Chapter 23

Transfer of Participants
Between Field Centers (FCs)

PURPOSE

There are two occasions for transfer of a family member or family who has been identified through the screening process.

1. Field Center to Field Center Transfers can occur when one Field Center (FC) has family member(s) in another Field Center's catchment area. This transfer involves reassigning the ID to the receiving Field Center and all study data collection for that individual to that FC. In most cases complete data collection would be conducted by the receiving FC staff. In rare instances, a previous telephone visit might have already been conducted hence family member would convert to an in-person visit.
2. Field Center to Field Center Transfers can also occur when one FC's staff person is seeing another FC's family member during a long distance visit trip. This may involve completing a visit that had previously been conducted as a telephone visit or with a remote blood draw or may entail a full visit with reassignment as above of the ID and all data collection.

Protocols for (a) local-to-local FC transfers and (b) long-distance FC transfers follow:

PROTOCOLS

<u>Local-to-Local FC Transfers</u>: Family members of probands from the three US Field Centers of the LLFS Study are often dispersed throughout the US. The long distance protocol (*please refer to LLFS MOP Chapter 24*) serves to track and prioritize visits to family members who live outside of any one of the three US Field Centers. We have also had occasions where some of these family members live within the defined catchment area of another one of the Field Centers. The following protocol was developed to clearly define the procedures to obtain a new ID, to consent, examine, data enter and track family members for each respective Field Center, transferring and receiving. A major goal of this protocol is to define the optimal point in the recruitment of such families to transfer the family members and to define the role of each Field Center in the process.

In order to be most efficient and to coordinate efforts across Field Centers, the originating FC should attempt to identify the full complement of potentially recruitable and transferable family members before transferring any single family member. In some instances this is not realistic. Therefore, the originating FC should transfer family members at a pace they are comfortable with, but should also inform the receiving FC that more individuals may be forthcoming. They should also have enrolled the core three family members at their FC to be sure that the added outside family members are contributing to enlarging the minimal family size and should provide the pedigree information that is pertinent for verification as well as for general information so that all staff members involved at the two centers can present themselves as knowledgeable about previously identified family members. In some cases, the visit may involve seeing a person or 2 that make the up the core 3 family members. If so, the same procedures hold

Because there may be identification of other family branches at any point in this process, an ongoing shared communication process will be necessary so that the originating FC can continue to serve to manage the entire family. For example, a family member who is identified as living in another FC area may further identify more family members who live outside of any FC or who live in a third FC's catchment area. Such family members should have been identified in the original TS2. Potentially, additional identification or

family interest and consent may come to LLFS via the transferred family member. Any such information obtained by the receiving FC should be provided back to the originating, transferring FC to update the TS2 form. The consent form will be copied for the originating FC to provide supporting documentation that the visit was completed and that consent was obtained for participation in the LLFS study.

It is also possible that a proband may be identified at one FC, but the majority of the family members be found in another FC or be long distance visits or both. If the majority (75%) of the sibship lives in another FC's area, the proband should be reassigned to the receiving center FC. This will improve case management of the family. There will be families that are truly split between two or who are scattered widely. In these cases, the originating transferring FC should manage that family. In all cases, full communication about families is essential to present a seamless scheduling and coordinating of communications to the family members. There will certainly be unanticipated unique circumstances that arise throughout the course of the study. Queries should be made to the operations committee so that the protocol can be modified if needed in the future.

In some cases, a proband may be screened and deemed eligible by one FC but all family members (including the proband) reside within another FC's catchment area. In this situation, the proband should be transferred to the local FC for further recruitment. The identifying FC should alert the Site Director and Clinic Coordinator of the receiving FC before DES transfer, and the original TS1 should be faxed to the receiving FC so as to have a complete chart. The TS2 and all other recruitment and enrollment processes will be conducted by the local FC once the DES transfer is completed.

Long Distance Field Center Transfers: In the course of conducting long distance visits, staff from one FC may examine family member(s) of a family identified by another FC. If the family member has not already had a telephone visit there will have been no prior consent form. The protocol and procedure would then be the same as for a local to local transfer. If a prior telephone visit has been done, then there would be a signed consent form in place at the transferring FC. Thus, in planning the long distance visit it is important to document which visits that are needed are partial or full visits. Once the long distance trip is approved, the transferring FC will provide a copy of this to the receiving FC and confirm the data collection aspects that have been completed. For example, the blood draw may or may not have yet been completed and could then be picked up by the traveling team rather than using the remote blood draw protocol.

PROCEDURES

The stepwise procedures outlined below should serve to improve efficiency for each FC when scheduling in-person local, as well as long distance visits, defining the data that can be shared so that all parties involved are knowledgeable about family size, location, and participation status.

Local-to-Local Field Center Transfer:

1. Before transferring a single family member, the family should be worked up using the TS1-TS3* documentation to determine the full complement of individuals potentially available for transfer.
2. Once this information has been obtained, a determination of whether or not an entire family or individual members should be transferred is made based on the location of the majority of family members. If the majority (75%)of the family members from FC-A are located in the catchment area of FC-B, then that entire family should be transferred from FC-A to FC-B. FC-A will then become the transfer visit center for the transferred family.
3. If a family member is transferred and then they decide not to participate or after multiple attempts is unable to be reached, they should be transferred back to the originating FC. This should be communicated to the originating Site Manager and Clinic Coordinator prior to the transfer back.

