

## Chapter 24

### LONG DISTANCE VISIT PROTOCOL

**Purpose and Overview.** The LLFS conducted a pilot study for recruitment to assess family size and structure in a sample of Medicare enrollees in each of the three U.S. field center catchment areas, as well as people responding to media coverage of the study. Experience from the pilot has made it clear that the locally recruited probands and their families may have additional family members living in cities that are outside of the respective catchment areas of the US field centers. Moreover, publicity about the study has generated interest from potential participants throughout the United States, including cities which are outside of the catchment areas of the three US field centers. Although the focus of LLFS recruitment will remain within the respective catchment areas for each site, limited national recruitment will be supported following specific guidelines outlined below. These guidelines are to provide specific criteria for determining which family members, residing out of the 3 predefined catchment areas, should be pursued in order to increase the total family size of a currently enrolled family, as well as whether those individuals should be enrolled via an in-person or telephone visit. These guidelines are also intended to aid in determining whether a site should seek to enroll extraordinary families from outside the catchment areas without burdening study staff and resources.

**Travel Review Committee.** Travel request postings should be made via submission of a Travel Request Form (*Chapter 24, Appendix 1*) to the DMCC and the Travel Committee Chair designee who is maintaining the spreadsheet. If a request meets the requirements outlined below, it will be added to the "Long Distance Travel Spreadsheet" (*see sample page in Chapter 24, Appendix 2*) based on state of residence. The process to determine whether a family or family member will be seen will be initiated by the Field Center Site Managers, in conjunction with the DMCC. This working group will identify "clusters" of families or family members in one area and propose the trip to the Travel Committee. Priority will be given to clusters of people that have sibling generation family members to be seen, those longest on the spreadsheet and age. Staffing for these trips will be decided based on available resources, which field center has largest number of people to be seen, and fiscal considerations. Upon identification of a viable trip, a budget will be submitted to the DMCC for review by them and the Travel Committee Chair, and then the Travel Committee Chair will present the trip to the LLFS Executive-PI Committee for a formal vote. This will be done during an Executive-PI Conference Call in the slot designated for discussion/review of travel requests.

At the original drafting of this protocol, it was proposed that each field center PI would serve a 6-month term as the chair of the Travel Review Committee. This assignment would include responsibility for the initial recruitment review process. This initial review will entail reviewing data sent by the DMCC concerning these families and making recommendations to the Travel Review Committee and/or Executive-PI Committee for consideration/approval of a long distance recruitment visit.

#### Criteria to Prioritize Trips:

1. Ascertainment of these exceptional families will be based on the size of the family and the potential recruitment of other eligible families in the area (e.g. assess rarity).
2. Family size will be a key factor in deciding which families will be considered eligible. A minimum of six family members (including the required two siblings, an offspring) living in the same area who have given verbal consent for a visit will be required for recruitment of a Long Distance Family.
3. Assess fragility of key family members and how quickly a visit may have to happen to avoid a major change in the status of the family.
4. Also take into account long distance visits to locally recruited core family members using the study website-based interactive map.

**Review Of Study Recruitment Goals.** Upon the incorporation of this 'new' recruitment protocol into the original LLFS recruitment protocol, the primary goals of the study are outlined below to ensure that recruitment efforts remain focused as described in the LLFS protocol:

1. Locating local families within a field center's respective catchment area will remain the top priority.
2. Recruitment outside of the catchment area will be permitted in order to complete the recruitment of families that were originally identified within the field center's catchment area (i.e., a "Extend Local Long Distance Visits"). These visits will be coordinated nationally and are to be conducted after review by the Travel Review Committee and formal approval by the Executive-PI Committee.
3. Recruitment of exceptional families that reside completely outside of the 3 US field center catchment areas (i.e., a "Long Distance Family Visit"), split between two long distance visits (i.e., "Split Long Distance Visits"), and split families between local field centers and long distance (i.e., Split Local and Long Distance Visits") will be coordinated nationally and are to be conducted only after review by the Travel Review Committee and formal approval by the Executive-PI Committee.

