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

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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.