The originating FC will, upon receipt of the return transfer, update the DES to reflect their current recruitment status. If their status changes at a later date, they can be re-transferred.

4. Responsibilities of the Transferring Field Center:
   - Complete a TS1a for each sibling identified on the TS2 as willing to be contacted.
   - Complete a PIF (TS3) if the individual to be transferred is a sibling as per study protocol.
   - Transfer all living family members identified from the TS3 to the TS2 as per study protocol.
   - Obtain permission to contact all family members from the TS2 or document refusal or unable to contact.
   - Complete a TS1a for any family member who has agreed to be contacted.
   - Alert the receiving FC Clinic Coordinator (with a copy to the Site Manager, if different) of the potential number of family member(s) in their area. Any pertinent information that would help determine the priority of the individual should be provided to the receiving FC to assist the receiving FC in prioritizing the transfer visit within their existing workload and priorities
   - Provide a copy of the full family pedigree, as well as the index family member's PIF and pedigree prior to the in-person visit, This will allow the receiving FC to have a general knowledge of the family structure and to complete a PIF if needed.
   - Provide any additional information regarding how to best contact family members (i.e. via email) or other pertinent information to the receiving FC Clinic Coordinator.
5. Responsibilities of the Receiving Field Center:
   - Schedule and complete the full in-person visit, including obtaining the full consent and the blood draw.
   - Complete all data entry that is needed and file the chart at the FC where the visit was conducted.
   - Notify the transferring FC when any in-person visits have been completed
   - Obtain blood work, receive any alert values and communicate results per protocol to the transferred participant.
   - Provide any information regarding additional family members giving verbal consent to the receiving FC, new family members identified or expressing interest or other information needed to further enroll members of the family to the transferring FC. Send a copy of the consent form for the files at the originating transferring FC.
   - Assume future follow-up contact and retention activity (i.e. birthday and/or holiday cards) since the receiving FC holds the signed informed consent. If during the follow-up additional family members are identified, that information needs to be communicated to the Site Manager and Clinical Coordinator of the originating FC.
   - Family members seen by the visiting FC will NOT be transferred back to the originating FC. Their chart and it's contents will remain with the visiting FC that holds the IRB approval.

Long Distance Field Center Transfer:

1. Before transferring a single family member, the family should be worked up using the TS1-TS3* documentation to determine the full complement of individuals potentially available for transfer.
2. Once this information has been obtained, it can be added to the long distance visit log for planning the long distance visits (*please refer to LLFS MOP Chapter 24*). Indicate on the log as to whether the visit will require a full visit or a partial visit (blood, blood and in-person evaluation, or in person evaluation only).
3. Responsibilities of the Transferring Field Center:
   - Complete a TS1a for each sibling identified on the TS2 as willing to be contacted.
   - Complete a PIF (TS3) if the individual to be transferred is a sibling as per study protocol.
   - Transfer all living family members identified from the TS3 to the TS2 as per study protocol.
   - Obtain permission to contact all family members from the TS2 or document refusal or unable to contact.
   - Complete a TS1a for any family member who has agreed to be contacted.

  - Once a long distance visit is approved, alert the team leader for the long distance visit of (with a copy to the Site Manager, if different) of the potential number of family member(s) to be transferred. Any pertinent information that would help determine the priority of the individual should be provided to the receiving FC to assist the receiving FC in prioritizing the transfer visit within the long distance travel plan. The requirements for full or partial visit should be confirmed.
  - Provide a copy of the full family pedigree, as well as the index family member's PIF and pedigree prior to the in-person visit. This will allow the receiving FC to have a general knowledge of the family structure and to complete a PIF if needed.
  - Provide any additional information regarding how to best contact family members (i.e. via email) or other pertinent information to the receiving FC staff person or travel team leader.
4. Responsibilities of the Receiving Field Center/travel team member:
  - Schedule and complete the full or partial in-person visit, including obtaining the consent.
  - Complete all data entry that is needed and file the chart at the FC staff person that traveled to perform the visit.
  - Complete all data entry.
  - Notify the transferring FC when any in-person visits have been completed.
  - If blood work was included in the visit, receive any alert values and communicate results per protocol to the transferred participant.
  - Provide any information regarding additional family members giving verbal consent to the receiving FC, new family members identified or expressing interest or other information needed to further enroll members of the family to the transferring FC.
  - Assume future follow-up contact and retention activity (birthday and/or holiday cards) since the visiting FC holds the informed consent. If during the follow-up additional family members are identified, that information needs to be communicated to the Site Manager and Clinical Coordinator of the originating FC.
  - Family members seen by the visiting FC will NOT be transferred back to the originating FC. Their chart and it's contents will remain with the visiting FC that holds the IRB approval.

Study Documents Referred to in this Chapter:

- TS1, proband and sibling status and location
- TS2, sibling and family member location and willingness to be contacted
- TS3 (PIF), individual proband and index person pedigree form