### Definitions:

- **Catchment Area.** Each study site has chosen a ('predefined' geographic area (identified by zip codes) for focused recruitment. 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, that requires travel outside of a field center catchment area. This recruitment may require air travel, overnight stay, car rental and hotel accommodation for the staff. If approved by the Travel Committee, the study site will be reimbursed for expenses by the DMCC following the disbursement procedure described below.
- **Extend Local Family Long Distance Visit.** An in-person visit to one or more family members of an already enrolled locally recruited family by one of the 3 field centers, but these family members reside outside of any of the 3 US catchment areas (e.g., for purpose of rounding out an already-recruited core family of at least three individuals, consisting of a proband, sib and offspring *of one or both of these two individuals*).
- **Long Distance Family.** A family identified for enrollment, but which all family members reside completely outside each of the 3 US field center catchment areas; i.e. recruitment of the 'key triad' which consists of at least the proband, one sib and one (or more) offspring of either of these two individuals would require a long distance visit to one location to enroll the family. FLoSS score requirement to post this family is  $\geq 15$ .
- **Split Long Distance Family Visits.** A family identified for enrollment but at least two long distance visits would be needed to enroll this family, i.e., the proband and sibling (assuming an offspring lives near one of them) live in two different places outside our 3 US catchment areas. FLoSS score requirement to post this type of LD family is  $\geq 15$ .
- **Split Local and Long Distance Family Visits.** A family identified for enrollment, but the proband (or sibling with or without offspring) lives within one of the 3 US field centers catchment areas but the other sibling (with or without offspring) to make the critical 3 requires a long distance visit. FLoSS score requirement to post this type of LD family is  $\geq 7$ .
- **Telephone Visit.** A visit conducted via telephone interview only, with blood obtained via a local lab or physician's office.

**Guidelines for Extending a Local Family Long Distance Visit.** Additional family members to be recruited that reside outside of a field center's catchment area should first be determined to be both interested and eligible following the eligibility protocol (TS1a) for family members. (See Chapter 2, Recruitment).

1. The first step is to determine whether this individual might fall into the catchment areas of another field center. If so, then responsibility for visiting that individual will be transferred to the other field center using the Transfer program in the DES.
2. If another field center is unable to perform the visit, then the original, local field center will determine whether this person will be visiting in one of the field center catchment areas within the next 3 months.
3. If the individual will not be visiting one of the field center catchment areas, then the local field center should determine the individual's willingness to be recruited and the number of family members in that same area. If the local field center decides that this family member should be considered for a Long Distance visit, a Travel Request Form should be completed and submitted. This form should not be submitted until the core local family (3 people minimum) have been enrolled and seen. Once the DMCC receives the request, they will post the information on the LD Spreadsheet in order to determine the potential to conduct Long Distance visits to multiple families from multiple field centers.
4. In the interim, a telephone consent and interview should be conducted and arrangements made to obtain the blood specimen through a local lab by the study site 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.
5. Individual family members on the LD Spreadsheet will be scheduled to be seen when a cluster reaches at least 6. Priority will go to those who are the oldest and in the sibling generation.

### **Guidelines for Recruiting a Long Distance Family**

1. A family must have a FLoSS  $\geq 15$  from the TS1 to be considered for eligibility and possible conduct of a Long Distance Family Visit.
2. A minimum of six family members (including the required two siblings, and offspring) living in the same geographical area (within a 3 hour radius of the visiting location) will be required. When the minimum family size is met, and all family members interested have been screened (TS1a/TS1a-c), then the field center should submit a Travel Request Form.
3. The Travel Review Committee will add eligible families to the Long Distance Spreadsheet for review.
4. Additional family members that may be interested, but live outside of the long distance area should be posted on the LD Spreadsheet after the key triad has been seen.

