***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?"***
- ***"The next test measures the strength in your legs."***
- (Demonstrate and explain the procedure.) "***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest".***
- ***"Please stand up keeping your arms folded across your chest."*** (Record result).
- If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result in item #11a and to the scoring page.

Single Chair Stand Test Results

11. a. Did participant feel safe to stand without help? (0=No, 1=Yes) .....__

b. Results of single chair stand test.....__
1=Participant stood without using arms (continue with repeated chair stand test)
2=Participant used arms to stand (end test)
3=Participant could not complete test (end test)

c. Why did patient not attempt or failed test?.....__
0=N/A, patient completed test, go to question 12
1=Tried but unable, go to question 103
2=Participant could not walk unassisted, go to question 103
3=Not attempted, you (examiner) felt unsafe, go to question 103
4=Not attempted, participant felt unsafe, go to question 103
5=Participant unable to understand instructions, go to question 103
6=Participant refused, go to question 103

Repeated Chair Stand Test

- "***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?"***
- (Demonstrate and explain the procedure): "***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch"***
- When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.
- Count out loud as the participant arises each time, up to five times.
- Stop if participant becomes tired or short of breath during repeated chair stands.
- Stop the stopwatch when he/she has straightened up completely for the fifth time.
- Also stop:
  - If participant uses his/her arms
  - After 1 minute, if participant has not completed rises
  - At your discretion, if concerned for participant's safety
- If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***
- If participant says "Yes," continue timing. If participant says "no", stop and reset the stopwatch.

12. a. Did participant feel safe to stand five times? (0=No, 1=Yes) .....__

b. Results: time (in seconds) for repeated chair stand test .....__ __.__ __
If unable to complete test or test refused, enter "00.00"

c. Results of repeated chair stand test.....__
1=Participant stood without using arms
2=Participant used arms to stand (end test. go to question 103)
3=Participant could not complete test (end test- go to question 103)

d. Why did patient not attempt or failed test?.....__
0=N/A, patient completed test, go to question 103
1=Tried but unable, go to question 103
2=Participant could not walk unassisted, go to question 103
3=Not attempted, you (examiner) felt unsafe, go to question 103
4=Not attempted, participant felt unsafe, go to question 103
5=Participant unable to understand instructions, go to question 103
6=Participant refused, go to question 103

Patient testing is now complete.

Study Staff continue:

100. Language used to complete this form? (1=English, 2=Spanish) .....__

103. Setting where this form was completed? .....__
1=Patient was tested at home
2=Patient was tested at the dialysis unit
3=Patient was tested in another clinical setting

104. Identify reason this entire instrument was not completed?.....__
1=N/A, instrument was completed.
2=See reasons described in sections above.
3=Attempted but unable to be completed - patient too sick.
4=Attempted but unable to be completed - patient did not want to be bothered at this time
5=Unable. Patient in hospital.
6=Unable. Patient withdrew consent.
7=Staff logistics
8=Pt. disabled, uses wheelchair only

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

201. Username of certified person who performed this test.....__ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
SINGLE FREQUENCY BIOELECTRIC IMPEDANCE (BIA) ASSESSMENT - FORM #242

Instructions: Prior to the measurement, **the patient should lie flat for 15-20 minutes to equilibrate fluid distribution**. See MOP for specific instructions on how to take the measurements. You will need to ask the patient whether he/she has an implanted defibrillator or pacemaker, and if he does, do not do the test. Do not do the test if the patient is a bilateral amputee.

It is preferable, but not mandatory, that all measurements be conducted in the supine position, if at all possible, and should be performed immediately prior to a mid-week HD treatment (i.e., Wednesday or Thursday).

Recommended Schedule: Daily Study: Baseline, F1, F4, and F12 *(BIA is not required for randomization as of 22/FEB/2007.)*
Nocturnal Study v3.0: Baseline, F4, and F12. (v2.1: F5 and F14)

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

4b. Time of test? (24 hr clock)... __ __:__ __

5. Height (measure supine length in those unable to stand) (cm)...............................__ __ __.__
For bilateral amputees, do not do test.

6. a. Current weight (kg)..__ __ __.__

b. Estimated dry weight (kg)..__ __ __.__

7. Body position (1=Supine [preferred], 2=Seated, 3=Semi-recumbent).......................................__

8. Side measured (1=Right, 2=Left) ....__

9. Measured resistance (R) (ohms) ....__ __ __

10. Measured reactance (Xc) (ohms)...__ __

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

201. Username of certified person who performed this test .... __ __ __ __ __ __ __

For Clinical Center Use Only:
202. Username of person entering this form: __ __ __ __ __ __ __

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

Frequent Hemodialysis Network
LAST DIALYSIS SESSION BEFORE THE MRI FORM - # 250

This form is completed after the study coordinator knows the date that an MRI was performed. The Study Coordinator goes back to the patient's dialysis data and obtains data on last dialysis session that was done prior to the MRI. This form is completed in conjunction with the MRI based on the following schedule.

Schedule: Daily: Baseline and F-12.
Nocturnal v3.0: Baseline and F-12. (*Nocturnal v2.1: Baseline and F-14).*

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

5. Date of this patient's last dialysis session before the MRI ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

6. End time of this patient's last dialysis session (24-hour clock)..... __ __ : __ __

7. Post weight after this patient's last dialysis session (kg).....__ __ __ . __

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

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

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
MRI Mailing Form # 251

No technician may do an MRI on an FHN study patient until they have submitted two test case MRI's to the Cardiac MRI Core Laboratory (CICL) and received feedback that the test MRI's were performed and processed correctly. MRI's are assumed to have been done at the MRI site associated with the patient's participating dialysis unit as recorded in the study database. This form should be completed at the time of the MRI or (*if the MRI is not done*) at the end of the visit window for the MRI (*if the MRI is not done, use the end date of the visit window as Date of MRI - Item #4*). If an MRI is done but is clearly of inadequate quality, repeat the MRI. Do not submit the MRI to the CICL and/or enter a mailing form.

It is preferable, but not mandatory, that the MRI be obtained either on a non-dialysis day or on the same day but after an HD session.

When this form has been completed, it should be photocopied. The copy should be sent with the MRI images to the CICL; make sure it is a clear, clean copy. The original should be entered by a Clinical Center and kept with the patient's other completed study forms. Be sure to make an extra copy of the patient's MRI scan. Ship the MRI and copy of Form 251 to the attention of:

Tam Tran, Mbabazi Kariisa
110 Davis Heart and Lung Institute
473 W 12th Ave
Columbus OH 43210
Phone: 614-366-6434

On shipping day, send an email message to: *fhn-mricore@bio.ri.ccf.org*. For the e-mail message, use the following template:
"Please be advised that the Cardiac MRI for patient xxxxxx-xx has been shipped by Fed-ex today, (dd/mmm/yy). Tracking number is xxxx-xxxx-xxxx. Please confirm with us upon receipt."

Items #1 - 6 are to be completed by the Study Coordinator.

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

5. Was the MRI done during the visit window? .... ___
   1=Yes
   2=No, patient refused
   3=No, logistic problem related to the patient
   4=No, medical problem (i.e., pacemaker, metallic implant, etc.)(for use in follow-up only)
   5=No, logistic problem related to the FHN site
   6=No, logistic problem related to the MRI site

If MRI done, continue. If not done, skip to item 200.

6. Type of study .... __
   1=Routine (in window)
   2=Make up for missed routine (in next window)
   3=Repeat

Items #7-35 are to be completed by the MRI Technician.

Heart Rate

7. Heart rate measured at the time of MRI (bpm) ....___ ___ ___

MRI

8. Time of MRI ....(military) __ __ : __ __

9. Was there regular rhythm? (0=No, 1=Yes) .... __

10. a. What was the gating? (1= ECG, 2=Pulse)..... __

    b. What gating method was used? ..... __
    1=Retrospective, as per FHN MRI Core protocol
    2=Prospective

Left Ventricular Function - Cine Short Axis

Note: Items 11 - 34 are not required to be entered into the database.

11. Position: 4-chamber view: ...a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
12. Position: Proximal to base: ...a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
13. Position: Base: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
14. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
15. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
16. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
17. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
18. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
19. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
20. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
21. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
22. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
23. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
24. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
25. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
26. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
27. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
28. Next: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
29. Position: Apex: .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
30. Position: Distal to Apex:.....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __

Cine Long Axis

31. Position: 3-Chamber View ....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
32. Position: 2-Chamber view .....a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __

Aortic Stiffness

33. Position: LV outflow tract: a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __
34. Position: Ascending aorta: a. Series Number __ __ b. Slice position __ __ __ __ __ __ __ __

35. Username of certified MRI tech who did this MRI. .....__ __ __ __ __ __ __ __

Items #36, 200-201 are to be completed by the Study Coordinator.

36. Date shipped to Central MRI Facility .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

For DCC Use Only:

199. MRI unreadable per core?..... __

200. Date DCC notified ..... __ __/__ __ __/__ __ __ __

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

201. Username of person reviewing this form prior to data entry ..... __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
MRI CENTRAL DATA ENTRY - FORM # 252A

This form is completed at the Cardiac MRI Core Laboratory (CICL). A staff member from the CICL will enter this into the study database. Many values will be calculated automatically and reported back to the Clinical Centers.

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

4b. Date this MRI read (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __

Hemodynamic (MRI scan)

5. Heart rate as measured centrally (bpm) .....__ __ __

Global Left Ventricular Function

6. Left ventricular end-diastolic volume: (ml)..... __ __ __.__ __

7. Left ventricular end-systolic volume: (ml) ..... __ __ __.__ __

Left Ventricular Mass

8. Left ventricular mass: (gr) ..... __ __ __.__ __

Global Right Ventricular Function

9. Right ventricular end-diastolic volume: (ml)..... __ __ __.__ __

10. Right ventricular end-systolic volume: (ml)..... __ __ __.__ __

Segmental Left Ventricular Function

11. Absolute systolic thickening: (mm)..... __ __ __.__

12. Relative systolic thickening: (%).....__ __ __.__ __

(Wall motion score index moved to Form 252B as Item #5.)

Aortic Stiffness

14. Maximal area: (cm^2) .....__ __.__ __

15. Minimal area: (cm^2) .....__ __.__ __

16. Maximal diameter: (cm^2) .....__.__ __ __

17. Minimal diameter: (cm^2).....__.__ __ __

201. Username of CICL staff member reading the MRI .....__ __ __ __ __ __ __ __

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

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

Frequent Hemodialysis Network

MRI WALL MOTION SCORE INDEX DATA ENTRY - FORM # 252B

This form is completed by the Cardiac MRI Core Laboratory (CICL) physician who reviews the MRI scan for the wall motion score index and clinical alerts. A staff member from the CICL will enter this into the study database.

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

4b. Date wall motion score index measured (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

Segmental Left Ventricular Function

5. Wall motion score index: .....__.__

201. Username of CICL staff member measuring wall motion score index .__ __ __ __ __ __ __ __

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

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

Frequent Hemodialysis Network
HEART RATE VARIABILITY MAILING FORM - FORM # 253

This form is to be completed for the Daily Study only. Review MOP for instructions on how to complete the Holter testing. When this form has been completed, it should be photocopied. The copy should be sent with the Holter CD to the Central Holter Lab; make sure it is a clear, clean copy. The original should be entered by a Clinical Center and kept with the patient's other completed study forms. Be sure to make an extra copy of the patient's Holter CD. Ship by overnight courier, the CD and completed copy of Form 253 to the attention of:

Christopher T. Chan, M.D.
Division of Nephrology Toronto General Hospital
Eaton North 8N-842
200 Elizabeth Street
Toronto, Ontario M5G 2C4
Phone: 416-340-3073

On shipping day, send an email message to: *holtercore@bio.ri.ccf.org (christopher.chan@uhn.on.ca* and *margaret.mcgrath-chong@uhn.on.ca).* For the e-mail message, use the following template: "Please be advised that the Holter for patient xxxxxx-xx has been shipped by (overnight courier) today, (dd/mmm/yy). The tracking number is xxxx-xxxx-xxxx. Please confirm with us upon receipt."

1. Participant ID # | 2. Alpha Code | 3a.Visit Type | 3b. Visit Number | 4. Start Date of Holter: dd/mon/yyyy *(Use target date if not done)*

5. Was the Holter (heart rate variability test) done? .....__
   1=Yes, Holter completed
   2=No, patient refused
   3=No, logistic problem related to the patient
   4=No, logistic problem related to the FHN site
   5=No, medical problem (i.e., sustained atrial fib-must review case with Dr. Chan, pacemaker, etc.)

If Holter done, continue. If not done, skip to item 200.

6. Type of collection .....__
   1=Routine (in window)
   2=Make up for missed routine (in next window)
   3=Repeat

7. Start time of Holter: (use 24-hour clock)..... __ __:__ __

8. Stop time of Holter: (use 24-hour clock)..... __ __:__ __

9. Username of person placing the Holter. .....__ __ __ __ __ __ __

10. Date shipped to the Central Reading Facility (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

Items 11 a-d are needed by the Holter Core but will not be entered into the database.

11. a. Name of person completing this form: _____

b. Telephone Number: __ __ __ /__ __ __ /__ __ __ __ ext. __ __ __ __ __

c. E-Mail Address: _____

d. Name of FHN Clinical Center: _____

For DCC Use Only:

199. a. Holter unreadable per core? .....__

b. Date DCC notified: __ __ __ /__ __ __ /__ __ __ __

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

201. Username of person completing or reviewing this form .....__ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
CENTRAL HOLTER READING FACILITY
DATA TRANSMISSION - FORM #254

Data are entered by the Central Holter Reading Facility.

1. Participant ID # | 2. Alpha Code | 3. Start Date of Holter: dd/mon/yyyy

4. Date received at central facility: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

5. Date read at central facility: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

6. Username of person reading the Holter: .....__ __ __ __ __ __ __

Mean RR:

7. Mean RR interval during the 24-hour period (milliseconds): ..... __ __ __ __

pNN50:

8. The proportion of differences in successive RR intervals >50ms (in percent): .....__ __ . __

SDNN:

9. The standard deviation of RR intervals: (milliseconds): ..... __ __ __ __

VLF:

10. Very low frequency domain (ms^2) spectral analysis: ..... __ __ __ . __

LF:

1l. Low frequency domain (ms^2) spectral analysis: ..... __ __ __ . __

HF:

12. High frequency domain (ms^2) spectral analysis: .....__ __ __ . __

LF/HF Ratio

13. LF/HF ratio: .....__ __ . __ __

200. User name of person entering this form: __ __ __ __ __ __ __

201. Date entered (dd/mon/yyyy): __ __/__ __ __/__ __ __ __

Frequent Hemodialysis Network (FHN)
U.S. BIOLOGICAL SPECIMEN REPOSITORY MAILING FORM - #255

NIDDK BioRepository Contact Information

Address: Fisher BioServices
Attn: Lab Manager
NIDDK Repository
20301 Century Blvd.
Building 6, Suite 400
Germantown, MD 20874

Email: **Bio-NIDDKRepository@thermofisher.com**

Phone: (240) 686-4703 (Heather Higgins)
Phone (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

You will need to complete one Form 255 for each PID in the shipment. Ship samples to the address above in the mailer provided. Spin tubes and ship them on cold packs. Mondays through Thursdays, notify the repository of shipments by e-mail* or by facsimile on the day the package is picked up by FedEx. Refer to Chapter 22 for details on how to process vacutainers for shipment. ***Do not ship on Fridays***. Enclose this original form in the mailer. Keep a copy of this form. *Enter items 1 to 9a only into the FHN database.*

On shipping day, send an email message to: *Bio-NIDDKRepository@thermofisher.com*. For the e-mail message, use the following template:
"Please be advised that biorepository samples for patient(s) xxxxxx-xx has/have been shipped by Fed-ex today, (dd/mmm/yy). Tracking number is xxxx-xxxx-xxxx. Please confirm with us upon receipt."

Section A: To be completed at the FHN site:

			-														

1a. Repository ID# | 1b. Participant ID # | 2. Alpha Code | 3a. Visit Type | 3b. Visit Number

4. Date specimen collected.....(dd/mon/yyyy)__ __/__ __ __/__ __ __ __
Note: for nocturnal study patients, date specimen collected will be the pre-dialysis date.
The post-dialysis collection date is presumed to be one day later.

5. a. Time of pre-dialysis blood draw .....(24 hour clock)__ __: __ __

b. Time of post-dialysis blood draw.....(24 hour clock)__ __: __ __

	DCC Use # *Hemolyzed?*
Serum	
6.a. Number of pre-dialysis 7.5 mL SST tubes (serum) sent to Repository..... ___	___
b. Number of post-dialysis 7.5 mL SST tubes (serum) sent to Repository..... ___	___
Plasma	
7.a. Number of pre-dialysis 8 mL PST tubes (plasma) sent to Repository .....___	___
b. Number of post-dialysis 8 mL PST tubes (plasma) sent to Repository .....___	___

8. Date shipped to Repository ..... (dd/mon/yyyy)__ __/__ __ __/__ __ __ __

9. a. Username of person completing this form.....__ __ __ __ __ __

Items 9 b, c, & d are required by NIDDK BioRepository at Fisher but will not be entered into the database.

b. Telephone number:.....__ __ __/__ __ __/__ __ __ __

c. E-mail address:_____

d. Name of FHN Clinical Center:.....

Items contained in the boxes are for individual center use only. They will not be entered into the database.

BioRepository notified via Email ____ Fax ____	Notified by:	Date of Notification:	Time:
Fed Ex Tracking #: _____		__ __ / __ __ __/ __ __ __ __ (dd/mon/yyyy)	__ __ : __ __ (24 hour clock)

Section B: To be completed by the NIDDK Bio Repository at Fisher

Completed by _____ Date of Receipt (dd/mon/yyyy) __ __/ __ __ __/ __ __ __ __

Do the PID's on this form correspond with the PID's on the vacutainer labels?.....Yes __ No __

Were any of the samples hemolyzed? (Notify DCC).....Yes ___ No ___

If not, describe the error as well as any other discrepancies and notify a supervisor_____

_____

_____

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network (FHN)
INTERNATIONAL BIOLOGICAL SPECIMEN REPOSITORY MAILING FORM - #256

NIDDK BioRepository Contact Information

Address: Fisher BioServices
Attn: Lab Manager
NIDDK Repository
20301 Century Blvd.
Building 6, Suite 400
Germantown, MD 20874

Email: Bio-NIDDKRepository@thermofisher.com

Phone: (240) 686-4703 (Heather Higgins)
Phone: (240) 686-4702 (Sandra Ke)
Fax: (301) 515-4049

You will need to complete one form F256 for each PID in the shipment. Ship samples to the address above in the mailer provided. See specific details in the FHN MOP Chapter 22, for detailed instructions for when to ship and how to complete the necessary documents for dry ice and international shipping. Notify the repository of shipments by e-mail* or by facsimile on the day the package is picked up by FedEx. Photocopy all forms and save copies for your files. Include all originals in the mailer. *Enter items 1 to 9a only into the FHN database.*

*On shipping day, send an email message to: *Bio-NIDDKRepository@thermofisher.com*. For the e-mail message, use the following template:
"Please be advised that biorepository samples for patient(s) xxxxxx-xx has/have been shipped by Fed-ex today, (dd/mmm/yy). Tracking number is xxxx-xxxx-xxxx. Please confirm with us upon receipt."

Section A. To be completed by Clinical Center

			-												

1a. Repository ID# | 1b. Participant ID # | 2. Alpha Code | 3a.Visit Type | 3b. Visit Number

4. Date specimen collected..... (dd/mon/yyyy)__ __/__ __ __/__ __ __ __

5. a. Time of pre-dialysis blood draw .....(24 hour clock)__ __: __ __

   b. Time of post-dialysis blood draw.....(24 hour clock)__ __: __ __

6. Serum Products Sent/Received:	Number Sent by FHN Site	Number Rec'd at at Fisher
Serum		
a. Number of 0.2 ml aliquots of pre-dialysis serum sent:.....	___ ___	___ ___
b. Number of other quantity ml aliquots of pre-dialysis serum sent:.....	___ ___	___ ___
c. Number of 0.2 ml aliquots of post-dialysis serum sent:	___ ___	___ ___
d. Number of other quantity of post-dialysis serum sent:.....	___ ___	___ ___

7. Plasma Products Sent/Received:	Number Sent by FHN Site	Number Rec'd at at Fisher
Plasma		
a. Number of .0.2 ml aliquots of pre-dialysis plasma sent:	___ ___	___ ___
b. Number of other quantity ml aliquots of pre-dialysis plasma sent:	___ ___	___ ___
c. Number of 0.2 ml aliquots of post-dialysis plasma sent:.....	___ ___	___ ___

Frequent Hemodialysis Network (FHN)
INTERNATIONAL BIOLOGICAL SPECIMEN REPOSITORY
MAILING FORM - #256

d. Number of other quantity ml aliquots of post-dialysis plasma sent:....._____ _____ _____ _____

8. Date shipped to Repository ..... (dd/mon/yyyy)__ __/__ __ __/__ __ __ __

9. a. Username of person completing this form.....__ __ __ __ __ __ __

Items 9 b, c, & d are required by NIDDK BioRepository at Fisher but will not be entered into the database.

b. Telephone number:.....__ __ __/__ __ __/__ __ __ __

c. E-mail address:_____

d. Name of FHN Clinical Center:_____

Items contained in the boxes are for individual center use only. They will not be entered into the database.

BioRepository notified via Email ____ Fax ____	Notified by:	Date of Notification:	Time: __ __ : __ __
Fed Ex Tracking #: _____		__ __ / __ __ __/ __ __ __ __ (dd/mon/yyyy)	(24 hour clock)

Section B: To be completed by the NIDDK BioRepository at Fisher

Completed by _____ Date of Receipt (dd/mon/yyyy) __ __/ __ __ __/ __ __ __ __

Do the PID's on this form correspond with the PID's on the cryovial labels?.....Yes ___ No ___

Were any of the samples hemolyzed? (Notify DCC).....Yes ___ No ___

If not, describe the error as well as any other discrepancies and notify a supervisor _____

_____

_____

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
CANADIAN REPOSITORY COLLECTION DATE – FORM #257

Instructions: For Canadian Center Use Only. Follow instructions in Chapter 22 of MOP for blood processing and freezing instructions. Complete and enter this Form 257 into database (Complete and enter Form 256 when shipping to the Repository).

1. Participant ID # | 2. Alpha Code | 3a. Visit Type | 3b. Visit #

4. Date blood collected for Repository (dd/mon/yyyy) ..... __ __/__ __ __/__ __ __ __

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

201. Username of person completing this form ..... __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
ACCESS USED FOR CHRONIC HEMODIALYSIS - FORM 271

Instructions:

Trial: This form is completed at baseline and whenever the patient's access currently being used for chronic hemodialysis changes.

Extended Follow-up Study: Complete this form at time of final Extended Follow-up Study visit to identify what access is currently being used (even if it is the same access used throughout the trial).

1. Participant ID # 2. Alpha Code

4. What is the access that the patient is currently using for chronic hemodialysis? ..... __
   1=AV fistula
   2=AV graft *(note: if any part of an access is a graft, then it is considered a graft)*
   3=Tunneled catheter
   4=Non-tunneled catheter *(note: use of non-tunneled catheter in baseline is an exclusion)*

5. Date access (identified in Q4) was placed? (dd/mon/yyyy). ..... __ __/__ __ __ /__ __ __ __
   (If this is the initial baseline access and placement date is unknown, use the date of the first known use)

For Grafts or Fistulas:

6. a. Position ..... __
   1=Forearm 3=Leg 8=Not applicable
   2=Upperarm 4=Chest (*be sure to complete Q7*)

   b. Side (1=Right, 2= Left, 8=Not applicable) ..... __

For Tunneled Catheters:

7. Location of tunneled catheter: ..... __

0=None	5=Right femoral	9=Right external jugular
1=Right internal jugular	6=Left femoral	
2=Left internal jugular	7=Left external jugular	
3=Right subclavian	8=Right translumbar inferior vena cava	
4=Left subclavian	(*if other codes are needed, email fhn-dcc*)	

8. Date that access first used for chronic HD therapy: (mon/yyyy) ..... __ __ __/__ __ __ __
   (If this access was in place before the patient was enrolled in baseline and the placement date is unknown, use the date of the first known use.)

