

Chapter 18

Visit 3 Participant Follow-Up

U.S. FIELD CENTER ADMINISTRATION

It is recommended that Annual Participant Follow-up be administered via telephone by study staff. If the participant is deemed unreachable, call the named contact on Panel 14, Contact Information. If the contact is not available, go to the next contact. If a participant requests, you can send forms to them by mail for completion (see Chapter 4 Consent and follow procedures). If sent by mail and not returned, multiple efforts should be attempted to reach the participant by phone. If no follow-up information can be obtained, record the date in the "Date Form Filled Out" on Panel 16-FU, Follow-up Questionnaire (Visit 3) and the appropriate missing code ('R' for refused; 'N' for not applicable; 'U' for unavailable; 'K' for missing; or 'H' for Visit 3 in-person replaces follow-up). This participant will be recorded in the dataset as missing. If a participant has been reported as deceased prior to annual follow-up, no phone call is necessary, and they should have already been marked as deceased and the proper forms were completed at the time of notification (see Table 1 below for details).

DENMARK FIELD CENTER ADMINISTRATION

Follow-up will be conducted for the Proband generation and Proband generation Spouse Controls by telephone and by mail for the Offspring generation and Offspring generation Spouse Controls. The Danish Field Center will also gather further use information from nationwide survival and health registers. This approach will be conducted because: 1) This gives complete follow-up through registers; 2) No Danish telephone dementia test is available and if implemented it would create large drop-out rates; and 3) It is very unlikely that the "telephone proxy dementia test" can be approved by the Danish IRB system.

DETAILED INSTRUCTIONS

Annual follow-up for Visit 3 will officially start on April 27, 2020 for at least three years during concurrent in-person visits. Follow-up should be conducted within a one calendar month window (i.e., 2 weeks before or 2 weeks after) of the anniversary date that the original in-person or telephone visit was completed. However, if the follow-up cannot be completed in that time frame, it is still best to ascertain the information out of the window than have missing data.

An in-person Visit 3 may be substituted for one annual telephone follow-up. In the follow-up year in which Visit 3 is completed Panels 1-15 will be administered via telephone or in-person during the exam. If this visit is within ± 3 months of the participants' anniversary date (from Visit 1), then this Visit 3 will replace Panel 16, Annual Follow-Up. If the Visit 3 in-person visit is not within the ± 3 month anniversary window, the participant will complete both the Visit 3 and Panel 16 when they enter their usual follow-up window. For all other follow-up years the participant will complete Panel 16 Annual Follow-Up as described in Table 1. When an offspring reaches age 70, they will convert to the extended follow-up on a yearly basis instead of every three years. Continued follow-up by telephone is important for tracking changes in functional status, onset of disease, and monitoring vital status of study participants. Administration of the extended follow-up including the medical history update is intended to add new diagnoses to the health record rather than to repeatedly capture previously reported medical conditions.

If a participant misses a telephone follow-up or the telephone follow-up is replaced by the third in person visit, the annual follow-up panel (panel 16) in REDCap should be completed using the date and the reason for non-completion (K for missing or H for in person visit replaces follow-up). The DMCC will then use this information and fill out the non-completion reason for all other forms that should be included in that follow-

up telephone call.

We complete Annual Follow-up Panels for all participants as follows:

Table 1. Explanation of Annual Follow-Up Options and Accompanying Panels		
A. Short Follow-up	B. Expanded Follow-up	C. Notification of Death
Offspring and Grandchildren <70 years all years except every 3rd year	All Probands Offspring/Grandchildren ≥70 yrs Offspring/Grandchildren every 3rd year	
Panel 16-FU: Annual Telephone Contact Questionnaire	Panel 16-FU: Annual Follow-up Questionnaire Panel 5-FU: Medical History Panel 6: Medication Inventory Panel 7b: TICS Panel 7d: Dementia Questionnaire (if triggered) Panel CDR	Panel 16-FU: Annual Follow-up Questionnaire Panel 18-FU: Decedent Proxy Interview

If any LLFS enrolled participant is reported as deceased during the annual follow-up telephone call or through another means (e.g., when doing a follow-up on another family member, someone calls the field center, get a letter from the family, or from local obituary, etc.), the Annual Follow-up form (Panel 16-FU) is marked accordingly and entered into REDCap. The field center will then initiate the completion of a **Decedent Proxy Interview Form (Panel 18-FU)**. Details regarding the completion of the Decedent Proxy Interview Form are at the end of this Chapter.

