

CHAPTER 19 PARTICIPANT TRANSFER TO A NEW DIALYSIS UNIT

19.1 Patient Transfer

Before any patient can be enrolled in the HFM Study, his or her designated dialysis facility must be documented in the HFM Study database as being ready to enroll. At the time of his or her enrollment in the HFM Study, his or her designated dialysis facility is listed on the Form 201, Screening form. This applies whether the participant is already on dialysis at that facility or not yet on dialysis.

If a patient's designated dialysis unit changes, it will be documented on either the Cannulation Form 302 or the Assess Clinical Maturation Form 305.

If the patient is transferring to a dialysis unit that is ready to reenroll in the HFM Study, data collection should continue according to the study protocol.

If the patient is transferring to a dialysis unit that is affiliated with his or her HFM Study Clinical Center but not yet ready to reenroll in the HFM Study, the PI and Study Coordinator should make a special effort to complete study readiness procedures on that facility.

If the patient is transferring to a dialysis unit that is not yet affiliated with his or her HFM Study Clinical Center but not yet ready to reenroll in the HFM Study, the PI should try to work with the dialysis unit to get that unit to become part of HFM Study.

If the site PI determines that the dialysis unit that the patient has transferred to will not provide data to the HFM Study, the coordinator should try to obtain key data directly from the patient by phone. This would include, for example, date the patient started dialysis, date the fistula started being used for dialysis, date of a transplant, or date a new access is placed.

In the unlikely event that a patient moves from one HFM Study Site to another (e.g., from Site 1 Boston to Site 2 Cincinnati), the DCC, the PI and Study Coordinator of the originating site, and the PI and Study Coordinator of the new site will have a teleconference to discuss plans for site documents (what the originating site will send to the new site) and reports (who will receive reports about this patients, who will answer inquiries about this patient, where will the patient appear in summary tables).