### **Guidelines for Recruiting a Split Long Distance Family**

1. A family that requires at least 2 long distance visits to complete the key triad must have a FLoSS  $\geq 15$  from the TS1 to be considered for eligibility and possible conduct of a Split Long Distance Family Visit.
2. Family's that meet this requirement should go ahead and screen (TS1a/TS1a-c) the key triad and any other family members that reside in those areas.
3. When Minimum Family Size has been met, a Travel Request Form should be submitted and then they will be posted on the LD Spreadsheet.
4. These individuals will now be considered when examining other potential clusters, with priority going to those clusters that can complete a family.

5. Additional family members that may be interested, but live outside of the split areas should be posted on the LD Spreadsheet after the key triad has been seen.

### **Guidelines for Recruiting a Split Local and Long Distance Family**

1. A Family that requires at least 1 long distance visits to complete the key triad must have a FLoSS  $\geq 7$  from the TS1 to be considered for eligibility to possibly conduct a Split Local and Long Distance Family Visit.
2. Family's that meet this requirement should go ahead and screen (TS1a/TS1a-c) the key triad and any other family members that reside in those areas.
3. When Minimum Family Size has been met, a Travel Request Form should be submitted and then they will be posted on the LD Spreadsheet.
4. These individuals will now be considered when examining other potential clusters. Clusters will receive priority when there are split families to be seen.
5. Additional family members that may be interested, but live outside of the split areas should be posted on the LD Spreadsheet after the key triad has been seen.

**Note:** These Guidelines will be reviewed quarterly by the Travel Review Committee, reporting back to the Executive-PI Committee, to determine whether we are capturing too many/few Long Distance families/family members. This committee, will in turn, report their findings to the Steering Committee for action if necessary.

### **Submission of Travel Request Forms**

1. Field centers will review recruitment for each family to determine which individuals outside of the catchment area are interested and willing to participate. The field center will prepare a travel request form with approval of the local PI or designee. These requests should be submitted after a prospective family member has been screened via the TS1a or TS1a-c and has agreed to participate in a home visit if/when we do remote visits in their area.
2. The Travel Request Form will include (see Chapter 24, Appendix 1):
  - What type of Remote Visit is being requested (see explanations below);
  - Potential number of family members who may be able to be seen on this visit;
  - For each family member to be seen:
    - LLFS Family ID;
    - LLFS Participant ID;
    - Relationship to Proband (eg, sibling, child, niece, spouse of niece);
    - Age;
    - Sex;
    - Location (example: could live nearby but not in same city); and
    - Whether a TS1a/TS1a-c, consent or Telephone Visit has been obtained for this person.
  - Comments section
  - FLoSS score for family;
  - Number of family members already enrolled

- The *potential* number of family members that could be enrolled (including the number proposed to be seen remotely);
- Proposed travel dates, if required (e.g. if a family reunion is occurring);
- A drawn pedigree labeled with the Proband ID and the corresponding FLoSS score;

No requests will be considered for inclusion on the spreadsheet and subsequent state maps unless a family pedigree is also submitted.

The chair will be responsible for reviewing the Travel Request Summary prepared by the DMCC on a weekly (or as-needed) basis to monitor the clustering of families in specific regions of the country, along with the FLoSS score, number of potential individuals to be recruited and frailty of the individuals under consideration.

### **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, using the template shown in Chapter 24, Appendix 3. 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 forwarded to the DMCC 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.
- Once all of these steps have been successfully completed, the Travel Committee Chair will make its' recommendation to the rest of the Travel Review Committee/EPI Committee. When making recommendations, the committee will be provided with a summary of the information collected above, including: the proposed location; the potential number of individuals to be seen on this visit; the FLoSS score(s); the anticipated cost of the trip and the coordinating field center; a copy of the pedigree(s); along with any other pertinent information such as subject frailty or special occasion such as a family gathering.
- Upon completion of a long distance visit, the coordinating field center is required to submit a brief report outlining the success of the trip including demographic information of the participants successfully seen and enrolled, number of participants successfully seen and enrolled versus the projected figures; success in obtaining fasting blood collection, as well as any hurdles or discoveries that were encountered which may help on future visits.