ANNUAL FOLLOW-UP TELEPHONE QUESTIONNAIRE (PANEL 16-FU)

Note to Interviewer: There is no scripting on how to open up the conversation when you do the follow-up call. Refer to our general interviewing guidelines chapter of the MOP. A suggested opening would be to introduce yourself, thank them for their participation in LLFS, and tell them the purpose of this call (to update their health history) and how long it will take (approximately 5 minutes for the brief follow-up and 30 minutes for the extended follow-up).

A sample script to begin with after the mailing of the WUSTL sIRB AFU informed consent document:

Hi, my name is [insert your name here] and I am calling from [insert your institution here] about the LONG LIFE Family Study. I am excited to share that we have been funded to continue our study. As part of this new funding, we sent you a letter with an updated informed consent document, as the study now has new regulatory oversight at Washington University in St. Louis. Do you recall receiving this letter?

No: *The letter has the updated consent form information required by Washington University in St. Louis. In brief, nothing about LLFS annual telephone follow-up has changed aside from the regulatory oversight being centralized at Washington University in St. Louis. Would you like us to send you another copy of the letter? You are currently due for your [X annual i.e. 13th annual] telephone follow-up call. As we have done in the past, we will ask you questions related to your health status, hospitalizations, and other questions related to your physical and cognitive function and activity levels. Today's call will take approximately [5 to 30 min depending on short vs long call]. You do not have to answer any questions that you do not want to. All information that I receive from you, including any identifying information, will be strictly confidential and*

kept in secure files. Your participation is voluntary; you do not have to answer these questions. Do I have permission to ask you some questions?

1 Yes

0 No

Depending on their no response, there can be a variety of ways to handle. 1) refusal; 2) withdrawal; 3) call back not currently available; 4) other... Please document in their chart their response].

HANDLING MISSING, REFUSED, UNAVAILABLE and WITHDRAW CODES FOR AFU:

Refused – Participant who explicitly states via phone, text, email that they do not want to complete the AFU this year, or who hang up on us even though they clearly know who is calling and why

Administrative (A) - Participant annual follow-up is missing. Use this code only when it is due to the staff not having time/resources to perform the AFU due to training for V3, video visits, COVID-19 delays, etc. This is a special missing code to aid staff in knowing which participants may be more open to be contacted for a V3 vs those who are regular missings or unavailable (i.e., not responding to our attempts).

Missing —Participant who does not answer phone calls, and does not respond to our voice mails and mailed AFU; AFUs are so late that they are nearing or entered the window for their next AFU. If we don’t have any working phone numbers, and no way to reach the participant, they should be marked missing for AFU. People who are unresponsive are “missing”. If we are still unable to locate them when recruiting for V3 (in person or split visit) they will then be marked as Lost to FU through the Recruitment Tracking form for V3 IP/Split.

Unavailable – Participants who are on active military duty, on a mission (we’ve had that before), hospitalized or ill, caring for a sick family member, a life event getting in the way of doing it now (COVID!), someone away from home for months (maybe military, caring for sick family member, etc.). Also include people who say they are “too busy” likely for any of those reasons just stated and more. All of these participants are unable to do the call NOW, but technically did not refuse. Sometimes they will ask you to call back in a week or month, etc, and you can wait to provide a disposition, but if after that period of time (if you are given one) and they aren’t reached, you should still mark them as unavailable. Marking Unavailable is subtly different from Missing, but important to track so we have a sense of who may possibly be more interested in V3. To reiterate, this category is reserved for people you have communicated with that tell you they can’t do it, not that they don’t want to do it. You have had some correspondence. If no correspondence at all, then the appropriate code is MISSING, not UNAVAILABLE.

