

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 | 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 | |

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.