5. Guidelines for Study Coordinators

5.1 Introduction

The study coordinator plays an integral role at each clinical center of the FHN Study. He/she, along with the Principal Investigator and Co-Investigators, keeps the study running smoothly at the clinical center level, with the assistance of the dialysis unit technicians.

The study coordinator must work closely with the physician at the clinical center to screen and enroll patients, to make sure patient information is gathered, recorded, entered and verified correctly, and to ensure that the FHN Study protocol is followed. He/she must coordinate the patients' visits with the physicians and the dialysis unit. He/she will work closely with the Consortium Centers, to help resolve problems that arise with patient data.

All FHN study coordinators must attend central training in order to be certified to participate in the FHN Study. Central training of the study coordinators will help enhance compliance with the protocol and will help in the development of uniform procedures for data acquisition. At the central training session, the study coordinators will learn about the FHN Study and be certified to complete forms, enter data into the Oracle database, and correct errors. If a study coordinator must leave his/her position at the clinical center, he/she should help train his/her replacement.

Each study coordinator will have a copy of and familiarize himself/herself with the protocol, the manual of operations (MOP) and data collection forms. These can be found on-line at the FHN website. The coordinator should make sure to keep all study documents up to date. The DCC staff welcomes questions about the protocol, MOP and Forms.

The most current version of address directory can be reviewed on the FHN website.

5.2 General Instructions for Completing Forms

Follow these instructions when completing FHN data forms.

- Use a black or blue ballpoint pen (Flairs, Pentel pens, etc. will smear). Write legibly so that data entry is accurate. You will keep all forms at your Clinical Center.

- Print and capitalize all letters.

- Make corrections as follows: put a line through the incorrect value; write the new value either above or next to the old value; write your initials and the date of the correction in the margin.
  bw 01/31/2006
  Example: 1 2

- Any forms that a patient completes must be reviewed before entry into the study database. Examine these forms to ensure they have been completed properly and that the writing is legible.

- Enter only one character or number on each dash.

- Each categorical data item has an assigned code. Be sure to enter the coded response.

  Example: Given 0=No, 1=Yes and the answer to the question on the form is **no**, the code should be transcribed on the form as: 0

- Round off values after a decimal point to fit into the given space. Do not add dashes or move a decimal point.

  Example: Given four dashes, a decimal point, and one dash, the value 123.57 should be entered as:

  1 2 3. 6

- The decimal point is always assumed to be at the far right if it is not included on the form. Do not add a decimal point.

- If a value is too large to fit in the provided spaces, notify the DCC that a larger field needs to be placed in the database.

- Dates should always be entered as dd/mon/yyyy. (e.g., 09/SEP/2005).

  * *When entering a birth date, be careful not to enter the current year.*

Patient Identification Number Assignment And Alpha Code

If a participant consents, each subject will be assigned a six-digit ID number. It will be made up of the dialysis unit number (4 digits) and a 2-digit number assigned by the coordinator. It is recommended that these 2-digit numbers be assigned sequentially so as not to run out of unique numbers (i.e., xxxx01, xxxx02, xxxx03, etc.). Once an ID number has been assigned to a specific participant, this participant CANNOT be assigned a different number throughout the study. This number CANNOT be reused for another participant in the study.

When entering Form 100/110 into the database, the box at the left will be used to enter and establish the participant's ID number. The dialysis unit will be selected with the dropdown list into the field labeled "dialysis unit". The key entry person will then enter the coordinator assigned 2-digit number into the field that is labeled "sequence" (01, 02, 03, etc.). Once they hit enter, the participant ID number will be displayed in Item #1-Patient ID field and the database will automatically move the cursor to the "visit date". The Alpha Code will be automatically assigned once the form has been entered and saved to the database. Be sure to document this alphanumeric code since the combination of the participant ID and the alphanumeric code is used to uniquely identify each participant in the study.

Visit Types

Visit types will appear on almost every form. The choices are:

S = Screening (will only be used on Forms 100/110)
B = Baseline
F = Follow-up

5.3 Site Registration

The FHN Study address book lists all Core Consortia, and Clinical Centers, and gives their study identification numbers. Clinical Centers, Dialysis Units, MRI Facilities, Lab Facilities and study personnel become registered when their data are entered in the Form 600 System: Form 600, 601, 602, 603, and 604 in the FHN Study Database.

