

Chapter 17

LONG DISTANCE VISIT PROTOCOL

Purpose and Overview. Visit 1 of LLFS included family members living in cities that were outside of the respective catchment areas of the US field centers as well as some families that resided entirely outside of the catchment areas of the three US field centers. These participants are to be included in Visit 2 of LLFS, and this chapter will guide as to whether those individuals should be enrolled via an in-person or telephone visit, give hints as to how to travel with the equipment on airlines, and logistical issues related to these visits.

If the participant lives in a remote area, we will allow a telephone interview followed up by a remote blood draw at a clinic near their residence, or use of the Oragene collection cup (mouthwash) to obtain DNA on these participants. Additionally, for any participant in which we are unable to obtain a blood draw, we will use the Oragene collection cup (mouthwash) to obtain DNA on these participants.

Travel Review Committee. For Visit 2 there is no travel review committee because the US Field Centers budgeted for long distance travel to participants in their respective renewal grant applications. In lieu of this, the Long Distance Visits subcommittee of the Field Operations committee will commence in an effort to coordinate the visits of the Field Centers and to address any issues that may arise regarding which Field Center will perform a long distance visit.

Criteria to Prioritize Trips:

1. Each field center should examine their preferred order of participants for Visit 2 and assess when and where the long distance visits may occur in that order.
2. If there is more than one family/participant in a specific geographic area, it is best to try and visit all families/participants for Visit 2 during the same long distance visit.
3. Field Center PIs need to re-initiate contact with remote clinics for blood draws.
4. DMCC staff is available to aid with planning which families should be grouped together based on location, if needed.
5. There will be a centralized long distance travel schedule to aid in Field Centers working together in an efficient and cost-effective manner to re-visit all participants. Additionally the Long Distance Visits subcommittee will be reinstated to address issues with scheduling and participants that may have moved closer to a different field center and thus may be seen by a different field center in Visit 2.

Review Of Study Recruitment Goals. The primary goals of the study are outlined below to ensure that Visit 2 efforts remain focused as described in the LLFS protocol:

1. Revisiting all willing participants from Visit 1.
2. Revisiting local families within a field center's respective catchment area will remain the top priority.
3. Visits for family members living outside of the catchment area are permitted in order to complete the families that were originally identified within the field center's catchment area. These visits will be coordinated centrally, as some participants may have moved closer to a different field center and thus it may be more expedient for another field center to visit that family member during visit 2 and its follow-up. These cases are likely to be discussed by the Long Distance Visit Subcommittee.
4. Visits for families that participated in Visit 1 that reside completely outside of the 3 US field center catchment areas (i.e., a "Long Distance Family Visit") will also be coordinated centrally, with potential

discussion by the Long Distance Visits subcommittee if necessary.

5. All participants from Visit 1 will retain their same study ID for Visit 2. If a participant has moved and is in a catchment area of another US field center, or lives in an area where another US field center already has a long distance visit scheduled, that participant will be consented and seen by the field center whose catchment area they live in. Thus for Visit 2, it is possible that participants will be ‘transferred’ to a new field center based on which center performed the long distance visit for Visit 2, based on logistics and economical use of resources. These transfers will be discussed on biweekly Long Distance Visit calls. No new study ID will be assigned to these transfers, but there will be a variable added to the dataset to acknowledge which field center is responsible for which participants at Visit 1 and 2 (details in section ‘Transfer of Participants Between Field Centers (FCs)’, below).

Definitions:

- **Catchment Area.** Each study site has chosen a 'predefined' geographic area (identified by zip codes) for participants. The boundaries for these areas are loosely defined but include Pennsylvania, New York and New England.
- **Long Distance Visit.** An in-person consent and examination, including blood draw (or Oragene collection cup for those unable to get a blood draw), that requires travel outside of a field center catchment area. This may require air travel, overnight stay, car rental and hotel accommodation for the staff. The study site has budgeted for these trips in their respective renewal budgets.
- **Telephone Visit.** A visit conducted via telephone interview only, with blood obtained via a local lab or physician's office, or using the Oragene collection cup to obtain DNA if a blood draw is not possible.

Guidelines for Extending a Local Family Long Distance Visit. Potential new family members that are interested and willing to participate but reside outside of a field center's catchment area are allowed.

1. The field center associated with the other family members is responsible for visiting this/these individuals.
2. If that field center is unable to perform the visit, then that field center will determine whether this person will be visiting in one of the field center catchment areas within the next 3-6 months or if another field center is able to visit this participant.
3. In the interim, a telephone consent and interview should be conducted and arrangements made to obtain the blood specimen (or Oragene collection cup) through a local lab by the field center that originally identified the family. Non-LLFS personnel (e.g. physician or contracted service) collection and processing of blood sample will be performed using the previously developed protocol.
4. Individual family members on the Long Distance Spreadsheet will be scheduled to be seen when a cluster reaches the point where a field center deems the trip will be worthwhile, based on budget and number of participants to be seen. Priority will go to those who are the oldest and in the sibling generation.

Long Distance Travel Coordination

Field centers are supporting and arranging their own long distance travel. Field centers will review the list of participant order, which includes last contact address, and assess who is a long distance visit, who is local, and who may be in a different field centers catchment area, and put that designation on the list. Non-local individuals will then be discussed by the Long Distance Visit subcommittee to decide which field center should perform Visit 2 once it is assessed that the participant is willing to participate in Visit 2.