### **Procedure For Handling Incoming National Inquiries**

As noted above, the DMCC will be responsible for managing a spreadsheet and state maps so that geographic clusters of eligible families outside of the existing catchment areas can be easily identified. This will facilitate efforts to identify families or members of participating families 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.

A toll-free telephone line has been activated by the DMCC (insert number here). This will route incoming calls based on the area code of the caller to a specified field center for inquiry. The area code assignments will be updated on an annual basis as new area codes are established frequently. A listing has been distributed to each field center's site manager indicating those regions of the US that have been assigned to

them for triage. Except for area codes that fall within a center's pre-established catchment area, the assignment of these calls will not have an affect on which field centers perform Long Distance core family visits.

Additionally, inquiries received from the LLFS Recruitment Website (<http://longlifefamilystudy.org>) will be routed to the field centers' recruitment teams based on the same area code assignments. These inquiries are stored into a data set located on a server at the DMCC; one to two times per week, any incoming inquiries will be exported to an Excel file for distribution to the Site Manager of the appropriate field center for follow-up.

It should be noted that this toll-free number is primarily intended to be used for press releases and publicity that will be distributed on a national basis. For all local recruitment efforts, the field centers should continue to reference their site-specific toll-free telephone numbers.

Long Distance Visit: Study Assessments, Phlebotomy and Surveys. Long-distance 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:

- (a) Physical and Cognitive Measures
- (b) BP/HR
- (c) 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)
- (d) Performance Measures
- (e) Cognitive Tests (with exception of Long-Term Recall)
- (f) Weight/Height and Waist Circumference (please do as many of these as possible during the 40 minute delay built in for long-term recall)
- (g) Long-Term Recall
- (h) Finish any Weight/Height and Waist Circumference Assessments not completed during the 40 minute break
- (i) Spirometry
- (j) CESD-NEO

### **Questionnaires/Other Instruments.**

- (a) Socio-demographics
- (b) Medications
- (c) Family Structure Review
- (d) Physical Function and Activity
- (e) 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.

**Sample Travel Request Form.** A sample of the approved Travel Request Form is provided on the following page.



**Date of Submission:** \_\_\_\_\_

**Submitting Field Center:** Choose One

**Contact Person:** \_\_\_\_\_

**Submit via E-Mail to:**  
**Stacy Andersen** ([stacy@bu.edu](mailto:stacy@bu.edu)) and **Amy Sleeter** ([asleeter@wustl.edu](mailto:asleeter@wustl.edu))

**LLFS TRAVEL REQUEST FORM**

1. Type of Remote Visit: Choose One
2. What is the potential number of Family Members to be seen during this visit? \_\_\_\_\_
3. Provide the following information for each Family Member to be seen:

LLFS Proband ID	LLFS Participant ID	Relationship to Proband	Age	Sex (M/F)	Location (City, State, ZIP)	Please Indicate (Y/N) if Completed for this Individual:		
						TS1a Form	Consent	Phone Visit
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						
		Self (Proband)						

Please provide any comments which may be relevant (i.e., including whether this proposed visit will include other families or members of other families, etc.): \_\_\_\_\_

4. Please provide the FLoSS (Prime) Score for this Family: \_\_\_\_\_
5. How many Family Members have already been enrolled (i.e. visit complete)? \_\_\_\_\_
6. In total, what is the potential number of Family Members that *might* be enrolled? \_\_\_\_\_
7. Is there a specific date required for this visit (e.g. scheduled family reunion, etc.)? No (Go to Q8)  
 7a. Specific date required for this visit: Not Applicable
8. Is family pedigree attached to this request (preferably in an electronic format)? No (Go to Q8a)  
 8a. Date when pedigree will be available for review: Not Applicable

**[Important Note(s):** No request will be considered until a pedigree has been provided. If you must fax the pedigree, please fax a copy to (314) 362-4227 and (412) 383-1308].

9. Other information which may be helpful or relevant to making a decision: \_\_\_\_\_

**Travel Committee Review and Approval:**

\_\_\_\_\_  
 Name Date