Consider Dialysis Unit 2304, El Camino Rose Garden. This dialysis unit is part of Clinical Center 23-Peninsula Satellite that is part of Core Consortium 2-UCSF. It is likely that the first three patients enrolled in baseline at this site will have ID numbers: 230401, 230402, and 230403. Data for the dialysis unit itself, unit 2304, would be key entered into Form 603.

A patient can be enrolled at one of the study clinical centers when the dialysis unit where the patient is treated has met all of the criteria enumerated in the Ready to Enroll report. . At this point, the unit becomes ready to enroll patients and the study coordinator will be able to key in and save a Form 100 (Nocturnal Study) or a Form 110 (Daily Study) enrolling its first patient.

5.4 Monitoring Site Registration

Progress in site registration will be summarized on the Ready-To-Enroll Report which are updated daily, and will be discussed on Steering Committee conference calls. Summaries of which sites are ready to enroll and which criteria are keeping other sites from becoming ready to enroll will be developed over the course of the study. These reports can be accessed on the FHN website.

5.5 Completing Baseline

Once a patient has enrolled in baseline with a Form 100 (Nocturnal Study) or a Form 110 (Daily Study), baseline procedures are performed as efficiently as possible. All baseline requirements must be met within 12 weeks from the visit date on Form 100/110 in order for a patient to be randomized.

Data to be collected during baseline are shown in MOP Chapter 2 for the Daily Study and in MOP Chapter 3 for the Nocturnal Study.

5.6 Checking Eligibility

At any point after a patient has been enrolled in baseline (i.e., Form 100/Form 110 in the database), anyone from the clinical center who has a database account can run a patient eligibility report for the patient by logging into the study database and selecting Reports>Patient Eligibility Report from the Menu. The Eligibility Report will show which required baseline forms and procedures have been done and which are still outstanding. The report will check if the data in the database support patient eligibility. If the report shows that a patient is not eligible, the reason(s) will be provided.

5.7 Randomizing Patients

When a patient's Eligibility Report shows that the patient is eligible to be randomized, the study team at the clinical center should meet to confirm that all staff members agree that the patient should

be randomized. The PI, Study Coordinator and others who have worked with the patient during baseline, should feel confident that the patient would come in six times a week for 12 months (if randomized to daily dialysis in the Daily Study) or that the patient would pass home nocturnal training and do home dialysis six nights a week for 14 months (if randomized to home dialysis in the Nocturnal Study). The PI, Study Coordinator and others who have worked with the patient during baseline, should feel confident that the patient will continue to participate in the study, perform needed tests and provide required data, whether he is randomized to the conventional group or the six-times a week group.

If the eligibility Report shows the patient to be eligible and the study team feels the patient will fully participate in the follow-up protocol, if randomized, the Study Coordinator or anyone from the clinical center who has a database account can randomize the patient by logging into the study database and selecting Reports>Randomize a Patient from the Menu.

5.8 Scheduling Follow-Up Visits

During follow-up, visits are scheduled on a calendar month system. Suppose a patient is enrolled in Baseline in October 2006 and randomized in December 2006. For that patient, Follow-up month 0 is December 2006. Month 1 is January 2007, Month 2 is February 2007, and so on, until Month 12 (when the patient has had 12 months of post randomization or follow-up data) is December 2007.

The database will accept data that are done outside of its recommended visit month. Even if the protocol says a measurement is done at F8, the database will accept it any month. Some data summaries will only consider the data to have been completed if it was done right in month 8, but it is anticipated that most data summaries will consider the data to have been completed if it is collected in the plus or minus one month visit window. Data required for F8 can be completed in months F7, F8, or F9.

Whenever possible, patient visits should be scheduled early in the month that they are required, so that there is time to complete the visit in the window even if the patient misses the first scheduled visit.

The study coordinator or her designee should schedule the visit. She should make sure the patient has any needed supplies (log forms, urine containers.) She should make sure that the patient receives a reminder call prior to the visit.

It is useful to have a graphic display of your clinical center's enrolled patients and where they are in follow up for each calendar month.