9. Does this patient have a second, different type of access that has been placed but is not currently being used? ..... __
   0=No 2=Yes, a fistula
   1=Yes, a graft 3=Yes, a catheter

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

Frequent Hemodialysis Network
KINETIC MODELING FORM - FORM #273

Instructions: This form is to be completed by the study coordinator and the dialysis unit technician on the FHN Trial kinetic modeling day sessions that occur during baseline, and monthly during follow-up. Kinetic modeling should not be performed at sessions with isolated ultrafiltration. However, kinetic modeling should be performed at a session designated for collection of kinetic modeling irrespective of any interruption time. A Form 274 must be completed with each kinetic modeling session to document information from the dialysis run sheet during the week preceding the kinetic modeling session. In nocturnal protocol version 3.0, two kinetic modeling sessions must be completed during baseline.

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

Questions 5–16 refer to specific dialysis treatment at which kinetic modeling is performed.

5. a. Type of session.....__
   1=Routine KM (in window), 2=Make up for missed routine (in next window), 3=Repeat

   b. Where was the dialysis conducted? (1=In-center dialysis unit, 2=At home).....__

6. Dialysis membrane type (from code list at end of document) .....__ __ __ __

7. Reuse number (enter 0 if this is the first use of the dialyzer) .....__ __ __

Weight

8. a. Patient target weight (estimated dry weight) (kg).....__ __ __.__

   b. Pre-dialysis weight (kg) .....__ __ __.__

   c. Post-dialysis weight (kg).....__ __ __.__

Access

9. a. Current type of vascular access.....__
   1=AV graft – forearm
   2=AV graft - upper arm
   3=AV fistula – forearm
   4=AV fistula – upper arm
   5=Catheter
   6=Femoral
   7=Using 2 accesses

   b. Has there been a surgical or radiological intervention to improve access function or a change in the type of access since the previous kinetic modeling session? ……..__
   0=No (no access intervention or change)
   2=Yes to either of the two options below:
   a) a surgical or radiological access intervention
   b) an access failure (access removed or can no longer be used)

   [If the answer to Q9b is "2", please answer questions 9b1-9b2 below. Otherwise skip to Q9c if on Nocturnal Trial.]

   b1. Has there been a surgical or radiological intervention to improve access function since the previous kinetic modeling session? …….……..__
   0=No (no access intervention)
   1=Yes (complete F276 for each instance)

9. b2. Did the access fail (access removed or can no longer be used) since the previous kinetic modeling session? ……..……..……..__
0=No (no access failure)
1=Yes (complete F277 for each instance)

(Note: if a new access was placed since the last KM session, complete F278. And if a different access is being used for HD, be sure to complete F271.)

9. c. For Nocturnal Trial Only: Was a buttonhole access used? (0=No, 1=Yes) .....__

10. What kind of needle was used for this patient's hemodialysis?.....__
(1=Single-needle, 2=Double-needle, 8=NA, pt. is using catheter)

11. Prescribed treatment time (minutes) for this session:.....__ __ __

12. a. Start time of dialysis treatment (24-hour time):..... __ __ :__ __

b. End time of dialysis treatment (24-hour time):..... __ __ :__ __

Enter the start and end time to reflect actual dialysis (in which the blood pump is on), and do not count the time period with isolated ultrafiltration.

13. Was there a serious interruption during this session? (0=No, 1=Yes).....__
(Serious interruption defined as interruption of > 15 min for in-center treatments, and > 30 min for nocturnal dialysis)

14. Machine readout of actual dialysis treatment time (minutes) .....__ __ __

15. Average blood flow achieved during session (ml/min).....__ __ __
Provide average blood flow during session if provided by dialysis machine. Otherwise, provide blood flow 30 minutes after start of dialysis.

16. Recorded dialysate flow (ml/min) .....__ __ __ __

Complications:

17. Complications experienced in the current dialysis treatment - use the following codes:
0=No
1=Yes, but not requiring saline, lowering of UF rate, or reduced blood flow
2=Yes, requiring either saline, lowering of UF rate, or reduced blood flow (nocturnal: need to give back saline at the end of dialysis due to hypotension or symptoms)

a. Cramping?.....__

b. Nausea or vomiting? .....__

c. Chest pain?.....__

Blood Pressures:

18. a. Pre-dialysis blood pressure (mmHg) (systolic/diastolic)..... __ __ __ /__ __ __

b. Post-dialysis blood pressure (mmHg) (systolic/diastolic) ..... __ __ __ /__ __ __

Dialysate:

19. Based on the dialysis run sheet, indicate the concentrations of the following substances in the **dialysate**:

Separate items for initial and final sodium in the dialysate are provided in case these are modified during dialysis. If these concentrations are not modified, leave the final concentrations blank. Only single concentrations for magnesium, calcium, and bicarbonate are presumed. If one of these did happen to be modified during dialysis, please enter the initial concentration.

a. Initial Sodium (mEq/L) ..... __ __ __
or in SI units (mmol/L) ..... __ __ __ __

b. Final Sodium (mEq/L) ..... __ __ __ __
or in SI units (mmol/L) ..... __ __ __

c. Initial Potassium (mEq/L) ..... __ . __
or in SI units (mmol/L) ..... __ . __

d. Magnesium (mEq/L) ..... __ . __ __
or in SI units (mmol/L) ..... __ . __ __

e. Calcium (mEq/L) ..... __ . __
or in SI units (mmol/L) ..... __ . __ __

f. Bicarbonate (mEq/L) ..... __ __
or in SI units (mmol/L) ..... __ __

g. Nocturnal Trial Only: Phosphorus (mg/dL) ..... __ . __
or in SI units (mmol/L) ..... __ . __ __

Patient's Lab Measurements

20. a. Pre-dialysis BUN (mg/dL) *(put "0" in decimal field, if not available)* ..... __ __ __ . __
or in SI units (mmol/L) ..... __ __ __ __

b. Post-dialysis BUN (mg/dL) *(put "0" in decimal field, if not available)* ..... __ __ __ . __
or in SI units (mmol/L) ..... __ __ __ __

c. Pre-dialysis serum creatinine (mg/dL) ..... __ __ . __
or in SI units (μmol/L) ..... __ __ __ __

d. Post-dialysis serum creatinine (mg/dL) ..... __ __ . __
or in SI units (μmol/L) ..... __ __ __ __

e. Pre-dialysis serum phosphate (mg/dL) ..... __ __ __ . __
or in SI units (mmol/L) ..... __ . __ __

Patient's Lab Measurements continued:

f. Post-dialysis serum phosphate (mg/dL)..... __ __ __ . __

or in SI units (mmol/L) ..... __ . __ __

Note: The date pre-samples are drawn is the date of the kinetic modeling session (see Q4). Enter the date the post-samples are drawn below in Q20h.

h. Date post-dialysis samples drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

21. a. Monthly serum albumin (g/dL).....__ __.__

or in SI units (g/L) ..... __ __ __ __

b. Date monthly serum albumin drawn (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

Nocturnal Trial Only:

The study coordinator should obtain the response to this question from the patient as close as possible to the day of this kinetic modeling session. (It is recommended that patients be asked to write this down on a log sheet.)

Patient response to the question "When you drew your blood just before this kinetic modeling session, what was the date and time of your last medium or large meal?"

22. a. Date when closest medium/large meal eaten (not including snacks) **just <u>before</u>** this dialysis session (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

b. Time of day when meal eaten (use 24-hour clock):..... __ __ :__ __

c. Did patient eat a medium/large meal **<u>during</u>** this dialysis session? (0=No, 1=Yes) .....__

Note: If you or the patient is not sure whether food eaten was a meal or a snack or whether the meal was small, medium, or large, ask your center's Principal Investigator to decide.

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

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

For Center Use Only:

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

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

****

Use the four-digit codes numbers on the following pages to answer Question #6. The list is in order by dialyzer membrane name, then model.

CODE	BRAND	MODEL
1001	Allmed	Opal 110 S
1002	Allmed	Opal 130 S
1003	Allmed	Opal 160 S
1004	Allmed	Opal 180 S
1005	Allmed	Opal 200 S
1006	Allmed	Opal 220 S
1007	Allmed	Quartz 100 S
1008	Allmed	Quartz 130 S
1009	Allmed	Quartz 160 S
1010	Allmed	Quartz 180 S
1011	Allmed	Ruby 130 S
1012	Allmed	Ruby 160 S
1013	Allmed	Ruby 180 S
1014	Allmed	Topaz 100 S
1015	Allmed	Topaz 130 S
1016	Allmed	Topaz 160 S
1017	Allmed	Topaz 180 S
1101	Asahi	AM 500H SD
1102	Asahi	AM 50H SD
1103	Asahi	AM 650H SD
1104	Asahi	AM 65H SD
1105	Asahi	AM 750U SD
1106	Asahi	AM 75U SD
1107	Asahi	AM BIO 100
1108	Asahi	AM BIO 1000
1109	Asahi	AM BIO 1000 WET
1110	Asahi	AM BIO 50
1111	Asahi	AM BIO 500 WET
1112	Asahi	AM BIO 65
1113	Asahi	AM BIO 650
1114	Asahi	AM BIO 650 WET
1115	Asahi	AM BIO 75
1116	Asahi	AM BIO 750
1117	Asahi	AM BIO 750 WET
1118	Asahi	AM BIO HX 1000
1119	Asahi	AM BIO HX 650
1120	Asahi	AM BIO HX 750
1121	Asahi	AM BIO UP 650
1122	Asahi	AM BIO UP 750
1123	Asahi	AM SD 1000 U
1124	Asahi	AM SD 300
1125	Asahi	AM SD 400 M
1126	Asahi	AM SD 400 U
1127	Asahi	AM SD 500 H
1128	Asahi	AM SD 500 M
1129	Asahi	AM SD 500 U
1130	Asahi	AM SD 650 H
1131	Asahi	AM SD 650 U
1132	Asahi	AM SD 750 U
1133	Asahi	AM UP 75 WET
1134	Asahi	AMR 50U
1135	Asahi	AMR 65U

CODE	BRAND	MODEL
1136	Asahi	AMR 75U
1137	Asahi	AMR 90U
1138	Asahi	APS 1050
1139	Asahi	APS 1050 MD
1140	Asahi	APS 1050S
1141	Asahi	APS 13 U
1142	Asahi	APS 15 U
1143	Asahi	APS 18 U
1144	Asahi	APS 21 U
1145	Asahi	APS 550
1146	Asahi	APS 550S
1147	Asahi	APS 650
1148	Asahi	APS 650 MD
1149	Asahi	APS 650S
1150	Asahi	APS 900
1151	Asahi	APS 900 MD
1152	Asahi	APS 900S
1153	Asahi	PAN 03
1154	Asahi	PAN 06
1155	Asahi	PAN 10
1156	Asahi	PAN 1000 SF
1157	Asahi	PAN 110 DX
1158	Asahi	PAN 65 DX
1159	Asahi	PAN 650 SF
1160	Asahi	PAN 85 DX
1161	Asahi	PAN 900 SF
1162	Asahi	PAN HFD 30
1163	Asahi	REXEED-25
1164	Asahi	REXEED-18R
1201	B. Braun Medtech	Diacap CE 1100
1202	B. Braun Medtech	Diacap CE 1400
1203	B. Braun Medtech	Diacap CE 1600
1204	B. Braun Medtech	Diacap CE 2000
1205	B. Braun Medtech	Diacap HE 1200
1206	B. Braun Medtech	Diacap HE 1200 G
1207	B. Braun Medtech	Diacap HE 1400
1208	B. Braun Medtech	Diacap HE 1400 G
1209	B. Braun Medtech	Diacap HE 1700
1210	B. Braun Medtech	Diacap HE 1700 G
1211	B. Braun Medtech	Diacap HI PS 10
1212	B. Braun Medtech	Diacap HI PS 12
1213	B. Braun Medtech	Diacap HI PS 15
1214	B. Braun Medtech	Diacap HI PS 18
1215	B. Braun Medtech	Diacap HI PS 20
1216	B. Braun Medtech	Diacap HI PS 8
1217	B. Braun Medtech	Diacap LO PS 10
1218	B. Braun Medtech	Diacap LO PS 12
1219	B. Braun Medtech	Diacap LO PS 15
1220	B. Braun Medtech	Diacap LO PS 18
1221	B. Braun Medtech	Diacap LO PS 20
1222	B. Braun Medtech	Diacap SMC 1.0
1223	B. Braun Medtech	Diacap SMC 1.0 SD
1224	B. Braun Medtech	Diacap SMC 1.2
1225	B. Braun Medtech	Diacap SMC 1.2 SD

CODE	BRAND	MODEL
1226	B. Braun Medtech	Diacap SMC 1.5
1227	B. Braun Medtech	Diacap SMC 1.5 SD
1228	B. Braun Medtech	Diacap SMC 1.8
1229	B. Braun Medtech	Diacap SMC 1.8 SD
1301	Baxter	CA 110 G
1302	Baxter	CA 130 G
1303	Baxter	CA 150 G
1304	Baxter	CA 170 G
1305	Baxter	CA 210 G
1306	Baxter	CA 50 G
1307	Baxter	CA 70 G
1308	Baxter	CA 90 G
1309	Baxter	CA-HP 110
1310	Baxter	CA-HP 130
1311	Baxter	CA-HP 150
1312	Baxter	CA-HP 170
1313	Baxter	CA-HP 210
1314	Baxter	CA-HP 90
1315	Baxter	CT 110 G
1316	Baxter	CT 150 G
1317	Baxter	CT 190 G
1318	Baxter	CT 90 G
1319	Baxter	Dicea 110 G
1320	Baxter	Dicea 130 G
1321	Baxter	Dicea 150 G
1322	Baxter	Dicea 170 G
1323	Baxter	Dicea 210 G
1324	Baxter	Dicea 90 G
1325	Baxter	Exeltra 150
1326	Baxter	Exeltra 170
1327	Baxter	Exeltra 190
1328	Baxter	Exeltra Plus 210
1329	Baxter	PSN 120
1330	Baxter	PSN 140
1331	Baxter	PSN 150
1332	Baxter	PSN 170
1333	Baxter	PSN 210
1334	Baxter	Syntra 120
1335	Baxter	Syntra 160
1336	Baxter	Tricea 110 G
1337	Baxter	Tricea 130 G
1338	Baxter	Tricea 150 G
1339	Baxter	Tricea 170 G
1340	Baxter	Tricea 190 G
1341	Baxter	Tricea 210 G
1342	Baxter	Xenium 170
1401	Bellco	BLS 512 G
1402	Bellco	BLS 512 SD
1403	Bellco	BLS 514 G
1404	Bellco	BLS 514 SD
1405	Bellco	BLS 517 G

CODE	BRAND	MODEL
1406	Bellco	BLS 517 SD
1407	Bellco	BLS 714 G
1408	Bellco	BLS 714 SD
1409	Bellco	BLS 716 G
1410	Bellco	BLS 716 SD
1411	Bellco	BLS 719 G
1412	Bellco	BLS 719 SD
1413	Bellco	BLS 803
1414	Bellco	BLS 805
1415	Bellco	BLS 807
1416	Bellco	BLS 809
1417	Bellco	BLS 812 G
1418	Bellco	BLS 812 SD
1419	Bellco	BLS 814 G
1420	Bellco	BLS 814 SD
1421	Bellco	BLS 816 G
1422	Bellco	BLS 816 SD
1423	Bellco	BLS 819 G
1424	Bellco	BLS 819 SD
1425	Bellco	NC 1285
1426	Bellco	NC 1285 G
1427	Bellco	NC 1285 SD
1428	Bellco	NC 1485
1429	Bellco	NC 1485 G
1430	Bellco	NC 1485 SD
1431	Bellco	NC 1785
1432	Bellco	NC 1785 G
1433	Bellco	NC 1785 SD
1434	Bellco	NC 2085
1435	Bellco	NC 2085 G
1436	Bellco	NC 2085 SD
1437	Bellco	NC 2285 G
1438	Bellco	NT 1175
1439	Bellco	NT 1208 H
1440	Bellco	NT 1208 HG
1441	Bellco	NT 1208 SD
1442	Bellco	NT 1265 H
1443	Bellco	NT 1265 HG
1444	Bellco	NT 1375
1445	Bellco	NT 1408 H
1446	Bellco	NT 1408 HG
1447	Bellco	NT 1408 SD
1448	Bellco	NT 1665 H
1449	Bellco	NT 1665 HG
1450	Bellco	NT 1675
1451	Bellco	NT 1808 H
1452	Bellco	NT 1808 HG
1453	Bellco	NT 1808 SD
1454	Bellco	NT 1975
1455	Bellco	SG 30 Plus
1456	Bellco	SG 40 Plus
1457	Bellco	SG 8 Plus

CODE	BRAND	MODEL
1501	Even	EBM 100
1502	Even	EBM 120

1503	Even	EBM 140
1504	Even	EBM 160
1505	Even	EBM 180
1506	Even	EBM 200
1507	Even	EC 100
1508	Even	EC 120
1509	Even	EC 140
1510	Even	EC 160
1511	Even	EC 190
1512	Even	EC 210
1513	Even	EC 260
1514	Even	EH 100
1515	Even	EH 120
1516	Even	EH 140
1517	Even	EH 160
1518	Even	EH 190
1519	Even	EH 210
1520	Even	EH 260
1601	Fidia	Diadema 110 HF
1602	Fidia	Diadema 110 LF
1603	Fidia	Diadema 110 MF
1604	Fidia	Diadema 130 HF
1605	Fidia	Diadema 130 LF
1606	Fidia	Diadema 130 MF
1607	Fidia	Diadema 150 HF
1608	Fidia	Diadema 150 LF
1609	Fidia	Diadema 150 MF
1610	Fidia	Diadema 170 HF
1611	Fidia	Diadema 170 LF
1612	Fidia	Diadema 170 MF
1613	Fidia	Diadema 190 HF
1614	Fidia	Diadema 190 LF
1615	Fidia	Diadema 190 MF
1616	Fidia	Diadema 210 HF
1617	Fidia	Diadema 210 LF
1618	Fidia	Diadema 210 MF
1619	Fidia	Even 110 H
1620	Fidia	Even 130 H
1621	Fidia	Even 150 H
1622	Fidia	Even 180 H
1623	Fidia	Even 200 H
1624	Fidia	Syntex 110 S
1625	Fidia	Syntex 130 S
1626	Fidia	Syntex 150 S
1627	Fidia	Syntex 170 S
1628	Fidia	Syntex 190 S
1629	Fidia	Syntex 210 S

CODE	BRAND	MODEL
1701	Fresenius	E 1
1702	Fresenius	E 1 S
1703	Fresenius	E 2
1704	Fresenius	E 2 DS
1705	Fresenius	E 2 S
1706	Fresenius	E 3
1707	Fresenius	E 3 DS
1708	Fresenius	E 3 S
1709	Fresenius	E 4
1710	Fresenius	E 4 DS
1711	Fresenius	E 4 S
1712	Fresenius	F 10 HPS
1713	Fresenius	F 3
1714	Fresenius	F 4
1715	Fresenius	F 4 HPS
1716	Fresenius	F 40
1717	Fresenius	F 40 S
1718	Fresenius	F 5
1719	Fresenius	F 5 HPS
1720	Fresenius	F 50
1721	Fresenius	F 50 S
1722	Fresenius	F 6
1723	Fresenius	F 6 HPS
1724	Fresenius	F 60
1725	Fresenius	F 60 Light
1726	Fresenius	F 60 S
1727	Fresenius	F 7
1728	Fresenius	F 7 HPS
1729	Fresenius	F 70 S
1730	Fresenius	F 8
1731	Fresenius	F 8 HPS
1732	Fresenius	FX 10
1733	Fresenius	FX 100
1734	Fresenius	FX 40
1735	Fresenius	FX 50
1736	Fresenius	FX 60
1737	Fresenius	FX 60 M
1738	Fresenius	FX 8
1739	Fresenius	FX 80
1740	Fresenius	FX 80 M
1741	Fresenius	HDF 100 S
1742	Fresenius	HF 60 LS
1743	Fresenius	HF 80
1744	Fresenius	HF 80 LS
1745	Fresenius	HF 80 Light
1746	Fresenius	HF 80 S
1747	Fresenius	Hemaflo 1.0
1748	Fresenius	Hemaflo 1.3
1749	Fresenius	Hemaflo 1.8
1750	Fresenius	Optiflux F 160 NR
1751	Fresenius	Optiflux F 180 A
1752	Fresenius	Optiflux F 180 NR
1753	Fresenius	Optiflux F 200 A
1754	Fresenius	Optiflux F 200 NR

CODE	BRAND	MODEL
1755	Fresenius	Primaflo 1.0 E
1756	Fresenius	Primaflo 1.3 E
1757	Fresenius	Primaflo 1.8 E
1758	Fresenius	HF 80 A
1759	Fresenius	Optiflux 180 B
1760	Fresenius	Optiflux 200 B
1801	Gambro	100 HG
1802	Gambro	Alwall GFE 09
1803	Gambro	Alwall GFE 11
1804	Gambro	Alwall GFE 12
1805	Gambro	Alwall GFE 15
1806	Gambro	Alwall GFE 18
1807	Gambro	Alwall GFS 12
1808	Gambro	Alwall GFS 16
1809	Gambro	Alwall GFS Plus 11
1810	Gambro	Alwall GFS Plus 12
1811	Gambro	Alwall GFS Plus 16
1812	Gambro	Alwall GFS Plus 20
1813	Gambro	Aria 550 *
1814	Gambro	Aria 700 *
1815	Gambro	Lundia Alpha 400 *
1816	Gambro	Lundia Alpha 500 *
1817	Gambro	Lundia Alpha 600 *
1818	Gambro	Lundia Alpha 700 *
1819	Gambro	Lundia Pro 100
1820	Gambro	Lundia Pro 200
1821	Gambro	Lundia Pro 500
1822	Gambro	Lundia Pro 500 G
1823	Gambro	Lundia Pro 600
1824	Gambro	Lundia Pro 600 G
1825	Gambro	Lundia Pro 800
1826	Gambro	Lundia Pro 800 G
1827	Gambro	Polyflux 10 L
1828	Gambro	Polyflux 11
1829	Gambro	Polyflux 11 S
1830	Gambro	Polyflux 14
1831	Gambro	Polyflux 14 L
1832	Gambro	Polyflux 14 S
1833	Gambro	Polyflux 140H
1834	Gambro	Polyflux 17
1835	Gambro	Polyflux 17 L
1836	Gambro	Polyflux 17 S
1837	Gambro	Polyflux 170 H
1838	Gambro	Polyflux 21
1839	Gambro	Polyflux 21 L
1840	Gambro	Polyflux 21 S
1841	Gambro	Polyflux 210 H
1842	Gambro	Polyflux 24 S
1843	Gambro	Polyflux 6 L
1844	Gambro	Polyflux 6 S
1845	Gambro	Polyflux 6B
1846	Gambro	Polyflux 8 L

