Chapter 2

VISIT 2 PROCEDURES.

A. REORDERING FOLLOW-UP BY AGE AND BY MAINTAINING FAMILY APPROACH

Recognizing that mortality is high among the proband generation, preference for scheduling in person follow-up visits is not going to follow the same order as the first in-home visit. The schedule for the second in-home visit is based on the age of the oldest living family member, and those families with the oldest living members will attempt to be seen as a unit, or very close in time. To accomplish this ordering, the DMCC will send a suggested order of participant in-home visits to each field center. These lists are the preferred order: however we realize that logistically it may not be possible to conform exactly to this order, and slight/moderate deviation from this preferred order is acceptable.

B. TIMING OF VISIT 2 IN RELATION TO VISIT 1 ANNIVERSARY DATE AND FOLLOW-UP

All participants have an anniversary date from their in-home Visit 1. This anniversary date is used for annual follow-up. Since the start date for Visit 2, as well as the order in which participants are seen is different from Visit 1, a strategy for incorporating Visit 2 and its Follow-up is necessary to ensure that all participants have either a follow-up visit (Visit 2 follow-up) or a Visit 2 during each calendar year in order to have complete data collection. Furthermore, if the new visit date for Visit 2 is less than ± 3 months from the participants' anniversary date, Visit 2 will replace the annual follow-up; otherwise the annual Visit 2 follow-up will be completed and then Visit 2 will be scheduled or conversely Visit 2 will be scheduled and then Visit 2 follow-up will ensure on their anniversary date (Figure A). This will ensure that each participant is seen/followed each year and will not be over burdened by participation in LLFS.

Visit 1 follow-up will continue for a participant until September 1, 2014. Beginning on September 1, 2014, all participants will change to Visit 2 forms, both in-home and follow-up. Thus, if the participant is not scheduled for an in-home visit until year 3, they will be receiving Visit 2 Follow-up forms from September 1, 2014 forward on their Visit 1 anniversary date. All follow-up visits will occur on/near the Visit 1 anniversary date, and only in-person Visit 2 will use the ±3 month window. After Visit 2 has been completed, the participant will receive Visit 2 follow-up at their usual anniversary date from Visit 1. Since it is anticipated that Visit 2 will take 3 years to complete, the change to Visit 2 forms is depicted in Figure B.

Figure A. Examples of sliding window based on Visit 1 anniversary date.

	Anniversary Date (Mon/Day)	**Acceptable Visit 2 Date Range (Mon/Day)**	**Estimated Visit 2 Date (Mon/Day)**	**Resultant Visits During Year**
Participant A	6/1	8/1-2/1	11/1	Visit 2 FU & Visit 2
Participant B	6/1	5/1-11/1	8/1	Visit 2
Participant C	6/1	11/1-5/1	2/1	Visit 2 & Visit 2 FU

Figure B. Possible scheduling scenarios for in-home and follow-up visits during the years of active in-home Visit 2.

	Year 1 of Visit 2	**Year 2 of Visit 2**	**Year 3 of Visit 2**	**Year 4 & beyond**
Participant A	Visit 2*	Visit 2 Follow-up	Visit 2 Follow-up	Visit 2 Follow-up
Participant B	Visit 2 Follow-up	Visit 2*	Visit 2 Follow-up	Visit 2 Follow-up
Participant C	Visit 2 Follow-up	Visit 2 Follow-up	Visit 2*	Visit 2 Follow-up

*Visit 2 could also be the combination of Visit 2 follow-up and in-home visit 2 based on scheduling of visit 2 and anniversary date, as shown in Figure A.

C. ENUMERATING GRANDCHILDREN OF THE PROBAND GENERATION

The Offspring generation will be asked about their biological children during in-home Visit 2. This is intended to allow us to enumerate the number of potential grandchildren of the proband generation available for possible recruitment during another funding cycle. We will NOT contact these individuals as part of Visit 2 or Visit 2 follow-up. The information we intend on collecting from the Offspring generation about their biological children (ie the grandchildren of the proband) is: number of biological children with recent spouse/partner, biological child relationship (son or daughter), name of child, date of birth, vital status, current address if living, date of death if deceased, and information on biological children with additional spouses/partners. This information is obtained during the socio-demographic section of the visit.

D. RECRUITMENT OF NEW FAMILY MEMBERS.

i) New Family Members. We will not actively recruit additional family members and/or their spouses, but will ask the proband and offspring participants if they know of any family members who would like to join the study. This call for additional family members should be conducted during the ongoing follow-up phone interview (Panel 16II) or at the time of the phone call to initiate the second in-person visit. Recruitment of family members who express interest in joining the study should be conducted using the procedures described for Visit 1.

ii) Change in Status of Spousal Controls. All spousal controls should be included in the in-person visit. New spouses in both the proband and offspring generations should be invited to participate using procedures described for Visit 1. All spouse controls formerly assessed should be included, even if their status has been changed by separation, divorce, or death of their partner, since the primary outcome variables for analysis will be change scores in a wide variety of phenotypes. The interviewers should ascertain the status of the spousal control during the ongoing follow-up phone interview or at the time of the phone call to initiate the second in-person visit. If the spouses' status has changed, the interviewers should obtain contact information from the participant and call the spouse to ask if they are willing to continue in the study.

E. SCREENING FOR MODERATE TO SEVERE COGNITIVE IMPAIRMENT.

Participants with moderate to severe cognitive impairment, as well as those with dementia, should be included in the follow-up visit, using information from informants as necessary. Neuropsychological testing should also be conducted to the extent that the participant is able to understand directions for testing. When planning the recruitment of participants for in-person follow-up visits, it will be useful to have information about their cognitive status at the time of the last telephone follow-up. Sites that have recorded qualitative information regarding the cognitive status of participants at the time of the last follow-up may refer to such notes when deciding whether or not proxy consent is likely to be necessary at the follow-up visit. It may also be useful to apply the following algorithm for identifying individuals for whom proxy consent **is likely to** be

necessary so that visits can be planned with family members available for this purpose. Individuals who are likely to need proxy consent are those who meet the following criteria for moderate to severe cognitive impairment (1 OR 2) AND (3).

1) The most recent TICS score < = 15 NOT DUE to hearing, environmental, or dispositional factors.

OR

2) The most recent phone follow-up completed by contact person DUE TO DEMENTIA

AND

3) Report of cognitive impairment by an informant on the DQ indicated by at least 4 "Yes" responses for items: 1-7, and 10

The syntax for this selection is:

((Ticstot <= 15 AND overall = 1) OR (Annual Follow-Up Telephone Contact Questionnaire Item 14a = 2 and 14c = 2)) AND ((DQ1 + DQ2 + DQ3 + DQ4 + DQ5 + DQ6 + DQ7 + DQ10) >=3).

If participants meet criteria for moderate or severe dementia