5.9 Coding Medications

The study has three medication-related forms, Form 203 for IV Iron, Form 204 for Injectable Medications, and Form 205 for all other medications (including over-the-counter meds). Medication will be coded by the data entry person during key entry by using the WHO Drug medication code

database. The data entry person enters characters in the drug's trade name or generic name, and then the data entry form displays a variety of drug codes with specific names. The key entry person selects and confirms the appropriate drug code, and saves it on the medication data form.

5.10 Coding and Reporting Adverse Events, Severe Adverse Events and Hospitalizations

Adverse Events (AE's) are coded and reported on Form 307 and Severe Adverse Events (SAE's) are coded and reported on Form 308. All hospitalizations are by definition SAE's and full details of hospitalizations are collected on Form 303. Refer to the individual forms for more details.

Diagnoses and symptoms will be coded by the data entry person during key entry by using the MedDRA database. The data entry person enters characters in the diagnosis or description of the symptom and then the data entry form displays a variety of diagnosis/symptom codes with specific names. The key entry person selects and confirms the appropriate code, and saves it in the database.

Note that Manual of Operations Chapter 25 describes the system for Outcome Committee review of hospitalizations.

5.11 Coding Deaths

Form 305 is completed to notify the database when a patient expires, and full details of the death are reported on Form 306. See the form for more information.

Table 5.1, Parts 1, 2 and 3 What makes a dialysis unit Ready to Enroll patients?

Part 1. We must know the following about the Clinical Center that the dialysis unit is under

• Consortium number (1, 2, or 3) • Clinical Center number • Name of the Clinical Center
Clinical Center Principal Investigator Name
Federal Express Shipping Address of the Clinical Center PI • Address Line 1 • City/Town • State/Province • Zip/Postal Code • Country • Telephone Number
Email address of Clinical Center Principal Investigator
Clinical Center Study Coordinator Name
Federal Express Shipping Address of the Clinical Center Study Coordinator • Address Line 1 • City/Town • State/Province • Zip/Postal Code • Country • Telephone Number
Email address of **the clinical center study coordinator**
One staff member trained in BIA
One staff member trained in Modified Mini-Mental
One CC staff trained in Trailmaking B
One CC staff trained in Feeling Thermometer
One staff member trained in Physical Function test
One staff member has successfully sent in a test repository kit
For Nocturnal Study: One staff member has been trained in Home Blood Pressure measures

Part 2. What do we need to know about the Dialysis Unit itself?

Item
Name of the dialysis unit
Mailing address of the dialysis unit
First name, last name of the medical director physician in charge of this dialysis unit
For U.S. Centers only: CMS (old HCFA) number for this dialysis unit
IRB Assurance number for IRB
Date main protocol submitted to this IRB
Date of IRB approval of main protocol
Date repository submitted to IRB (may be part of the main protocol)
Date of IRB approval protocol VERSION 2.1
Rural, suburban or urban status known

Part 3. What do we need to know about the MRI unit this dialysis center is linked to?

Item
a. Name of the supervising MRI physician in charge of the MRI unit
b. First Name, Last Name of the MRI tech
c. Federal Express Shipping Address of the MRI tech
• Address Line 1
• City/Town
• State/Province
• Zip/Postal Code
• Country
• Telephone number
d. Email address of the MRI tech
e. We need to know that one Staff Member of this MRI unit has done two test cardiac MRI's and submitted them to Sanjay and Sanjay approved both of them

Table 5.2 Summarizing "ready to enroll"

How the DCC will report summaries of "Ready to Enroll"

February 15, 2006

This is a page from the Ready to Enroll **Summary**. This report runs nightly and is automatically updated on the FHN website. Each clinical center will be able to review its status on any of its dialysis units at any time. This is a sample taken from the Daily Study Ready to Enroll Report.