Withdraw – Explicitly states they no longer want to participate in LLFS. We should hear that directly from the participant but I’m aware of situations when a spouse will say “they don’t want to do this anymore”. I always try to kindly ask if I can please verify that with the enrolled participant, but you have to tread lightly.

Yes: do you have any questions? You are currently due for your [X annual i.e. 13th annual] telephone follow-up call. As we have done in the past, we will ask you questions related to your health status, hospitalizations, and other questions related to your physical and cognitive function and activity levels. Today’s call will take approximately [5 to 30 min depending on short vs long call]. You do not have to answer any questions that you do not want to. All information that I receive from you, including any identifying information, will be strictly confidential and kept in secure files. Your participation is voluntary; you do not have to answer these questions. Do I have permission to ask you some questions?

1 Yes

0 No

Depending on their no response, there can be a variety of ways to handle. 1) refusal; 2) withdrawal; 3) call back not currently available; 4) other...Please document in their chart their response.

Mark the header to indicate whether this form was administered to the participant via the telephone, by a designated study partner/Proxy or by mail. Prior to contacting the participant, please complete the question on the top of page 1, making certain that you check the appropriate follow-up contact (i.e., first, second, third year, etc.). In addition, pre-populate Questions 3a and 4a from Panel 14, Contact Information, for the first follow-up, and use the information obtained from this Panel for subsequent follow-up years.

If you are administering this questionnaire to a study partner/proxy, insert the participant's name instead of stating "your" for all applicable questions.

Question 1a: Interview will mark this question based on information received when making the follow-up phone call. **Beginning April 27, 2020, due to coronavirus/COVID-19, if the participant is deceased, we will ask if the death is COVID-19 related and note the response in the margin. The margin notes will be entered into REDCap at the very end of the panel,** go to Q1b. If the participant is living, continue to Question 2 with the participant or their study partner/proxy.

Question 1b: If the participant is marked as deceased in Q1a, ask for date of death and record on the form. The interview is now complete. Please follow your field center data management procedures for marking someone deceased in REDCap.

Question 2: This question asks about the participant's current overall health. Read the question and the first 5 responses. Do not read the "Don't know" and "Refused" responses.

Question 2a-2f: This question is self-explanatory. If the answer is "yes", go to Q2a1-Q2f1, if "no", "don't know", or "refused" go to Q2b-Q2f.

Question 2a1-2f1: These questions are self-explanatory. If the answer is "yes", go to Q2a2-Q2f2, if "no" go to Q2b-Q2f.

Question 2a2-2f2: For each hospitalization in Q2a-Q2f, ask the participant or their study partner/proxy the Admission and Discharge dates. If the exact dates are unknown ask for their best estimate; if the dates are unknown, indicate as such with a "D". Next, ask the diagnosis at discharge and the name of the hospital and the city and state where the hospital is located. Proceed to Q3a.

Question 3a: This question is self-explanatory. The past year refers to the period of time since the participant was seen for LLFS. Have that date available. If the answer is "yes", go to Q3b, if "no" go to Q4a.

Question 3b: Please record the number of times the participant was hospitalized since they were seen for LLFS. If at least one hospitalization, go to Q3c.

Question 3c: For each hospitalization indicated in Q3b, ask the participant or their study partner/proxy the Admission and Discharge dates. If the exact dates are unknown ask for their best estimate; if the dates are unknown, indicate as such with a "D". Next, ask the diagnosis at discharge and the name of the hospital and the city and state where the hospital is located. If there are more than three hospitalizations, please list them on a separate sheet. Proceed to Q4a.

Questions 4a-10b: These questions ask about the participant's current functional status. Please note the skip patterns on this form. Refer to Chapter 10 for specific details on administration of these questions, including detailed information on the skip patterns. These questions are identical to those currently administered in Panel 3.

