CHAPTER 4 BASELINE PRE-SURGERY DATA

4.1 General Principles of Pre-Surgery Data Collection

Patients can be enrolled when their clinical center, surgical facility, and designated dialysis unit are documented as ready to enroll in the HFM Study Database. This will be shown on the HFM Study Ready to Enroll Report, which will be updated daily.

It is recognized that some patient data, notably the baseline ultrasound, may be collected prior to patient consent. Of course, patient data should not be key entered into the study database until a patient has consented to the study.

Once a patient has consented, it is expected that all baseline data will be collected prior to access placement surgery. However,

1. if the patient does not consent to biological sample storage, this will be documented on Form 201 and biological samples will not be collected.

2. if the patient does not consent to DNA, this will be documented on Form 201 and DNA will not be collected.

3. if the patient does not consent to vein tissue storage, this will be documented on Form 201 and vein tissue will not be stored.

If an enrolled patient has an upper extremity fistula created but one of the following situations has occurred, follow up on that patient will be discontinued and this will be documented on the Baseline Drop Out Form 240.

- Pre-operative US was not performed on the arm where the study fistula was created

- Pre-operative US was done on the arm where the study fistula was created but was inadequate or *unreadable* and could not be repeated before surgery

- The study protocol includes pre-operative FMD and NMD vascular function testing. However, if only one of these two can be performed, the patient will still be allowed to continue in the study. (If neither is performed, the patient will not proceed to follow up.)

- Pre-operative venous plethysmography vascular function testing was not performed

- Pre-operative arterial pulse wave velocity vascular function testing was not performed

- Patient is not yet on chronic dialysis and was over 80 years of age at access creation surgery

- Surgery was performed by a surgeon not participating in the study

- At the time of surgery, learned that the patient will not be available for the 2-week ultrasound studies

- At the time of surgery, learned that the patient will not be available for the 6-week ultrasound studies

- Local IRB consent form guidelines. Too much time passed between the time the consent form was signed and the time of surgery, and a new consent could not be obtained

- Patient changed mind/decided not to participate (on day of surgery or before)

The HFM Study weekly report will regularly summarize missing baseline data and or missing baseline forms for all patients who have had their access placement surgery.

4.2 Baseline Pre-Surgery Data Collection

The following data forms should be completed during baseline for each HFM Study patient

1. 201 Screening Form

2. 202 Demographics, Comorbidities, and Exposures Form

3. 203 Baseline Pre-Operative Physical Exam Form

4. 204 Renal, Dialysis, Access History Form

If a patient starts dialysis with PD on 1/1/08 and changes to HD on 1/1/09 answers to Q.12 and 13 will be different. Or if a patient starts HD in 2006, gets a transplant in 2008, and restarts HD in 2009 the answers will be different since 2009 will be the most recent initiation of maintenance hemodialysis. Transient dialysis (i.e., a few treatments over the course of a week or two) will not be documented. Previous dialysis for acute renal failure with subsequent discontinuation of dialysis for at least 3 months before study entry is considered "not yet on chronic dialysis". Previous chronic dialysis with subsequent discontinuation for kidney transplantation but no dialysis for at least 3 months before study entry is considered "not yet on chronic dialysis".

5. 205 Medication Data Form

6. 206 Baseline lab Data Form

7. 207 Future Linkage with USRDS Form

8. 208 Pre-Operative Physical Activity Form

9. 210 Getting Ready for Vascular Study Form

10. 211 Venous Plethysmography study – local results form

11. 212 Arterial Pulse Wave Velocity – local results form

12. 213 Brachial Artery FMD/NMD Image Study – local clinical center form

13. 214 Brachial Artery FMD/NMD Image Study – central core results form

If a patient drops out of the study for a reason that is related to the vascular function studies, we need to have all of the vascular function study forms (Forms 211, 212, 213 and 214) entered into the database, with an explanation in the text field explaining what happened. For patients who dropped out of the study for another reason, we only need vascular function study forms entered if a study was attempted, but failed for some reason. For patients who had surgery done and have not dropped out right after, we need to have all of the vascular function studies forms entered. If a vascular study was not done, or not done correctly, we still need the form completed and entered with an explanation in the text field. The only exception is when the patient dropped out before any of the vascular function studies were scheduled. In this case only, vascular function study forms do not need to be entered.

14. 216 Local Ultrasound Imaging and Transmission Form

15. 217 Receipt of Ultrasound form

16. 218 Pre-Operative Ultrasound Data

17. 224 Post-Operative Ultrasound Data

18. 230 AVF Creation Surgery Notification Form

19. 231 Details of the Surgery Form

20. 240 Baseline Drop Out or Not Eligible to be Followed Form (only completed for any patient who will not be part of the follow-up cohort)

Patients who were dropped from the study **before fistula surgery**, but now appear eligible, can be re-enrolled. The patient's original ID must be used (do not assign a new PID) and the following steps are taken:

1. Re-consent patient if required by your IRB

2. Send an inquiry to the DCC to delete the Form 240 (Baseline Drop Out or Not Eligible to be Followed) from the database. Note on your paper form the date the form was deleted and retain in your patient's chart.

3. If any of the pre-operative testing was done >90 days before AVF creation, it will need to be repeated; i.e., pre-operative ultrasound, vascular function studies, and/or blood collection (except DNA).

4. Baseline Forms 202-206 should be repeated if completed >9 months before AVF creation (e-mail DCC when this has been done so old forms can be moved and new forms entered into the database).

Note: If a patient was enrolled in the study and had an AVF created, this patient cannot be re-enrolled in the study for any reason (including creation of a brand new AVF after drop-out, fistula abandonment or transplant).

21. 606 Mailing of Serum Specimen to Fisher (NIDDK) Biosample Repository Form (Heather Higgins)

22. 607 Mailing Blood to NIDDK DNA Repository (at U of Washington - Jennifer Gravley)

23. 608 Mailing of Vein Tissue with RNA Later Preservative and with Proteomics Preservative on DRY ICE to NIDDK Biosample Repository Form (Heather Higgins)

24. 609 Mailing of Frozen Vein Tissue on DRY ICE to the Histology Core at the University of Washington Form (Charles Alpers)

25. 610 Mailing of Formalin Fixed Vein Tissue in Ethanol at Room Temperature to the Histology Core at the University of Washington Form