CODE	BRAND	MODEL
1847	Gambro	Polyflux 8B
1848	Gambro	Polyflux 24 R
1849	Gambro	Polyflux 21 R
1850	Gambro	Polyflux 17 R
1851	Gambro	Revaclear
1852	Gambro	Revaclear-Max
1901	Gross-O-Pharm	Future 1.0
1902	Gross-O-Pharm	Future 1.2
1903	Gross-O-Pharm	Future 1.4
1904	Gross-O-Pharm	Future 1.6
1905	Gross-O-Pharm	Present 1.0
1906	Gross-O-Pharm	Present 1.2
1907	Gross-O-Pharm	Present 1.4
1908	Gross-O-Pharm	Present 1.6
1909	Gross-O-Pharm	Synergie 0.61
1910	Gross-O-Pharm	Synergie 0.9
1911	Gross-O-Pharm	Synergie 1.21
1912	Gross-O-Pharm	Synergie 1.5
2001	Haidylena	HL 100
2002	Haidylena	HL 100 B
2003	Haidylena	HL 100 H
2004	Haidylena	HL 110
2005	Haidylena	HL 110 H
2006	Haidylena	HL 120
2007	Haidylena	HL 120 H
2008	Haidylena	HL 130
2009	Haidylena	HL 130 B
2010	Haidylena	HL 130 H
2011	Haidylena	HL 130 HS
2012	Haidylena	HL 130 S
2013	Haidylena	HL 140 H
2014	Haidylena	HL 160
2015	Haidylena	HL 160 B
2016	Haidylena	HL 160 H
2017	Haidylena	HL 180 H
2018	Haidylena	HL 200 H
2019	Haidylena	HL 220 H
2020	Haidylena	HL 90
2021	Haidylena	HP 100
2022	Haidylena	HP 100 S
2023	Haidylena	HP 120
2024	Haidylena	HP 120 S
2025	Haidylena	HP 130
2026	Haidylena	HP 130 S
2027	Haidylena	HP 160
2028	Haidylena	HP 160 S
2029	Haidylena	HP 180
2030	Haidylena	HP 180 S
2031	Haidylena	HP 200
2032	Haidylena	HP 200 S
2033	Haidylena	HPH 130S
2034	Haidylena	HPH 160S
2035	Haidylena	HPH 180H

CODE	BRAND	MODEL
2036	Haidylena	HPH 180S
2037	Haidylena	HPM 100S
2038	Haidylena	HPM 130S
2039	Haidylena	HPM 160S

2040	Haidylena	HPM 180S
2101	Helbio	Ac 10
2102	Helbio	Ac 13
2103	Helbio	Ac 15
2104	Helbio	Ac 18
2105	Helbio	Ac 22
2106	Helbio	Bio 100
2107	Helbio	Bio 1000
2108	Helbio	Bio 120
2109	Helbio	Bio 1200
2110	Helbio	Bio 140
2111	Helbio	Bio 1400
2112	Helbio	Bio 160
2113	Helbio	Bio 1600
2114	Helbio	Bio 180
2115	Helbio	Bio 1800
2116	Helbio	Bio 200
2117	Helbio	Bio 2000
2118	Helbio	Dia 10
2119	Helbio	Dia 100
2120	Helbio	Dia 13
2121	Helbio	Dia 130
2122	Helbio	Dia 15
2123	Helbio	Dia 150
2124	Helbio	Dia 18
2125	Helbio	Dia 180
2126	Helbio	Dia 22
2127	Helbio	Dia 220
2128	Helbio	SYN+100
2129	Helbio	SYN+120
2130	Helbio	SYN+140
2131	Helbio	SYN+160
2132	Helbio	SYN+180
2133	Helbio	SYN+200
2134	Helbio	Tria 130
2135	Helbio	Tria 1300
2136	Helbio	Tria 150
2137	Helbio	Tria 1500
2138	Helbio	Tria 180
2139	Helbio	Tria 1800
2140	Helbio	Tria 210
2141	Helbio	Tria 2100
2201	Hemofarm	E 2
2202	Hemofarm	E 2 H
2203	Hemofarm	E 3
2204	Hemofarm	E 3 H
CODE	BRAND	MODEL
2205	Hemofarm	E 4
2206	Hemofarm	E 4 H
2207	Hemofarm	F 4
2208	Hemofarm	F 4 HPS
2209	Hemofarm	F 40
2210	Hemofarm	F 40 S
2211	Hemofarm	F 5
2212	Hemofarm	F 5 HPS
2213	Hemofarm	F 50
2214	Hemofarm	F 50 S
2215	Hemofarm	F 6
2216	Hemofarm	F 6 HPS
2217	Hemofarm	F 60
2218	Hemofarm	F 60 S
2301	Hospal	Crystal 2800 ST *
2302	Hospal	Crystal 3400 ST *
2303	Hospal	Crystal 4000 ST *
2304	Hospal	Diacepal DA 12
2305	Hospal	Diacepal DA 14
2306	Hospal	Diacepal DA 16
2307	Hospal	Diacepal DA 20
2308	Hospal	Disscap 120 SE
2309	Hospal	Disscap 150 SE
2310	Hospal	Disscap 180 SE
2311	Hospal	Disscap 2100 SE
2312	Hospal	Filtral 10
2313	Hospal	Filtral 12
2314	Hospal	Filtral 16
2315	Hospal	Filtral 20
2316	Hospal	Filtral 6
2317	Hospal	H 1
2318	Hospal	H 4
2319	Hospal	H 6
2320	Hospal	H 9
2321	Hospal	HG 100
2322	Hospal	HG 400
2323	Hospal	HG 500
2324	Hospal	HG 600
2325	Hospal	HG 700
2326	Hospal	M 4
2327	Hospal	M 6
2328	Hospal	M 9
2329	Hospal	Nephral ST 200
2330	Hospal	Nephral ST 300
2331	Hospal	Nephral ST 400
2332	Hospal	Nephral ST 500
2401	Idemsa	100
2403	Idemsa	100 MHP
2404	Idemsa	1000
2405	Idemsa	1000 HF
CODE	BRAND	MODEL
2406	Idemsa	12
2408	Idemsa	12 H
2410	Idemsa	120
2412	Idemsa	120 MHP
2413	Idemsa	1200
2414	Idemsa	1200 HF
2415	Idemsa	140
2417	Idemsa	140 MHP
2418	Idemsa	1400
2419	Idemsa	1400 HF
2420	Idemsa	15
2422	Idemsa	15 H
2424	Idemsa	160
2426	Idemsa	160 MHP
2427	Idemsa	1600
2428	Idemsa	1600 HF
2429	Idemsa	180
2431	Idemsa	180 MHP
2432	Idemsa	1800
2433	Idemsa	1800 HF
2434	Idemsa	20
2436	Idemsa	20 H
2438	Idemsa	200
2440	Idemsa	200 MHP
2441	Idemsa	2000
2442	Idemsa	2000 HF
2443	Idemsa	23
2445	Idemsa	23 H
2447	Idemsa	25
2449	Idemsa	25 H
2451	Idemsa	28
2453	Idemsa	28 H
2455	Idemsa	30
2457	Idemsa	30 H
2459	Idemsa	32
2461	Idemsa	32 H
2463	Idemsa	34
2465	Idemsa	34 H
2467	Idemsa	36
2469	Idemsa	36 H
2471	Idemsa	H 1100
2473	Idemsa	H 1300
2475	Idemsa	H 1500
2477	Idemsa	H 1800
2479	Idemsa	H 2000
2481	Idemsa	H 900
2483	Idemsa	LP 100
2484	Idemsa	LP 120
2485	Idemsa	LP 140
2486	Idemsa	LP 160
2487	Idemsa	LP 180
2488	Idemsa	LP 200
2489	Idemsa	P 100
2490	Idemsa	P 120
CODE	BRAND	MODEL
2491	Idemsa	P 140
2492	Idemsa	P 160
2493	Idemsa	P 180
2494	Idemsa	P 200
2501	JMS	BF 110
2502	JMS	BF 130
2503	JMS	BF 150
2504	JMS	BF 170
2505	JMS	JC 1080
2506	JMS	JC 1280
2507	JMS	JC 1480
2508	JMS	JC 1680
2509	JMS	JH 1080
2510	JMS	JH 1280
2511	JMS	JH 1480
2512	JMS	JH 1680
2513	JMS	SM 110
2514	JMS	SM 130
2515	JMS	SM 150
2516	JMS	SM 170
2601	Kawasumi	Diapes R 12
2602	Kawasumi	Diapes R 15
2603	Kawasumi	Diapes R 18
2604	Kawasumi	MA 08 H
2605	Kawasumi	MA 08 U
2606	Kawasumi	MA 10 H
2607	Kawasumi	MA 10 U
2608	Kawasumi	MA 12 H
2609	Kawasumi	MA 12 U
2610	Kawasumi	MA 15 H
2611	Kawasumi	MA 15 U
2612	Kawasumi	MA 18 H
2613	Kawasumi	MA 18 U
2614	Kawasumi	ME 08 H
2615	Kawasumi	ME 08 U
2616	Kawasumi	ME 10 H
2617	Kawasumi	ME 10 U
2618	Kawasumi	ME 12 H
2619	Kawasumi	ME 12 U
2620	Kawasumi	ME 15 H
2621	Kawasumi	ME 15 U
2622	Kawasumi	ME 18 H
2623	Kawasumi	ME 18 U
2624	Kawasumi	RA 08 H
2625	Kawasumi	RA 08 M
2626	Kawasumi	RA 08 U
2627	Kawasumi	RA 1.0 SH
2628	Kawasumi	RA 1.25 SH
2629	Kawasumi	RA 1.55 SH
2630	Kawasumi	RA 10 H
CODE	BRAND	MODEL
2631	Kawasumi	RA 10 M
2632	Kawasumi	RA 10 U
2633	Kawasumi	RA 12 H
2634	Kawasumi	RA 12 M
2635	Kawasumi	RA 12 U
2636	Kawasumi	RA 15 H
2637	Kawasumi	RA 15 M
2638	Kawasumi	RA 15 U
2639	Kawasumi	RA 18 H
2640	Kawasumi	RA 18 M

2641	Kawasumi	RA 18 U
2642	Kawasumi	RE 08 H
2643	Kawasumi	RE 08 M
2644	Kawasumi	RE 08 U
2645	Kawasumi	RE 10 H
2646	Kawasumi	RE 10 M
2647	Kawasumi	RE 10 U
2648	Kawasumi	RE 12 H
2649	Kawasumi	RE 12 M
2650	Kawasumi	RE 12 U
2651	Kawasumi	RE 15 H
2652	Kawasumi	RE 15 M
2653	Kawasumi	RE 15 U
2654	Kawasumi	RE 18 H
2655	Kawasumi	RE 18 M
2656	Kawasumi	RE 18 U
2657	Kawasumi	SMC A 10
2658	Kawasumi	SMC A 13
2659	Kawasumi	SMC A 16
2660	Kawasumi	SMC A 19
2661	Kawasumi	SMC R 10
2662	Kawasumi	SMC R 13
2663	Kawasumi	SMC R 16
2664	Kawasumi	SPAN 1.0
2665	Kawasumi	SPAN 1.3
2666	Kawasumi	SPAN 1.6
2667	Kawasumi	SPAN E 20
2701	Kimal	KF 1000
2702	Kimal	KF 1200
2703	Kimal	KF 1400
2704	Kimal	KF 1600
2705	Kimal	KF 1800
2706	Kimal	KF 2000
2801	Kuraray	KF 201 0.8
2802	Kuraray	KF 201 0.8 C
2803	Kuraray	KF 201 1.0 C
2804	Kuraray	KF 201 1.0 D
2805	Kuraray	KF 201 1.3 C
2806	Kuraray	KF 201 1.3 D
2807	Kuraray	KF 201 1.6 C

CODE	BRAND	MODEL
2808	Kuraray	KF 201 1.6 D
2809	Kuraray	KF 201 1.8 C
2810	Kuraray	KF 201 10 CH
2811	Kuraray	KF 201 13 CH
2812	Kuraray	KF 201 CH 1.6
2813	Kuraray	KF 201 N 0.7
2814	Kuraray	KF 201 N 1.0
2815	Kuraray	KF 201 N 1.3
2816	Kuraray	KF 201 N 1.6
2817	Kuraray	kf 201 1.0 m
2818	Kuraray	kf 201 1.3 m
2819	Kuraray	kf 201 1.6 m
2820	Kuraray	kf 201 1.8 m
2901	Meditech	BioF 10
2903	Meditech	BioF 12
2905	Meditech	BioF 15
2907	Meditech	MF 4
2908	Meditech	MF 40
2909	Meditech	MF 6
2910	Meditech	MF 60
2911	Meditech	MO 08 EO
2912	Meditech	MO 08 R
2913	Meditech	MO 10 EO
2914	Meditech	MO 10 R
2915	Meditech	MO 12 EO
2916	Meditech	MO 12 R
2917	Meditech	MO 15
2919	Meditech	MO 16 EO
2920	Meditech	MO 16 R
2921	Meditech	MO 18 EO
2922	Meditech	MO 18 R
2923	Meditech	MO 20 EO
2924	Meditech	MO 20 R
2925	Meditech	NP 08
2927	Meditech	NP 10
2929	Meditech	NP 12
2931	Meditech	NP 15
2933	Meditech	NP 18
3001	Minntech	Primus 1350
3002	Minntech	Primus 2000
3101	Nephro System	HFP 10
3102	Nephro System	HFP 14
3103	Nephro System	HFP 20
3104	Nephro System	MO 08 A
3105	Nephro System	MO 08 E
3106	Nephro System	MO 08 U
3107	Nephro System	MO 08 UA
3108	Nephro System	MO 10 A

CODE	BRAND	MODEL
3109	Nephro System	MO 10 E
3110	Nephro System	MO 10 U
3111	Nephro System	MO 10 UA
3112	Nephro System	MO 12 A
3113	Nephro System	MO 12 E
3114	Nephro System	MO 12 U
3115	Nephro System	MO 12 UA
3116	Nephro System	MO 15 A
3117	Nephro System	MO 15 E
3118	Nephro System	MO 15 U
3119	Nephro System	MO 15 UA
3120	Nephro System	MO 18 A
3121	Nephro System	MO 18 E
3122	Nephro System	MO 18 U
3123	Nephro System	MO 18 UA
3124	Nephro System	NP 08 A
3125	Nephro System	NP 08 E
3126	Nephro System	NP 08 U
3127	Nephro System	NP 08 UA
3128	Nephro System	NP 10 A
3129	Nephro System	NP 10 E
3130	Nephro System	NP 10 U
3131	Nephro System	NP 10 UA
3132	Nephro System	NP 12 A
3133	Nephro System	NP 12 E
3134	Nephro System	NP 12 U
3135	Nephro System	NP 12 UA
3136	Nephro System	NP 15 A
3137	Nephro System	NP 15 E
3138	Nephro System	NP 15 U
3139	Nephro System	NP 15 UA
3140	Nephro System	NP 18 A
3141	Nephro System	NP 18 E
3142	Nephro System	NP 18 U
3143	Nephro System	NP 18 UA
3201	Nikkiso	ALF 100
3202	Nikkiso	ALF 120
3203	Nikkiso	ALF 120 A
3204	Nikkiso	ALF 160
3205	Nikkiso	ALF 160 A
3206	Nikkiso	ALF 180
3207	Nikkiso	ALF 180 A
3208	Nikkiso	ALF 80
3209	Nikkiso	ALH-08 GW
3210	Nikkiso	ALH-10 GW
3211	Nikkiso	ALH-12 GW
3212	Nikkiso	ALH-16 GW
3213	Nikkiso	BLF-08 GW
3214	Nikkiso	BLF-10 GW
3215	Nikkiso	BLF-12 GW
3216	Nikkiso	BLF-16 AW
3217	Nikkiso	BLF-16 GW

CODE	BRAND	MODEL
3218	Nikkiso	BLF-18 GW
3219	Nikkiso	BLH 16 AW
3220	Nikkiso	BLH-08 GW
3221	Nikkiso	BLH-10 GW
3222	Nikkiso	BLH-12 GW
3223	Nikkiso	BLH-16 GW
3224	Nikkiso	FLX 10 GWS
3225	Nikkiso	FLX 12 GWS
3226	Nikkiso	FLX 15 GWS
3227	Nikkiso	FLX 18 GWS
3228	Nikkiso	FLX 21 GWS
3229	Nikkiso	FLX 8 GWS
3230	Nikkiso	FLY 10 GWS
3231	Nikkiso	FLY 12 GWS
3232	Nikkiso	FLY 15 GWS
3233	Nikkiso	FLY 18 GWS
3234	Nikkiso	FLY 21 GWS
3301	Nipro	FB 110 A
3302	Nipro	FB 110 H
3303	Nipro	FB 110 T
3304	Nipro	FB 110 U
3305	Nipro	FB 110 UH
3306	Nipro	FB 130 A
3307	Nipro	FB 130 H
3308	Nipro	FB 130 T
3309	Nipro	FB 130 U
3310	Nipro	FB 130 UH
3311	Nipro	FB 150 A
3312	Nipro	FB 150 H
3313	Nipro	FB 150 T
3314	Nipro	FB 150 U
3315	Nipro	FB 150 UH
3316	Nipro	FB 170 A
3317	Nipro	FB 170 H
3318	Nipro	FB 170 T
3319	Nipro	FB 170 U
3320	Nipro	FB 170 UH
3321	Nipro	FB 190 A
3322	Nipro	FB 190 H
3323	Nipro	FB 190 T
3324	Nipro	FB 190 U
3325	Nipro	FB 190 UH
3326	Nipro	FB 210 A
3327	Nipro	FB 210 H
3328	Nipro	FB 210 T
3329	Nipro	FB 210 U
3330	Nipro	FB 210 UH
3331	Nipro	FB 50 A
3332	Nipro	FB 50 H
3333	Nipro	FB 50 T
3334	Nipro	FB 50 U
3336	Nipro	FB 70 A

CODE	BRAND	MODEL
3337	Nipro	FB 70 H
3338	Nipro	FB 70 T
3339	Nipro	FB 70 U
3340	Nipro	FB 70 UH
3341	Nipro	FB 90 A
3342	Nipro	FB 90 H
3343	Nipro	FB 90 T
3344	Nipro	FB 90 U
3345	Nipro	FB 90 UH
3346	Nipro	Sureflux 110 E
3347	Nipro	Sureflux 110 FH
3348	Nipro	Sureflux 110 G
3349	Nipro	Sureflux 110 L
3350	Nipro	Sureflux 130 E
3351	Nipro	Sureflux 130 G

3352	Nipro	Sureflux 130 L
3353	Nipro	Sureflux 150 E
3354	Nipro	Sureflux 150 FH
3355	Nipro	Sureflux 150 G
3356	Nipro	Sureflux 150 L
3357	Nipro	Sureflux 170 E
3358	Nipro	Sureflux 170 G
3359	Nipro	Sureflux 170 L
3360	Nipro	Sureflux 190 E
3361	Nipro	Sureflux 190 FH
3362	Nipro	Sureflux 190 G
3363	Nipro	Sureflux 190 L
3364	Nipro	Sureflux 210 E
3365	Nipro	Sureflux 210 FH
3366	Nipro	Sureflux 210 G
3367	Nipro	Sureflux 210 L
3368	Nipro	Sureflux 30 L
3369	Nipro	Sureflux 50 E
3370	Nipro	Sureflux 50 G
3371	Nipro	Sureflux 50 L
3372	Nipro	Sureflux 70 E
3373	Nipro	Sureflux 70 G
3374	Nipro	Sureflux 70 L
3375	Nipro	Sureflux 90 E
3376	Nipro	Sureflux 90 G
3377	Nipro	Sureflux 90 L
3378	Nipro	Sureflux FB 210 U
3379	Nipro	Surelyzer PES 110 DH
3380	Nipro	Surelyzer PES 150 DH
3381	Nipro	Surelyzer PES 190 DH

3401	Pierrel Medical Care	Opal 110 S
3402	Pierrel Medical Care	Opal 130 S
3403	Pierrel Medical Care	Opal 160 S
3404	Pierrel Medical Care	Opal 180 S
3405	Pierrel Medical Care	Opal 200 S
3406	Pierrel Medical Care	Opal 220 S
3407	Pierrel Medical Care	Ruby 130 S

CODE	BRAND	MODEL
3408	Pierrel Medical Care	Ruby 160 S
3409	Pierrel Medical Care	Ruby 180 S
3410	Pierrel Medical Care	Topaz 100 S
3411	Pierrel Medical Care	Topaz 130 S
3412	Pierrel Medical Care	Topaz 160 S
3413	Pierrel Medical Care	Topaz 180 S

3501	RenaSelect	Altair 10
3502	RenaSelect	Altair 12
3503	RenaSelect	Altair 14
3504	RenaSelect	Altair 16
3505	RenaSelect	Nouvelle 10
3506	RenaSelect	Nouvelle 12
3507	RenaSelect	Nouvelle 14
3508	RenaSelect	Nouvelle 16

3601	Riggers	Altair 10
3602	Riggers	Altair 12
3603	Riggers	Altair 16
3604	Riggers	Nouvelle 10
3605	Riggers	Nouvelle 12
3606	Riggers	Nouvelle 16
3607	Riggers	Orion 10
3608	Riggers	Orion 12
3609	Riggers	Orion 16
3610	Riggers	Synergie 1.0
3611	Riggers	Synergie 1.2
3612	Riggers	Synergie 1.6

3701	Saxonia	DC 09 2 1
3702	Saxonia	DC 11 2 1
3703	Saxonia	DC 12 2 1
3704	Saxonia	DC 16 2 1
3705	Saxonia	DH 09 2 1
3706	Saxonia	DH 11 2 1
3707	Saxonia	DH 13 2 1
3708	Saxonia	DH 16 2 1
3709	Saxonia	Saxon 1030 E
3710	Saxonia	Saxon 1065 H
3711	Saxonia	Saxon 1080 C
3712	Saxonia	Saxon 1080 H
3713	Saxonia	Saxon 1265 H
3714	Saxonia	Saxon 1280 C
3715	Saxonia	Saxon 1280 H
3716	Saxonia	Saxon 1330 E
3717	Saxonia	Saxon 1465 H
3718	Saxonia	Saxon 1480 C
3719	Saxonia	Saxon 1480 H
3720	Saxonia	Saxon 1665 H
3721	Saxonia	Saxon 1680 C
3722	Saxonia	Saxon 1680 H

CODE	BRAND	MODEL
3801	Schiwa	Basicflux 1.0
3802	Schiwa	Basicflux 1.3
3803	Schiwa	Basicflux 1.8
3804	Schiwa	Perflux SD 1.0
3805	Schiwa	Perflux SD 1.3
3806	Schiwa	Perflux SD 1.8

3901	Terumo	Clirans C 061
3902	Terumo	Clirans C 08 L
3903	Terumo	Clirans C 081
3904	Terumo	Clirans C 081 L
3905	Terumo	Clirans C 10 L
3906	Terumo	Clirans C 10 NL
3907	Terumo	Clirans C 101
3908	Terumo	Clirans C 101 L
3909	Terumo	Clirans C 12 L
3910	Terumo	Clirans C 12 NL
3911	Terumo	Clirans C 121
3912	Terumo	Clirans C 121 L
3913	Terumo	Clirans C 15 L
3914	Terumo	Clirans C 15 NL
3915	Terumo	Clirans C 151
3916	Terumo	Clirans C 151 L
3917	Terumo	Clirans E 12 NL
3918	Terumo	Clirans E 12 NLA
3919	Terumo	Clirans E 15 NL
3920	Terumo	Clirans E 15 NLA
3921	Terumo	Clirans E 18 NL
3922	Terumo	Clirans E 18 NLA
3923	Terumo	Clirans EE 12 NL
3924	Terumo	Clirans EE 12 NLA
3925	Terumo	Clirans EE 15 NL
3926	Terumo	Clirans EE 15 NLA
3927	Terumo	Clirans EE 18 NL
3928	Terumo	Clirans EE 18 NLA
3929	Terumo	Clirans EE 20 NL
3930	Terumo	Clirans M 081
3931	Terumo	Clirans M 101
3932	Terumo	Clirans M 121
3933	Terumo	Clirans M 151
3934	Terumo	Clirans NT 120 L
3935	Terumo	Clirans NT 150 L
3936	Terumo	Clirans NT 175 L
3937	Terumo	Clirans S 12 NL
3938	Terumo	Clirans S 15 NL
3939	Terumo	Clirans S 18 NL
3940	Terumo	Clirans SE 12 NL
3941	Terumo	Clirans SE 15 NL
3942	Terumo	Clirans SE 18 NL
3943	Terumo	Clirans T 150 L
3944	Terumo	Clirans T 150 LM
3945	Terumo	Clirans T 175 L
3946	Terumo	Clirans T 175 LM