Questions 10c1-10c5: These questions are identical to those included in Panel 3 and instructions are detailed in Chapter 10 of the Visit 3 MOP.

Question 10d: This question is self-explanatory.

Question 10e: This question is self-explanatory.

***Note:** Questions 10f-10g will not be completed by the University of Southern Denmark. Skip to Question 14a.*

Questions 10f-10g: These questions are self-explanatory.

Question 11: Indicate whether the participants' contact information on file is accurate, has changed or if a move is planned. If there is a change, denote them on Panel 14; otherwise, proceed to Q12a0.

Question 12a0-12i0: Confirm with participant that they want each of their listed contacts to remain on file. If there are any changes, denote them on Panel 14. Note that this form has up to 9 contacts, but most participants only have 2-3. It is important to make sure that you have at least 2 good contacts in case we can't reach someone.

Question 12b-12i: Verify contact person #1-#9 (if applicable) information is up to date. If changes are needed, update Panel 14.

Question 13: If the interviewer has any additional information that they would like to record, do so in the field for Question 13. Proceed to Q14a.

Question 14a: Please identify the person completing this form. If it is the study participant, proceed to Q15, If it is the contact person/study partner/proxy for the participant or someone else, go to Q14b.

Question 14b: Indicate the relationship between the person completing this form and the study participant and proceed to Q14c.

Question 14c: Please mark the reason why someone other than the participant is completing this form.

Questions 15a-j: Please administer the Pittsburgh Fatigability Scale by reading the script verbatim on the top of form. For detailed directions on this questionnaire, refer to Chapter 10.

Beginning April 27, 2020, due to coronavirus, add these questions.

Script: In light of the Coronavirus pandemic, we have a few additional questions to ask you.

Question 16: self-explanatory, ask and record response.

Question 17: self-explanatory, ask and record response and follow skip pattern.

Question 17a: record the date using the convention: day/month/year

Questions 18a-18u: ask participant if they had each symptom at time of testing/presumed positive and also if they currently have the symptom.

Questions 19a-19h: ask participant what type of treatment they received. If the participant notes a hospitalization, ensure that the hospitalization information is captured in question 3a of AFU.

Question 20: self-explanatory, ask and record response.

Question 21: self-explanatory, ask and record response.

Questions 22a-22f: ask the participant about how the COVID-19 pandemic affected their emotional status and well-being. For each line, ask the participant if it was most, occasionally, some, or rarely within a typical week during the COVID-19 Pandemic.

Question 23: ask the participant the question verbatim. This assesses the current overall well-being of the participant.

Question 24: ask the participant the question to address their overall well-being in the future.

Question 25: ask participant if there are any other concerns or personal challenges related to COVID-19 pandemic they wish to share with us.

If this is a short-follow-up call (Column A), then read the end interview script at the bottom of Panel 16-FU, otherwise, proceed to the next set of questionnaires – Panel 5-FU Medical History.

MEDICAL HISTORY QUESTIONNAIRE (PANEL 5-FU)

Mark the header to indicate whether this form was administered to the participant via the telephone, by a designated study partner/Proxy or by mail.

Question 1: Read the question and record the response using the appropriate response form if this is an 'in-person' interview. Mark the correct response on the questionnaire.

Question 2: Script: *"I am going to read you a list of conditions. Please respond 'yes' or 'no' if you have been told by a doctor that you had this condition since we **last inquired about this condition** on [insert date]."*

Important Note regarding Date to Anchor Responses: The hard copy questionnaire wording is *"since we last interviewed you"* but the new suggested script provides for better clarification of the period. For those in Column A of Table 1 above (page 18-2), "since we inquired about this condition" would be the date of their last annual telephone follow-up or Visit 2 or Visit 3 (whichever comes last). For those in Column B of Table 1, "since we inquired about this condition" would be the last time this expanded follow-up questionnaire was administered to them. Please refer to the PreFill form for these important dates.

