

Chapter 21

LONG DISTANCE VISIT PROTOCOL

Purpose and Overview. Visits 1 and 2 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 3 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. Note for Visit 3, there is a high likelihood that a large percentage of the third (grandchild) generation may live outside of the three US field center catchment areas. As it is a priority to conduct in-person visits on the grandchildren generation that agree to participate, we may be conducting more of these long distance visits than for Visit 2.

If the participant lives in an outlying area, we will allow a telephone interview followed up by a remote blood draw using ExamOne, at a clinic near their residence, or use of the saliva collection kit to obtain DNA on these participants. Additionally, for any participant in which we are unable to obtain a blood draw, we will use the saliva collection kit to obtain DNA on these participants.

Long Distance Visit (LDV) Subcommittee: 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 3 (the prioritized list from the DMCC based on the LOD score and/or participant age) 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 3 during the same long distance visit.
3. Field Center coordinators need to re-initiate contact with ExamOne for remote blood draws.
4. 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 3.

Review Of Study Recruitment Goals. The primary goals of the study are outlined below to ensure that Visit 3 efforts remain focused as described in the LLFS protocol:

1. Revisiting all willing participants from Visit 1 or Visit 2.
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 and cost-efficient for another field center to visit that family member during visit 3 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 or Visit 2 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 will retain their same study ID for Visit 3. 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 3, it is possible that participants will be ‘transferred’ to a new field center based on which center performed the long distance visit for Visit 3, based on logistics and economical use of resources. These transfers will be discussed on monthly 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 each visit (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 saliva collection kit 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 saliva collection kit 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 saliva collection kit) 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 from a high LOD score family.

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 3 once it is assessed that the participant is willing to participate in Visit 3.

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 (or their designee) 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 mail to all family members expressing an interest in participation.

Long Distance Visit Clusters

The chair of the Long Distance Visit Subcommittee will be responsible for managing a spreadsheet and state maps so that geographic clusters of Visit 1 and 2 participants outside of the existing catchment areas can be easily identified. This will facilitate efforts to identify Visit 3 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 3. If it is more feasible for staff from a different field center than in Visit 2 to visit a participant for Visit 3, that participant will become the responsibility of the field center performing Visit 3 (details in section ‘Transfer of Participants Between Field Centers (FCs)’, below). Whichever field center performs the in-person Visit 3 will also be responsible for performing subsequent Visit 3 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.

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

- BP/HR
- Phlebotomy (or on a separate visit)
- Performance Measures including sit to stand test
- 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
- Ankle-brachial index
- Neuro-motor Exam
- Finish any WT/HT and Waist Circumference Measures not completed during 40 minute break, including additional measures for new enrollees
- Spirometry
- CDR and DQ

Questionnaires/Other Instruments – Interviewer Administered and Review Self-administered

- Medical History (interviewer administer and review)
- Medications (interviewer administer)
- CDR and DQ (interviewer administer, if applicable)
- CES-D (interviewer administer at the very end of the visit)
- Socio-demographics (review)
- Physical Function and Activity (review)
- IADL's (review)
- Personal History (review)
- Dietary Food Frequency Questionnaire (review)
- NEO (interviewer administer - new participants only)
- Health Habits (review - new participants only)

The above list was ranked keeping in mind that some questionnaires can be administered over the telephone with the participant or left with the participant to complete and return mail to the Field Center. In some situations, the participant may be unable to complete some or all of the examinations due to either physical or mental impairment. In these cases, some of the forms may be administered to a study partner/proxy/LAR. If the in person visit is a split visit, the order outlined above should also be followed.

Because the blood sample must be fasting, it may be preferable to schedule the phlebotomy as a separate visit. **If so, the blood sample should be collected within four weeks AFTER the exam.** Do not arrange for the blood sample collection before the exam is completed because informed consent is part of the exam.

Transfer of Participants Between Field Centers (FCs)

If a participant has moved from the catchment area of one field center to another field center catchment area (or will be seen on a long distance visit conducted by a field center other than their own), 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 2. Whichever field center performs the third 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 3 and Visit 3 Follow-up, specifically for cases where Visit 3 and Visit 3 follow-up is performed by a different field center from Visits 1 or 2.

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 3, 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 LDV subcommittee call.
2. The study coordinator from the Visit 2 field center needs to notify (via email) the DMCC (Rosa Lin, rosa@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 2 field center, and which field center has agreed to visit this participant for Visit 3.
3. The DMCC will then assign this transferred participant to the Data Access Group associated with the Visit 3 field center in REDCap. After this occurs, the Visit 2 field center will no longer be able to access this participants record in REDCap as it will now belong to the Visit 3 field center. The Visit 3 field center will have access to the Visit 2 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-person visit if the participant will be having blood drawn by a local lab rather than study staff. It is best to make the blood draw arrangements with either a local or national lab before the visit takes place so you can share the instructions at the visit.

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 involves seeing a large number of participants we should mail all of the blank study panels to the hotel in advance so that they do not need to be taken on the plane. Always be sure to have a few extra copies of the panels (or travel with them on a jump drive) in case they didn't make it to the hotel or the hotel loses the shipped box so that you can have them copied at an office center. Another alternative is to access them via the study website if you have an internet connection (<https://dsgproject.atlassian.net/wiki/spaces/LLFS/pages/85819429/Visit+3+MOP+Panels+and+Chapters+Sept+15+2019+to+Present>).