CODE	BRAND	MODEL
3947	Terumo	Clirans T 220 L
3948	Terumo	Clirans T 220 LM

4001	Toray	BS 1.3
4002	Toray	BS 1.3 U
4003	Toray	BS 1.6
4004	Toray	BS 1.6 UL
4005	Toray	BS 1.8
4006	Toray	BS 1.8 UL
4007	Toray	BS 2.1 UL
4008	Toray	Filtryzer B1 0.6
4009	Toray	Filtryzer B1 0.8
4010	Toray	Filtryzer B1 1.0
4011	Toray	Filtryzer B1 1.0 H
4012	Toray	Filtryzer B1 1.3 H
4013	Toray	Filtryzer B1 1.6 H
4014	Toray	Filtryzer B1 1.6 U
4015	Toray	Filtryzer B1 2.1 U
4016	Toray	Filtryzer B2 0.5
4017	Toray	Filtryzer B2 0.8
4018	Toray	Filtryzer B2 1.0
4019	Toray	Filtryzer B2 1.0 H
4020	Toray	Filtryzer B2 1.2 H
4021	Toray	Filtryzer B2 1.5 H
4022	Toray	Filtryzer B2 2.0
4023	Toray	Filtryzer B3 0.5 A
4024	Toray	Filtryzer B3 0.8 A
4025	Toray	Filtryzer B3 1.0 A
4026	Toray	Filtryzer B3 1.3 A
4027	Toray	Filtryzer B3 1.6 A
4028	Toray	Filtryzer B3 2.0 A
4029	Toray	Filtryzer BK 1.0 F
4030	Toray	Filtryzer BK 1.0 P
4031	Toray	Filtryzer BK 1.0 U
4032	Toray	Filtryzer BK 1.3 F
4033	Toray	Filtryzer BK 1.3 P
4034	Toray	Filtryzer BK 1.3 U
4035	Toray	Filtryzer BK 1.6 F
4036	Toray	Filtryzer BK 1.6 P
4037	Toray	Filtryzer BK 1.6 U
4038	Toray	Filtryzer BK 2.1 F
4039	Toray	Filtryzer BK 2.1 P
4040	Toray	Filtryzer BK 2.1 U

4101	VMP	AHF 10
4102	VMP	AHF 14
4103	VMP	CDF 100
4104	VMP	CDF 120
4105	VMP	CDF 140
4106	VMP	CDF 160
4107	VMP	CDF 180
4108	VMP	CDF 200

Frequent Hemodialysis Network
RETROSPECTIVE KINETIC MODELING DATA - FORM #274

Instructions: This table is completed every month, using dialysis flow sheets to look at the past week excluding the reference day. Although the table accommodates up to 6 sessions, use only as many columns as needed (starting from the left) to cover all treatments in the preceding week, including dialysis sessions and treatments with isolated ultrafiltration only.

1. Participant ID #	2. Alpha Code	3a. Visit Type	3b. Visit Number

4. a. Was kinetic modeling done this month? (0=No; 1=Yes) ..... __

b. If yes, date of KM (if no, use last date within visit window): (dd/mon/yyyy) ..... __ __ / __ __ __/ __ __ __ __

Data Item	5. **Session – #1**	6. **Session – #2**	7. **Session – #3**
a. Treatment Date (dd/mon/yyyy)	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __
b. Start Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
c. End Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
d. Predialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
e. Minimum intradialytic systolic BP[2]	__ __ __	__ __ __	__ __ __
f. Minimum intradialytic diastolic BP	__ __ __	__ __ __	__ __ __
g. Hypotensive episode?[1]	__	__	__
h. Significant interruption?[3]	__	__	__
i. Pre-dialysis systolic BP	__ __ __	__ __ __	__ __ __
j. Pre-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
k. Post-dialysis systolic BP	__ __ __	__ __ __	__ __ __
l. Post-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
m. Post-dialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
p. Was this a dialysis session? (0=No, isolated ultrafiltration; 1=Yes)	__	__	__

[1]For Item 4g, hypotensive episode, enter 0=No, 1=Symptoms of hypotension led to lowering of UF rate or reduced blood flow, 2=Symptoms of hypotension led to administration of saline, 3=Symptoms of hypotension led to lowering of UF rate and administration of saline.

[2]For Item e: specify systolic and diastolic blood pressure at time of minimum systolic blood pressure.

[3]For Item h, significant interruption, enter 0=No, 1=Yes. For an in-center dialysis treatment, a significant interruption is any interruption of 15 minutes or greater. For a home dialysis treatment, a significant interruption is any interruption of 30 minutes or greater.

Data Item	8. **Session – #4**	9. **Session – #5**	10. **Session – #6**
a. Treatment Date (dd/mon/yyyy)	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __
b. Start Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
c. End Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
d. Predialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
e. Minimum intradialytic systolic BP	__ __ __	__ __ __	__ __ __
f. Minimum intradialytic diastolic BP	__ __ __	__ __ __	__ __ __
g. Hypotensive episode?[1]	__	__	__
h. Significant interruption?[2]	__	__	__
i. Pre-dialysis systolic BP	__ __ __	__ __ __	__ __ __
j. Pre-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
k. Post-dialysis systolic BP	__ __ __	__ __ __	__ __ __
l. Post-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
m. Post-dialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
p. Was this a dialysis session? (0=No, isolated ultrafiltration; 1=Yes)	__	__	__

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

[1]For Item 4g, hypotensive episode, enter 0=No, 1=Symptoms of hypotension led to lowering of UF rate or reduced blood flow, 2=Symptoms of hypotension led to administration of saline, 3=Symptoms of hypotension led to lowering of UF rate and administration of saline.
[2]For Item e: specify systolic and diastolic blood pressure at time of minimum systolic blood pressure.
[3]For Item h, significant interruption, enter 0=No, 1=Yes. For an in-center dialysis treatment, a significant interruption is any interruption of 15 minutes or greater. For a home dialysis treatment, a significant interruption is any interruption of 30 minutes or greater.

Frequent Hemodialysis Network
ATTENDANCE AT IN-CENTER DIALYSIS SESSIONS - FORM#275

This form is completed during follow-up for all Daily Trial patients (and those in the Nocturnal Trial who are receiving dialysis in-center. Use Form 279 for Nocturnal Trial patients dialyzing at home). Form 275 is to be completed by the study coordinator or dialysis unit technician at the start of each calendar month following randomization in order to document missed dialysis treatments during the prior calendar month. Do not count those treatments completed for ultrafiltration only.

1. Participant ID # | 2. Alpha Code | 3a. Visit Type | 3b. Visit Number (of the calendar month listed below)

4. Indicate calendar month to which this form applies: ..... (mon/yyyy): __ __ __ / __ __ __ __

5. Did this patient avoid continual care of your FHN hemodialysis unit through the calendar month for any of the reasons listed below: (For questions 5a-d: 0=No, 1=Yes)

   a. Patient was admitted to a rehabilitation unit or nursing home.....__

   b. Patient was hospitalized on some of the days that patient should have been dialyzed at your unit.....__
   (Be sure to fill out hospitalization forms 302 and 303.)

   c. Patient was out of town part of the time .....__

   d. Patient was being cared for by some other dialysis unit than yours for some other reason .....__

For Questions 6-8: <u>EXCLUDE</u> the time that the patient was not under the care of the FHN dialysis unit:

6. What was the number of treatments that the patient should have had <u>at your dialysis unit</u> under the protocol ?.....__ __
(Do not include those treatments completed for ultrafiltration only)

7. How many treatments <u>at your unit</u> were missed during the designated calendar month?..__ __

8. How many treatments did the patient actually have <u>at your unit`</u>?.....__ __
(Do not include those treatments completed for ultrafiltration only)

Note: The responses to questions 7 and 8 should add up to the response in question 6.

200. Date 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) __ __/__ __ __ /__ __ __ __

Frequent Hemodialysis Network
ACCESS REPAIR PROCEDURE - FORM #276

Instructions: This form is completed whenever an access procedure is done to help maintain or restore function of the access that is currently being used for HD. For access failure or removal, complete Form 277. For placement of a new access, complete Form 278. *If you only wish to indicate that a new access is being used for hemodialysis, fill out Form 271.*

The following do not count as FHN access repair procedures and do not merit a Form 276, so do NOT complete this form if:

- the patient only had diagnostic venogram without any other procedures.
- the patient only had one or more dwells of tPA
- the only procedure done was banding
- the procedures was done within a dialysis unit. This form is intended for procedures done in a vascular access center or in a hospital
- there is angioplasty of a central vein or stent placement on a central vein

Wait until at least one dialysis procedure is done after the access placement before you complete this form (Otherwise you will never be able to answer "yes" to the question about the success of the repair.)

1. Participant ID # | 2. Alpha Code | 3. Date of Access Procedure: dd/mon/yyyy

4. Type of access that the procedure was carried out on: .....__
   1=Arteriovenous fistula
   2=Arteriovenous graft
   3=Tunneled (permanent) catheter
   4=Non-tunneled (temporary) catheter

5. Date access (identified in Q4) was placed? (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
   (If this access was in place before the patient was enrolled in baseline and the placement date is unknown, use the date of the first known use.)

Type of Procedure(s) Performed

6. For patients with fistulas and grafts indicated in item 4 above:
   For items 6a-e: Use 0=No, 1=Yes, to identify whether the procedure was performed by a non-physician(Non-MD) or physician(MD).

	Non-MD?	**MD?**
a. Angioplasty:	__	__
b. Stent placement:	__	__
c. Thrombolysis (pharmacologic removal of a clot):	__	__
d. Thrombectomy (physical or mechanical removal of a clot):	__	__
e. Surgical revision (not banding)	__	__

7. For patients with catheters indicated in item 4 above
For items 7a-c: Use 0=No, 1=Yes, to identify whether the procedure was performed by a non-physician(Non-MD) or physician(MD).

Non-MD? MD?

a. Repair of catheter by stripping of fibrin sheath: .....__.....__

b. Thrombolysis: .....__.....__

c. Repair of broken catheter component: .....__.....__

8. Was this procedure successful? .....__
1=Yes, the access is now being used as patient's main access for HD.
(If the patient was using a different access before this repair and a Form 271 was completed, fill out another Form 271 to indicate that the patient is now using the repaired access. If there was no interruption in the use of the repaired access, there is no need to fill out Form 271 again.)
2=It appears to have been successful, but a week or more has passed and the access cannot yet be used or the access has not been used.
(Complete Forms 278 and 271 if a new access was placed and is being used to dialyze the patient in the meanwhile. When the repaired access is able to be used again, then complete 271 again.)
3=No, the access required further salvage procedures. Complete a new Form 276 for each additional procedure.
4=No, the access can no longer be used. Complete Form 277 access failure form and 278 if a new access was placed.

For DCC Use Only:

199. a. Event reason: .....__

b. Date updated: ..... __ __/__ __ __/__ __ __ __

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

Frequent Hemodialysis Network
PERMANENT ACCESS FAILURE OR ACCESS REMOVAL FORM #277

Instructions: This form is completed whenever an access that is currently being used for HD is removed or otherwise can no longer be used (defined as "permanent failure.") Do not use this form if the access is still being used. Access repair procedures are recorded on form 276. New access placement is recorded on Form 278. If you only wish to indicate that a new access is being used for hemodialysis, fill out Form 271.

1. Participant ID # | 2. Alpha Code | 3. Date of Access failure: dd/mon/yyyy

4. Type of access that permanently failed:.....__
   1=Arteriovenous fistula
   2=Arteriovenous graft
   3=Tunneled catheter
   4=Non-tunneled catheter

5. Date access (identified in Q4) was placed? (dd/mon/yyyy). ..... __ __/__ __ __ /__ __ __ __
   (If this is the initial baseline access and placement date is unknown, use the date of the first known use)

6. Primary Reason for permanent failure.....__ __
   For Fistulas and Grafts (designated in item 4 above), use these codes:
   01=Irreparable stenosis or thrombosis (clot)
   02=Ligated for Aneurysm
   03=Ligated for Steal syndrome
   04=Ligated for Ischemic neuropathy
   05=Ligated for Congestive heart failure
   06=Infection
   07=Severe swelling/hematoma formation
   08=Other irreparable condition/problem (i.e., laceration)

   For Catheters (designated in item 4 above, use these codes:
   20=Removed because of infection
   21=Removed because of mechanical failure or poor flows or thrombosis
   22=Removed electively because another access such as a fistula or graft is now being used

If the reason for permanent failure is not on the above code list, email fhn-dcc@bio.ri.ccf.org

7. Was the access removed? (0=No, 1=Yes) .....__

For DCC Use Only:

199. a. Event reason:..... __

b. Date updated: ..... __ __/__ __ __/__ __ __ __

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

Frequent Hemodialysis Network
NEW ACCESS PLACEMENT - FORM #278

Instructions: This form is completed at any time during baseline or follow up, whenever a new access is placed. Access repair procedures are recorded on Form 276. Access failure or removal is reported on Form 277. New access placement is recorded on Form 278. To indicate that a new access is being used for hemodialysis, fill out Form 271.

If two accesses are placed on one day, complete this form twice, once for each access that was placed.

Wait until at least one dialysis procedure is done after the access placement before you complete this form. (Otherwise you will never be able to answer "yes" to the question about whether the access is currently being used.)

1. Participant ID # 2. Alpha Code 3. Date of Access Placement: dd/mon/yyyy

New Access Placement

4. What was the type of access that was placed:.....__
   1=Arteriovenous fistula
   2=Arteriovenous graft
   3=Tunneled (permanent) catheter
   4=Non-tunneled (permanent) catheter

5. Is this the access currently being used for HD?.....__
   0=No. Remember to complete Form 271 once this access is actively used as the patient's main access.
   1=Yes. Fill out Form 271 now.

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

Frequent Hemodialysis Network
CLINICAL CENTER HOSPITALIZATION NOTIFICATION
FORM #302

Baseline: If a patient is hospitalized during baseline, complete this Form 302 only as soon as the Clinical Center becomes aware that a patient has been hospitalized. *If the trial caused the hospitalization, then a Form 303 must be completed along with a Form 308.*

Follow-Up: This form is completed as soon as the Clinical Center becomes aware that a patient has been hospitalized. A Form 303 and Form 308 must be completed and entered.

1. Participant ID # | 2. Alpha Code | 3. Hospital admission date: dd/mon/yyyy

4. Is the patient still in the hospital? .....__
(0=No-discharged, 1=No-died (enter Form 305/306), 2=Yes-still in hospital)

Remember to complete a Clinical Center Detailed Hospitalization Form #303, SAE Form #308. Send/fax the hospitalization packet to the DCC within three months after the patient was discharged.

5. Primary reason for this hospitalization .....__ __ __ __ __
(see code list from Form 303. *Note: A terminal code of 0 indicates a procedure and cannot be used as a primary reason code.*

6. Secondary reason for this hospitalization .....__ __ __ __ __
(see code list from Form 303)

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

201. Username of person completing this form.....__ __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
CLINICAL CENTER HOSPITALIZATION FORM #303

Baseline: If a patient is hospitalized during baseline and it was identified that *the trial caused the hospitalization, then this Form 303 must be completed and entered along with a Form 308.*

Follow-Up: A Form 303 must be completed for all hospitalizations that required an overnight stay. A Form 308 must be completed and entered. Detailed documentation regarding the patient's hospitalization (i.e., discharge summaries, lab reports, etc.) must be submitted to the DCC within 6 weeks after the patient was discharged.

Follow-up Extension Study: A Form 303 must be completed for all hospitalizations that required an overnight stay for patients who consent to participate. In the Daily study, only hospitalizations that occurred during follow-up months F-12 through F-18. ***In the Nocturnal study, all hospitalizations will be collected regardless of follow-up month?*** All information regarding a patient's hospitalization and outcome should be detailed in Q15 since Form 308 is not completed (in the Extension Study only). Detailed documentation regarding the patient's hospitalization (i.e., discharge summaries, lab reports, etc.) should be submitted to the DCC. If no medical records are available, the PI should write a detailed summary letter for use by the Outcomes Committee.

Recall that hospitalizations for transplants will be reviewed by the Outcomes Committee but no other hospitalizations after the transplant are to be submitted. This also applies to patients who switch to peritoneal dialysis (PD) or regained kidney function.

1. Participant ID # 2. Alpha Code 3. Date of hospital admission: dd/mon/yyyy

4. Primary reason for this hospitalization .....__ __ __ __ __
   See code list starting on page 4. *Note: A terminal code of 0 indicates a procedure and cannot be used as a primary reason code.*

5. Secondary reason for this hospitalization .....__ __ __ __ __
   (see code list on starting on page 4).

6. Billing category for economic analyses .....__ __
   - 01 = Diseases & disorders of the nervous system
   - 02 = Diseases & disorders of the eye
   - 03 = Diseases & disorders of the ear / nose / mouth & throat
   - 04 = Diseases & disorders of the respiratory system
   - 05 = Diseases & disorders of the circulatory system
   - 06 = Diseases & disorders of the digestive system
   - 07 = Diseases & disorders of the hepatobiliary system & pancreas
   - 08 = Diseases & disorders of the musculoskeletal system & connective tissue
   - 09 = Diseases & disorders of the skin / subcutaneous tissue & breast
   - 10 = Endocrine / nutritional & metabolic diseases & disorders
   - 11 = Diseases & disorders of the kidney & urinary tract
   - 12 = Diseases & disorders of the male reproductive system
   - 13 = Diseases & disorders of the female reproductive system

Continued on next page…

14 = Pregnancy / childbirth & the puerperium
15 = Newborns & other neonates with condition originating in perinatal period
16 = Diseases & disorders of blood / blood forming organs / immunological disorder
17 = Myeloproliferative diseases & disorders / poorly differentiated neoplasm
18 = Infectious & parasitic diseases / systemic or unspecified sites
19 = Mental diseases & disorders
20 = Alcohol/drug use & alcohol/drug induced organic mental disorders
21 = Injuries / poisonings & toxic effects of drugs
22 = Burns
23 = Factors influencing health stat & other contacts with health services
24 = Multiple significant trauma
25 = Human immunodeficiency virus infections

7.a. Did the patient have a surgical procedure done during this hospitalization?
(0=No, 1=Yes, 9=Unknown) .....__

b. Was this an access-related surgical procedure (0=No, 1=Yes)? .....

Access Related Issues

8. Access Hospitalization Status:.....__
1=This was a "Non-Access hospitalization" - admitted for a problem unrelated to access
2=Admitted for an access problem, "Access hospitalization" without non-access complications
3=Admitted for an access problem, "Access hospitalization" with non-access complications that were not due to access problems.
4=This was an "Access hospitalization" with non-access complications that were due to access problems.

9. Was access repair or removal required? ..... __
Code 0=No, 1=Yes, complete the Access Procedure/Removal form 276.

10. Was a new access placed?..... __
Code 0=No, 1=Yes, complete New Access Placement Form 278.

Cardiovascular Disease (Code 0=No, 1=Yes, 9=Unknown)

11. a. Was there new onset of or worsening angina pectoris or ischemic heart disease?.....__

b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)?.....__

c. Was there a myocardial infarction?.....__

d. Was there new onset of or worsening arrhythmias?.....__

e. Was there new onset of or worsening other heart disease (exclude pericarditis) .....__
(Note - if any of the above are true, this was a cardiovascular hospitalization)

Hospitalization for Infection (Code 0=No, 1=Yes)

12. a. Was there bacteremia or sepsis? .....__

    b. Was there organ or deep tissue infection (serious)? .....__
    (Note – if either of the above are true, this was an infection hospitalization)

Patient Status

13. a. Current status of patient .....__
    1=Still in hospital (only use this option if several weeks have elapsed)
    2=Died, complete Forms 305 and 306
    3=Discharged to be admitted to rehab, a nursing home or other facility
    4=Discharged to home

13. b. If item 13a = 3 or 4, date of discharge (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

14. If you know the DRG for this hospitalization, record it here: .....__ __ __
    (Use 999 if unknown)

15. **Required:** Comments. (For patients still in the trial follow-up period, Write in as much as you wish. For patients in the Follow-up Extension study, please provide detailed text as no Form 308 is required. Use back of sheet if necessary. Key enter text.)

_____

_____

_____

_____

_____

_____

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

201. Username of person completing this form.....__ __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

For DCC Use Only:

204. a. Falls outside of Ext. Follow-up Study reporting period (1=Yes) __

b. Date DCC reviewed: __ __/__ __ __ /__ __ __ __

See Q4 & Q5 category codes starting on the next page.

FHN STUDY: Hospitalizations - Code List of Diagnoses and Procedures (For Form 303, Q4 & 5)

Coding Instructions: When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
Note: A terminal code of 0 indicates a procedure and cannot be used as a primary reason code in Q4.

An asterisk (*) indicates that the disease or condition is also classified as an "infection outcome".