- If the participant responds Never told or No, mark "No" and continue on to the next item on the list.
- If the participant responds Yes, mark "Yes" and then ask the age they were first told they had the condition and whether or not they currently have the condition before moving on to the next condition. If they don't know the age, ask them to make their best guess. Make sure that you do not report a condition that has already been previously reported at a past visit. Check the PreFill form to be sure. Reporting the condition again will cause unnecessary quality control checks and edits. Please refer to the detailed instructions in MOP Chapter 12 for completing Question 2 for the Visit 3 regarding this issue.
- If the participant refuses to respond, mark "Refused" and continue on to the next item on the list.
- If the participant responds Don't know, mark "Don't know" and continue on to the next listed item.

- If the participant answers yes to chest surgery, other cancer, other fractures, and/or other illness, ask him/her to specify what type. For any person reporting and "other cancer" in section 3g, please probe as to whether this cancer was malignant or not. For example, if the participant says "growth", follow-up by asking "What type of growth was it, and was this growth a malignant cancer"? Or, if the person says "pre-cancerous lesion", follow-up by asking "Was this a malignant cancer"? In the margin of the form write down all the information that the participant provides. If study staff is unsure as to whether this truly is a cancer or not, please bring this to the attention of your clinic coordinator immediately following the visit, and they will determine if this entry should be included under "other cancer".

Starting **April 27, 2020**, under 'Other Illnesses' for Q2, we will specifically ask about coronavirus/COVID-19.

- Yes=definitive positive test or told by a doctor you are presumed positive based on symptoms
- No=negative test or no symptoms
- Don't know=presumptive due to symptoms but no testing and NOT told presumed positive by doctor (probe about symptoms and put in margin)
- Current:
 - Yes=still experiencing symptoms
 - No=symptoms resolved

Question 3: Q3 asks about falls in the past year. Record the participant's answer. If the participant responds "yes", please continue to Q3b and Q3c. If s/he does not know for sure how many times s/he has fallen, record his/her best guess.

Question 4: Q4 asks about current weight. Record the participant's answer. If s/he does not know for sure, record his/her best guess.

Question 5: Q5 asks about weight change over the last year. If the weight change was greater than 5 pounds or 2.27 kilograms, complete Q5b, Q5c, and Q5d. For Q5d, emphasize that this is the **overall** weight lost or gain. So if the person gained 10 lbs and then lost 5 lbs in the past year, the correct response will be a weight gain of 5lbs. If the participant seems uncertain about the amount of weight gained or lost, ask him/her to estimate.

MEDICATION INVENTORY (PANEL 6)

Mark the header to indicate whether this form was administered to the participant via the telephone, by a designated study partner/Proxy or by mail.

Please refer to the detailed instructions for completion of this panel in Chapter 16 Medication Inventory.

TELEPHONE INTERVIEW FOR COGNITIVE STATUS (PANEL 7B)

Please refer to the detailed instructions for completion of the TICS in Chapter 11 Cognitive Assessment. This will end the annual telephone follow-up.

End Interview Script: "Thank you very much for answering these questions. I enjoyed talking with you. Please remember to call us if you move or your mailing address changes. I look forward to speaking with you again at approximately the same time next year. Again, thank you for your ongoing interest and participation in this important study."

DEMENTIA QUESTIONNAIRE (PANEL 7D)

Please refer to the detailed instructions for completion of the Dementia Questionnaire in Chapter 11 Cognitive Assessment, if this form is triggered.

CDR

Please refer to the detailed instructions for completion of the CDR in Chapter 11 Cognitive Assessment.

DECEDENT PROXY INTERVIEW (PANEL 18-FU)

The Decedent Proxy Interview (Panel 18-FU) is a short interview that is to be administered to the Designated Family Reporter/Proxy/study partner after a reported death of an LLFS participant. This form should be completed by the field center, as soon as possible, upon becoming aware of the death in order to ascertain the most complete information. Questions concerning medical conditions, hospitalizations, activities of daily living (function), and memory are included. Many of these questions have been included in other forms, during both the in-person visit and annual follow-ups, to provide longitudinal data. An introductory script and notes to the interviewer pertaining to specific questions are included directly on the form.