

# F100

## Hemodialysis Fistula Maturation Study (HFM/MANVAS Studies) Clinical Center / Principal Investigator Form (Form # 100)

1. Clinical Center Number ..... CC\_N  
 1=Boston University Medical Center    4=University of Texas Southwestern    7=Manchester  
 2=University of Cincinnati    5=University of Utah    8=University of Alabama  
 3=University of Florida    6=University of Washington

### Access Coordination at this Clinical Center

2. At this clinical center, are nephrologists involved with decisions on when to refer patients to surgery for vascular access placement? (0=no, 1=yes) ..... VAC\_WHEN
3. At this clinical center, are nephrologists involved with decisions on where to refer patients to surgery for vascular access placement? (0=no, 1=yes) ..... VAC\_WHERE
4. Type of officially designated vascular access coordinator at this facility? (0=none, 1=nephrology, 2=surgical, 3=both) ..... VAC\_TYPE  
*If this clinical center has vascular access coordinator(s), complete details on Form 101.*

### Principal Investigator

5. Clinical Center Principal Investigator
- a. Last name ..... PI\_LNAME
- b. First name ..... PI\_FNAME
- c. HFM Study username ..... PI\_USERID  
 (The study username will be populated automatically.)
- d. E-mail Address ..... PI\_EMAIL
- e. Phone Number ..... PI\_PHONE
- f. Extension ..... PI\_EXT
- g. Fax Number ..... PI\_FAX
- h. Federal Express Shipping Address
- Line 1: ..... PI\_FDEX\_ADDR1
- Line 2: ..... PI\_FDEX\_ADDR2
- Line 3: ..... PI\_FDEX\_ADDR3
- Line 4: ..... PI\_FDEX\_ADDR4
- City: ..... PI\_FDEX\_CITY
- State: ..... PI\_FDEX\_ST
- Zip code: ..... PI\_FDEX\_ZIP
- i. Active status of the Principal Investigator (0=no longer active, 1=active) ..... PI\_STATUS

j. If q.5i = 0 (no longer active), date the PI became inactive (mm/dd/yyyy)..... PI\_INACTIVE\_DT

**Primary IRB**

6. HFM Study ID of this IRB..... IRB\_ID

Use Code list (The list will show 101 for primary Boston IRB, 201 for primary Cincinnati IRB, 301 for primary Florida IRB, 401 for primary UTSW IRB, 501 for primary Utah IRB, 601 for primary UW IRB, 801 for primary Alabama IRB)

7. Name of the primary IRB for this clinical center.....IRB\_NAME

8. IRB Assurance # (Example: FWA 0000####) .....IRB\_ASSUR\_NO

9. Date Protocol V1.1 of 12/22/09 submitted to IRB (mm/dd/yyyy) .....IRB\_SUB\_V1\_DT

10. Date of IRB approval of Protocol V1.1 (mm/dd/yyyy)..... IRB\_APP\_V1\_DT

Note: Send one blank copy of the final IRB-approved consent form along with a copy of the IRB approval letter to 1) **Rebekah Rasooly** at the NIDDK Repository and 2) the Data Coordinating Center. Complete form 130 when NIDDK approves the consent form.

11. a. Did the IRB approve plans for collection of repository serum/plasma specimens (0=no, 1=yes) IRB\_BLD

b. If yes, date of approval of plans for collection of repository serum/plasma specimens (mm/dd/yyyy)..... IRB\_BLD\_DT

c. If no, reason why there is no IRB approval for this .....IRB\_BLD\_RSN  
1 = Approval pending.  
2 = IRB did not approve repository serum/plasma specimen collection protocol/consent form

12. a. Did the IRB approve plans for collection of repository DNA (0=no, 1=yes) .....IRB\_DNA

b. If yes, date of IRB approval for collection of DNA (mm/dd/yyyy) .....IRB\_DNA\_DT

c. If no, reason why there is no IRB approval for this.....IRB\_DNA\_RSN  
1 = Approval pending  
2 = IRB did not approve the repository DNA collection protocol/consent form