1. ISCHEMIC HEART DISEASE (IHD)

Also see category: coronary heart disease (CHD) or coronary artery disease (CAD)

01AA(_)	Chest pain of non-cardiac or unclear etiology (R/O MI admission)
01AB(_)	CAD
01AC(_)	Angina
01AD0	Bypass surgery (CABG)
01AE0	Coronary angiographies
01AF0	Coronary angioplasty (PTCA) or atherectomy
01AG	Myocardial infarction (acute)(MI)
01AH	Cardiac arrest

2. CONGESTIVE HEART FAILURE (CHF)

02AA(_)	CHF
02AB(_)	CHF due to volume overload
02AC(_)	Pulmonary edema (cardiogenic)
02AD(_)	Pleural effusion(s)
02AE0	Thoracentesis (diagnostic or therapeutic)
02AF	Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03AA(_)	Syncope (also presyncope and syncopal episode)
03AB(_)	Atrial fibrillation
03AC(_)	Ventricular tachycardia
03AD(_)	Supraventricular tachycardia
03AE(_)	Sick sinus (tachy-brady) syndrome
03AF(_)	Atrioventricular conduction block
03AG(_)	Hyperkalemia
03AH(_)	Other new or other arrhythmia and conduction problem
03AI0	Cardioversion
03AJ0	Electrophysiologic studies (EPS)
03AK0	Pacemaker placement
03AL0	Pacemaker malfunction/repair
03AM0	Implantable cardioverter-defibrillator (ICD)

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04AA(_) Pericarditis
04AB(_) Endocarditis
04AC(_) Myocarditis
04AD(_) Cardiomyopathy (without IHD or CHF)
04AE(_) Pericardial effusion
04AF(_) Aortic valve stenosis or insufficiency
04AG(_) Mitral valve stenosis, regurgitation, or prolapse
04AH(_) Other valve defect
04AI(_) Other heart condition
04AJ(_) Cardiac tamponade
04AK0 Pericardiocentesis
04AL0 Aortic valve replacement
04AM0 Mitral valve replacement
04AN0 Balloon valvuloplasty
04AP0 Pericardial Window

5. HYPERTENSION (HTN) / HYPOTENSION

05AA(_) Hypertensive crisis or accelerated HTN
05AB(_) Hypotensive crisis or accelerated hypotension

6. CEREBRAL VASCULAR DISEASE (CVD)

06AA(_) Transient ischemic attack (TIA)
06AB(_) Cerebral vascular accident (CVA)
06AC(_) Carotid artery stenosis
06AD(_) Cerebral artery aneurysm
06AE(_) Subarachnoid or cerebral hemorrhage
06AF(_) Other CVD condition
06AG0 Carotid endarterectomy (CEA)
06AH0 Carotid angiogram

7. PERIPHERAL VASCULAR DISEASE (PVD)

07AA(_) Deep vein thrombosis (DVT)
07AB(_) Pulmonary embolism
07AC(_) Peripheral vascular disease
07AD(_) Ischemic foot ulcers
07AE(_) Gangrene of toes or foot*
07AF(_) Abdominal aortic aneurysm (AAA)
07AG(_) Thoracic aortic aneurysm (TAA)

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

07AH(_) Hemorrhage from ruptured vascular aneurysm
07AI(_) Aortic aneurysm (not specified)
07AJ(_) Other aneurysm
07AK(_) Mesenteric ischemia or infarction (ischemic bowel)
07AL(_) Cellulitis (non-access related)*
07AM(_) Gangrene with septicemia-shock due to PVD
07AN(_) Other condition due to PVD or other disorder of arteries
07AO(_) Polyarteritis nodosa and other arteritides
07AP Arterial embolism
07AQ0 AAA repair
07AR0 TAA repair
07AS0 Angioplasty for PVD
07AT0 Bypass graft for PVD
07AW0 Amputation site: toe(s)+
07AX0 Amputation site: transmetatarsal+
07BA0 Left below the knee amputation+
07BB0 Right below the knee amputation+
07BC0 Left above the knee amputation+
07BD0 Right above the knee amputation+
+Be sure to complete Form 202 for any amputation

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08AA(_) Diabetic foot infection*
08AB(_) Gangrene of foot or toes (absence of PVD)*
08AC(_) Hypothyroidism
08AD(_) Other disorders of thyroid gland
08AE Diabetes with ketoacidosis
08AF Diabetes with hyperosmolar state or coma
08AG Hypoglycemic coma
08AH0 Pancreatic transplant
08AI(_) Other endocrine disorder
08AJ Onset of diabetes
08AK0 Parathyroidectomy
08AL(_) Hyperparathyroidism
08AM(_) Hypoparathyroidism
08AN(_) Other calcium-phosphorus disorder
08AO(_) Hyperglycemia
08AP(_) Diabetic foot ulcer
08AQ(_) Hypoglycemia (without coma)

9. RESPIRATORY DISEASES

09AA(_) Asthma
09AB(_) COPD

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

09AC(_) Bronchitis
09AD(_) Pneumothorax
09AE(_) Empyema*
09AF(_) Lung abscess*
09AG(_) Pulmonary TB*
09AH(_) Respiratory failure not requiring intubation and mechanical ventilation
09AI(_) Respiratory failure requiring intubation and mechanical ventilation
09AJ(_) Adult Respiratory Distress Syndrome (ARDS)
09AK Respiratory failure of unknown cause
09AL(_) Other respiratory disease
09AM(_) Pulmonary hemorrhage
09AN(_) Pneumonia (nosocomial)*
09AO(_) Pneumonia (community acquired)*
09AP(_) Pneumonia-sepsis*
09AQ(_) Pneumonia (bacterial)*
09AR(_) Pneumonia (fungal)*
09AS(_) Pneumonia (viral)*
09AT(_) Pneumocystis pneumonia*
09AU(_) Aspiration pneumonia*
09AV(_) Pneumonia (unspecified pathogen)*
09AW0 Open lung biopsy
09AX0 Lung lobectomy
09AY(_) Upper respiratory tract disorders (including dyspnea, shortness of breath)
09AZ0 ENT procedures
09BA Angioedema
09BB Acute epiglottitis

10. MALIGNANCY

10AA(_) Hematologic malignancy (AML, ALL, CLL)
10AB(_) Lymphoma (unspecified)
10AC(_) Hodgkin's lymphoma
10AD(_) Non-Hodgkin's lymphoma
10AE(_) Multiple myeloma
10AF(_) Colon cancer
10AG(_) Breast cancer
10AH(_) Prostatic cancer
10AI(_) Ovarian cancer
10AJ(_) Lung cancer
10AK(_) Gastric cancer
10AL(_) Pancreatic cancer
10AM(_) Thyroid cancer
10AN(_) Cervical cancer
10AO(_) Endometrial cancer
10AP(_) Primary cancer of liver

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

10AQ(_) Head and neck squamous cell carcinoma
10AR(_) Testicular cancer
10AS(_) Renal cancer
10AT(_) Bladder cancer
10AU(_) Melanoma
10AV(_) Other skin cancer
10AW(_) Other malignancy or neoplasia
10AX(_) Metastatic carcinoma unknown primary
10AY(_) Complication(s) of pre-admission diagnosed cancer
10BA0 Diagnosis: surgical biopsy
10BB0 Other biopsy procedure
10BC0 Other diagnostic procedure
10BD0 Treatment: radiation therapy
10BE0 chemotherapy
10BF0 surgical excision
10BG0 other treatment
10BH0 Mastectomy (subtotal or total)
10BI0 Hysterectomy

11. HEPATOBILIARY DISEASE

11AA(_) Hepatitis B
11AB(_) Hepatitis C
11AC(_) Toxic/drug-induced hepatitis
11AD(_) Hepatitis (other; unknown cause)
11AE(_) Cirrhosis
11AF(_) Ascites
11AG(_) Portal hypertension or esophageal varices
11AH(_) Variceal bleed
11AI(_) Hepatic failure/severe dysfunction
11AJ(_) Cholecystitis/cholangitis*
11AK(_) Other hepatobiliary disease
11AL(_) Biliary sepsis*
11AM0 Cholecystectomy
11AN0 Liver transplant
11AO0 Shunt procedure
11AP0 Paracentesis (diagnostic or therapeutic)

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12AA(_) Gout
12AB(_) Wegener's granulomatosis
12AC(_) Systemic vasculitis
12AD(_) Systemic Lupus Erythematosus (SLE)
12AE(_) Avascular necrosis
12AF(_) Osteomyelitis*

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

12AG(_) Septic arthritis*
12AH(_) Back problems
12AI(_) Other musculoskeletal or connective tissue disease
12AJ(_) Bone fracture
12AK0 Carpal tunnel surgery
12AL0 Arthroscopy
12AM0 Hip replacement
12AN0 Knee replacement
12AO0 Knee procedures (other than replacement)
12AP0 Internal fixation or surgical reduction of bone fracture
12AQ0 Other orthopedic surgery
12AR0 Back and/or neck procedure
12AS(_) Musculoskeletal pain
12AT0 Orthopedic related rehabilitation

13. GASTROINTESTINAL CONDITIONS (GI)

13AA(_) Upper GI bleed
13AB(_) Lower GI bleed
13AC(_) GI bleeding, site unknown
13AD(_) Peptic/duodenal ulcer disease
13AE(_) Gastritis
13AF(_) Reflux esophagitis (with or without hiatal hernia)
13AG(_) Diverticulitis*
13AH(_) Colonic polyps
13AI(_) Ulcerative colitis (UC)
13AJ(_) Enteritis (Crohn's disease)
13AK(_) Septicemia due to peritonitis*
13AL(_) Pancreatitis
13AM(_) Necrotizing enterocolitis*
13AN(_) *C. difficile* associated enterocolitis*
13AO(_) Peritonitis*
13AP(_) Fungal peritonitis*
13AQ(_) Appendicitis*
13AR(_) Ischemic bowel
13AS(_) Intra-abdominal abscess*
13AT(_) Abdominal pain, cause unknown
13AU(_) Malabsorption
13AV(_) Perforated viscus (peptic ulcer or bowel)*
13AX(_) Gastroparesis
13BA0 Colectomy (partial or total)
13BB0 Gastrectomy
13BC0 Colostomy or ileostomy
13BD0 Gastrostomy/enterostomy
13BE0 Appendectomy

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

13BF0 Laparotomy
13BG0 Other GI procedure
13BH(_) Other GI Condition

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14AA(_) Mental status change (acute)
14AB(_) Seizure disorder
14AC(_) Disequilibrium - syndrome
14AD(_) Coma-stupor (traumatic cause)
14AE(_) Coma-stupor (toxic-drug induced)
14AF(_) Coma-stupor (metabolic cause, non-diabetic)
14AG(_) Coma-stupor (anoxic encephalopathy)
14AH(_) Coma-stupor (other unknown cause)
14AI(_) Alcohol non-accidental
14AJ(_) Drug overdose
14AK(_) Head trauma
14AL(_) Parkinson's disease
14AM(_) Multiple sclerosis
14AN(_) Subdural or epidural hematoma
14AO(_) Depression
14AP(_) Nervous system neoplasm
14AQ(_) Alcohol/drug abuse related (detoxification included)
14AR(_) Other psychiatric or mental disorder
14AS(_) Viral meningitis*
14AT(_) Meningitis (non-viral)
14AU(_) Other CNS infection*
14AV(_) Ataxia
14AW(_) Cranial or peripheral nerve disorder
14AX(_) Other nonvascular nervous system condition
14AY(_) Suicide attempt
14AZ(_) Neuropic pain in extremity

15. URINARY TRACT CONDITIONS/RENAL CONDITIONS

15AA(_) Urinary tract infection requiring antibiotics*
15AB(_) Nephrolithiasis
15AC(_) Benign prostatic hypertrophy (BPH)
15AD(_) Prostatitis
15AE(_) Orchitis
15AF(_) Cystic kidney disease (PKD or acquired)
15AG(_) Cyst-related hemorrhage
15AH(_) Cyst-related infection
15AI(_) Urinary tract hemorrhage
15AJ0 Nephrectomy unilateral

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

15AK0 Nephrectomy bilateral
15AL0 Prostatectomy (radical)
15AM0 Transurethral prostatectomy (TURP)
15AN0 Other transurethral procedures (cystoscopy included)
15AO0 Other urologic procedure
15AP(_) Hematuria
15AQ0 Kidney transplant
15AR(_) Acute transplant rejection
15AS(_) Renal failure
15AT(_) Uremia/acute renal insufficiency
15AU Evaluation for transplant
15AV(_) Urinary retention
15AW(_) Chronic transplant rejection

16. HIV/AIDS

16AA(_) AIDS-related infection*
16AB(_) Other AIDS-related condition (non-infection)
16AC(_) HIV positive

17. OPHTHALMOLOGIC CONDITIONS

17AA(_) Retinal or vitreous hemorrhage
17AB(_) Endophthalmitis*
17AC(_) Other disorder of the eye
17AD0 Iris or lens procedure (cataract surgery included)
17AG0 Orbital procedure (vitrectomy included)
17AH0 Retina procedure (laser surgery included)
17AI0 Other ophthalmologic procedure

18. INFECTIONS

18AA(_) Abscess (lung, empyema, intra-abdominal, brain, soft tissue--not access-related)*
18AB(_) Miliary TB*
18AC(_) Extrapulmonary TB*
18AD(_) Disseminated candidiasis*
18AE(_) Other fungal infection**
18AF(_) Viral infection (including CMV)*
18AG(_) Other viral infection (not hepatitis)*
18AH(_) Protozoan or parasitic infection (not PCP)*
18AI(_) Other infection (not recorded in previous category)*
18AJ(_) Septic shock*
18AK(_) Bacteremia (known source, not access-related)*
18AL(_) Bacteremia (unknown source, not access-related)*
18AM(_) Bacteremia (known source, access-related)*

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

18AN(_) Bacteremia (unknown source, access-related)*
18AO(_) Fever of unknown origin*

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19AA(_) Coagulation disorders
19AB(_) Thrombocytopenia (secondary)
19AC(_) Thrombocytopenia (idiopathic)
19AD(_) Disseminated Intravascular Coagulation (DIC)
19AE(_) Other consumption coagulopathy
19AF(_) Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19AG(_) Other, including peripheral hematoma
19AH(_) Anemia
19AI Monitor anticoagulation status for elective surgery (ie., dental)

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20AA0 Elective surgical access repair
20AB(_) Soft tissue infection, cellulitis, abscess (access related)*
20AC(_) Bacteremia or sepsis, access related*
20AD(_) Clotted access
20AE(_) Venous thrombosis, access related
20AF(_) Arterial thrombosis or embolism, access related
20AG(_) Steal syndrome, limb ischemia, access related
20AH(_) Hemorrhage from vascular access
20AI(_) Nerve entrapment, access related
20AJ0 Fistulogram, arteriogram, or other invasive imaging procedure
20AK0 Access declotting procedure
20AL0 Angioplasty or stent placement for vascular access
20AM0 Non-elective surgical access repair
20AN0 Temporary access placement
20AO(_) Pneumothorax, hemothorax as result of temporary access placement
20AP(_) Subclavian vein stenosis as result of temporary access
20AQ0 New access creation (AV-fistula)
20AR0 New access placement (AV-graft)
20AS(_) Other access-related condition
20AT0 Other access-related procedure
20AU(_) New vascular access needed
20AV0 New perm-cath placement

21. OTHER HEMODIALYSIS COMPLICATIONS

21AA(_) Uremia
21AB(_) Hemorrhage from dialysis circuit
21AC(_) Air embolism

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

21AD(_) Anaphylaxis, treatment related
21AE(_) Hemolysis, treatment related
21AF(_) Electrolyte and acid-base disorder (other than hyperkalemia), treatment related
21AG(_) Dialysis-induced hypotension
21AH(_) Other accident related to treatment
21AI(_) Febrile reaction, not infection
21AJ0 Start of hemodialysis
21AK Withdrawal from dialysis

22. OTHER SURGICAL PROCEDURES

22AA(_) Trauma
22AB(_) Major hemorrhage (not GI or pulmonary)
22AC(_) Hemorrhagic shock
22AD0 Skin graft/skin ulcer debridement
22AE0 Hernia procedure
22AF0 Other elective surgery procedure
22AG0 Removal of benign tumor
22AH0 Elective dental surgical procedure

23. OTHER

23AA(_) Other hemorrhage
23AB(_) Other trauma
23AC(_) Drug overdose (accidental)
23AD Accident unrelated to treatment
23AE Drug reaction (anaphylaxis)
23AF Drug reaction (not anaphylaxis, not overdose)
23AG Other electrolyte/acid-base disorder, not treatment related
23AH Cachexia
23AI Morbid Obesity
23AJ Gynecologic or Obstetric condition

24. UNKNOWN

24AA Unknown reason for hospitalization

++++*If you have a condition not found on this listing, please contact the DCC (fhn-dcc@bio.ri.ccf.org) for a new code*+++++

When parentheses (_) are next to the code, you need to add one of the following: 1 = New, 2 = Worsening, 3 = Not a new condition
*Disease or condition is also classified as an "infection outcome".

Frequent Hemodialysis Network
CLINICAL CENTER DEATH NOTIFICATION FORM #305

This form is completed as soon as the Clinical Center becomes aware that a patient has died.

Baseline: If it was identified that the trial caused the death during the baseline period, then Form 306 must be completed and entered along with a completed Form 308. If a death occurred during baseline and the trial did not cause the death then you only need enter this Form 305.

Follow-Up: A Form 306 must be completed for all deaths that occurred in the follow-up period in addition to a Form 308. Detailed documentation regarding the patient's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) must be submitted to the DCC within 6 weeks after the patient expired.

1. Participant ID # 2.Alpha Code 4. Date of Death: dd/mmm/yyyy

Based on the information you have available to you now, what do you think is the:
(for Causes of Death, use the Death Code List from Form 306.*)*

5. a. Primary cause of death.....__ __ __ __

b. Secondary cause of death.....__ __ __ __

c. Other cause of death.....__ __ __ __

d. Other cause of death.....__ __ __ __

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

201. Username of person completing this form.....__ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
DETAILED DEATH FORM - FORM #306

Baseline: If a death occurred during the baseline period, complete Form, 305, Form 306 and a Form 308. Detailed documentation* will be required particularly if it was identified that the trial may have caused the patient's death.

Follow-Up: A Form 306 must be completed for all deaths that occurred in the follow-up period in addition to a Form 308.

*Detailed documentation regarding the patient's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) must be submitted to the DCC within 6 weeks after the patient expired.

1. Participant ID # 2. Alpha Code 3. Date of death: dd/mon/yyyy

Part 1: To be completed by the Study Coordinator:

4. Date Death Review Packet submitted to DCC: (dd/mon/yyyy) ..... __ __/__ __ __/__ __ __ __

5. Where did the death occur? ..... __
   1 = In a hospital, in the emergency room
   2 = In a hospital, not in the emergency room
   3 = In the dialysis unit
   4 = In a nursing home or other skilled care facility
   5 = In the patient's home
   6 = Other known location
   7 = Location unknown

6. Was an autopsy performed? (0=No, 1=Yes, 9=unknown) ..... __
   If YES, be sure to include the autopsy report in the Death Review Packet.

Part 2: To be completed by the Principal Investigator:

7. For causes of death, use the attached Death Code List starting on page 2.
   a. Primary cause of death ..... __ __ __ __
   b. Secondary cause of death ..... __ __ __ __
   c. Other cause of death ..... __ __ __ __
   d. Other cause of death ..... __ __ __ __

Note that a narrative summary from the Principal Investigator of the events leading to the patient's death and the circumstances surrounding the death will be recorded on the SAE form.

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

201. Username of person completing this form ..... __ __ __ __ __ __ __

For Clinical Center Use Only:

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

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

FHN TRIAL CODE LIST OF CAUSES OF DEATH

Note: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

1. ISCHEMIC HEART DISEASE (IHD)

01DA Sudden death (due to IHD)
01DB Myocardial infarction (acute) (MI)
01DC Angina:2
01DD Atherosclerotic heart disease (CAD):2
01DE Other acute and subacute forms of ischemic heart disease
01DF Old myocardial infarction:2
01DG Other forms of chronic ischemic heart disease:2

2. CONGESTIVE HEART FAILURE (CHF)

02DA CHF
02DB CHF or pulmonary edema due to exogenous fluid (volume overload)
02DC Pulmonary edema (cardiogenic)
02DD Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

03DA Sudden death (due to arrhythmia, not due to IHD)
03DB Atrioventricular conduction block
03DC Sick sinus syndrome
03DD Atrial fibrillation
03DE Ventricular tachycardia
03DF Other cardiac arrhythmia and conduction disorder
03DG Hyperkalemia
03DH Ventricular fibrillation

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

04DA Sudden death (due to heart conditions other than IHD/arrhythmia)
04DB Pericarditis
04DC Endocarditis *
04DD Myocarditis
04DE Pericardial effusion:2
04DF Cardiac tamponade
04DG Aortic valve stenosis or insufficiency:2
04DH Mitral valve stenosis, regurgitation, or prolapse:2
04DI Other valve defect:2
04DJ Prosthetic valve malfunction:2
04DK Cardiomyopathy (without IHD or CHF)

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

5. HYPERTENSION (HTN)/HYPOTENSION

05DA Hypertensive crisis or accelerated HTN
05DB Hypotensive crisis or accelerated hypotension

6. CEREBRAL VASCULAR DISEASE (CVD)

06DA Cerebral vascular accident (CVA)
06DB Carotid artery stenosis:2
06DC Cerebral artery aneurysm:2
06DD Subarachnoid or cerebral hemorrhage
06DE Other cerebrovascular disease

7. PERIPHERAL VASCULAR DISEASE (PVD)

07DA Hemorrhage from ruptured vascular aneurysm
07DB Peripheral vascular disease (atherosclerotic):2
07DC Deep vein thrombosis (DVT):2
07DD Pulmonary embolism (PE)
07DE Abdominal aortic aneurysm (AAA):2
07DF Thoracic aortic aneurysm (TAA):2
07DG Aortic aneurysm (not specified as AAA or TAA):2
07DH Other aneurysm:2
07DI Arterial embolism and thrombosis
07DJ Mesenteric ischemia or infarction/ischemic bowel
07DK Gangrene with septicemia-shock due to PVD *
07DL Polyarteritis nodosa and other arteritides:2
07DM Other disorders of arteries:2

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

08DA Diabetes mellitus, Type I (insulin dependent):2
08DB Diabetes mellitus, Type II (non insulin dependent, could be insulin required):2
08DC Diabetes mellitus, type unclassified or unknown:2
08DD Diabetes with ketoacidosis
08DE Diabetes with hyperosmolar state or coma (hyperglycemia)
08DF Diabetes with other coma
08DG Hypoglycemia coma
08DH Diabetic foot infection *
08DI Hypothyroidism:2
08DJ Disorders of the thyroid gland:2
08DK Other endocrine disorder:2
08DJ Hyperparathyroidism:2
08DK Hypoparathyroidism:2
08DL Other disorder of calcium and phosphorus metabolism

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

9. RESPIRATORY DISEASES

09DA Asthma
09DB COPD exacerbation
09DC Bronchitis (chronic):2
09DD COPD:2
09DE Pneumonia (community acquired)*
09DF Pneumonia (nosocomial)*
09DG Pneumonia-sepsis*
09DH Pneumonia (bacterial)*
09DI Pneumonia (fungal)*
09DJ Pneumonia (viral)*
09DK Pneumocystic pneumonia*
09DL Pneumonia (unspecified pathogen)*
09DM Empyema*
09DN Lung abscess*
09DO Pneumothorax
09DP Pulmonary hemorrhage
09DQ Cor pulmonale:2
09DR Pulmonary TB*
09DS Aspiration pneumonia
09DT Adult Respiratory Distress Syndrome (ARDS)
09DU Respiratory failure of unknown cause
09DV Sleep apnea:2
09DW Other respiratory cause

10. MALIGNANCY

10DA Hematologic malignancy (AML, CML, ALL, CLL)
10DB Lymphoma (unspecified)
10DC Hodgkin's lymphoma
10DD Non-Hodgkin's lymphoma
10DE Multiple myeloma
10DF Colon cancer
10DG Breast cancer
10DH Prostate cancer
10DI Ovarian cancer
10DJ Lung cancer
10DK Gastric cancer
10DL Pancreatic cancer
10DM Thyroid cancer
10DN Cervical cancer
10DO Endometrial cancer
10DP Primary cancer of the liver
10DQ Head and neck squamous cell carcinoma
10DR Testicular cancer

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

10DS Renal cancer
10DT Bladder cancer
10DU Melanoma
10DV Other skin cancer
10DW Other malignancy or neoplasia
10DX Metastatic cancer with unknown primary

11. HEPATOBILIARY DISEASES

11DA Hepatitis B
11DB Hepatitis C
11DC Toxic/drug induced hepatitis
11DD Hepatitis (other unknown cause)
11DE Cirrhosis:2
11DF Ascites:2
11DG Portal hypertension or esophageal varices:2
11DH Hemorrhage from esophageal varices
11DI Hepatic (liver) failure/severe hepatic dysfunction
11DJ Polycystic liver disease:2
11DK Cholecystitis/cholangitis*
11DL Biliary sepsis*
11DM Other hepatobiliary disease

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

12DA Wegener's granulomatosis
12DB Systemic vasculitis
12DC Rheumatoid arthritis:2
12DD Systemic lupus erythematosus (SLE)
12DE Osteomyelitis*
12DF Septic arthritis*
12DG Osteoporosis:2
12DH Bone fracture(s):2
12DI Renal osteodystrophy:2

13. GASTROINTESTINAL CONDITIONS (GI)

13DA Upper GI bleed
13DB Lower GI bleed
13DC GI bleeding, site unknown
13DD Peptic ulcer disease:2
13DE Gastritis:2
13DF Diverticulosis:2
13DG Ulcerative colitis (UC):2
13DH Enteritis (Crohn's disease):2
13DI Perforation of peptic ulcer
13DJ Perforation of bowel