Travel Review Committee Requirements To Proceed With Long Distance Visits

The coordinating field center will be responsible for completing all of the following steps prior to formally scheduling a long distance visit:

- Compilation of a proposed expense budget. The budget should include the dates of travel, means of travel, housing, names of all personnel that will participate in the trip, as well as a complete listing of the individuals that have agreed to be seen.
- Once a budget has been drafted, this should be approved by the field center PI for review and analysis of monetary resources available.
- Collaboration with the other field centers who have individuals to be seen in this location;
- Confirmation of the willingness and eligibility of each family member to be visited; consent forms should be sent by courier mail to all family members expressing an interest in participation.

Long Distance Visit Clusters

The DMCC will be responsible for managing a spreadsheet and state maps so that geographic clusters of Visit 1 participants outside of the existing catchment areas can be easily identified. This will facilitate efforts to identify Visit 2 participants that might reside or cluster in specific geographical areas. The spreadsheet will identify clusters by state, which will then be mapped using either MSN or Google mapping programs to determine more specific logistical regions. Field centers will work with each other to then coordinate who goes on what visits based on the field center of the participant during Visit 1. If it is more feasible for staff from a different field center than in Visit 1 to visit a participant for Visit 2, that participant will become the responsibility of the field center performing Visit 2 (details in section ‘Transfer of Participants Between Field Centers (FCs)’, below). Whichever field center performs the in-person Visit 2 will also be responsible for performing Visit 2 Follow-Up. These cases will be discussed during the Long Distance Visit Subcommittee meetings, and the Long Distance Visit Subcommittee will monitor when the trips occur to facilitate coordination.

Long Distance Visit: Study Assessments, Phlebotomy and Surveys.

Long-distance participants/families will undergo the same sequence of assessments and surveys as those participants seen in study site catchment areas, and as outlined below and in the LLFS Manual of Operations and Procedures, Chapter 1. As additional long- distance visits are conducted, the Field Ops Committee will determine whether any changes need to be made to this plan.

Preferred Order of Exams. The sequence of procedures at a home visit is not mandated and may be administered at the discretion of the individual Field Centers in an order which would best build rapport with the participant. However, if there is any indication that the participant may be too weak to complete the series of assessments, the information collected should be done so according to the scientific value of the data:

Physical/Cognitive Measures

- Phlebotomy (at the time of the long-distance visit or a blood draw at a local laboratory can be arranged in advance of the long-distance visit, Oragene Collection Cup can be used if a blood draw is not possible)
- BP/HR
- Medications
- Performance Measures
- Cognitive Tests (with exception of long-term recall)
- WT/HT & Waist Circumference (please do as many of these measures as possible during the 40 minute wait for long term recall)
- Long-term recall
- Carotid ultrasound
- Finish any WT/HT and Waist Circumference Measures not completed during 40 minute break
- Spirometry
- CES-D

Questionnaires/Other Instruments

- Socio-demographics
- Medical History
- Physical Function and Activity
- Personal History

The above list was ranked with the understanding that some questionnaires can be completed over the phone or left with the participant to complete and return by mail to the Field Center. In cases where the participant may be unable to complete all of the assessments due to a cognitive or physical impairment, some of the forms will be administered to a proxy.

Transfer of Participants Between Field Centers (FCs)

As stated earlier, there will be no study ID transfer of participants between Field Centers for Visit 2. If a participant has moved from the catchment area of one field center to another field center catchment area, it is anticipated that the field centers will work with each other to see this participant in the most cost and time efficient manner while the participant retains their identical study ID from Visit 1. Whichever field center performs the second in-home visit, that field center is then responsible for performing long term telephone follow-up of that participant since they will be consented under that field center. There will be an additional variable added to the dataset which will identify which field center performed Visit 2 and Visit 2 Follow-up, specifically for cases where Visit 2 and Visit 2 follow-up is performed by a different field center.

Procedure for transferring participants from one field center to another

When either the Long Distance Subcommittee or a field center researcher determines that a participant should be seen at a different field center for visit 2, the following procedure should be followed.

1. If not already done so, this potential transfer should be discussed and confirmed amongst field centers on the long distance subcommittee call.
2. The study coordinator from the visit 1 field center needs to notify (via email) the DMCC (Rosa Lin, rosa@dsg.wustl.edu, and Mary Wojczynski, mwojczynski@wustl.edu) of the transfer. Details to include are the LLFS ID of the participant to be transferred, visit 1 field center, and which field center has agreed to visit this participant for Visit 2.
3. The DMCC will then assign this transferred participant to the Data Access Group associated with the Visit 2 field center in REDCap. After this occurs, the visit 1 field center will no longer be able to access this participants record in REDCap as it will now belong to the Visit 2 field center. The Visit 2 field center will have access to the Visit 1 in person and follow-up data for this transferred participant in REDCap.

Tips for Traveling on Airlines with Study Equipment

1. On long distance trips, it is best to have one suitcase full of all of the equipment. Airport security almost always opens this suitcase to look through (usually leaving a note inside saying that they inspected it). Therefore be sure to arrive at the airport early to allow extra time for security to inspect this checked bag.
2. Wrap each item of equipment in bubble wrap to prevent damage when the suitcase is thrown around at the airport.
3. Ship the blood kits to the arranged hotel where you will be staying and leave them with the participants after completing the in-home testing session. A research assistant back at the office will schedule the blood draw for the next morning with either a local or national lab (*Field Centers need to re-establish these connections; EXAMONE*).
4. If you are drawing blood on participants the next morning, ask the hotel to freeze the ice packs in the blood kits for us the night before. Not all hotels may be willing to do this, so it may be helpful to pick a hotel with a fridge/freezer combo in each hotel room.
5. If the long distance visit involved seeing a large number of participants we would mail all of the panels to the hotel in advance so that you do not have to take them on the plane. Always be sure to have a few extra copies of the panels in case they didn't make it to the hotel or the hotel loses the shipped box.

Study Documents Referred to in this Chapter:

- Participant current contact information