CHAPTER 17 EXTERNAL QUALITY CONTROL

17.1 Quality Control of Clinical Centers

Various metrics will be used to measure data quality at the HFM Study Clinical Centers. Many of these will be included in the HFM Study Weekly Report. These will be summarized by clinical center and will include, for example:

- Proportion of those consenting to USRDS Data Linkage for whom the USRDS reports receipt of linkage data
- Proportion of those consenting to biological sample storage for whom samples are submitted
- Proportion of these samples arriving in usable condition
- Proportion of those consenting to DNA Collection for whom samples are submitted
- Proportion of these samples arriving in usable condition
- Proportion of those consenting to vein tissue collection for whom samples are submitted to the NIDDK Repository
- Proportion of these samples arriving in usable condition
- Proportion of those consenting to vein tissue collection for whom samples are submitted to the University of Washington Core
- Proportion of these samples arriving in usable condition
- Number and type of missing baseline forms for patients from that Clinical Center who have completed surgery
- Time from date of ultrasound to date Form 220 key entered (Baseline ultrasounds performed before patient consent will not be included in this summary)
- Time from date of surgery to data entry for Form 230 AVF Creation Surgery Notification Form
- Time from date of surgery to data entry for Form 231 Details of the Surgery Form
- Number of unresolved data discrepancy inquiries that have been outstanding for one to two weeks and for more than two weeks
- Time from date of inquiry to date of response
- Number of 2-week and 6-week ultrasounds
    1. Done on target date or within +/- 3 days from the target date
    2. Done +/- 3 to seven days from target date
    3. Done 7 to 14 days from target date
    4. Done more than 14 days from target date or missing

17.2 Quality Control of the Ultrasound Lab

Various metrics will be used to measure data quality. Many of these will be included in the HFM Study Weekly Report. These will include, for example, time from date ultrasound images received

from the Clinical Center to date ultrasound results submitted into the DCC database.

17.3 Quality Control of the Vascular Function Lab

Various metrics will be used to measure data quality. Many of these will be included in the HFM Study Weekly Report. These will include, for example, time from receipt of FMD/NMD images to time results submitted into the DCC database.

17.4 Quality Control of the Vein Tissue Core

Various metrics will be used to measure data quality. Many of these will be included in the HFM Study Weekly Report. These will include, for example, time from when the Vein Tissue Core receives the vein tissue until time the Vein Tissue Core enters the tissue receipt form.

17.5 Summary of Certification

17.5.1 Ultrasound Facilities

Ultrasound facility data are collected on Form 113. It is preferable that all ultrasounds for a given HFM Study participant be done at the same ultrasound facility. However, it is recognized that for some patients, the pre-surgical ultrasound will be done at one facility and the ultrasounds done after access placement surgery will be done at another facility. This is acceptable. However, all post-surgical ultrasounds should be done at the same facility for a given patient.

17.5.2 Outside Vascular Technologists and Sonographer at Baseline

It is possible that some baseline HFM Study ultrasounds will be performed by personnel who have not been certified in HFM Study procedures because some of these ultrasounds may be done before the participant joins the HFM Study. It is anticipated that all local ultrasound labs will follow procedures similar to the planned HFM Study ultrasound procedures, so these local ultrasounds will be usable for HFM Study purposes. Once a patient has joined the HFM study and had his/her access surgery, all subsequent ultrasounds should be done by trained HFM Study Vascular Technologists/Sonographers.

17.5.3 Training/Certification of Vascular Technologists and Sonographers

Prior to the start of the HFM Study, two or more Vascular Technologists and Sonographers were trained at the HFM Study Ultrasound Core Lab in Birmingham, Alabama. The people trained centrally are the only people considered trained and certified for HFM Study ultrasounds. Central training sessions will be held periodically as needed if extra people must be certified because of new hires and/or staff turnover.

Those trained in Alabama are not trained trainers and cannot certify new personnel. Only the HFM Study Ultrasound Core Lab in Birmingham, Alabama, can train and certify new personnel.

17.5.4 Training/Certification of those who will perform Vascular Function Studies

Prior to the start of the HFM Study, a member of the vascular function core lab travelled to each clinical site and trained two or more vascular function study technicians to do 1) HFM Study brachial artery FMD/NMD studies; 2) HFM Study arterial pulse wave velocity studies; and HFM Study venous occlusion plethysmography studies. At the start of the study, only the people trained by a member of the vascular function core lab were considered trained and certified for each of these vascular function tests.

Those trained by a member of the vascular function core lab are considered trained trainers and can

train and certify new personnel. If a new person is trained, the Personnel Form 101 will show (for HFM Study brachial artery FMD/NMD studies; HFM Study arterial pulse wave velocity studies; and HFM Study venous occlusion plethysmography studies) the study id of the local "trained trainer" HFM Study person who did the training and the date of the training.

Note that those who were trained centrally at the start of the study are designated as trained trainers but those who they train are not. Only centrally trained personnel are considered to be trained trainers, capable of training new or replacement workers.

17.5.5 Training/Certification for collection and processing of HFM Study vein tissue specimens

Training in collection of vein tissue and appropriate processing for vein tissue was conducted at the HFM Study Central training prior to the start of the study.

Personnel were trained on how to cut a piece of vein tissue into four segments and how to process each of these four segments. It is recognized that in some cases, a surgeon will cut the vein tissue into four pieces before turning the pieces over to the HFM Study staff member. This is acceptable.

The HFM Study staff member is responsible for making sure each of the four pieces of vein is processed appropriately and that two pieces are sent to the NIDDK repository and two pieces are sent to the University of Washington following the procedures described in Manual of Operations Chapter 12.

At the start of the study, only the people trained centrally were considered trained and certified to process vein tissue. Those trained at the central training session are considered trained trainers and can train and certify new personnel.

If a new person is trained, the Personnel Form 101 will show the study id of the "trained trainer" local HFM Study person who did the training and the date of the training.

Note that those who were trained centrally at the start of the study are designated as trained trainers but those who they train are not. Only centrally trained personnel are considered to be trained trainers, capable of training new or replacement workers.

Central training for vein tissue collection may be repeated at future HFM Study Coordinator Annual Training Sessions.

17.6 Site Visits

17.6.1 "In Person" Site Visits of the Clinical Centers

It is anticipated that each clinical center will be site visited once fairly early in the study. A clinical center will not be site visited until each surgical facility that will be participating in HFM Study has placed at least one fistula and until at least ten surgical procedures have been performed at that clinical center. The site visit team will include representatives from NIH, the DCC, and the quality control committee. The team may include a study coordinator from another clinical center. An agenda will be distributed prior to these meeting. The agenda will include details on local institutional support for the study, details on recruitment, retention, and quality control. The site visit team may request to review patient binders.

17.6.2 "Teleconference" Site Visits

"Teleconference" Site Visits may be held 1) to review early clinic set up or recruitment issues, 2) to follow up on "In Person" Site Visits, or 3) to review details on recruitment, retention, and quality control. The site visit team will include representatives from NIH, the DCC, and the quality control committee. An agenda will be distributed prior to these teleconferences.

17.6.3 Site visits of the Cores

Site Visits may be held at the Ultrasound Core, the Vascular Function Core, or the Vein Tissue Core. The site visit team will include representatives from NIH, the DCC, and the quality control committee. The team may also include an outside expert.