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

13DK Diverticulitis*
13DL Necrotizing enterocolitis*
13DM *C. difficile* associated enterocolitis*
13DN Peritonitis*
13DO Appendicitis*
13DP Septicemia due to peritonitis*
13DQ Fungal peritonitis*
13DR Pancreatitis
13DS Intra-abdominal abscess*
13DT Arteriovenous malformation (AVM)- is this the correct category?
13DU Other GI condition:2

14. NONVASCULAR NERVOUS SYSTEM DISEASES
14DA Dementia (Alzheimer's):2
14DB Dementia (other, unknown, including dialysis dementia):2
14DC Seizure disorder (chronic):2
14DD Seizure episode
14DE Depression:2
14DF Suicide (not due to withdrawal from dialysis, which is code 23DA)
14DG Drug overdose (alcohol/drug abuse--street drugs or other non-accidental chemical abuse)
14DH Subdural or epidural hematoma (spontaneous or traumatic)
14DI Meningitis (non viral, bacterial, or fungal or TB)*
14DJ Brain abscess*
14DK Other CNS infection*
14DL Head trauma (brain injury)
14DM Ischemic brain damage, anoxic encephalopathy
14DN Other psychiatric or mental disorder:2
14DO Parkinson's disease:2
14DP Multiple sclerosis (MS):2
14DQ Other demyelinating diseases of CNS:2
14DR Cranial or peripheral nerve disorder:2
14DS Other nonvascular nervous system condition

15. URINARY TRACT CONDITIONS
15DA Urinary tract infection (chronic UTIs):2
15DB UTI-septicemia*
15DC Nephrolithiasis:2
15DD Prostatitis*
15DE Benign prostatic hypertrophy:2
15DF Orchitis*
15DG Cystic kidney disease (PKD or acquired):2
15DH Cyst-related hemorrhage
15DI Cyst-related infection*
15DJ Urinary tract hemorrhage

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

15DK Hemorrhage from renal transplant site
15DL Other renal and urologic condition (excluding ESRD)

16. HIV/AIDS
16DA HIV positive (not AIDS)
16DB AIDS
16DC AIDS-related infection
16DD Other AIDS-related condition (not infection)

17. OPHTHALMOLOGIC CONDITIONS
17DA Endophthalmitis*
17DB Legally blind:2

18. INFECTIONS (NOT ACCESS RELATED)
18DA Abscess (not recorded in previous category)*
18DB Other infection (not recorded in previous category)*
18DC Septic shock*
18DD Septicemia (bacteremia) (known source, not access related)*
18DE Septicemia (bacteremia) (unknown source, not access related)*
18DF Extrapulmonary TB*
18DG Miliary TB*
18DH Disseminated candida infection*
18DI Other fungal infection*
18DJ Viral infection (CMV)*
18DK Other viral infection (not hepatitis)*
18DL Protozoan or parasitic infection (not PCP)*

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS
19DA Anemia:2
19DB Bone marrow depression:2
19DC Leukocytopenia:2
19DD Coagulation disorder:2
19DE Thrombocytopenia:2
19DF Disseminated Intravascular Coagulation (DIC)
19DG Other consumption coagulopathy:2
19DH Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)
19DI Other non-malignant hematologic condition

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS
20DA Septicemia (bacteremia) access related*
20DB Hemorrhage from vascular access
20DC Venous thrombosis access related:2
20DD Arterial thrombosis or embolism access related

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

20DE Other access infection
20DF Other complication of temporary access placement

21. OTHER HEMODIALYSIS COMPLICATIONS
21DA Hemorrhage from dialysis circuit
21DB Air embolism
21DC Anaphylaxis, treatment related
21DD Hemolysis, treatment related
21DE Electrolyte and acid-base disorder, treatment related (other than hyperkalemia)
21DF Dialysis-induced hypotension
21DG Other accident related to treatment

22. OTHER SURGICAL COMPLICATIONS
22DA Hemorrhage from surgery
22DB Complications from surgery
22DC Complications from anesthesia

23. OTHER
23DA Withdrawal from dialysis:2
23DB Other hemorrhage
23DC Cachexia
23DD Other trauma
23DE Drug overdose (accidental)
23DF Accident unrelated to treatment
23DG Drug reaction, anaphylaxis
23DH Drug reaction, not anaphylaxis, not overdose
23DI Other electrolyte and acid-base disorder (not related to hemodialysis treatment)
23DJ Homicide
23DK Refusal of lifesaving therapy
23DL Multi-organ system failure (pt. in ICU):2
23DM Multi-organ system failure (pt. not in ICU):2
23DN Multi-organ system failure (therapy induced):2
23DO Multi-organ system failure (not therapy induced):2
23DP Natural cause
23DQ Patient ever on immunosuppressive therapy

24. UNKNOWN
24DA Sudden death, unknown cause
24DB Other death, unknown cause

25. HYPERTENSIVE CARDIOVASCULAR DISEASE (HCVD)
25DA Hypertensive cardiovascular disease

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.
An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

Frequent Hemodialysis Network
ADVERSE REACTION FORM - FORM #307

Instructions: This form is completed for adverse events (AE) that do not meet the criteria for serious adverse events (SAE). For serious adverse events, complete Form 308.

It is up to the PI's clinical judgment to decide when an adverse event has occurred. You should file an adverse event form when the Clinical Center Study Team (PI and Study Coordinator) feels that the patient has had an event (such as, a sign, symptom or disease) that the Study Team feels is important. Each Clinical Center should follow its own local IRB's procedures for local reports of AE's and SAE's.

All adverse events occurring after randomization should be reported. During baseline, complete and enter a Form 307 only if the AE was caused by the FHN trial.

1. Participant ID # 2. Alpha Code

3. Date of onset: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

4. Date of initial report ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

Adverse Event Description: Record diagnoses and/or signs and/or symptoms below. The database will allow as many other conditions and MedDRA code numbers as needed for the AE report. Conditions and MedDRA codes you may see include, but are not limited to: hemorrhage (MedDRA code 10019595), device leakage (MedDRA 10012587), infection (MedDRA code 10021789), air embolism (MedDRA code 10001526).

Condition	MedDRA Code
5a.	
5b.	
5c.	

6. Has there been a prior history of similar event?.....__
0=No, 1=Yes, 9=Unknown

7.a. In the Clinical Center PI's judgment, was this event caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol?.....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely

Note: If the answer to question 7a was possibly, probably, or definitely, indicate in your description of the AE (Item #9) if the AE was caused by the hemodialysis machine, blood tubing sets, dialyzers, dialysate, central venous catheters or enuresis alarms for detecting blood leaks.

If this event was possibly, probably, or definitely related to study device, write the model name and model number of the dialysis machine used in the text field.

b. In the Clinical Center PI's judgment, was this event caused by the patient's randomly assigned dialysis regimen? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not applicable if participant is in baseline.

7. c. If the event was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent? .....__
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

8. Action taken.....__
0=None, 1=Permanent discontinuation (complete Form 301), 2=Other

9. Please write a brief summary of what happened and what action was taken.

10. Outcome of event *(This can be updated later - weekly reports and routine inquiries will remind the physician/coordinator to complete this form)* .....__
0=Recovered without treatment
1=Recovered with treatment
2=Event continuing without treatment
3=Event continuing and controlled with treatment
4=Event continuing and not controlled with treatment
5=Participant died (Be sure to complete Forms 305 and 306.)
6=Not yet available

11. Date of outcome..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

12. Date clinical center became aware of the outcome (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

13. Please write a brief summary of the outcome:

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

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

For Clinical Center Use Only:

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

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

Frequent Hemodialysis Network
SERIOUS ADVERSE REACTION FORM - FORM #308

Instructions: This form is completed for serious adverse events (SAE). The definition of "serious" is that the event results in death, or is life threatening, or requires inpatient hospitalization or prolongation of existing hospitalization, or results in a persistent or significant/incapacity, or results in congenital anomaly/birth defect, or any medical event which requires treatment to prevent one of the medical outcomes listed above.

- For non-serious adverse events, complete Adverse Event Form 307 instead of this form.
- For hospitalizations, complete Forms 302 and 303 in addition to this form.
- In the event of a patient death, complete Forms 305 and 306 in addition to this form.

1. Participant ID # 2. Alpha Code

3. a. Date of onset: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

b. Date Clinical Center learned of the SAE..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

4. **SAE Categorization**: (Code 0=No, 1=Yes)

a. Did the patient die? .....__

b. Was the event life threatening? .....__

c. Was there a hospitalization? .....__

c.1. Date of hospitalization: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

Be sure to complete and enter Forms 302 and 303.

d. Was there prolongation of existing hospitalization? .....__

e. Did the event result in a persistent or significant incapacity? .....__

f. Did the event result in a congenital anomaly/birth defect? .....__

g. Was this a medical event which required treatment to prevent one of the medical outcomes listed above? .....__

SAE Description: Record diagnoses and/or signs and/or symptoms below. The database will allow as many other conditions and MedDRA code numbers as needed for the SAE report.. Conditions and MedDRA codes you may see include, but are not limited to: hemorrhage (MedDRA code 10019595), device leakage (MedDRA 10012587), infection (MedDRA code 10021789), air embolism (MedDRA code 10001526).

Condition	MedDRA Code
5a.	
5b.	
5c.	

6. Has there been a prior history of similar event?.....__
(0=No, 1=Yes, 9=Unknown)

7. a. In the Clinical Center PI's judgment, was this event caused by any device, procedure, or intervention that was specifically done as part of the FHN Trial Protocol? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely
Note: If the answer to question 7a was possibly, probably, or definitely, indicate in your description of the SAE (Item #9) if the SAE was caused by the hemodialysis machine, blood tubing sets, dialyzers, dialysate, central venous catheters or enuresis alarms for detecting blood leaks.
If this event was possibly, probably, or definitely related to study device, write the model name and model number of the dialysis machine used in the text field.

b. In the Clinical Center PI's judgment, was this event caused by the patient's randomly assigned dialysis regimen? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely

c. If the event was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent? .....__
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

8. Action taken.....__
0=None
1=Permanent discontinuation (If transplanted, complete F313. If expired, complete F305, F306)
2=Other

9. Please write a brief summary of what happened and what action was taken

Outcome of event on page 3

10. Outcome of event .....__
    0=Recovered without treatment
    1=Recovered with treatment
    2=Event continuing without treatment
    3=Event continuing and controlled with treatment
    4=Event continuing and not controlled with treatment
    5=Participant died (Be sure to complete Form 306.)
    6=Not yet available

11. Date of outcome..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

12. Date clinical center became aware of the outcome (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

13. Please write a brief summary of the outcome

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

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

For Clinical Center Use Only:

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

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

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)

_____

_____

_____

_____

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

Frequent Hemodialysis Network
DETECTED THERAPY DEVIATION - FORM #310

This form should be completed following each calendar month in which the patient missed four or more dialysis sessions, or in which the actual treatment time averaged at least 30 minutes below the minimum allowable time over a period of 1 week or greater 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 does not need to be completed if a Form 309 - Planned Therapy Deviation was completed for the given month.

1. Participant ID #   2. Alpha Code   3a. Visit Type   3b. Visit Number   4. Date of 1st Detected Deviation: 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 missed 4 or more treatments (from randomized treatment assignment) during the next month: .... __
   b. The patient missed an average of at least 30 minutes or more treatment time for a period of at least 1 week: .... __
   c. The patient had 4 or more extra treatments (from randomized treatment assignment) in a given month........ __
   d. Nocturnal Trial only: the patient received some dialysis in-center this month instead of at home .... __
6. 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
7. Was the deviation the result of a hospitalization or travel or some other life event that precluded adherence? (0=No, skip to Q9, 1=Yes, answer Q8) .... __
8. If Q7 is Yes, indicate which of the following apply: (For 8a-b: use 0=No, 1=Yes)
   a. Hospitalization? (Be sure to complete Forms 302, 303)........ __
   b. Travel? .... __

   (Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)
9. Was deviation the result of a medical decision by a physician?........ __
   (0=No, skip to Q11, 1=Yes, answer Q10)
10. If Q9 is Yes, indicate which of the following apply: (For 10 a-h, se 0=No, 1=Yes)
    a. Hypotension?........ __
    b. Phosphate depletion?........ __
    c. Patient fatigue?........ __

(Q10 d-h, Medical reasons continued on next page)

Q10 (deviation due to medical reason continued: Code 0=No, 1=Yes)

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

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

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 (Q17) ..... __
(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)

11. Was the deviation the result of patient non-adherence? ..... __
(0=No, skip to Q13, 1=Yes, answer Q12, 2=Yes, other reason explained in Q17)

12. If Q11 is Yes, indicate which of the following apply: (For 12a-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)

13. Was the deviation the result of logistical or scheduling issues with the dialysis unit? (0=No, skip to Q15, 1=Yes, answer Q14) ..... __

14. If Q13 is Yes, indicate which of the following apply: (For 14a-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)

15. Was the deviation the result of logistical or other issues with performing dialysis in the home? (0=No, skip to Q17, 1=Yes, answer Q16) ..... __

16. If Q15 is Yes, indicate which of the following apply: (For 16a-c: use 0=No, 1=Yes)

a. Dialysis machine breakdown? ..... __

b. Water treatment breakdown or other plumbing issue? ..... __

c. Lack of dialysis supplies? ..... __
(Email the DCC at fhn-dcc@bio.ri.ccf.org if an additional reason is identified)

17. Other Comments: Please describe what is going on with this patient (Use the back of the paper form, if needed). (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 this form: __ __ __ __ __ __ __ __

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

Frequent Hemodialysis Network
CENTRAL HOLTER READING FACILITY
CLINICAL ALERTS FORM - FORM #311

This form is to be completed and entered by the Central Holter Reading Facility when a clinical alert(s) has been identified.

1. Participant ID #	2. Alpha Code	3. Start date of Holter: dd/mon/yyyy

4. Date data received at central facility..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

5. Date data read at central facility ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

6. Username of person reading the Holter. .....__ __ __ __ __ __ __ __

Clinical Alerts (For items 7-13: 0=No, 1=Yes)

7. Ventricular tachycardia? ..... __

8. Torsades de pointes?.....__

9. AV block 2b? ..... __

10. AV block 3?.....__

11. Sinus arrest or SA blocks? ..... __

12. Atrial fibrillation? .....__

13. Other significant clinical finding? .....__

14. Comments: _____

_____

_____

_____

_____

_____

For Central Holter Reading Facility Use Only:

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

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

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

Frequent Hemodialysis Network
CENTRAL CARDIAC MRI FACILITY
CLINICAL ALERTS FORM - FORM #312

This form is to be completed and entered by the Central Cardiac MRI Facility when a clinical alert(s) has been identified.

1. Participant ID # 2. Alpha Code 3. Date of MRI: dd/mon/yyyy

4. Date data received at central facility: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

5. Date data read at central facility: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

6. Username of person reading the cardiac MRI: .....__ __ __ __ __ __ __

Clinical Alerts (For items 7-11: 0=No, 1=Yes)

7. Lung mass? ..... __

8. Esophageal mass? .....__

9. Cardiac mass? ..... __

10. Large pericardial effusion? .....__

11. Other significant clinical finding? .....__

12. Comments: _____

_____

_____

_____

_____

_____

For Central Cardiac MRI Facility Use Only:

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

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

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

Frequent Hemodialysis Network
POST RANDOMIZATION PATIENT TRANSPLANT OR PERITONEAL DIALYSIS FORM #313

Instructions: This Form 313 should be completed by a study coordinator when a randomized patient has a renal transplant or switches to peritoneal dialysis.

1. Participant ID # 2. Alpha Code 3. Event Date: dd/mon/yyyy

4. What patient event are you reporting? .....__
   1=Patient received a kidney transplant
   2=Patient switched to peritoneal dialysis

5. Briefly describe what happened in the text field below, noting especially whether this event could have been predicted. (Use back of sheet if necessary.)

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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

Frequent Dialysis Network
TRANSFER FORM - FORM # 400

This form is completed whenever a participant transfers to another FHN ***clinical center or participating dialysis unit.*** . This form is completed at the participating site and faxed to the DCC at 216-445-2781 for data entry.

1. Participant ID Number 2. Alpha Code

3. Date of transfer .....(dd/mmm/yyyy) __ __/__ __ __/__ __ __ __

4. a. Clinical Center number where participant is transferring to.....__ __

   b. Dialysis unit number where participant is transferring to .....__ __ __ __

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

201. Username of person completing this form .....__ __ __ __ __ __ __ __

For DCC Use Only:

Date transferred out of FHN: (dd/mmm/yyyy) ____ ____ /____ ____ ____/____ ____ ____ ____

Date received at the DCC (dd/mmm/yyyy) ____ ____ /____ ____ ____/____ ____ ____ ____

Username of DCC person entering this form ___ ___ ___ ___ ___ ___ ___ ___

This page will be printed out separately so that the DCC does not receive confidential information

Participant Information
(May be written on another sheet.)

Stored locally. Not key entered into the study database. Do not forward this information to the DCC.

Name of participant: _____

Address: _____

Address: _____

Phone number: _____

Alternate contact: _____

Physicians' names: _____

Contact information: _____

Frequent Dialysis Network

RE-ENROLLMENT OF A PREVIOUSLY ENROLLED PATIENT FORM - FORM # 401

This form is completed whenever a previously enrolled participant re-enrolls in the FHN trial. You will need to fax this form to the DCC (216-445-2781) in order for it to be entered into the database. Fax only Form 401 to the DCC.

1. Participant ID Number 2. Alpha Code

3. Date dropped:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

Before faxing this Form 401 to the DCC, you must have the following forms fully completed and ready to re-enroll: 100/110, 202,206, 273, and 274.

Identify the date these new forms were completed:

4. a. Form 100/110 completed date:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

b. Form 202 completed date:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

c. Form 206 completed date:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

d. Form 273 completed date:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

e. Form 274 completed date:..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

5. Date re-enrolled: ..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __
(Use visit date from the Form 100/110)

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

201. Username of person completing this form.....__ __ __ __ __ __ __

For DCC Use Only:

Date received at the DCC (dd/mon/yyyy): __ __ /__ __ __/__ __ __ __

Username of DCC person entering this form: __ __ __ __ __ __ __

Frequent Hemodialysis Network
CANADIAN CENTERS VITAL STATUS FORM - FORM #404

This form should be completed for randomized patients who have reached a point in the study where **only vital and dialysis status is available**. This form should be completed semi-annually based on their date of randomization.

1. Participant ID # 2. Alpha Code

3. Status date (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __
Status date refers to the most current date when a patient's status (alive or dead) is known.

4. Vital Status (0=Dead, 1=Alive) .....__
Check with your province's department of vital statistics to determine the vital status of each patient.

5. Dialysis status: .....__ __
Patient is:
0 = Dead
1 = Currently refusing any dialysis
2 = Currently refusing dialysis "as prescribed"
3 = Currently on in-center hemodialysis 3 times per week
4 = Currently on in-center hemodialysis 4-5 times per week
5 = Currently on in-center hemodialysis 6 times per week
6 = Currently on in-center hemodialysis elsewhere
7 = Currently on home 3x/wk during the day hemodialysis
8 = Currently on home nocturnal hemodialysis
9 = Currently on peritoneal dialysis
10= Had a kidney transplant
11= Regained renal function
12=Pt receiving short daily dialysis (< 4 hrs/day for 5-6 days/week)

(If there was some other reason, contact the DCC and a new code will be provided)

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

Frequent Hemodialysis Network
END OF TRIAL PATIENT STATUS FORM - FORM #405

Instructions: The DCC will provide each clinical center with a list of randomized patient who are alive (not identified as having died) and still on hemodialysis (not identified as having switched to PD or transplanted) according the DCC's database. Find each of these patients and ask them to participate in the Extended Follow-up Study.

This end-of-trial status form is used to capture information on each randomized patient's vital and dialysis status now or at the last time you could find the patient. This form also identifies which patients have consented to the Extended Follow-up Study.

1. Participant ID # 2. Alpha Code

3. Vital Status (0=Dead, 1=Alive/not known to have died) ..... __

4. Status date (dd/mon/yyyy)..... __ __/__ __ __/__ __ __ __
Status date is death date for those who have died or the last date the patient was known to be alive for everyone else.(If you just asked someone to consent to the extended follow-up study, the status date would be the date you asked the patient to consent. If a patient is lost, the status date would be the last date the patient was known to be alive, the last date anyone on the FHN team spoke to him or her.)

5. Usual dialysis pattern (as of date this form completed): ..... __ __
1 = Refusing any dialysis
2 = in-center hemodialysis, 2-3 times per week
3 = in-center hemodialysis, 4-5 times per week
4 = in-center hemodialysis, 6-7 times per week
5 = in-center nocturnal hemodialysis, 2-3 times per week
6 = in-center nocturnal hemodialysis, 4-5 times per week
7 = in-center nocturnal hemodialysis, 6-7 times per week
8 = in-center hemodialysis, no further information available
20 = at-home during the day hemodialysis, 2-3 times per week
21 = at-home during the day hemodialysis, 4-5 times per week
22 = at-home during the day hemodialysis, 6-7 times per week
23 = at-home nocturnal hemodialysis, 2-3 times per week
24 = at-home nocturnal hemodialysis, 4-5 times per week
25 = at-home nocturnal hemodialysis, 6-7 times per week
26 = at-home hemodialysis, no further information available
30 = On peritoneal dialysis
31 = Had a kidney transplant
98 = We know patient is alive but dialysis status is unknown.
99 = Unknown. We cannot find this patient.

If response to Q5 is 30 or 31, skip to Q200 at end of form.

6. If response to Q5=98 or 99, describe how you tried to determine dialysis status or tried to find the patient. Include the date that you searched the Social Security Death Index (try http://ssdi.rootsweb.ancestry.com) and who did the search. Include the price paid for peoplefinder or another in-person or on-line search. Include family members and neighbors a team member spoke to, which team member spoke to them and when the team member spoke to them. *(see next page)*

*Q6, cont.*_____

_____

_____

_____

_____

It is recommended that randomized patients alive and still on hemodialysis, according to the DCC's database, be asked to consent to the extended follow-up study. *If a patient cannot be asked, this can be documented in Q11.*

7. Extended Follow-up Study Consent: ..... __
   1=Patient was not asked to consent to the extended follow-up study
   2=Patient was asked but did **not** consent to the extended follow-up study
   3=Patient consented to the extended follow-up study
   4=Dialysis Unit is not participating in FHN Extended Follow-up Study

Complete Q8 and Q9 for those asked to consent:

8. Username of FHN person who asked patient to consent: ..... __ __ __ __ __ __ __

9. Consent status date (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __
   (Use date asked for those who did not consent and date of consent for those who consented.)

Complete Q10 if the patient consented to the extended follow-up study:

10. Patient response: Repository Consent ..... __
    0=No; Patient did **not** consent to serum/plasma sample collection for storage at Biorepository.
    1=Yes; Patient consented to serum/plasma sample collection for storage at Biorepository.

Complete Q11 if the patient was not asked to consent (Q7 = 1) or if the patient did not consent to the extension (Q7 = 2) or if the patient consented to extension but not repository storage (Q10 = 0).

11. Explain why patient was not asked or not consenting to extended follow-up study or sample collection:

_____

_____

_____

_____

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

FREQUENT HEMODIALYSIS NETWORK
Consent for Repositories Form - Form #406

This form should be completed for all individuals who were asked to participant in the Repository collections, **even if they refused**. If a participant was asked to participate in the Repository collections and refused, complete questions 1, 2, 3, 200 and 201.