13. a. Did the IRB approve plans for collection of repository vein tissue (0=no, 1=yes) .....IRB\_VEIN

b. If yes, date of IRB approval for collection of vein tissue (mm/dd/yyyy) ..... IRB\_VEIN\_DT

c. If no, reason why there is no IRB approval for this.....IRB\_VEIN\_RSN  
1 = Approval pending  
2 = IRB did not approve the repository vein tissue collection protocol/consent form

**Clinical Center Practices for post-op follow up and ultrasounds**

14. Does this clinical center have a usual practice for the number and frequency of post-op visits to the surgeon? (0=no, it varies; 1=yes) ..... CC\_PRACTICE\_YN

15. If q.14 is answered 1=yes, what is the usual practice? .....CC\_PRACTICE

0 = no usual practice for number and frequency of post-op visits to surgeon  
1 = 1 visit. This post-op visit with the surgeon is done within the first 2 weeks after surgery  
2 = 1 visit. This post-op visit with the surgeon is done 2 to 4 weeks after surgery  
3 = 1 visit. This post-op visit with the surgeon is done more than 4 weeks after surgery.  
4 = 2 or more visits. One visit at about 2 weeks, one visit at about 6 weeks, with continued

visits until access is usable.

5 = 2 or more visits. Pattern other than the pattern described above.

- 16. Does this clinical center have any usual post-op protocol? (0=no, it varies; 1=yes) CC\_PROTOCOL\_YN
- 17. If q.16 is answered 1=yes, what is included in this clinical center's post-op protocol? (Answer items a-d with 0=never or almost never, 1=sometimes, 2=always or almost always)
  - a. Patient is instructed to squeeze a ball. ....CC\_BALL
  - b. Patient is prescribed post-op antiplatelet agents to assist in patency.....CC\_APLT\_ASSIST
  - c. Patient is prescribed anticoagulants, such as Warfarin, to assist in patency CC\_NONAPLT\_ASSIST
  - d. Patient is prescribed post-op drugs other than antiplatelets and antithrombotic agents for some other reason..... CC\_NONAPLT\_OTH

- 18. Does this clinical center have a routine policy on post-op ultrasounds? (0=no, it varies; 1=yes) ..... CC\_US\_YN

- 19. If q.18 is answered 1=yes, what is this clinical center's routine policy? .....CC\_US
  - 0 = the policy is that no routine post-op ultrasound is done
  - 1 = routine post-op ultrasound done about one week post surgery
  - 2 = routine post-op ultrasound done about two weeks post surgery
  - 3 = routine post-op ultrasound done about three weeks post surgery
  - 4 = routine post-op ultrasound done about four weeks post surgery
  - 5 = routine post-op ultrasound done about five week post surgery
  - 6 = routine post-op ultrasound done about six weeks post surgery
  - 7 = one routine post-op ultrasound done after some other time interval
  - 8 = more than one routine post-op ultrasound is done

**Section for PI Surgeon(s)**

- 20. Is this Clinical Center's PI a surgeon? (0=no, 1=yes) .....PI\_SURGEON  
If no, skip to Item 200. If yes, complete the PI Surgeon data section below.
- 21. PI Surgeon's year of birth (yyyy)..... PI\_YOB
- 22. Month/year PI Surgeon completed residency (mm/yyyy)..... PI\_RESIDENT\_DT
- 23. Does this surgeon have sub-specialty board certification(s) (0=no, 1=yes) .... PI\_SUBSPEC\_CERT
- 24. If Q. 23 = yes, what sub-specialty(ies) is the surgeon board certified for?
  - a. General (0=no, 1=yes) ..... PI\_SUBSPEC\_GEN
  - b. Month/year PI Surgeon completed general surgery training (mm/yyyy) PI\_SUBSPEC\_GEN\_DT
  - c. Vascular (0=no, 1=yes) ..... PI\_SUBSPEC\_VAS
  - d. Month/year PI Surgeon completed vascular surgery training (mm/yyyy) PI\_SUBSPEC\_VAS\_DT
  - e. Cardiothoracic (0=no, 1=yes) .....PI\_SUBSPEC\_CT
  - f. Month/year PI Surgeon completed cardiothoracic surgery training (mm/yyyy)PI\_SUBSPEC\_CT\_DT
  - g. Transplant (0=no, 1=yes) ..... PI\_SUBSPEC\_TX
  - h. Month/year PI Surgeon completed transplant surgery training (mm/yyyy)PI\_SUBSPEC\_TX\_DT
  - i. Other (0=no, 1=yes) ..... PI\_SUBSPEC\_OTH