Ready to Enroll Report - Daily Study	**11 RRI New York City (RRINY)**		
Questions	**1106 Queens Artificial Kidney Center**	**1108 Yorkville Dialysis Center**	**1109 Irving Place Dialysis Center**
Name, Number of Clinical Center----------(f601, q1)	Y	Y	Y
Clinical Center PI Name ----------(f600, q12)	Y	Y	Y
Fedex Address of Clinical Center PI ----------(f600, q10 a,e,f,g,h)	Y	Y	Y
Telephone Number of Clinical Center PI ----------(f600, q5,14)	Y	Y	Y
Email Address of Clinical Center PI ----------(f600, q4,14)	Y	Y	Y
Clinical Center Coordinator Name ----------(f600, q1,2)	Y	Y	Y
Fedex Address of Study Coord ----------(f600, q10 a,e,f,g,h)	Y	Y	Y
Telephone Number of Study Coordinator ----------(f600, q5,14)	Y	Y	Y
Email Address of Study Coordinator ----------(f600, q4,14)	Y	Y	Y
One Clinical Center staff member has done a holter which was approved by Chris Chan ----------(DCC files)	Y	Y	Y
One CC staff trained in BIA ----------(DCC files)	Y	Y	Y
One CC staff trained in Trailmaking B ----------(DCC files)	Y	Y	Y
One CC staff trained in Feeling Thermometer ----------(DCC files)	Y	Y	Y
One CC staff trained in Mod. Mini-Mental ----------(DCC files)	Y	Y	Y
One CC staff trained in Physical Function ----------(DCC files)	Y	Y	Y
One CC staff sent a test repository kit that was approved by NIDDK repository staff ----------(DCC files)	Y	Y	Y
One CC staff trained in Holter placement ----------(DCC files)	Y	Y	Y
Name, Number of the Dialysis Unit ----------(f603, q101)	Y	Y	Y
Local lab has been identified ----------(f602, q1,2)	Y	Y	Y
Name of medical director ----------(f603, q200,202,203)	Y	Y	Y
Dialysis Unit Address ----------(f603, q102 a,e,f,g,h)	Y	Y	Y
CMS (HCFA) number of the dialysis unit ----------(f603, q301)	Y	Y	Y
Assurance # for IRB this unit uses ----------(f603, q301)	Y	Y	Y
Date main protocol submitted to this IRB ----------(f603, q105)	Y	Y	Y
Date of IRB approval of main protocol ----------(f603, q107)	Y	Y	Y
Date of IRB approval protocol VERSION 2.1 ----------(f603, q107b)	Y	Y	Y
Date repository consent submitted to IRB ----------(f603, q108)	Y	Y	Y
Rural, suburban or urban status known ----------(f603, q110)	Y	Y	Y
Flow monitoring status known ----------(f603, q304)	Y	Y	Y
# of stations used at the unit knwon ----------(f603, q305)	Y	Y	Y
# of patients that could be treated known ----------(f603, q306)	Y	Y	Y
Profit, nonprofit, mixed status known ----------(f603, q307)	Y	Y	Y
Water standard status known ---------- (f603, q308)	Y	Y	Y
Ultra filters for pure water on majority known----------(f603, q309)	Y	Y	Y
Dialyzer reuse status known ----------(f603, q312a)	Y	Y	Y
Volumetric control of hyper filtration ----------(f603, q310)	Y	Y	Y
Experience with Frequent In-Center Dx ----------(f603, q311a)	Y	Y	Y
# in-center frequent patients before FHN ----------(f603, q311 a,c)	NA	NA	NA
MRI Facility to be used ----------(f604, q1 & f603 link)	Y	Y	Y

Ready to Enroll Report - Daily Study	11 RRI New York City (RRINY)		
Questions	**1106 Queens Artificial Kidney Center**	**1108 Yorkville Dialysis Center**	**1109 Irving Place Dialysis Center**
Name supervising MRI Physician----------(f600, q14 & f603, q202,203)	Y	Y	Y
Name of at least one MRI Tech ----------(f600, q14 & f603, q202,203)	Y	Y	Y
MRI tech Fedex address ----------(f600, q11 a,e,f,g,h & f603 link)	Y	Y	Y
Telephone # of MRI tech ----------(f600, q5,14 & f603 link)	Y	Y	Y
Email address of MRI tech ----------(f600, q4,14 & f603 link)	Y	Y	Y
2 test case MRIs approved by MRI Core			
"	Y	Y	Y
Reviewed talking points with Core Consortium PI ----------(DCC files)	NA	NA	NA