1. Participant ID # 2. Alpha Code

3. Did the participant consent for collection of biological specimens (serum) on a consent form that has been approved by the NIDDK repository leadership? (0=No, 1=Yes) ..... __

4. Date biological specimens consent signed:(dd/mon/yyyy)..... __ __ /__ __ __ /__ __ __ __

DCC Use Only:

5. Date patient withdrew consent to store samples in repository? ..... __ __/__ __ __/__ __ __ __

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

Frequent Hemodialysis Network
OUTCOMES COMMITTEE HOSPITALIZATION REVIEW - FORM #501

This form is to be completed by the assigned Outcomes Committee (OC) member.

1. Participant ID # | 2. Alpha Code | 3a. Date of hospital admission: dd/mon/yyyy

OC Member reviews the hospitalization and re-checks whether it was a CV or access-related hospitalization.

Transplant Status

3b. Transplant hospitalization status..... __
1=There was no transplant during this hospitalization.
2=There was a transplant and new kidney is functioning. Patient no longer requires dialysis.
3=There was a transplant but it failed. Patient still requires dialysis.
4=There was a transplant, but the new kidney had delayed graft function. Patient required dialysis at time of hospital discharge.

Access Related Issues

4. Access Hospitalization Status..... __
1=This was a "Non-Access hospitalization," admitted for a problem unrelated to access.
2=Admitted for an access problem, "Access hospitalization," without non-access complications.
3=Admitted for an access problem, "Access hospitalization," with non-access complications that were not due to access problems.
4=This was an "Access hospitalization" with non-access complications that were due to access problems.

5. **Cardiovascular disease** (For 5a-e: 0=No, 1=Yes**)**

a. Was there new onset of or worsening angina pectoris or ischemic heart disease? ..... __

b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)? ..... __

c. Was there a myocardial infarction? ..... __

d. Was there new onset of or worsening arrhythmias? ..... __

e. Was there new onset of or worsening other heart disease (exclude pericarditis) ..... __

(Note - if any of the above are "Yes", this was a cardiovascular hospitalization)

Hospitalization for Infection (Code 0=No, 1=Yes**)**

6. a. Was there bacteremia or sepsis? ..... __

b. Was there organ or deep tissue infection (serious)? ..... __

(Note – if either of the above are true, this was an infection hospitalization)

Trial Relatedness

7. a. In the Reviewer's judgment, was this event caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol? ..... __
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

Question 7 continued on next page

*Not Applicable – Extended Follow-Up Study Only.

Q7, continued

If the answer to question 7a was possibly, probably, or definitely, was the AE/SAE caused by: (Code 0=No, 1=Yes)

7.a.1. Hemodialysis machine .....__
7.a.2. Blood tubing sets: .....__
7.a.3. Dialyzer:.....__
7.a.4. Dialysate: .....__
7.a.5. Central venous catheter:.....__
7.a.6. Enuresis alarms for detecting blood leaks.....__
7.a.7. Dialysis needles: .....__

b. In the Reviewer's judgment, was this event caused by the patient's randomly assigned dialysis regimen? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

c. If the event was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent? .....__
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent
8=Not Applicable*

Treatment Arm

8. Which treatment arm did the Outcomes Committee Reviewer think the patient was randomized to? .....__
1=Definitely standard (3x) arm
2=Probably standard (3x) arm
3=Could not determine
4=Probably frequent (6x) arm
5=Definitely frequent (6x) arm

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

201. Username of Outcomes Committee Reviewer completing of this form .....__ __ __ __ __ __ __

For DCC Use Only:

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

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

Based on OC Review:

204. Hospitalization Code - Primary Reason: __ __ __ __ __

205. Hospitalization Code - Secondary Reason: __ __ __ __ __

206. Hospitalization Code - Other Reason: __ __ __ __ __

*Not Applicable – Extended Follow-Up Study Only.

Frequent Hemodialysis Network
OUTCOMES COMMITTEE PATIENT DEATH REVIEW - FORM #503

This form is to be completed by the assigned Outcomes Committee (OC) reviewer.

1. Participant ID # | 2. Alpha Code | 3a. Date of death: dd/mon/yyyy

3b. Was this death the outcome of a reported hospitalization? ..... __
0=No, patient not hospitalized at time of death
1=Yes, patient hospitalized at time of death, complete item 3b.1.

3. b.1. Hospital admission date: ..... __ __/__ __ __/__ __ __ __
dd/mon/yyyy

3c. **Transplant** status ..... __
1=There was no transplant at time of death.
2=There was a transplant and new kidney was functioning. Patient no longer required dialysis at time of death.
3=There was a transplant but it failed. Patient still required dialysis at time of death.
4=There was a transplant, but the new kidney had delayed graft function. Patient required dialysis at time of death.

4. **Access** Death Status ..... __
1=This was a "Non-Access death"
2="Access death," without non-access complications.
3="Access death," with non-access complications that were not due to access problems.
4="Access death" with non-access complications that were due to access problems.

5. Death due to **Cardiovascular** disease (For 5a-e: 0=No, 1=Yes**)**
a. Was there new onset of or worsening angina pectoris or ischemic heart disease? ..... __
b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)? ..... __
c. Was there a myocardial infarction? ..... __
d. Was there new onset of or worsening arrhythmias? ..... __
e. Was there new onset of or worsening other heart disease (exclude pericarditis) ..... __
(Note - if any of the above are "Yes", this was a cardiovascular death)

6. Death due to **Infection** (Code 0=No, 1=Yes**)**
. a. Was there bacteremia or sepsis? ..... __
b. Was there organ or deep tissue infection (serious)? ..... __
(Note – if either of the above are true, this was an infection death)

Trial Relatedness

7. a. In the Reviewer's judgment, was this death caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol? ..... __
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

Question 7 continues on next page

*Not Applicable – Extended Follow-Up Study Only

Q7 continued

If the answer to question 7a was possibly, probably, or definitely, was the AE/SAE caused by: (Code 0=No, 1=Yes)

7.a.1. Hemodialysis machine ..... __
7.a.2. Blood tubing sets: ..... __
7.a.3. Dialyzer: ..... __
7.a.4. Dialysate: ..... __
7.a.5. Central venous catheter: ..... __
7.a.6. Enuresis alarms for detecting blood leaks ..... __
7.a.7. Dialysis needles: ..... __

b. In the Reviewer's judgment, was this death caused by the patient's randomly assigned dialysis regimen? ..... __
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

c. If the death was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent? ..... __
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent
8=Not Applicable*

Treatment Arm

8. Which treatment arm did the Outcomes Committee Reviewer think the patient was randomized to? ..... __
1=Definitely standard (3x) arm
2=Probably standard (3x) arm
3=Could not determine
4=Probably frequent (6x) arm
5=Definitely frequent (6x) arm

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

201. Username of Outcomes Committee Reviewer completing of this form ..... __ __ __ __ __ __ __

For DCC Use Only:

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

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

Based on OC Review:

204. Death Code - Primary Reason: __ __ __ __ __

205. Death Code - Secondary Reason: __ __ __ __ __

206. Death Code - Other Reason: __ __ __ __ __

*Not Applicable – Extended Follow-Up Study Only

Frequent Hemodialysis Network
STUDY STAFF INFORMATION FORM - #600

Instructions: Complete and enter this form for each member of your study staff. All information on this form will be used to create a separate report.

This form keeps track of your phone numbers and shipping addresses so you will need to make sure that these contact items are kept up to date. You may update study staff records at any time and as many times as needed. Updates will be forwarded to DCC staff for the address directory and aliases, as needed.

The first time a staff member's information is entered, you can just start entering information. If you need to update any information for a staff member that is already entered in the system, use F7 to query up the record (Click on Enter Query [or F7], type individual's last name, click on Execute Query [or F8]).

Note: If an individual is no longer a member of the FHN team, you will need to go to Form 601, personnel table to inactivate the staff member status. This in turn, will inactivate any links on Form(s) 603.

For names, the computer will store 30 upper case characters.

1. Last name? ..... _____
2. First name? ..... _____
3. Middle initial or name? ..... _____
4. E-mail address: ..... _____
5. Office telephone number: .....(__ __ __) __ __ __-__ __ __ __
   (Note: Australian clinical center staff members need to complete item 10h-"Country" and the database will pull up the correct phone number format.)
6. Extension number: .....__ __ __ __ __
7. Fax number: .....(__ __ __)__ __ __-__ __ __ __
8. a. Pager number: .....(__ __ __)__ __ __-__ __ __ __

   b. Code number for pager, if needed: .....__ __ __ __ __ __ __ __ __ __
9. Cell phone number:.....(__ __ __)__ __ __-__ __ __ __
10. Mailing Address:
    a. Line 1: ..... _____
    b. Line 2: ..... _____
    c. Line 3: ..... _____
    d. Line 4: ..... _____
    e. City/Town: ..... _____
    f. State/Province: ..... _____

g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada, 3=Australia) ..... __

11. Federal Express Shipping Address: (required) *(telephone number used for shipping will be the one identified in Item #5, unless otherwise specified.)*

a. Line 1: ..... _____

b. Line 2: ..... _____

c. Line 3: ..... _____

d. Line 4: ..... _____

e. City/Town: ..... _____

f. State/Province: ..... _____

g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada, Australia) ..... __

12. Clinical Center number ..... __ __

13. For those with two centers, enter your second center number ..... __ __

14. Primary role in the FHN study? ..... __ __

01=Consortium Core Principal Investigator	10=Dialysis Unit Medical Director
02=Clinical Center Principal Investigator	11=Dialysis Unit Nurse
03=Co-Investigator	12=Dialysis Unit Staff Member
04=Consortium Core Study Coordinator	13=Lab Technician
05=Study Coordinator	14=Supervising Lab Technician
06=Study Nurse (other than coordinator)	15=Billing Staff Member
07=Supervising Cardiac MRI Physician	16=Data entry
08=MRI Technician	17=MRI facility administrator
09=Holter Technician	

200. Date this form initially completed for the staff member identified in Item1(dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

Display Only:

201. Date of most recent update (dd/mon/yyyy): __ __/__ __ __ /__ __ __ __

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

203. Date initially entered: (dd/mon/yyyy) __ __/__ __ __ /__ __ __ __

Frequent Hemodialysis Network
CLINICAL CENTER FORM - #601

Instructions: Complete this form for each clinical center. Names of each study facility have been provided to the Data Coordinating Center (DCC) and a specific number was assigned to each one. If you do not see the name of your Clinical Center (CC), contact the DCC. This form can be updated as many times as needed and should be kept current throughout the FHN Trial period.

To start entering on Form 601, you must first query up the CC you want to update. Use F7 to query up the record (click on Enter Query [or F7], type your CC number or use list of values, click on Execute Query [or F8]). All updates for your study's facilities should be made on this form. (For updates to individual staff members, use Form 600 to update pertinent information.)

Form updates will be forwarded to the DCC for various reports, FHN trial aliases and address directory. For names, the computer will store 30 upper case characters. Use this form to deactivate any staff member who no longer works on the FHN trial.

Before patients can be enrolled, you will need to complete other facility related forms, too:
Form 603 must be completed for each participating dialysis unit.
Form 602 must be completed to identify each local laboratory used to process lab specimens and provide results for the FHN trial. Form 602 for each Holter lab used in the Daily Study.
Form 604 identifies the Cardiac MRI Facilities associated with your clinical center and the dialysis units that will be using that MRI facility.

The information provided on this form and Forms 600, 602, 603 and 604 links all other facility and staff.

Use this form to inactivate former FHN staff members (Go to Q204-Saff Member Status. Place cursor on the row of the individual you want to inactivate, type in "2-inactive", In Q205-Status Date, identify the date the staff member stopped working on the FHN trial. Once saved, the database will inactivate this staff member on all other forms to which this individual was linked.

Section 1: Facility Information

1. Name of this facility?..... _____ __ __
   (Use list of values to pull up the name and number of the facility)

2. Facility Mailing Address: (required)

   a. Line 1: ..... _____
   b. Line 2: ..... _____
   c. Line 3: ..... _____
   d. Line 4: ..... _____
   e. City/Town: ..... _____
   f. State/Province: ..... _____
   g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada, 3=Australia) ..... __

3. Federal Express Shipping Address: (required)

a. Line 1: ..... _____

b. Line 2: ..... _____

c. Line 3: ..... _____

d. Line 4: ..... _____

e. City/Town: ..... _____

f. State/Province: _____

g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada, 3=Australia) ..... __

i. Telephone number: ..... __ __ __-__ __ __-__ __ __ __

j. Extension ..... __ __ __ __ __

IRB Information

4. Date protocol submitted to IRB/REB: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

5. IRB Assurance # ..... (Example: FWA 0000####) __ __ __ __ __ __ __ __ __ __ __

6. a. Date of IRB approval of main protocol: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

b. Date of IRB approval of protocol revision 2.1: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

c. Date nocturnal protocol v3.0 submitted to IRB: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

d. Date of IRB approval of nocturnal protocol revision 3.0: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

e. Daily: date pre-enrollment screening form submitted to IRB. (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

f. Daily: date IRB approved pre-enrollment screening form: .... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

(Send one blank copy of the approved consent form and one copy of the IRB approval letter to 1. your Consortium Core, 2. the Data Coordinating Center *and 3. the NIDDK repository*).

7. Date of submission of repository consent to NIDDK ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

8. Date of IRB approval for collection of repository biologic specimens: .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

9. Date of approval by NIDDK.....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

10. Date test repository kit approved by NIDDK staff: .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

SECTION 2. Personnel Linkage. The table in this section links all the facility and staff forms. Please review the instructions thoroughly before trying to complete this section as this table provides

the important links to other study forms that have already been entered.

A Form 600 must already be entered in the database for this person in order to complete this table.

200. Staff member's last name: Type in the last name of the staff member you want linked to this ..... clinical center.

201. Staff member's first name: Type in the first name of the staff member.

202. Staff ID number: This number will automatically populate this column once Q200 and 201 ..... are entered. You can use this id number to query up an individual if you need to update any ..... roles.

203. Role. Use the responses below to identify this individual's primary role at this dialysis unit.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility administrator

204. Staff member status: Use the following responses to record this person's status on the study.
1=Active (individual is actively participating as a member of the FHN study team)
2=Inactive (individual is no longer part of the FHN study team, no longer employed at this dialysis unit, etc.)

205. Date of staff member status: Provide the date when the staff member status changed using dd/mon/yyyy format.

206. Express shipping address: Use the following responses to provide the appropriate address to ..... be used
to ship items to this addressee.
1=Use this individual's shipping address provided on Form 600.
2=Use this unit's shipping address identified above in Item 3.
3=Use this unit's clinical center address identified on Form 603.

207. Mailing address: Use the following responses to provide the appropriate address to be used to ship items to this addressee.
1=Use this individual's mailing address provided on Form 600.
2=Use this unit's mailing address identified above in Item 2.
3=Use this unit's clinical center address identified on Form 603.

Table appears on page 4.

Last Name (200)	First Name (201)	Staff ID # (202)	Role in Study (203)	Staff Status (204)	Status Date (205)	Express Address (206)	Mailing Address (207)

Codes:

203. Role. Individual's primary role at this unit.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility administrator

204. Staff member status: 1=Active, 2=Inactive

206. Express shipping address: 1=Use this individual's shipping address provided on Form 600, 2=Use this center's shipping address identified in Item 3.

207. Mailing address: 1=Use this individual's mailing address provided on Form 600, 2=Use this center's mailing address identified in Item 2.

Frequent Hemodialysis Network
OTHER STUDY FACILITIES FORM - #602

Instructions: Please complete this Form 602 for any local biochemistry laboratory that may be used for the FHN Trial. If this is a local laboratory that is new to the FHN Trial, you will need to contact the Data Coordinating Center (*fhn-dcc@bio.ri.ccf.org*) for a pre-assigned laboratory number, prior to entering data into the database. Provide the name of the local lab, address and telephone number. Complete a separate Form 602 for each Holter lab used in the Daily Study. (Complete Form 604 for cardiac MRI facility.)

To start entering information on Form 602, you must first query up the laboratory you want to update. Use F7 to query up the record (click on Enter Query [or F7], type your lab number or use list of values, click on Execute Query [or F8]). All updates for your study's local laboratory(ies) should be made on this form.

The information provided on this form along with Form 603 links the dialysis unit. All updates for this facility should be made on this form. Updates will be forwarded to the DCC for various reports and address directory.

Section 1: Facility Information

1. Name of this facility?..... _____ __ __ __ __
2. What is this facility's primary function in the FHN study? .....__
   1=Biochemistry Laboratory
   2=Holter Monitoring Facility (Daily Study only)
3. Country: (1=U.S., 2=Canada, 3=Australia) ..... __
4. Telephone number: .....__ __ __-__ __ __-__ __ __ __

   If Item #2=Biochemistry Lab, complete Items #5-6; otherwise skip to Section 2.
5. Lower limit of normal range for parathyroid hormone at this lab:.....__ __ __ __
6. Upper limit of normal range for parathyroid hormone at this lab: .....__ __ __ __

Section 2. Dialysis Unit Linkage The table in this section links all the dialysis units that will be using this facility. Please review the instructions thoroughly before trying to complete this section as this table provides the important links to other study forms that have already been entered.

A Form 603 must already be entered in the database in order to complete this table.

200. Dialysis Unit Name: Enter name of Dialysis Unit (use list of values) you want linked to this facility.
201. Dialysis Unit ID number: This number will automatically populate this column once Q200 is entered.
202. Start date of this facility: Provide the date in dd/mon/yyyy format when the dialysis unit started using this facility.
203. End date of facility: Provide the date in dd/mon/yyyy format when the dialysis unit stopped using this facility.

Dialysis Unit Name (200)	DU ID# (201)	Start Date (202)	End Date (203)

Frequent Hemodialysis Network
DIALYSIS UNIT FORM - #603

Instructions: Each dialysis unit associated with your clinical center will have a separate form. The name of each dialysis unit (DU) has been provided to the Data Coordinating Center (DCC) and a specific number assigned to each one. If you do not see the name of the DU you want, contact the DCC. You only need to complete Section 3 only once. The other sections of this form should be updated as needed.

This form must be completed in its entirety before a dialysis unit (along with other information contained on other forms*) is considered ready to enroll patients. A Ready-To-Enroll report appears on the FHN Trial's information page under "Reports and Graphs."

To start entering information on Form 603, you must first query up the DU you want.. Use F7 to query up the record (click on Enter Query [or F7], type your DU number or use list of values, click on Execute Query [or F8]). All updates for your DU should be made on this form. (For updates to individual staff members, use Form 600 to update pertinent information.)

*Before patients can be enrolled, you will need to complete other facility related forms, too:
Form 603 must be completed for each participating dialysis unit.
Form 602 must be completed to identify each local laboratory used to process lab specimens and provide results for the FHN trial. Form 602 for each Holter lab used in the Daily Study.
Form 604 identifies the Cardiac MRI Facilities associated with your clinical center and the dialysis units that will be using that MRI facility.

Section 1: Dialysis Unit Information

101. Name of this unit?... _____ __ __ __ __
(Use list of values to pull up the name and number of the facility)

102. Unit's Mailing Address:

a. Line 1: ..... _____
b. Line 2: ..... _____
c. Line 3: ..... _____
d. Line 4: ..... _____
e. City/Town: ..... _____
f. State/Province: ..... _____
g. Zip/Postal Code: ..... _____
h. Country: (1=U.S., 2=Canada, 3=Australia) ..... __

103. Federal Express Shipping Address:

a. Line 1: ..... _____
b. Line 2: ..... _____
c. Line 3: ..... _____

d. Line 4: ..... _____

e. City/Town: ..... _____

f. State/Province: ..... _____

g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada, 3=Australia) ..... __

i. Telephone number: ..... __ __ __-__ __ __-__ __ __ __

j. Extension ..... __ __ __ __ __

IRB Information

104. Does this dialysis unit use the IRB specified on its clinical center's Form 601? .....__
0=No, complete items 105-110, 1=Yes, skip to Section 2

105. Date protocol submitted to IRB: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

106. IRB Assurance # .....(Example: FWA 0000####) __ __ __ __ __ __ __ __ __ __ __

107. a. Date of IRB approval of main protocol:..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

b. Date of IRB approval of protocol revision 2.1: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

c. Date nocturnal protocol v3.0 submitted to IRB: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

d. Date of IRB approval of nocturnal protocol revision 3.0: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

e. Daily: date pre-enrollment screening form submitted to IRB. (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

f. Daily: date IRB approved pre-enrollment screening form:.... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

(Send one blank copy of the approved consent form and one copy of the IRB approval letter to 1. your Consortium Core, 2. the Data Coordinating Center *and 3. the NIDDK repository*)

108. Date of submission of repository consent to NIDDK..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

109. Date of IRB approval for collection of repository biologic specimens: .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

110. Date of approval by NIDDK .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

SECTION 2. Personnel Linkage The table in this section links all the facility and staff forms.
Please review the instructions thoroughly before trying to complete this section as this table provides the important links to other study forms that have already been entered.

A Form 600 must already be entered in the database for this person in order to complete this table.

200. Staff member's last name: Type in the last name of the staff member you want linked to this site.

201. Staff member's first name: Type in the first name of the staff member.

202. Staff ID number: This number will automatically populate this column once Q200 and 201 are entered. .....You can use this id number to query up an individual if you need to update any roles.

203. Role. Use the responses below to identify this individual's primary role at this dialysis unit.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility administrator

204. Staff member status: Use the following responses to record this person's status on the study.
1=Active (individual is actively participating as a member of the FHN study team)
2=Inactive (individual is no longer part of the FHN study team, no longer employed at this dialysis unit, etc.)

205. Date of staff member status: Provide the date when the staff member status changed using dd/mon/yyyy format.

206. Express shipping address: Use the following responses to provide the appropriate address to be used to ship items to this addressee.
1=Use this individual's shipping address provided on Form 600.
2=Use this unit's shipping address identified above in Item 103.
3=Use this unit's clinical center address identified on Form 601.

207. Mailing address: Use the following responses to provide the appropriate address to be used to ship items to this addressee.
1=Use this individual's mailing address provided on Form 600.
2=Use this unit's mailing address identified above in Item #102.
3=Use this unit's clinical center address identified on Form 601.

Table appears on page 4 of this form.

Last Name (200)	First Name (201)	Staff ID # (202)	Role in Study (203)	Staff Status (204)	Status Date (205)	Express Address (206)	Mailing Address (207)

Codes:

203. Role. Individual's primary role at this unit.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility administrator

204. Staff member status: 1=Active, 2=Inactive

206. Express shipping address: 1=Use this individual's shipping address provided on Form 600, 2=Use this unit's shipping address identified in Item #103. 3=Use this unit's clinical center address identified on Form 601.

207.Mailing address: 1=Use this individual's mailing address provided on Form 600, 2=Use this unit's mailing address identified in Item #102. 3=Use this unit's clinical center address identified on Form 601.

Section 3. Dialysis Unit Details

Instructions: You will need to first obtain data prior to entering any data in this section. *You will only have to complete this once for each dialysis unit.*

301. If U.S. site, CMS/HCFA Provider Identification Number: .....__ __ __ __ __ __

302. Does this unit need a centrifuge? (1=No, 2=Yes) .....__

303. Is this unit rural, suburban or urban? .....__
1=Rural, 2=Suburban, 3=Urban

If the clinical site is a nocturnal home HD training site, for questions 304-313, indicate the information for the inpatient unit affiliated with the home HD training center.