- If other, please specify \_\_\_\_\_ ....PI\_SUBSPEC\_OTH\_SPEC
- j. Month/year PI Surgeon completed *other* surgery training (mm/yyyy) .. PI\_SUBSPEC\_OTH\_DT
25. Outside of HFM Study, does this PI Surgeon generally use **pre-operative** ultrasound mapping? ..... PI\_PRE\_US\_MAP  
(0=no, 1=selectively, 2=routinely)
26. Outside of HFM Study, does this PI Surgeon generally use **post-operative** ultrasounds of any kind?.....PI\_POST\_US\_GENERAL  
(0=no, 1=selectively, 2=routinely)
27. What is this PI Surgeon’s usual routine for post-op ultrasounds? .....PI\_POST\_US\_ROUTINE  
0 = the policy is that no routine post-op ultrasound is done  
1 = one post-op ultrasound done about one week post surgery  
2 = one post-op ultrasound done about two weeks post surgery  
3 = one post-op ultrasound done about three weeks post surgery  
4 = one post-op ultrasound done about four weeks post surgery  
5 = one post-op ultrasound done about five week post surgery  
6 = one post-op ultrasound done about six weeks post surgery  
7 = one post-op ultrasound done after some other time interval  
8 = more than one routine post-op ultrasound is done
28. What is the PI’s usual practice for the number and frequency of post-op visits? .PI\_POST\_VISITS  
0 = no usual practice for number and frequency of post-op visits to PI Surgeon  
1 = 1 visit. This post-op visit with the PI Surgeon is done within the first 2 weeks after surgery  
2 = 1 visit. This post-op visit with the PI Surgeon is done 2 to 4 weeks after surgery  
3 = 1 visit. This post-op visit with the PU Surgeon is done more than 4 weeks after surgery.  
4 = 2 or more visits. One at about 2 weeks, one at about 6 weeks, continued visits until access is usable  
5 = 2 or more visits. Pattern other than the pattern described above.
29. What is the post-op protocol that this PI Surgeon follows?  
Respond with 0=never or almost never, 1=sometimes, 2=always or almost always
- a. Patient is instructed to squeeze a ball. .... PI\_BALL
- b. Patient is prescribed post-op antiplatelet agents to assist in patency..... PI\_APLT\_ASSIST
- c. Patient is prescribed post-op drugs other than antiplatelets  
to assist in patency .....PI\_NONAPLT\_ASSIST
- d. Patient is prescribed post-op drugs other than antiplatelets  
for some other reason.....PI\_NONAPLT\_OTH
30. Approximately how many new AVFs (not grafts, revisions or converted AVFs from grafts) did this PI Surgeon create in 2007?.....PI\_AVF\_2007
31. Approximately how many new AVFs (not grafts, revisions or converted AVFs from grafts) did this PI Surgeon create in 2008?.....PI\_AVF\_2008
32. Approximately how many new AVFs (not grafts, revisions or converted AVFs from grafts) did this PI Surgeon create in 2009?.....PI\_AVF\_2009
200. Date this form completed (mm/dd/yyyy) ..... COMP\_DT
201. Username of person completing / reviewing completeness of this form.....COMP\_USER

<b>Clinical Center Use Only</b>	
Date Form Entered (mm/dd/yyyy) ___/___/___	ENTER_DT
Username of person entering this form _____	ENTER_USER