304. Type of flow monitoring used? .....__
0=Not used, 1=Transonic, 8=Other

305. How many stations are currently used at this unit? .....__ __ __

306. Approximately, how many (total) chronic (3 x weekly) hemodialysis patients could be treated per week in this unit with the current number of shifts?.....__ __ __

307. Is this dialysis unit for profit or non-profit? (1=Profit, 2=Non-profit, 3=Mixed) .....__

308. What water standards are being used for patients on conventional hemodialysis in this unit?__
1=AAMI Standards 2=European Pharmacopoeia 3=Canadian

309. Are additional ultrafilters being used to produce ultrapure water for the majority of patients on conventional hemodialysis in this unit? (0=No, 1=Yes).....__

310. Do the machines at this unit allow for volumetric control of hyperfiltration?(0=No, 1=Yes)__

311. a. Does this unit have experience with frequent in-center daily dialysis (>5 days/week)? (0=No, skip to Q312, 1=Yes, continue) .....__

b. If yes, what year did this unit start performing frequent daily dialysis? ..... __ __ __ __

c. Approximately, total number of patients who have been treated with in-center frequent daily hemodialysis before this study? .....__ __ __

312. a. Does this unit reuse dialyzers? (0=No, skip to Q313, 1=Yes, complete Q312b.) .....__

b. If yes, what sterilant(s) are used? .....__ , __ , __
0=None, 1=Bleach, 2=Renalin, 3=Heat, 4=Glutaraldehyde, 5=Formaldehyde

313. Does this dialysis unit have access to the following health care professionals?

(For 313 a-d: use 0=No, 1=Yes)

a. Physiotherapist? .....__

b. Social Worker? .....__

c. Dietician? .....__

d. Physician? .....__

314. a. Does this unit have experience with home nocturnal dialysis? .....__
(0=No, skip to Q315, 1=Yes, continue)

b. If yes, what year did this unit start performing home nocturnal dialysis?..... __ __ __ __

314. c. Approximately, total number of patients who have been treated with at home nocturnal hemodialysis before this study? .....__ __ __

315. Is this an inpatient dialysis unit or an outlying dialysis unit?.....__
1=Inpatient, 2=Outlying

For in-patient dialysis units participating in the nocturnal study, provide confirmation:

316. Can you confirm that patients enrolled in this study will not reuse membranes from patients when study patients are dialyzed at this dialysis unit? (0=No, Yes, confirmed) .....__

Outlying dialysis units participating in the nocturnal study are asked not to reuse membranes if possible.

Frequent Hemodialysis Network
CARDIAC MRI FACILITY FORM - #604

Instructions: Please complete this Form 604 for any Cardiac MRI Facilities that may be used for the FHN Study. If this is a cardiac MRI facility new to the FHN study, you will need to contact the Data Coordinating Center for a pre-assigned MRI unit number, prior to entering data into the database.

To start entering information on Form 604, you must first query up the MRI facility you want to update. Use F7 to query up the record (click on Enter Query [or F7], type your MRI facility number or use list of values, click on Execute Query [or F8]). All updates for your study's MRI facilities should be made on this form. (For updates to individual staff members, use Form 600 to update pertinent information.)

The information provided on this form along with Form 603 links the dialysis units.

Section 1: Facility Information

1. Name of this Cardiac MRI facility?....._____ __ __
   (Use list of values)

Section 2. Dialysis Unit Linkage. The table in this section links all the dialysis units that will be using this Cardiac MRI facility. Please review the instructions thoroughly before trying to complete this section as this table provides the important links to other study forms that have already been entered.

A Form 603 must already be entered in the database in order to complete this table.

200. Dialysis Unit Name: Enter name of Dialysis Unit (use list of values) you want linked to this cardiac MRI facility.

201. Dialysis Unit ID number: This number will automatically populate this column once Q200 is entered.

202. Start date of MRI facility: Provide the date in dd/mon/yyyy format when the dialysis unit started using this facility.

203. End date of MRI facility: Provide the date in dd/mon/yyyy format when the dialysis unit stopped using this facility.

Dialysis Unit Name (200)	DU ID# (201)	Start Date (202)	End Date (203)

Section 3. Personnel Linkage. The table in this section links all the facility and staff forms. Please review the instructions thoroughly before trying to complete this section as this table provides the important links to other study forms that have already been entered.

A Form 600 must already be entered in the database for this person in order to complete this table.

300 Staff member's last name: Type in the last name of the staff member you want linked to this site.

301 Staff member's first name: Type in the first name of the staff member.

302 Staff ID number: This number ill automatically populate this column once Q300 and 301 are entered. You can use this id number to query up an individual if you need to update any roles.

303 Role. Use the responses below to identify this individual's primary role <u>at the MRI Facility</u>.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility Administrator

304 Staff member status: Use the following responses to record this person's status on the study.
1=Active (individual is actively participating as a member of the FHN study team)
2=Inactive (individual is no longer part of the FHN study team, no longer employed at this dialysis unit, etc.)

305. Date of staff member status: Provide the date when the staff member status changed using dd/mon/yyyy format.

Last Name (300)	First Name (301)	Staff ID # (302)	Role in Study (303)	Staff Status (304)	Status Date (305)

Frequent Hemodialysis Network
CONSORTIUM CORE FORM - #605

Instructions: Please complete this form for your Consortium Core. Names of each study facility have been provided to the Data Coordinating Center (DCC) and a specific number assigned to each. If you do not see the name of the facility you want, contact the DCC.

A Form 601 should be completed for each participating clinical center. A separate form, Form 602 should be completed for each biochemistry laboratory used to process lab specimens and provide results for the FHN study. Complete a Form 602 for each Holter lab used in the Daily Study. Cardiac MRI Facility information is on Form 604.

The information provided on this form and Forms 600, 601, 602, 603 and 604 links all other facility and staff .

All updates for your core should be made on this form. (For updates to individual staff members, use Form 600 to update pertinent information.)

Form updates will be forwarded to the DCC for various reports and address directory. For names, the computer will store 30 upper case characters.

Section 1: Core Consortium Information

1. Name of this Consortium..... _____ __
   (Use list of values to pull up the name and number of the facility)

2. Facility Mailing Address: (required)

   a. Line 1: ..... _____
   b. Line 2: ..... _____
   c. Line 3: ..... _____
   d. Line 4: ..... _____
   e. City/Town: ..... _____
   f. State/Province: ..... _____
   g. Zip/Postal Code: ..... _____
   h. Country: (1=U.S., 2=Canada)..... __

3. Federal Express Shipping Address: (required)

   a. Line 1: ..... _____
   b. Line 2: ..... _____
   c. Line 3: ..... _____
   d. Line 4: ..... _____

e. City/Town: ..... _____

f. State/Province: _____

g. Zip/Postal Code: ..... _____

h. Country: (1=U.S., 2=Canada)..... __

i. Telephone number: .....__ __ __-__ __ __-__ __ __ __

IRB Information

4. Date protocol submitted to IRB:.....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

5. IRB Assurance #.....(Example: FWA 0000####) __ __ __ __ __ __ __ __ __ __ __

6. Date of IRB approval of main protocol:.....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

(Send one blank copy of the approved consent form and one copy of the IRB approval letter to 1. the Data Coordinating Center *and 2. the NIDDK repository*)

7. Date of submission of repository consent to NIDDK .....(dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

8. *Date of IRB approval for collection of repository biologic specimens:.....(dd/mon/yyyy)* __ __ /__ __ __ /__ __ __ __

9. *Date of approval by NIDDK*.....*(dd/mon/yyyy)* __ __ /__ __ __ /__ __ __ __

SECTION 2. Personnel Linkage The table in this section links all the facility and staff forms. Please review the instructions thoroughly before trying to complete this section as this table provides the important links to other study forms that have already been entered.

A Form 600 must already be entered in the database for this person in order to complete this table.

200. Staff member's last name: Type in the last name of the staff member you want linked to this site.

201. Staff member's first name: Type in the first name of the staff member.

202. Staff ID number: This number will automatically populate this column once Q200 and 201 are entered. You can use this id number to query up an individual if you need to update any roles.

203. Role. Use the responses below to identify this individual's primary role at this core.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility Administrator

204. Staff member status: Use the following responses to record this person's status on the study.
1=Active (individual is actively participating as a member of the FHN study team)
2=Inactive (individual is no longer part of the FHN study team, no longer employed at this dialysis unit, etc.)

205. Date of staff member status: Provide the date when the staff member status changed using dd/mon/yyyy format.

206. Express shipping address: Use the following responses to provide the appropriate address to be used
to ship items to this addressee.
1=Use this individual's shipping address provided on Form 600.
2=Use this unit's shipping address identified above in Item 3.
3=Use this unit's clinical center address identified on Form 603.

207. Mailing address: Use the following responses to provide the appropriate address to be used to ship items to this addressee.
1=Use this individual's mailing address provided on Form 600.
2=Use this unit's mailing address identified above in Item 2.
3=Use this unit's clinical center address identified on Form 603.

Last Name (200)	First Name (201)	Staff ID # (202)	Role in Study (203)	Staff Status (204)	Status Date (205)	Express Address (206)	Mailing Address (207)

Codes:

203. Role. Individual's primary role at this unit.

01=Consortium Core Principal Investigator
02=Clinical Center Principal Investigator
03=Co-Investigator
04=Consortium Core Study Coordinator
05=Study Coordinator
06=Study Nurse (other than coordinator)
07=Supervising Cardiac MRI Physician
08=MRI Technician
09=Holter Technician
10=Dialysis Unit Medical Director
11=Dialysis Unit Nurse
12=Dialysis Unit Staff Member
13=Lab Technician
14=Supervising Lab Technician
15=Billing Staff Member
16=Data entry
17=MRI facility Administrator

204. Staff member status: 1=Active, 2=Inactive

206. Express shipping address: 1=Use this individual's shipping address provided on Form 600, 2=Use this center's shipping address identified in Item 3.

207. Mailing address: 1=Use this individual's mailing address provided on Form 600, 2=Use this center's mailing address identified in Item 2.

Frequent Hemodialysis Network
DOCUMENTATION OF LOCAL LABORATORY METHOD, INSTRUMENT, AND NORMAL RANGES - FORM 606

This form is completed for each local lab used by an FHN dialysis unit once at the start of data collection then again every three months to see whether any method, any instrument, or normal range changes for serum albumin, creatinine, phosphorus or PTH.

v											

1a. ID number of Laboratory (from Form 602)

1b. Qtr (mm)/Year (yyyy)

The database will list all those dialysis units using this lab providing the DU is linked on Form 602. If you identify that a Dialysis Unit is not linked to this form, you must update Form 602.

2. a. Initial data collection.....__
   0=No, answer 2b,
   1=Yes, complete <u>all</u> fields on this form)

   b. Quarterly lab check.....__
   0=No, skip to Q3,
   1=Yes, complete only the fields within the section(s) that need updating

<u>Serum ALBUMIN</u>

3. Date of serum albumin test change: (dd/mon/yyyy)..... __ __/__ __ __ /__ __ __ __

4. Method and Instrument.....__ __
   01=Dye Binding-BCG: Abbott Aeroset
   02=Dye Binding-BCG: Abbott Architect
   03=Dye Binding-BCG: Bayer Advia 1650/2400
   04=Dye Binding-BCG: Beckman Synchron LX20
   05=Dye Binding-BCG: Dade Behrg Dimension
   06=Dye Binding-BCG: OLY 400-640/2700/5400
   07=Dye Binding-BCG: Roche Cobas Fara/Mira
   08=Dye Binding-BCG: Roche Cobas Integra
   09=Dye Binding-BCG: Roche Modular
   10=Dye Binding-BCG: Roche/Hitachi 747
   11=Dye Binding-BCG: Roche/Hitachi 911
   12=Dye Binding-BCG: Roche/Hitachi 912
   13=Dye Binding-BCG: Roche/Hitachi 917
   14=Dye Binding-BCG: Toshiba TBA-FR Series
   15=Dye Binding-BCG: Vitros 250 Chem System
   16=Dye Binding-BCG: Vitros 5, 1 FS Chem System
   17=Dye Binding-BCG: Vitros 950 Chem System
   18=Dye Binding-BCG w/RA: Roche Cobas Integra
   19=Dye Binding-BCP: Abbot Aeroset
   20=Dye Binding-BCP: W/Ra: Abbott Architect
   21=Dye Binding-BCP: W/Ra: Beck Syn CX3-7D, CX9ALX
   22=Dye Binding-BCP: W/Ra: Beck Syn CX4/5CE, 7/RTS
   23=Dye Binding-BCP: W/Ra: Beckman Synchron CX4/5
   24=Dye Binding-BCP: W/Ra: Beckman Synchron LX 20
   25=Dye Binding-BCP: W/Ra: Beckman Unicel DxC Syn

responses continued on next page

26=Dye Binding-BCP: W/Ra: Dade Behrg Dimension
27=Dye Binding-BCP: Roche Modular
28=Dye Binding-BCP: Roche/Hitachi 917
29=Nephelometry
30= Dye Binding BCP: Instrument unspecified

5. Low end of normal range for serum albumin (g/dL) ..... __ __.__
6. High end of normal range for serum albumin (g/dL) ..... __ __.__

SI Units

7. Low end of normal range for serum albumin (g/L) .....__ __ __ __
8. High end of normal range for serum albumin (g/L) .....__ __ __ __

Serum CREATININE

9. Date of serum creatinine test change: (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
10. Method and Instrument .....__ __

01=Alk Picrate w/Lloyds: Dade Behrg Dimension
02= Alk Picrate w/o Lloyds: Beck Syn CX3-7D, Cx9ALX
03= Alk Picrate w/o Lloyds: Beck Syn CX4/5CE, 7/RTS
04= Alk Picrate w/o Lloyds: Beckman Synchron LX20
05= Alk Picrate w/o Lloyds: Dade Behrg Dimension
06= Alk Picrate w/o Lloyds: Roche Cobas Integra
07=Enzymatic: Bayer Advia 1650/2400
08=Enzymatic: Oly 400-640/2700/5400
09=Enzymatic: Roche Cobas Integra
10=Enzymatic: Roche Modular
11=Enzymatic: Roche/Hitachi 747
12=Enzymatic: Roche/Hitachi 917
13=Enzymatic: Toshiba TBA-FR Series
14=Enzymatic: Vitros 250 Chem System
15=Enzymatic: Vitros 5, 1 FS Chem System
16=Enzymatic: Vitros 950 Chem System
17=Enzymatic: Vitros DT6011 Chem System
18=Kinetic Alk. Picrate: Abbott Aeroset
19=Kinetic Alk. Picrate: Abbott Architect
20=Kinetic Alk. Picrate: Bayer Advia 1650/2400
21=Kinetic Alk. Picrate: Beck Syn CX3-7D, CX9ALX
22=Kinetic Alk. Picrate: Beck Syn CX4/5CE, 7/RTS
23=Kinetic Alk. Picrate: Beckman Synchron CX3
24=Kinetic Alk. Picrate: Beckman Syncron CX4/5
25=Kinetic Alk. Picrate: Beckman Syncron LX20
26=Kinetic Alk. Picrate: Beckman Unicel DXC Syn
27=Kinetic Alk. Picrate: Dade Behrg Dimension
28=Kinetic Alk. Picrate: Oly 400-640/2700/5400
29=Kinetic Alk. Picrate: Roche Cobas Fara/Mira
30=Kinetic Alk. Picrate: Roche Cobas Integra
31=Kinetic Alk. Picrate: Roche Modular
32=Kinetic Alk. Picrate: Roche/Hitachi 911
33=Kinetic Alk. Picrate: Roche/Hitachi 912
34=Kinetic Alk. Picrate: Roche/Hitachi 917
35=Kinetic Alk. Picrate: Toshiba TBA-FR Series
36=Rate-Blk Kin Alk Pic: Bayer Advia 1650/2400

responses continued on next page

37=Rate-Blk Kin Alk Pic: Beck Syn CX3-7d, CX9ALX
38=Rate-Blk Kin Alk Pic: Beckman Synchron LX20
39=Rate-Blk Kin Alk Pic: Dade Behrg Dimension
40=Rate-Blk Kin Alk Pic: Roche Cobas Integra
41=Rate-Blk Kin Alk Pic: Roche Modular
42=Rate-Blk Kin Alk Pic: Roche/Hitachi 912
43=Rate-Blk Kin Alk Pic: Roche/Hitachi 917
44=Kinetic Alk Picrate: Instrument Unspecified

11. Low end of normal range for serum creatinine (mg/dL) ..... __ __.__
12. High end of normal range for serum creatinine (mg/dL)..... __ __.__

SI Units

13. Low end of normal range for serum creatinine (µmol/L) .....__ __ __.__
14. High end of normal range for serum creatinine (µmol/L) .....__ __ __.__

Serum PHOSPHORUS

15. Date of serum phosphorus test change: (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __
16. Method and Instrument .....__ __

01=Enzymatic: Bayer Advia 1650/2400
02=Enzymatic: Roche Modular
03=Enzymatic: Toshiba Tba-Fr Series
04=Phospomol. w/Any Red.: Beck Syn CX3-7d, CX9ALX
05=Phospomol. w/Any Red.: Beck Syn CX4/5CE, 7/RTS
06=Phospomol. w/Any Red.: Beckman Synchron LX20
07=Phospomol. w/Any Red.: Beckman Unicel DXC Syn
09=Phospomol. w/ Any Red.: Dade Behrg Dimension
09=Phospomol. w/Any Red.: Roche Cobas Integra
10=Phospomol. w/Any Red.: Vitros 250 Chem System
11=Phospomol. w/Any Red.: Vitros 5, 1 FS Chem Syst
12=Phospomol. w/Any Red.: Vitros 950 Chem System
13=Phosphomolybdate UV: Abbott Aeroset
14=Phosphomolybdate UV: Abbott Architect
15=Phosphomolybdate UV: Bayer Advia 1650/2400
16=Phosphomolybdate UV: Beck Syn CX3-7D, Cx9ALX
17=Phosphomolybdate UV: Beck Syn CX4/5CE, 7/RTS
18=Phosphomolybdate UV: Beckman Synchron CX4/5
19=Phosphomolybdate UV: Beckman Synchron LX20
20=Phosphomolybdate UV: Beckman Unicel DXC Syn
21=Phosphomolybdate UV: Dade Behrg Dimension
22=Phosphomolybdate UV: Oly 400-640/2700/5400
23=Phosphomolybdate UV: Roche Cobas Integra
24=Phosphomolybdate UV: Roche Modular
25=Phosphomolybdate UV: Roche/Hitachi 911
26=Phosphomolybdate UV: Roche/Hitachi 912
27=Phosphomolybdate UV: Roche/Hitachi 917
28=Phosphomolybdate UV: Instrument unspecified

17. Low end of normal range for serum phosphorus (mg/dL)..... __ __.__
18. High end of normal range for serum phosphorus (mg/dL)..... __ __.__

SI Units

19. Low end of normal range for serum phosphorus (mmol/d) .....__ . __ __

20. High end of normal range for serum phosphorus (mmol/d) .....__ .__ __

PTH

21 Date of PTH test change: (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

22. Instrument .....__ __

01=Bayer Acs:180
02=Bayer Advia Centaur
03=Diasorin IRMA
04=DPC immulite 2000
05=DPC immulite 2500
06=DPC immulite Turbo
07=DPC immulite/1000
08=Roche E170
09=Roche Elecsys 1010/2010
10=Beckman DxL

23. Low end of normal range for PTH for normal patients (pg/mL = ng/L) .....__ __.__

24. High end of normal range for PTH for normal patients (pg/mL = ng/L) .....__ __.__

SI Units

25. Low end of normal range for PTH for normal patients (pmol) .....__ __.__

26. High end of normal range for PTH for normal patients (pmol).....__ __.__

27. Low end of normal range for PTH for ESRD patients (pg/mL = ng/L) .....__ __.__

28. High end of normal range for PTH for ESRD patients (pg/mL = ng/L) .....__ __.__

SI Units

29. Low end of normal range for PTH for ESRD patients (pmol) .....__ __.__

30. High end of normal range for PTH for ESRD patients (pmol).....__ __.__

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

Frequent Hemodialysis Network
THIRTY DAYS AFTER F12 DATA - FORM #700

Instructions:
Starting with the first dialysis session held at least 30 days after a patient's F12 month ends, one week of data should be obtained from the dialysis unit's run sheets. This data will include start time, end time, and pre-and-post weight and blood pressure for each dialysis session held during that week.

The table accommodates up to 6 sessions. Use as many columns as needed (starting from the left) to cover all treatments in the **one week** that starts with the first dialysis session held at least 30 days after a patient's F12 month ends . Include both dialysis sessions and treatments with isolated ultrafiltration only.

1. Participant ID # 2a. Alpha Code

For All Subjects After End of the FHN Trial

2b. Where does pt. currently receive his/her hemodialysis? (1=Home, 2=In-Center) ..... __

2c. Has this pt experienced any SAE's between the end of the study and when F700 entered? ..... __

(0=No, 1=Yes – complete appropriate forms)

Data Item	3. **Session – #1**	4. **Session – #2**	5. **Session – #3**
a. Treatment Date (dd/mon/yyyy)	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __
b. Start Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
c. End Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
d. Predialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
e. Minimum intradialytic systolic BP[2]	__ __ __	__ __ __	__ __ __
f. Minimum intradialytic diastolic BP[2]	__ __ __	__ __ __	__ __ __
g. Hypotensive episode?[1]	__	__	__
h. Significant interruption?[3]	__	__	__
i. Pre-dialysis systolic BP	__ __ __	__ __ __	__ __ __
j. Pre-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
k. Post-dialysis systolic BP	__ __ __	__ __ __	__ __ __
l. Post-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
m. Post-dialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
p. Was this a dialysis session? (0=No, isolated ultrafiltration; 1=Yes)	__	__	__

[1]For Item g, hypotensive episode, enter 0=No, 1=Symptoms of hypotension led to lowering of UF rate or reduced blood flow, 2=Symptoms of hypotension led to administration of saline, 3=Symptoms of hypotension led to lowering of UF rate and administration of saline.

[2]For Item e: specify systolic and diastolic blood pressure at time of minimum systolic blood pressure.

[3]For Item h, significant interruption, enter 0=No, 1=Yes. For an in-center dialysis treatment, a significant interruption is any interruption of 15 minutes or greater. For a home dialysis treatment, a significant interruption is any interruption of 30 minutes or greater.

Data Item	6. **Session – #4**	7. **Session – #5**	8. **Session – #6**
a. Treatment Date (dd/mon/yyyy)	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __	__ __/__ __ __/__ __ __ __
b. Start Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
c. End Time (24 hr clock)	__ __:__ __	__ __:__ __	__ __:__ __
d. Predialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
e. Minimum intradialytic systolic BP[2]	__ __ __	__ __ __	__ __ __
f. Minimum intradialytic diastolic BP[2]	__ __ __	__ __ __	__ __ __
g. Hypotensive episode?[1]	__	__	__
h. Significant interruption?[3]	__	__	__
i. Pre-dialysis systolic BP	__ __ __	__ __ __	__ __ __
j. Pre-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
k. Post-dialysis systolic BP	__ __ __	__ __ __	__ __ __
l. Post-dialysis diastolic BP	__ __ __	__ __ __	__ __ __
m. Post-dialysis weight (kg)	__ __ __.__	__ __ __.__	__ __ __.__
p. Was this a dialysis session? (0=No, isolated ultrafiltration; 1=Yes)	__	__	__

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

[1]For Item g, hypotensive episode, enter 0=No, 1=Symptoms of hypotension led to lowering of UF rate or reduced blood flow, 2=Symptoms of hypotension led to administration of saline, 3=Symptoms of hypotension led to lowering of UF rate and administration of saline.
[2]For Item e: specify systolic and diastolic blood pressure at time of minimum systolic blood pressure.
[3]For Item h, significant interruption, enter 0=No, 1=Yes. For an in-center dialysis treatment, a significant interruption is any interruption of 15 minutes or greater. For a home dialysis treatment, a significant interruption is any interruption of 30 minutes or greater.